|  | Results |
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| 1. | [PHARMACEUTICAL INDUSTRY RETHINKS ITS BUSINESS MODEL : PATENT CLIFF LOOMING FOR ORIGINATOR PHARMA FIRMS](#doc_id_1) Europolitics (daily in English), December 20, 2012 Thursday, 352 words, Sophie Mosca |

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| 2. | [Lawsuit Challenges Ranbaxy's Rights to Generic Drug](#doc_id_2) The New York Times, December 7, 2012 Friday, Section B; Column 0; Business/Financial Desk; Pg. 2, 564 words, By KATIE THOMAS |

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| 3. | [Ranbaxy halts generic Lipitor over glass in pills](#doc_id_3) The International Herald Tribune, December 1, 2012 Saturday, FINANCE; Pg. 17, 904 words, KATIE THOMAS |

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| 4. | [Ranbaxy Laboratories starts sales and promotion launch of Absorica Capsules](#doc_id_4) Pharma, November 27, 2012 Tuesday, 101 words |

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| 5. | [BEYOND TAMPA BAY](#doc_id_5) Tampa Bay Times, November 24, 2012 Saturday, LOCAL; BEYOND TAMPA BAY; Pg. 4B, 435 words |

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| 6. | [Fate of Indian generic drugs hangs on Novartis case](#doc_id_6) The Business Times Singapore, September 4, 2012 Tuesday, EDITORIAL & OPINION; The Bottom Line, 824 words, Yogi Aggarwal |

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| 7. | [AstraZeneca feels the burn](#doc_id_7) Investors Chronicle - magazine and web content, August 16, 2012, 172 words |

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| 8. | [E.U. charges drug firms over delays for generics; Regulators say keeping cheaper treatments from market hurt consumers](#doc_id_8) The International Herald Tribune, July 26, 2012 Thursday, FINANCE; Pg. 17, 601 words, EDWARD WYATT |

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| 9. | [India's poor to benefit from free drugs; Government to propose distribution of generics, a blow to big companies](#doc_id_9) The International Herald Tribune, July 7, 2012 Saturday, FINANCE; Pg. 11, 1379 words, VIKAS BAJAJ |

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| 10. | [Business News in Brief](#doc_id_10) The Philadelphia Inquirer, July 7, 2012 Saturday, BUSINESS; P-com Biz; Pg. WEB, 450 words, Inquirer Staff Report |

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| 11. | [BEYOND TAMPA BAY](#doc_id_11) Tampa Bay Times, July 7, 2012 Saturday, LOCAL; BEYOND TAMPA BAY; Pg. 4B, 432 words |

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| 12. | [The Washington Post](#doc_id_12) July 7, 2012 Saturday, A-SECTION; Pg. A11, 770 words |

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| 13. | [State patients to benefit as Roche is persuaded to cut price of cancer drug](#doc_id_13) Business Day (South Africa), June 20, 2012 Wednesday, PRINT:PAGE, 540 words, TAMAR KAHN |

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| 14. | [Inquiry called over prescription `rip-off'](#doc_id_14) The Australian, May 29, 2012 Tuesday, LOCAL; Pg. 8, 374 words, SUE DUNLEVY |

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| 15. | [Free drugs costing taxpayers $410m GENERIC SUPPLY EXPOSES FLAW IN SUBSIDY SCHEME](#doc_id_15) The Australian, May 28, 2012 Monday, LOCAL; Pg. 3, 579 words, SUE DUNLEVY |

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| 16. | [Ranbaxy moves in as patents expire](#doc_id_16) Australian Financial Review, May 7, 2012 Monday, COMPANIES AND MARKETS; Pg. 17, 463 words, Carrie LaFrenz |

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| 17. | [We pay a heavy price for patent absurdities](#doc_id_17) Weekend Australian, March 31, 2012 Saturday, REVIEW; Pg. 8, 415 words, SUE DUNLEVY |

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| 18. | [Pfizer reaches for painkillers](#doc_id_18) Australian Financial Review, March 27, 2012 Tuesday, COMPANIES AND MARKETS; Pg. 12, 1578 words, Carrie LaFrenz and Emma Connors |

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| 19. | [Pharmacists attacked for subsidy rort; Letter showed how to use system](#doc_id_19) Canberra Times (Australia), March 22, 2012 Thursday, A; Pg. 2, 500 words, Melissa Davey |

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| 20. | [Pharmacists attacked for subsidy rort; Letter showed how to use system](#doc_id_20) Canberra Times (Australia), March 22, 2012 Thursday, A; Pg. 2, 500 words, Melissa Davey |

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| 21. | [Pharmacists 'putting profits before patients'](#doc_id_21) Sydney Morning Herald (Australia), March 22, 2012 Thursday, NEWS AND FEATURES; Pg. 1, 646 words, Melissa Davey HEALTH |

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| 22. | [Bitter pill for consumers](#doc_id_22) Australian Financial Review, February 18, 2012 Saturday, NEWS; Pg. 10, 455 words, Emma Connors |

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| 23. | [How chemists beat customers to cheaper drugs](#doc_id_23) Australian Financial Review, February 18, 2012 Saturday, PERSPECTIVE; Pg. 46, 1940 words, Emma Connors |

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| 24. | [Indian drugmaker reaches deal with FDA; Ranbaxy to review India and US plants, change way it operates](#doc_id_24) The Straits Times (Singapore), January 27, 2012 Friday, ASIA, 622 words, Nirmala Ganapathy, India Correspondent |

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| 25. | [Pfizer promotes 'Lipitor for You' program](#doc_id_25) PR Week (US), January 19, 2012, NEWS, 396 words, Virgil Dickson |

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| 26. | [Lipitor takes up drug fight](#doc_id_26) The Advertiser (Australia), January 14, 2012 Saturday, FINANCE; Pg. 76, 275 words |

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| 27. | [Watson chief pledges more deals](#doc_id_27) Daily Deal/The Deal, January 11, 2012 Wednesday, 501 words, by Ben Fidler In San Francisco |

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| 28. | [Generics strip protective coating off Lipitor's sales](#doc_id_28) The Advertiser (Australia), December 21, 2011 Wednesday, FINANCE; Pg. 61, 205 words |

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| 29. | [Lipitor goes, but not without a fight](#doc_id_29) Daily Deal/The Deal, December 2, 2011 Friday, 713 words, by Ben Fidler |

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| 30. | [Generic Lipitor for launch](#doc_id_30) The New Zealand Herald, December 2, 2011 Friday, BUSINESS; General, 74 words |

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| 31. | [Watson launches first generic Lipitor](#doc_id_31) The Independent (London), December 1, 2011 Thursday, BUSINESS; Pg. 60, 361 words, STEPHEN FOLEY |

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| 32. | [With patent for best-selling drug expiring, Pfizer raises hurdles for rivals](#doc_id_32) The International Herald Tribune, December 1, 2011 Thursday, FINANCE; Pg. 14, 1336 words, DUFF WILSON |

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| 33. | [Senators Question Deals to Block Generic Lipitor](#doc_id_33) The New York Times, December 1, 2011 Thursday, Section B; Column 0; Business/Financial Desk; Pg. 3, 516 words, By DUFF WILSON |

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| 34. | [Drug copycats stand by](#doc_id_34) The Times (London), December 1, 2011 Thursday, BUSINESS; Pg. 61, 80 words, AFP |

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| 35. | [Top-seller Lipitor goes generic](#doc_id_35) The Philadelphia Inquirer, November 30, 2011 Wednesday, BUSINESS; P-com Biz; Pg. A17, 700 words, By David Sell; Inquirer Staff Writer |

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| 36. | [LIPITOR USERS TO SEE BANK BALANCE GET HEALTHIER](#doc_id_36) St. Petersburg Times (Florida), November 30, 2011 Wednesday, TAMPA BAY; Pg. 1B, 572 words, IRENE MAHER, Times Staff Writer |

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| 37. | [As Lipitor nears the cliff, Pfizer does deals](#doc_id_37) Daily Deal/The Deal, November 22, 2011 Tuesday, 423 words, by Ben Fidler |

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| 38. | [Africa; The End of Cheap Medicine?](#doc_id_38) Africa News, November 15, 2011 Tuesday, 2987 words, This is Africa (London) |

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| 39. | [Plan Would Delay Sales Of Generic For Lipitor](#doc_id_39) The New York Times, November 12, 2011 Saturday, Section B; Column 0; Business/Financial Desk; Pg. 1, 845 words, By DUFF WILSON. James B. Stewart, whose Common Sense column normally appears on this page, is away. |

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| 40. | [Pfizer squares up to competition](#doc_id_40) The Irish Times, November 2, 2011 Wednesday, FINANCE; Business Today; Pg. 16, 153 words |

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| 41. | [Its Sales Strong, Pfizer Increases a Share Buyback](#doc_id_41) The New York Times, November 2, 2011 Wednesday, Section B; Column 0; Business/Financial Desk; PRESCRIPTIONS; Pg. 2, 1422 words, By DUFF WILSON |

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| 42. | [Santen looks abroad with Novagali](#doc_id_42) Daily Deal/The Deal, September 28, 2011 Wednesday, 679 words, by Ben Fidler |

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| 43. | [Drug firm takeovers stoke fears in India; Officials' worry: foreign firms may raise prices](#doc_id_43) The Straits Times (Singapore), September 17, 2011 Saturday, ASIA, 716 words, Nirmala Ganapathy, India Correspondent |

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| 44. | [Sanofi makes acquisition in India](#doc_id_44) Daily Deal/The Deal, August 24, 2011 Wednesday, 629 words, by Ben Fidler |

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| 45. | [600 bln yen loan to fund Takeda's Swiss deal](#doc_id_45) The Nikkei Weekly (Japan), August 1, 2011 Monday, 513 words |

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| 46. | [Bitter pill for drug industry](#doc_id_46) Australian Financial Review, June 6, 2011 Monday, NEWS; Features; Pg. 53, 1552 words, Emma Connors |

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| 47. | [India casts a protective eye on its drug industry](#doc_id_47) The Washington Post, March 12, 2011 Saturday, A-SECTION; Pg. A13, 860 words, Rama Lakshmi |

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| 48. | [Big pharma's report card](#doc_id_48) Investors Chronicle - magazine and web content, February 18, 2011, 984 words |

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| 49. | [Daiichi Sankyo takes four-pronged approach](#doc_id_49) The Nikkei Weekly (Japan), August 30, 2010 Monday, 729 words |

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| 50. | [Looking for fortunes in sickness and health; Drug maker's ex-chief dreams of pan-Asian network of hospitals](#doc_id_50) The International Herald Tribune, August 27, 2010 Friday, FINANCE; Pg. 14, 1403 words, BY WAYNE ARNOLD |

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| 51. | [The cerebral tycoon; Fortis chairman Malvinder Mohan Singh has an investment banker's penchant for dealmaking. But he is also instinctively a step-by-step institution builder, a believer in creating systems, processes and frameworks, and raising efficiencies. By Vikram Khanna](#doc_id_51) The Business Times Singapore, August 14, 2010 Saturday, RAFFLES CONVERSATION, 2194 words |

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| 52. | [Emerging markets draw drugmakers](#doc_id_52) The Nikkei Weekly (Japan), August 9, 2010 Monday, 397 words |

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| 53. | [India seeks its place among top drug makers; Local producers grow rapidly as those in West encounter higher costs](#doc_id_53) The International Herald Tribune, July 8, 2010 Thursday, FINANCE; Pg. 1, 1583 words, BY HEATHER TIMMONS |

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| 54. | [Drugmakers reap bigger profits from foreign units acquired through M&A](#doc_id_54) The Nikkei Weekly (Japan), June 28, 2010 Monday, 309 words |

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| 55. | [Drug multinationals look to the global south](#doc_id_55) Business Day (South Africa), June 25, 2010, ECONOMY, BUSINESS & FINANCE, 656 words, Nick Wilson |

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| 56. | [Big pharma eyes Indian drug firms; But despite the sales of leading companies, the situation is not as grim as it might appear](#doc_id_56) The Business Times Singapore, June 11, 2010 Friday, VIEWS AND OPINIONS; Opinion, 1102 words, Yogi Aggarwal |

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| 57. | [F.D.A. Again Warns the Generic Maker Apotex About the Conditions at Its Plants](#doc_id_57) The New York Times, April 16, 2010 Friday, Section B; Column 0; Business/Financial Desk; Pg. 6, 853 words, By NATASHA SINGER |

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| 58. | [Tough competition in generics game](#doc_id_58) The Australian, March 31, 2010 Wednesday, FINANCE; Pg. 40, 727 words, Tim Boreham |

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| 59. | [Focus: Healthcare - Finally, the prognosis looks good](#doc_id_59) Investment Adviser, March 22, 2010, 1090 words |

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| 60. | [AstraZeneca takes on generic drugs partner as patents fade](#doc_id_60) The Times (London), March 12, 2010 Friday, BUSINESS; Pg. 45, 309 words, Rhys Blakely |

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| 61. | [IN BRIEF: Japan no longer machine tool king](#doc_id_61) The Nikkei Weekly (Japan), March 1, 2010 Monday, 405 words |

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| 62. | [On a high INTRODUCTION: Nonbranded drugs are expected to continue their strong growth. But could the dearth of their new branded rivals cause the sector to hit a wall?](#doc_id_62) ICIS Chemical Business, February 15, 2010, FEATURES, 1412 words, Doris De Guzman |

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| 63. | [Pharmaceuticals aim at emerging markets](#doc_id_63) The Nikkei Weekly (Japan), February 8, 2010 Monday, 760 words |

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| 64. | [Pfizer to cull 100 drugs from pipeline](#doc_id_64) Daily Deal/The Deal, January 27, 2010 Wednesday, 430 words, by Kenneth Bredemeier |

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| 65. | [That Wile E. Coyote moment](#doc_id_65) Daily Deal/The Deal, January 22, 2010 Friday, 141 words |

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| 66. | [AstraZeneca makes peace with Teva to protect Nexium sales](#doc_id_66) The Independent (London), January 8, 2010 Friday, BUSINESS; Pg. 48, 259 words, Alistair Dawber |

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| 67. | [Brokers say AstraZeneca's US patent settlement with Teva positive](#doc_id_67) Pharma, January 8, 2010 Friday, 232 words |

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| 68. | [AstraZeneca given shot in the arm by patent deal](#doc_id_68) The Times (London), January 8, 2010 Friday, BUSINESS; Pg. 57, 327 words, Catherine Boyle |

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| 69. | [Why piling eye drops high can make a lot of sense to Novartis](#doc_id_69) The Times (London), January 5, 2010 Tuesday, BUSINESS; Pg. 45, 369 words, Dominic Walsh |

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| 70. | [Hospira buys Orchid unit](#doc_id_70) Daily Deal/The Deal, December 15, 2009 Tuesday, 427 words, by Andrew Bulkeley |

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| 71. | [Drugmakers shifting their focus](#doc_id_71) The Nikkei Weekly (Japan), November 2, 2009 Monday, 614 words |

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| 72. | [Cipher starts Phase III study of acne treatment CIP-ISOTRETINOIN](#doc_id_72) Pharma, October 7, 2009 Wednesday, 309 words |

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| 73. | [West blocking India's generic drugs; They block shipments at European ports and step up lawsuits to stop the sale of generics](#doc_id_73) The Business Times Singapore, September 24, 2009 Thursday, VIEWS AND OPINIONS; Opinion, 1057 words, Yogi Aggarwal |

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| 74. | [M&As loom as drug patents expire](#doc_id_74) The Nikkei Weekly (Japan), May 18, 2009 Monday, 688 words |

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| 75. | [INTRODUCTION:](#doc_id_75) ICIS Chemical Business, March 16, 2009, FEATURES, 1347 words, Kumar Amitav Chaliha |

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| 76. | [Beware thepatent cliff! INTRODUCTION: Blockbusters have been driving growth in the pharma sector, but looming patent expiries are forcing companies in new directions](#doc_id_76) ICIS Chemical Business, March 16, 2009, FEATURES, 1420 words, Anna Jagger |

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| 77. | [High hopes forbiosimilars INTRODUCTION: Once in doubt, the future of biosimilars is advancing along a path smoothed by European groundwork](#doc_id_77) ICIS Chemical Business, March 16, 2009, FEATURES, 1709 words, Cynthia Challener |

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| 78. | [Agility and innovation, at Economistπs 15th annual pharmaceuticals conference](#doc_id_78) Pharma Marketletter, March 2, 2009 Monday, 1735 words |

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| 79. | [Need to know](#doc_id_79) The Times (London), February 27, 2009 Friday, BUSINESS; Pg. 52, 2111 words |

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| 80. | [Beyondthe limelight INTRODUCTION: A modest domestic market constrains the ambitions of Korea's pharmaceutical fine chemical manufacturers](#doc_id_80) ICIS Chemical Business, February 9, 2009, FEATURES, 1169 words, Clay Boswell |

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| 81. | [GlaxoSmithKline says coming personnel cuts are not related to downturn in the economy](#doc_id_81) The Times (London), February 2, 2009 Monday, BUSINESS; Pg. 41, 585 words, Patrick Loughran |

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| 82. | [Drug Industry Flux Proves Good Therapy for Suppliers](#doc_id_82) Chemical Week, January 19, 2009, COVER STORY; Pg. 19, 3130 words, DEEPTI RAMESH |

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| 83. | [Pfizer wins new protection on Lipitor](#doc_id_83) National Post's Financial Post & FP Investing (Canada), January 7, 2009 Wednesday, FINANCIAL POST; National Report; Pg. FP4, 191 words, Bloomberg News |

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| 84. | [Pfizer gets clarified Lipitor patent](#doc_id_84) Pharma Marketletter, January 7, 2009 Wednesday, 210 words |

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| 85. | [InterContinental Hotels rises as Guoco buys stake; Market report](#doc_id_85) The Times (London), January 3, 2009 Saturday, BUSINESS; Pg. 55, 546 words, Robert Lindsay |

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| 86. | [Price-fixing in itself insufficient to establish conspiracy to defraud; Law Report](#doc_id_86) The Times (London), January 1, 2009 Thursday, NEWS; Pg. 49, 1408 words |

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| 87. | [M&A briefly noted: Nov. 7, 2008](#doc_id_87) Daily Deal/The Deal, November 10, 2008 Monday, M AND A, 812 words, Edited by Greg Johnson |

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| 88. | [The Safety Gap](#doc_id_88) The New York Times, November 2, 2008 Sunday, Section MM; Column 0; Magazine Desk; Pg. 46, 5079 words, By GARDINER HARRIS. Gardiner Harris, a correspondent in The New York Times's Washington bureau, reports on public health. |

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| 89. | [Generics no panacea, drug firms find](#doc_id_89) The Nikkei Weekly (Japan), October 27, 2008 Monday, 963 words |

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| 90. | [Shot in the arm for generics](#doc_id_90) Weekend Australian, October 18, 2008 Saturday, REVIEW; Pg. 13, 1105 words, Adam Cresswell |

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| 91. | [The populationbomb INTRODUCTION: Demand for generic drugs in Japan is set to explode, with the collision of an aging population and skyrocketing drug costs](#doc_id_91) ICIS Chemical Business, September 29, 2008, FEATURES, 1195 words, John Richardson |

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| 92. | [Firms alter tactics amid changing U.S. market](#doc_id_92) The Nikkei Weekly (Japan), September 22, 2008 Monday, 686 words |

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| 93. | [The drug hunters; Acquisitions are the prescription for Big Pharma](#doc_id_93) National Post's Financial Post & FP Investing (Canada), September 12, 2008 Friday, FINANCIAL POST; Pg. FP13, 705 words, Ben Hirschler, Reuters |

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| 94. | [Shionogi grabs Sciele for $1.4B](#doc_id_94) Daily Deal/The Deal, September 3, 2008 Wednesday, M AND A; Deal International, 328 words, by Renee Cordes |

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| 95. | [Denmark upholds two of Pfizer's Lipitor patents](#doc_id_95) Pharma Marketletter, August 29, 2008 Friday, 134 words |

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| 96. | [Private Equity GetsHeated In India: India's homegrown funds tackle their country's PE market with a vengeance](#doc_id_96) Investment Dealers Digest, August 11, 2008, 1666 words, Kelly Holman |

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| 97. | [Africa; Daily HIV/Aids Report](#doc_id_97) Africa News, July 31, 2008 Thursday, 3939 words, Kaisernetwork.org |

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| 98. | [Israel's Teva buys US copycat drug rival for $7.5bn: Acquisition gives group extra European presence: Patent expiries heating up cut-price medicine market](#doc_id_98) The Guardian (London) - Final Edition, July 19, 2008 Saturday, GUARDIAN FINANCIAL PAGES; Pg. 39, 600 words, Andrew Clark, New York |

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| 99. | [Teva to create generic drug giant in $7.5bn Barr buyout](#doc_id_99) The Independent (London), July 19, 2008 Saturday, BUSINESS; Pg. 50, 460 words, Alistair Dawber |

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| 100. | [Access to Medicines: index praises GSK, as Sanofi-Aventis argues commercial case](#doc_id_100) Pharma Marketletter, July 17, 2008 Thursday, 927 words |

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| 101. | [Will this save millions of lives?; HEALTH](#doc_id_101) The Age (Melbourne, Australia), July 12, 2008 Saturday, INSIGHT; Pg. 3, 2917 words, Simon Mann - Simon Mann is a senior writer |

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| 102. | [AstraZeneca wins admirers](#doc_id_102) Investors Chronicle - magazine and web content, July 9, 2008, 451 words |

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| 103. | [Land ofdiscovery INTRODUCTION: India is pushing into fresh territory by evolving from a commodity-driven drug market into a research-driven development center. But challenges abound](#doc_id_103) ICIS Chemical Business, July 7, 2008, FEATURES, 1509 words, Feliza Mirasol |

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| 104. | [Land ofdiscovery PARA:: INTRODUCTION:: PARA:: India is pushing into fresh territory by evolving from a commodity-driven drug market into a research-driven development center. But challenges abound PARA::](#doc_id_104) ICIS Chemical Business, July 7, 2008, FEATURES, 1558 words, Feliza Mirasol |

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| 105. | [AstraZeneca gets shot in the arm as court backs it in 'copies' case; PHARMACEUTICALS](#doc_id_105) Birmingham Post, July 3, 2008, Thursday, BUSINESS; Pg. 24, 331 words |

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| 106. | [Pfizer and Ranbaxy Settle Lipitor Patent Dispute](#doc_id_106) Chemical Week, June 23, 2008, PHARMACEUTICALS & FINE CHEMICALS; Pg. 25, 284 words, DR |

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| 107. | [India's generic prescription for Big Pharma CITY PROFILE Malvinder Mohan Singh's family has sold its stake in Ranbaxy, India's largest pharmaceuticals company - but not sold out on its dream of selling cheap, effective drugs to the world's poor. Andrew Cave reports](#doc_id_107) The Sunday Telegraph (LONDON), June 22, 2008 Sunday, CITY; Pg. 7, 1596 words, Andrew Cave |

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| 108. | [Pfizer deal stalls sale of cholesterol generic](#doc_id_108) The International Herald Tribune, June 20, 2008 Friday, FINANCE; Pg. 16, 790 words, Stephanie Saul - The New York Times Media Group |

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| 109. | [Sanofi purchase of Zentiva hailed](#doc_id_109) Daily Deal/The Deal, June 19, 2008 Thursday, M AND A; Deal International, 839 words, by Cheryl Meyer and Paul Whitfield |

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| 110. | [Pfizer, Ranbaxy reach deal over U.S. generic version of Lipitor](#doc_id_110) The Globe and Mail (Canada), June 19, 2008 Thursday, REPORT ON BUSINESS: THE WALL STREET JOURNAL; PHARMACEUTICALS; Pg. B13, 611 words, AVERY JOHNSON |

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| 111. | [In short](#doc_id_111) The Irish Times, June 19, 2008 Thursday, FINANCE; Other Stories; Pg. 20, 517 words |

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| 112. | [Lipitor monopoly to end in 2011; Indian drug maker Ranbaxy's settlement with Pfizer will lead to a flood of lower-cost generics on the U.S. market](#doc_id_112) National Post's Financial Post & FP Investing (Canada), June 19, 2008 Thursday, FINANCIAL POST; Pg. FP16, 850 words, Ransdell Pierson, Reuters |

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| 113. | [Settlement Delays a Generic Lipitor For Many Months, a Boon to Pfizer](#doc_id_113) The New York Times, June 19, 2008 Thursday, Section C; Column 0; Business/Financial Desk; Pg. 1, 1026 words, By STEPHANIE SAUL |

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| 114. | [Pfizer to settle patent disputes with Ranbaxy](#doc_id_114) Pharma Marketletter, June 19, 2008 Thursday, 143 words |

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| 115. | [pfizer buys more time for lipitor](#doc_id_115) WALL STREET JOURNAL ABSTRACTS, June 19, 2008 Thursday, Section B; Column 1; Pg. 1, 65 words, Avery Johnson |

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| 116. | [HIV-Aids and STDs; Daily HIV/Aids Report](#doc_id_116) Africa News, June 18, 2008 Wednesday, 2185 words, Kaisernetwork.org |

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| 117. | [Daiichi Sankyo targets generics](#doc_id_117) The Nikkei Weekly (Japan), June 16, 2008 Monday, 724 words |

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| 118. | [Pfizer 'may counter' EUR3bn Ranbaxy deal](#doc_id_118) The Irish Times, June 14, 2008 Saturday, FINANCE; Other Stories; Pg. 21, 331 words |

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| 119. | [Generic-drug makers appear to be attractive targets; DEALTALK](#doc_id_119) The International Herald Tribune, June 13, 2008 Friday, FINANCE; Pg. 17, 648 words, Lewis Krauskopf - Reuters |

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| 131. | [USPTO confirms patentability of basic Lipitor patent](#doc_id_131) Pharma Marketletter, May 1, 2008 Thursday, 121 words |

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| 139. | [SHARE PRICES: Big guns lead FTSE 100 revival after five days; MARKET REPORT](#doc_id_139) Birmingham Post, April 16, 2008, Wednesday, NEWS; Pg. 18, 483 words |

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[Return to List](#cite_id_1)

1 of 200 DOCUMENTS



Europolitics (daily in English)

**December** 20, 2012 Thursday

**PHARMACEUTICAL INDUSTRY RETHINKS ITS BUSINESS MODEL : PATENT CLIFF LOOMING FOR ORIGINATOR PHARMA FIRMS**

**BYLINE:** Sophie Mosca

**SECTION:** No. 4553

**LENGTH:** 352 words

The years 2012 and 2013 are nightmarish for the pharmaceutical industry. They represent the end of the era of the blockbuster drugs that are the stars of global sales, generating more than EUR1 billion per year. The result will be a considerable loss of earnings for the big pharmaceutical firms, estimated by some experts at US$150 billion (EUR116 billion) over the next five years for the sector, ie 20% of its turnover and half the turnover of the planet's top ten pharmaceutical firms. The record in **patent** losses, according to IMS Health, will be set in 2012 with an amount of US$46 billion (EUR35.5 billion).

Topping the list in the depleting goldmine for pharmaceutical firms is the expiry, in late November in the United States and in May 2012 in Europe, of the **patent** for Lipitor (also called Tahor), Pfizer's anti-cholesterol star and the planet's most widely sold medicine (US$10.7 billion in 2010), which accounts for nearly 20% of the firm's annual turnover. The Indian generic pharmaceutical firm **Ranbaxy** has obtained exclusive rights for the sale of its copy of Atorvastatin - the molecule marketed by Pfizer under the names Lipitor and Tahar - for six months in the United States.

Zyprexa suffered the same fate at the end of 2011 in the United States. In 2010, this drug made up 22% of Eli Lilly's turnover (US$2.5 billion). And in May 2012, the **patent** for Plavix expired in the United States. This anti-blood clotting drug, patented jointly by Sanofi and Bristol-Myers Squibb, is the world's second most widely sold medicine. It generated US$9.4 billion in turnover for the two firms in 2010. Novartis will also lose in 2013 the **patent** for Diovan, a hypertension product (US$6 billion of its turnover).

In December, Britain's AstraZeneca will lose the **patents** for Seroquel, used to treat schizophrenia, the second largest seller in its portfolio (US$3.7 billion) and despite its challenges in court, a generic drug has obtained authorisation to replace it.

To offset these colossal losses, the originator drug firms are setting up various defence strategies, outlined in the following pages.

**LOAD-DATE:** December 19, 2012

**LANGUAGE:** ENGLISH

**PUBLICATION-TYPE:** Newspaper

**JOURNAL-CODE:** EURE

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[Return to List](#cite_id_2)

2 of 200 DOCUMENTS

The New York Times

**December** 7, 2012 Friday

Late Edition - Final

**Lawsuit Challenges Ranbaxy's Rights to Generic Drug**

**BYLINE:** By KATIE THOMAS

**SECTION:** Section B; Column 0; Business/Financial Desk; Pg. 2

**LENGTH:** 564 words

The Swiss drug maker Novartis had been bracing all year for the day in late September when Diovan, its top-selling blood pressure drug, would lose **patent** protection and a cheaper generic version would become available.

But September has come and gone, and now, nearly three months later, there is still no generic alternative to Diovan on the market. The Food and Drug Administration has not given final clearance to **Ranbaxy**, the generic drug maker that won the exclusive right to sell the drug for the first six months after its **patent** expired.

Now a competing generic company, Mylan, is suing the F.D.A. to force the agency to revoke **Ranbaxy's** exclusive rights and allow Mylan to begin selling the drug. A hearing on the matter is scheduled for Friday in federal court in Washington. Mylan is exclusively selling a related drug, a combination of Diovan and a diuretic, whose **patent** protection also expired in September.

The delay in approval of generic Diovan has proved to be an unexpected bright spot for Novartis, since Diovan brought in more than $1.9 billion in United States sales last year, according to the health care research firm IMS Health. ''It's like extra cash,'' said Kim Vukhac, an analyst for CrÈdit Agricole.

But it represents another setback for **Ranbaxy**, which is operating under a federal consent decree and last month recalled more than 40 lots of generic Lipitor after discovering that the pills may have contained tiny glass particles. **Ranbaxy** has since halted all production of the drug, and the company told The Wall Street Journal this week that it believed the cause was splintered glass from the lining of a tank at a plant in India.

A spokeswoman for the F.D.A. declined to comment on why it had failed to approve **Ranbaxy's** generic Diovan, known as valsartan, saying federal law prohibited her from commenting on pending applications. She also declined to comment on Mylan's lawsuit.

In court papers, Mylan described the F.D.A.'s actions as ''arbitrary, capricious and unlawful'' and said the agency should not have granted **Ranbaxy** the sole right to sell the drug. Under federal law, a company that is the first to successfully challenge a **patent** and show it can make a drug is granted a six-month exclusivity period that is highly prized in the world of generics. But the law requires that those companies receive approval from the F.D.A. within 30 months, and in this case, **Ranbaxy** did not get approval until four months past the deadline.

The agency grants exceptions to the 30-month rule if procedures or requirements change significantly after a drug maker files its application, and in the case of **Ranbaxy**, it said that the rules for manufacturing Diovan had changed during that period. But Mylan has argued that the F.D.A. did not explain its reasoning and that the rule change was proposed long before **Ranbaxy** reached its deadline.

A spokeswoman for Mylan declined to comment. **Ranbaxy** said in a statement that it planned to begin selling the drug as soon as it received approval from the F.D.A.

Ms. Vukhac said Mylan had a litigious history, noting that last year, the company unsuccessfully challenged **Ranbaxy's** exclusive right to sell generic Lipitor on the grounds of previous manufacturing violations. It also sued Teva this year over its right to exclusively sell a generic version of Provigil, the antidrowsiness drug, in a case that was later settled.

**URL:** http://www.nytimes.com/2012/12/07/business/mylan-sues-fda-over-**ranbaxys**-rights-to-diovan.html

**LOAD-DATE:** December 7, 2012

**LANGUAGE:** ENGLISH

**PUBLICATION-TYPE:** Newspaper

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[Return to List](#cite_id_3)

3 of 200 DOCUMENTS

The International Herald Tribune

**December** 1, 2012 Saturday

**Ranbaxy halts generic Lipitor over glass in pills**

**BYLINE:** KATIE THOMAS

**SECTION:** FINANCE; Pg. 17

**LENGTH:** 904 words

**ABSTRACT**

**Ranbaxy,** the largest producer of the generic version of Lipitor, has halted production of the drug until it can figure out how some pills were contaminated with glass particles.

**FULL TEXT**

**Ranbaxy**, the largest producer of the generic version of the cholesterol treatment Lipitor, has halted production of the drug until it can figure out why glass particles may have ended up in pills distributed to the public, the U.S. Food and Drug Administration has announced.

The agency said it had not received any reports of patients' being harmed by the particles, which are about the size of a grain of sand. In November, **Ranbaxy** recalled more than 40 lots of the drug because of the glass contamination.

The company, which is based in India, has declined to say where the drug was manufactured or why the problem occurred, but a spokeswoman for the F.D.A. said Thursday that the company would stop producing the pill's active ingredient, which is made in India, until the investigation was completed.

The contamination was the latest episode in a history of manufacturing lapses at **Ranbaxy**, which is a subsidiary of the Japanese pharmaceutical company Daiichi Sankyo. The company has been operating under a court-ordered consent decree since January, after U.S. authorities identified a host of manufacturing problems at the company's plants in India and the United States, and concluded that **Ranbaxy** had submitted false data in drug applications to the F.D.A.

The decree prevents **Ranbaxy** from manufacturing drugs at its most troubled facilities until it can show it is meeting U.S. standards, though it was allowed to continue making products - including the generic version of Lipitor - at other plants.

The F.D.A. spokeswoman, Sarah Clark-Lynn, said the affected lots had not been made at ''the same facilities whose conduct gave rise to the consent decree.'' Nonetheless, she said in an e-mail Monday, ''the consent decree provides the F.D.A. with additional tools to address violations for other **Ranbaxy** facilities.''

A spokesman for **Ranbaxy** declined to comment beyond an informational statement on the company's Web site.

Some drug-manufacturing experts said **Ranbaxy's** latest troubles highlighted the disparities between the oversight of plants in the United States and plants elsewhere.

''I have pretty good faith in companies and plants that make drugs in this country, because I know from my own experience that they try to do a good job,'' said Prabir K. Basu, executive director of the Illinois-based National Institute for Pharmaceutical Technology and Education, who previously worked in manufacturing and global outsourcing for pharmaceutical companies, including Searle and Pharmacia. ''But my confidence is not that high when we are getting products from outside the country.''

He pointed to studies that have shown the F.D.A. inspects foreign generic-manufacturing plants about once every seven to 13 years, compared with once every two years for domestic manufacturers. A law passed over the summer will eventually require the F.D.A. to apply the same standards when inspecting all manufacturing plants, regardless of what country they are in.

Allan Coukell, director of medical programs at the Pew Health Group and an expert on drug safety, said the new law would level what he described as an uneven playing field, but ''it's incumbent on F.D.A. to hire the staff and to make the shift to a risk-based inspection system.''

Under the law, fees collected from generic manufacturers will help pay for more inspectors.

Mr. Basu said the law, called the Generic Drug User Fee Amendments of 2012 and known as Gdufa, was a step in the right direction, but fixing the problem would require more than simply hiring more people. ''This is a very difficult and complex system, and how do we ensure the integrity of this supply chain?'' he said. ''I don't know how much Gdufa will help.''

**Ranbaxy** has held a significant share of the market for generic Lipitor, also known as atorvastatin, since it became one of the first companies to sell it after Pfizer lost **patent** protection last November; another company, Watson, sold a generic version that was authorized and manufactured by Pfizer. In October, **Ranbaxy's** product accounted for 43 percent of prescriptions for atorvastatin, a widely used drug to lower cholesterol levels, according to an analysis by Michael Faerm, an analyst for Credit Suisse who used prescription data from the research firm IMS Health.

In its statement Thursday, the F.D.A. said it did not expect a shortage of atorvastatin. Erin Fox, who tracks drug shortages as director of the Drug Information Service at the University of Utah, said drugs in pill form have long shelf lives and suppliers can keep large quantities in stock. Other generic manufacturers with approval to sell the drug include Apotex, Dr. Reddy's Laboratories, Mylan, Sandoz and Teva, according to the F.D.A. Web site.

**Ranbaxy** has posted a list of the recalled lots on its Web site, and has warned that patients should not stop taking the drug without guidance from their doctors. The lot numbers are found on the side of **Ranbaxy** pill bottles and the company advised patients to check with their pharmacist if customers received pills in a container dispensed by the pharmacy.

The agency said the potential for injury because of the contamination appeared to be low and ''if any adverse events are experienced, they would be temporary.''

**LOAD-DATE:** November 30, 2012

**LANGUAGE:** ENGLISH

**PUBLICATION-TYPE:** Newspaper

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[Return to List](#cite_id_4)

4 of 200 DOCUMENTS



Pharma

**November** 27, 2012 Tuesday

**Ranbaxy Laboratories starts sales and promotion launch of Absorica Capsules**

**LENGTH:** 101 words

M2PHARMA-November 27, 2012-**Ranbaxy** Laboratories starts sales and promotion launch of Absorica Capsules

**Ranbaxy** Laboratories Inc, a wholly owned subsidiary of **Ranbaxy** Laboratories Limited, announced yesterday that it has commenced a sales and promotion launch of Absorica (Isotretinoin) Capsules.

The product is licensed from Cipher Pharmaceuticals Inc of Mississauga, Ontario and is indicated for the treatment of severe recalcitrant nodular acne in patients 12 years of age and older.

The medicine has been formulated using patented Lidose(r) technology and can be administered without regards to meals.

**LOAD-DATE:** November 27, 2012

**LANGUAGE:** ENGLISH

**PUBLICATION-TYPE:** Newswire

**JOURNAL-CODE:** PHARMA

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[Return to List](#cite_id_5)

5 of 200 DOCUMENTS



Tampa Bay Times

**November** 24, 2012 Saturday

4 State / Suncoast Edition

**BEYOND TAMPA BAY**

**SECTION:** LOCAL; BEYOND TAMPA BAY; Pg. 4B

**LENGTH:** 435 words

EMBOLDENED by rapid growth in e-commerce shipping, the cash-strapped U.S. Postal Service is moving aggressively this holiday season to start a premium service for Internet shoppers seeking the instant gratification of a store purchase: same-day package delivery. Teaming up with major retailers, the post office will begin the expedited service in San Francisco on Dec. 12 at a price similar to its competitors. If things run smoothly, the program will quickly expand next year to other big cities such as Boston, Chicago and New York.

\* \* \*

WAL-MART'S INDIAN JOINT VENTURE, Bharti Walmart, said Friday that it has suspended several employees as part of an internal corruption investigation, another blow to the U.S. company's plans for aggressive expansion in a giant market that is largely untapped by foreign retailers. India's Economic Times newspaper reported that the company's chief financial officer was among the five employees suspended, a claim the company declined to verify.

\* \* \*

**RANBAXY** PHARMACEUTICALS is recalling several doses of its generic version of Lipitor because some batches of the cholesterol fighter may contain small glass particles. The generic drugmaker's website says it is recalling 10-, 20- and 40-milligram doses of atorvastatin calcium tablets. The recall is tied to certain lot numbers of the drug, and not to an 80-milligram version of the tablets. Lipitor was the world's top-selling drug until it lost **patent** protection nearly a year ago. **Ranbaxy** is one of several companies selling generic versions of the drug.

\* \* \*

UBS is reportedly expected to face a multimillion-dollar fine in connection with the $2.3 billion trading loss caused by a former trader. The potential fine by British authorities against the Swiss bank may by $47 million to $80 million, and could be announced as early as next week, according to a person with knowledge of the matter who asked not to be identified by the New York Times. On Tuesday, former UBS trader Kweku M. Adoboli received a seven-year jail sentence on two counts of fraud in connection with the loss for abusing his position at the Swiss bank from 2008 to 2011.

\* \* \*

BRITISH OIL GROUP BP said Friday that it had appointed Lamar McKay to run its exploration, development and production operations worldwide at the start of next year, as the company wrapped up a restructuring of the unit following the disastrous oil spill in the Gulf of Mexico in 2010. McKay is taking over from BP's chief executive, Robert W. Dudley, who took over management of the so-called upstream unit in an effort to improve risk management in the wake of the spill.

**LOAD-DATE:** November 26, 2012

**LANGUAGE:** ENGLISH

**GRAPHIC:** PHOTO - Associated Press (2011): People wait for their turn to ship items at the U.S. Postal Service Airport station in Los Angeles. The cash-strapped Postal Service is moving to start a premium service for Internet shoppers. PHOTO: Former UBS trader Kweku Adoboli leaves a London court on Sept. 16, 2011.

**PUBLICATION-TYPE:** Newspaper

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[Return to List](#cite_id_6)

6 of 200 DOCUMENTS

The Business Times Singapore

**September** 4, 2012 Tuesday

**Fate of Indian generic drugs hangs on Novartis case**

**BYLINE:** Yogi Aggarwal

**SECTION:** EDITORIAL & OPINION; The Bottom Line

**LENGTH:** 824 words

WILL the Indian government be forced to recognise a **patent** for a cancer treatment drug claimed to be effective for people with a deadly form of leukaemia? India's Supreme Court will witness this important legal battle on Sept 11.

The court will finally decide whether the Swiss company Novartis can seek **patent** protection for a variation of its cancer drug imatinib mesylate (also called Gleevec) which was rejected by the Indian **patent** office in 2006 for several reasons, including section 3(d) of the Indian **patents** act which requires **patents** only be granted on medicines that are only truly new and innovative. Novartis's subsequent challenge to the order in the Madras High Court was also rejected. The case has been winding through the Indian legal system for about six years now.

Indian generic versions of imatinib mesylate go for less than a tenth of what Novartis prices it in the West, forcing Novartis to offer it for free or at very low cost in India. But its Indian sales are a microscopic proportion of the US$4.7 billion worldwide of Gleevac. Thus the sales of this drug are not significant to the company's bottom line.

What is crucial is an attempt to finish the threat the Indian pharma industry poses to the giants in Europe and the US. It's not just that India has become "the pharmacy of the developing world" supplying affordable medicines to sub-Saharan Africa and elsewhere. The case Novartis is pursuing in India is really aimed at closing down any space left for generic companies to operate. Western governments have also been applying discreet, but enormous, pressure on the government of Prime Minister Manmohan Singh, to close down the generic drug industry.

The international NGO, Doctors without Borders, says: "If Novartis won the case, India would no longer be able to supply much of the developing world with quality affordable medicines." If Novartis succeeds in weakening the interpretation of Section 3(d), it would force India to grant far more **patents** than it is required to under World Trade Organisation trade rules.

A recent UNDP study, "Five years into product **patent** regime, the experience of India", states that foreign companies account for only 20 per cent of the Indian market and even after the introduction of the new **patent** law, the market share of foreign companies is still falling. It adds that "India and Japan are the only two countries where pharmaceutical companies of the US and Europe do not dominate". Besides this, the Indian pharmaceutical industry has become highly export intensive with exports of more than US$10 billion. It is today producing 20 per cent of the world's generics.

A 2011 PricewaterHouse report says: "The global pharma industry is under serious pressure. Large numbers of forthcoming **patent** expiries, a dry pipeline of new drugs, regulatory challenges and pricing restrictions have slowed down the growth of pharma industry's main markets."

With about US$70 billion of drugs going off **patent** in the next five years, India with its increasingly sophisticated pharmaceutical industry is likely to become a competitor of global pharma in some key areas, and PwC feels India is capable of manufacturing a substantial share of the product to support the resulting generics opportunities.

It is this, and the threat posed to other drugs for which generics are made in India, that is worrying companies such as Novartis. For instance, Roche is fighting court cases to uphold its **patent** on the anti-cancer drug Tarceva or erlotinib. Indian drug makers argue that it does not meet the standards under section 3(d). Gilead Sciences is appealing against India's rejection of a **patent** application for its drug Viread, which is used to treat HIV infection.

Courts have allowed generic versions of these drugs to be sold in India, but these may have to be stopped if Novartis wins its case next month.

There are other ways of targeting the rich potential of the Indian pharma companies. Mergers and acquisitions have, in recent times, become more common in the fiercely independent industry. The largest was the acquisition of a 58 per cent stake in **Ranbaxy,** the largest Indian pharma company, by Diiachi Sankyo of Japan for US$5.48 billion in 2008. Another was the takeover of Piramal Healthcare by Abbot Laboratories of the US for US$3.8 billion 2010. That is one way for pharma giants to get a larger share of the expanding global generics business.

The more common way is to tire out the competition with long and expensive legal cases. Other methods such as human trials of potentially dangerous drugs are not uncommon. In The Constant Gardner, the best-selling English spy novelist John Le Carre reveals the extent to which the pharma giants will go to maintain their profits.

However, in the small but vigorous Indian competition they may have found an adversary who has the gumption to take them on.

**The writer is a Mumbai-based journalist who contributes regularly to BT**

**LOAD-DATE:** September 3, 2012

**LANGUAGE:** ENGLISH

**PUBLICATION-TYPE:** Newspaper

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[Return to List](#cite_id_7)

7 of 200 DOCUMENTS

Investors Chronicle - magazine and web content

**August** 16, 2012

**AstraZeneca feels the burn**

**SECTION:** 0261-3115

**LENGTH:** 172 words

AstraZeneca's deal with Pfizer to sell heartburn medicine Nexium over-the-counter is a step in the right direction, but not enough to overcome its anaemic development pipeline

AstraZeneca is in line for a $250m (GBP159m) boost after it signed an agreement with US pharma giant Pfizer to market heartburn treatment Nexium over-the-counter around the world, with royalties to come in addition.

The deal is not a world beater in the context of Nexium's $6.3bn annual sales. But it does show that Astra is starting to think about how to enhance the earning power of its remaining blockbuster products as they wind down towards **patent** expiry - indeed, Astra has about two years to get the remaining value out of Nexium, one of its biggest earners, before a deal with generics company **Ranbaxy** to sell a licensed generic version of the drug comes into force.

Although the deal is interesting, it doesn't change the basic outlook for AstraZeneca, which is struggling with one of the worst development pipelines in the sector. Sell at 3,000p.

Sell

**LOAD-DATE:** August 20, 2012

**LANGUAGE:** ENGLISH

**PUBLICATION-TYPE:** Magazine

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[Return to List](#cite_id_8)

8 of 200 DOCUMENTS

The International Herald Tribune

**July** 26, 2012 Thursday

**E.U. charges drug firms over delays for generics;**

**Regulators say keeping cheaper treatments from market hurt consumers**

**BYLINE:** EDWARD WYATT

**SECTION:** FINANCE; Pg. 17

**LENGTH:** 601 words

**DATELINE:** WASHINGTON

**ABSTRACT**

The European Commission said a Danish drug company paid manufacturers of generics to keep their products off the market.

**FULL TEXT**

Antitrust regulators in the European Union brought their first enforcement action on Wednesday in ''pay for delay'' drug cases, in which a maker of name-brand pharmaceuticals pays makers of generic drugs to keep competing products off the market.

The European Commission told Lundbeck, a Danish drug company, that it believed the company's agreements with generic companies violated antitrust laws by preventing the entry for as long as two years of competing generic versions of citalopram, an antidepressant sold as Celexa that is one of Lundbeck's biggest sellers.

The notice came in a ''statement of objections,'' which lays out charges to which a company can reply, including requesting a formal hearing before the European Commission. Eight other companies that the commission said ''belonged to the generic groups that concluded the agreements'' were also named in the complaint.

In a statement, Lundbeck called the charges ''groundless'' and said it believed that its business practices ''are consistent with all relevant national and E.U. competition legislation.''

Mette Carlstedt, senior vice president for corporate legal matters at Lundbeck, said in the statement that the company's policy ''is to comply with all applicable laws, including competition laws, and this policy is taken very seriously by the company and its employees.''

The commission said Lundbeck ''may have caused substantial consumer harm'' with direct payments to the generic drug makers, promises to buy their stocks of generic drugs so they could be destroyed, and guaranteeing their future profits in a distribution agreement.

Lundbeck was able to charge more for its name-brand drug than it would have if generic competitors had been on the market, the commission said.

The other companies named in the case were Merck, Generics UK, Arrow, Resolution Chemicals, Xellia Pharmaceuticals, Alpharma, A.L. Industrier and **Ranbaxy.**

The commission also said it planned to bring charges soon in an investigation of Les Laboratoires Servier over its cardiovascular drug perindopril. The commission said Servier and several generic competitors made deals that hindered the entry of generic forms of the drug into European markets.

European antitrust regulators opened formal investigations of Servier in 2009 and Lundbeck in 2010 following a larger inquiry into competitive practices in the drug business.

In 2009, the commission said its broad investigation of the industry found numerous practices, including pay-for-delay deals, that ''potentially led to distortions of competition and delays to entry of new, innovative as well as cheaper generic medicines into the E.U. market.''

The U.S. Federal Trade Commission has investigated numerous pay-for-delay deals among American drug companies and has charged several with anticompetitive behavior. But the F.T.C. and private plaintiffs have had a harder time convincing U.S. courts that the companies should be punished for the deals.

This month, for the first time in nearly a decade, a federal appeals court ruled that the payments to keep a generic drug off the market were anticompetitive on their face. Before that ruling, several appeals courts had said that such deals were legal as long as they did not exceed the scope of an unexpired **patent** on the name-brand drug.The European Commission also said it was investigating several U.S. companies - Cephalon, Teva, Johnson & Johnson, Novartis and Sandoz - for possible violations of competition rules.

**LOAD-DATE:** July 25, 2012

**LANGUAGE:** ENGLISH

**PUBLICATION-TYPE:** Newspaper

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[Return to List](#cite_id_9)

9 of 200 DOCUMENTS

The International Herald Tribune

**July** 7, 2012 Saturday

**India's poor to benefit from free drugs;**

**Government to propose distribution of generics, a blow to big companies**

**BYLINE:** VIKAS BAJAJ

**SECTION:** FINANCE; Pg. 11

**LENGTH:** 1379 words

**DATELINE:** MUMBAI

**ABSTRACT**

As part of a five-year-plan, the Indian government announced that it planned to provide free drugs at government-run clinics and hospitals, removing a major expense from household budgets.

**FULL TEXT**

In what would be a landmark increase in the Indian government's spending on public health, New Delhi is completing a proposal to provide hundreds of essential drugs free to patients in government-run hospitals and clinics at a cost of nearly $5 billion over five years.

The proposal, which was announced Thursday and could receive government approval next month, would try to fill a gaping hole in the provision of health care at state-owned hospitals, many of which require patients to buy their own drugs, including substances as basic as intravenous fluids. Specialists say it could also be the first step toward a more comprehensive universal health care system in India, which, with 1.2 billion people, is the world's second most populous country, after China.

Drugs account for more than 70 percent of out-of-pocket medical costs for Indians. Government hospitals and clinics provide free or low-cost care, but most of them struggle to keep up with demand, and the quality of care can be poor.

For Western drug makers, which have long chafed at India's comparatively weak protection of their **patents**, the government's plan could be another blow. Although they have only a tiny share of the Indian market, Western drug companies are looking at India and other emerging markets as a vital source of growth as sales flatten in the United States and Europe. Under the proposal, the government would buy only cheap generic versions of drugs, making it more difficult for brand-name drugs to be sold.

The policy move is part of India's stated goal of increasing spending on health care to about 2.5 percent of its gross domestic product from about 1.4 percent. For comparison's sake in 2009, the Indian government spent about 1.2 percent of its G.D.P. on health care, while the Chinese government spent about 2.3 percent and Sri Lanka spent about 1.8 percent.

An official in the Indian Ministry of Health and Family Welfare said the federal government would spend about 200 billion rupees, or $3.6 billion, on the program over five years. State governments, which are being consulted on the proposal, would be asked to chip in another 66 billion rupees. The proposal is part of the country's 12th five-year plan, which covers the government's big spending programs from 2012 to 2017 and is expected to be approved in August.

''This new initiative, if approved as a part of the five-year proposal, would be a giant step in vastly expanding the access to medicines,'' the official, Dr. Arun K. Panda, a joint secretary in the ministry, said in an e-mail message.

Dr. K. Srinath Reddy, who led a committee advising the government on health care for the five-year plan, said the distribution of free drugs could be the first step in a process of providing tax-supported universal health care in India, which he said could take 10 to 15 years.

Initially, India would probably provide 350 drugs that are on a government list of essential medicines, said Dr. Reddy, who has no connection to the Indian generic drug company Dr. Reddy's Laboratories. Many of the drugs probably would be produced by India's many generic drug companies, which include Cipla, Lupin and **Ranbaxy.** In February, Prime Minister Manmohan Singh announced that the Health Ministry had begun setting up an agency to buy drugs in bulk.

Big Western pharmaceutical companies like Abbott Laboratories that have acquired Indian generic drug makers could also supply the government, but the program would exclude more lucrative brand-name drugs like Lipitor and Plavix produced by those companies.

Spending on drugs in India was $14.3 billion in 2011, including $3.3 billion for brand-name drugs, according to the IMS Institute for Healthcare Informatics. It is expected that total drug spending will more than double by 2016, to $29 billion.

For Western drug makers in India, the target is not the poor, but the growing middle and upper-middle classes, many of whom use private clinics and doctors, which are excluded from the current subsidy proposal. Given questions about the quality and regulation of India's generic-drug manufacturers, Western companies are hoping that Indians with money to spare will choose brand-name drugs or so-called branded generics, which carry the names of major drug makers.

''We think that there is still a big opportunity in India,'' said Mark Grayson, a spokesman for the Pharmaceutical Research and Manufacturers of America, the industry trade group. ''We believe that the economic situation for many Indians is getting better, and we believe there will be a place for good, branded generics.''

Nevertheless, Western pharmaceutical companies face many challenges in India. In March, its **patent** regulator ordered Bayer to license a cancer drug to an Indian generic drug maker under a compulsory license. The move, a first for India, raised fears among foreign companies that they could be required to license more of their medicines to generic producers.

For about 35 years, India did not grant drug **patents** in an effort to provide cheap medicine to its people. That helped establish a thriving generic drug industry. In 2005, it started issuing **patents** for drugs created in or after 1995.

Given the pervasive corruption in India and the poor state of the medical system, it is unclear how effectively the government could carry out the new drug program.

Yusuf K. Hamied, the chairman and managing director of Cipla, a Mumbai-based company that is one of the largest producers of generic medicines in India and the world, expressed skepticism.

Mr. Hamied, a proponent of generic drugs, said Thursday that he had read only news reports about the proposal to provide free drugs and was unsure the government could put it into effect.

''Not easy and does not appear workable, except if they give free medicines made by the public sector drug companies,'' he wrote in an e-mail message. ''They don't make a full range, so it will be difficult for them. The government should consult us for practical solutions to their policy implementation.''

Dr. Reddy said that to be successful, officials will have to put in place an efficient procurement, distribution and tracking system to ensure that drugs get to the people who need them and are not stolen by officials involved in distribution, as happens to much of the wheat and rice distributed by Indian states to poor families.

Government hospitals are often run poorly, and many Indians, including the poor, prefer to pay for care in private institutions at great personal cost. About 71 percent of spending on health in India comes directly from people's pockets, compared with 61 percent in China and 54 percent in Sri Lanka.

Corruption and mismanagement are endemic, especially in the health systems of India's poorest states. Last year, three doctors in charge of a large federally financed health initiative in Uttar Pradesh, the most populous state, were brutally killed amid widespread irregularities in the management of the program.

''Unfortunately, in the Indian system, anything can be subverted if you allow it to be subverted,'' said Dr. Reddy, who is the president of the Public Health Foundation of India, a group that is financed by the government and nonprofit organizations like the Bill and Melinda Gates Foundation.

But two Indian states, Tamil Nadu and Rajasthan, already distribute free drugs and have attracted more people to government hospitals as a result. Last year, the National Rural Health Mission began dispensing free drugs to pregnant women to encourage them to deliver their babies at medical institutions, said Dr. Panda, the health ministry official.

Still, Dr. Reddy said that the provision of free medicines in government hospitals and clinics had declined sharply in recent decades.

In 2004, just 9 percent of drugs prescribed to patients admitted to government institutions were free, down from 31 percent in 1987. For outpatients, the share was even lower, at 5 percent in 2004, down from 18 percent.

''As a result of high health care costs, 40 million Indians are pushed into poverty each year,'' Dr. Reddy said.

**LOAD-DATE:** July 6, 2012

**LANGUAGE:** ENGLISH

**PUBLICATION-TYPE:** Newspaper

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[Return to List](#cite_id_10)

10 of 200 DOCUMENTS

The Philadelphia Inquirer

**July** 7, 2012 Saturday

WEB Edition

**Business News in Brief**

**BYLINE:** Inquirer Staff Report

**SECTION:** BUSINESS; P-com Biz; Pg. WEB

**LENGTH:** 450 words

IN THE REGIONNuStar sells 50% of N.J. refinery

Ownership of another Philadelphia-area refinery is about to change. NuStar Energy L.P. said it would sell 50 percent of its asphalt operations, which include refineries in Paulsboro and in Savannah, Ga., to a joint venture in a transaction expected to be completed by Sept. 30. Lindsay Goldberg L.L.C., a New York private-equity firm with $10 billion under management, will pay $175 million for a 50 percent interest in the joint venture, with San Antonio-based NuStar holding the other 50 percent stake. The two refineries have a combined refining capacity of 104,000 barrels a day. NuStar acquired the Gloucester County and Georgia refineries and three asphalt terminals from Citgo, the Venezuela-owned oil company, for $550 million in 2008. Shares of NuStar Energy closed Friday at $52.91, down $1.02 or 1.9 percent &mdash; Mike Armstrong

ELSEWHEREDrugmakers sued over Lipitor

Five large drug and grocery chains are suing Pfizer Inc. and generic drugmaker **Ranbaxy** Laboratories, alleging they conspired to delay sales of cheap generic versions of the blockbuster cholesterol drug Lipitor. Lipitor, the world's top-selling drug ever, got U.S. generic competition on Nov. 30. A lawsuit filed by Walgreen Co., the Kroger Co. and three other retailers contends that generics should have been available nearly two years earlier, when Lipitor's original **patent** expired. Pfizer denies the contentions and says it will fight the lawsuit. **Ranbaxy** declined to comment. &mdash; AP

IMF to cut global growth forecast

International Monetary Fund Managing Director Christine Lagarde said the fund would cut its forecast for global economic growth in a quarterly assessment to be released this month. She did not say which nations or regions were contributing to the lowered assessment for 2012, characterizing it as "tilted to the downside" compared with the IMF's 3.5 percent global growth projection given three months ago. She declined to give more details. Growth in most major economies has showed signs of slowing in recent months, partly due to Europe's chronic debt crisis and economic malaise. &mdash; AP

Ga. bank is 32d failure this year

Federal regulators have closed a small bank in Georgia, bringing the number of U.S. banks that have failed this year to 32. The Federal Deposit Insurance Corp. said it had seized Montgomery Bank & Trust, based in Ailey. The bank, which had two branches, had about $173.6 million in assets and $164.4 million in deposits as of March 31. Ameris Bank of Moultrie, Ga., agreed to take over the failed bank's deposits. Regulators estimate that the bank's failure will cost the insurance fund $75.2 million. &mdash; AP

**LOAD-DATE:** July 7, 2012

**LANGUAGE:** ENGLISH

**PUBLICATION-TYPE:** Newspaper

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[Return to List](#cite_id_11)

11 of 200 DOCUMENTS



Tampa Bay Times

**July** 7, 2012 Saturday

4 State / Suncoast Edition

**BEYOND TAMPA BAY**

**SECTION:** LOCAL; BEYOND TAMPA BAY; Pg. 4B

**LENGTH:** 432 words

Electronics retailer Best Buy is laying off 600 staffers in its Geek Squad technical support division and 1,800 other store workers as it seeks to restructure operations and improve results. The cuts amount to about 1.4 percent of the company's total staff of 167,000. Best Buy spokesman Bruce Hight says the layoffs are part of the company's "ongoing turnaround plan." In March, the company said it would implement a restructuring designed to trim $800 million in costs.

\* \* \*

Yahoo and Facebook agreed Friday to settle a legal fight over their **patent** holdings, ending what was shaping up to be one of the nastier court battles in Silicon Valley in recent memory. Under the terms of the pact, the two Internet companies will expand an existing partnership, including a deeper integration of Facebook's tools into Yahoo's content pages. The two companies have also agreed to cross-license some of their **patent** holdings, which forbids either side from suing the other over intellectual property issues in the future.

\* \* \*

American Airlines and its parent company are suing to stop providing health care and life insurance benefits to current retirees. AMR Corp. and American filed the lawsuit Friday as part of their bankruptcy case in federal court in New York. The airline wants the bankruptcy judge to rule that it can end the benefits as a way to cut costs in "sound business judgment." American says it never promised benefits to last the retirees' entire lives, and it reserved the right to change the benefits plan. The company has about 40,000 retirees.

\* \* \*

Five drug and grocery chains, including Walgreen and Kroger, are suing Pfizer and a second drugmaker, alleging they conspired to delay sales of generic versions of the blockbuster cholesterol drug Lipitor, which got U.S. generic competition on Nov. 30. The lawsuit accuses Pfizer of **patent** fraud as well as "illegal, anti-competitive conduct" with generic drugmaker **Ranbaxy** Laboratories to block other generic drugmakers from selling versions of Lipitor until recently.

\* \* \*

"We have an overarching goal here, which is to restore trust in the consumer financial marketplace."

RICHARD CORDRAY, director of the Consumer Financial Protection Bureau, saying that over the next six months the Consumer Financial Protection Bureau intends to remake the process of getting a mortgage, making it easier for borrowers to understand the kind of loan they are getting and its cost

\* \* \*

$30.2M

AMOUNT AIG, the insurance giant saved by a massive federal bailout, wants the government to pay it back in tax interest, saying it overpaid its taxes in 1991

**LOAD-DATE:** July 9, 2012

**LANGUAGE:** ENGLISH

**GRAPHIC:** PHOTO

**PUBLICATION-TYPE:** Newspaper

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[Return to List](#cite_id_12)

12 of 200 DOCUMENTS



The Washington Post

**July** 7, 2012 Saturday

Met 2 Edition

**SECTION:** A-SECTION; Pg. A11

**LENGTH:** 770 words

**banks**

**Probe expands on rate-fixing scheme**

A global investigation into manipulation of interbank lending rates widened Friday with Britain's fraud squad taking up the case and news emerging that Germany's markets regulator has launched a probe into Deutsche Bank.

Authorities in the United States, Europe, Japan and Canada are examining more than a dozen big banks over suspected rigging of the London interbank offered rate (Libor). Britain's Barclays has so far been the only bank to admit wrongdoing, agreeing last week to pay a fine of more than $450 million.

The rate-fixing scandal has exploded into the front ranks of politics, especially in Britain, where politicians say the bankers responsible should end up in jail.

Barclays chief executive Bob Diamond was forced to resign this week and told a parliamentary committee that some of his firm's former staff could face criminal charges.

The Libor rates, compiled from estimates by large banks of how much they believe they have to pay to borrow from one another, are used to determine interest rates on trillions of dollars worth of contracts around the world.

Germany's BaFin regulator is probing Deutsche Bank with a "special investigation," a process initiated by the regulator that is more severe than a routine investigation initiated by a third party, according to a banker and a regulator, both of whom spoke on the condition that they not be named.

- Reuters

**WORLD economy**

**IMF outlook bleakon global growth**

The International Monetary Fund will reduce its estimate for global growth this year on weakness in investment, jobs and manufacturing in Europe, the United States, Brazil, India and China, Managing Director Christine Lagarde said Friday.

"The global growth outlook will be somewhat less than we anticipated just three months ago," Lagarde said in a speech in Tokyo. "And even that lower projection will depend on the right policy actions being taken." The new outlook will be announced in 10 days, after an April estimate of 3.5 percent, she said.

Interest-rate cuts in China and Europe on Thursday and the Bank of England's boost to anasset-purchase program underscored the fragility of the global recovery as austerity measures and debt burdens weigh on advanced nations.

The "key emerging markets" of Brazil, China and India are showing signs of slowdown, Lagarde said. Those three countries, along with Russia, will comprise more than 20 percent of the world economy this year, according to IMF data.

The IMF has already lowered its U.S. growth estimate to 2 percent from April's 2.1 percent.

Japanese Prime Minister Yoshihiko Noda told Lagarde that sustained gains in the yen because of the euro region's crisis are damaging his country's economy, according to a statement Friday. "The euro zone crisis is the most important problem facing the global economy at present," Noda said. The strength of the yen "does not reflect the real state of Japan's economy."

- Bloomberg News

**Also in Business**

lAmerican International Group, the insurance giant saved by a massive federal bailout, is suing the U.S. government to recover $30.2 million for an alleged tax overpayment in 1991. The lawsuit notes that AIG is trying to resolve underpayments and overpayments of taxes through 1999 and the refund request has been pending before the Internal Revenue Service since 2007. AIG said it filed the lawsuit Thursday because the statute of limitations on its claims is about to run out.

lHTC, Asia's second-largest smartphone maker, posted its third consecutive drop in profit after cutting its revenue forecast amid competition from Apple and Samsung. Second-quarter net income declined 58 percent from a year earlier to $247 million, the Taipei, Taiwan-based company said in a statement on its Web site Friday.

lFive drug and grocery chains are suing Pfizer and a second drugmaker, alleging that they conspired to delay sales of cheap generic versions of the blockbuster cholesterol drug Lipitor. The lawsuit - filed Thursday by Walgreen, Kroger and three other retailers in U.S. District Court in Trenton, N.J. - claims that generics should have been available nearly two years earlier, when Lipitor's original **patent** expired. The suit accuses Pfizer of **patent** fraud as well as "illegal, anti-competitive conduct" with generic drugmaker **Ranbaxy** Laboratories of India to block other generic drugmakers from selling versions of Lipitor, also called atorvastatin calcium, until recently.

- From news services

**Coming This Week**

lIn Sunday Business: If built, the Keystone XL pipeline could bolster U.S.-Canadian ties.

lOn Monday: Consumer credit report and Alcoa earnings.

**technology**

**LOAD-DATE:** July 7, 2012

**LANGUAGE:** ENGLISH

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**PUBLICATION-TYPE:** Newspaper

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[Return to List](#cite_id_13)

13 of 200 DOCUMENTS

Business Day (South Africa)

**June** 20, 2012 Wednesday

Business Day Edition

**State patients to benefit as Roche is persuaded to cut price of cancer drug**

**BYLINE:** TAMAR KAHN

**SECTION:** PRINT:PAGE

**LENGTH:** 540 words

State patients to benefit as Roche is persuaded to cut price of cancer drug

Science and Health Editor

CAPE TOWN - The Department of Health has persuaded pharmaceutical company Roche to halve the price of its cancer drug rituximab, opening the way for the government to provide it to more patients. The drug belongs to an expensive class of medicines called biologics, and is used for treating non-Hodgkin's lymphoma, leukaemia, and severe rheumatoid arthritis.

Branded MabThera by Roche, the drug has until now been too expensive for the state to procure on a wide scale, the department's deputy director-general for health regulation and compliance, Anban Pillay, said on Monday.

The fact that it is on the national tender means provinces with the capacity to offer cancer treatment will purchase the drug, within the constraints of their budgets. The main cancer treatment centres are in Gauteng, KwaZulu-Natal, the Western Cape and the Free State.

Roche is a price-setter for MabThera, as the only market with a rival product is India. The drug generated $1,52bn in revenue for Roche during the third quarter of last year.

However, its market dominance may face a challenge in the near future, as Hyderabad-based Dr Reddy's has previously said it will market its version of the drug - branded Reditux - beyond India's borders once the **patent** on rituximab expires in the US in 2015. Other generic companies including Cipla and **Ranbaxy** are also developing capacity to make biologics.

The department's latest two-year oncology tender, on its website, shows the government is willing to pay R7950 for a 50ml vial of the injectable rituximab, and R1590 for a 10ml vial.

Dr Pillay said the health department was also in discussion with Roche over the scope for a & more affordable& price for its breast cancer drug Herceptin, which was too expensive.

Herceptin is available only to state patients who are enrolled in clinical trials, and to people who belong to medical schemes willing to pay for it.

Medical schemes vary in the extent to which they will foot the bill; some schemes pay for a year's treatment, while others will pay for only nine weeks.

Until this year, some breast cancer patients in KwaZulu-Natal were able to get Herceptin at government hospitals on a limited basis, according to clinical oncologist Poovan Govender.

Doctors had been able to motivate for Herceptin on a patient-by-patient basis, but the budget constraints facing the province meant this was no longer possible, he said.

Dr Pillay said some biologics that were unaffordable to the state - such as Novartis's leukaemia drug Gleevec - were available at no charge to some public sector patients through what are known as & patient access& programmes, where the drugs are donated by the company.

However, these programmes were not open to private sector patients, as they breached the medicine pricing laws, which say there must be a uniform price for the private market.

Roche had not responded to a request for comment at the time of going to press.

& We would like to see that oncology is managed from a national point of view, and that everyone gets access to the same treatment everywhere,& said Linda Greff from the advocacy group, Cancer Alliance.

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Anban Pillay

**LOAD-DATE:** June 20, 2012

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**PUBLICATION-TYPE:** Newspaper

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[Return to List](#cite_id_14)

14 of 200 DOCUMENTS

The Australian

**May** 29, 2012 Tuesday

1 - All-round Country Edition

**Inquiry called over prescription `rip-off'**

**BYLINE:** SUE DUNLEVY

**SECTION:** LOCAL; Pg. 8

**LENGTH:** 374 words

MORE than 900 new hospital beds, almost 100,000 extra stays or 23,000 hip replacements could be bought with the $410 million a year being wasted on subsidies for the nation's biggest-selling medicine, which is being given away to chemists.

The Consumers Health Forum has called for an independent inquiry into the Pharmaceutical Benefits Scheme after The Australian revealed yesterday that generic drug company **Ranbaxy** is giving chemists $14,500 worth of Trovas, its version of the anti-cholesterol pill Lipitor.

The company is offering to sell future packs of the treatment at a 90 per cent discount on the government price as it tries to build market share now that the medicine has come off **patent**.

Despite this offer taxpayers are paying up to $73 per script for the drug whenever it is dispensed under the PBS, because the government has set the price at levels that are 10 times higher than the market price.

Consumers Health Forum chief Carol Bennett said that the ``outrageous'' rip-off was a double whammy for the 250,000 general patients using the anti-cholesterol treatment because they not only lost as taxpayers but must pay a $35.40 patient co-payment when they have a script filled. She demanded to know what the government would do about the waste.

``We should certainly have an independent inquiry to look at this,'' she said.

Australian Medical Association president Steve Hambleton said many of his patients could not afford all their prescriptions and it was ``appalling'' that the drug subsidy scheme was paying more than the market price.

The government needed to speed up its price disclosure process, which would take 18 months to capture any savings from the **Ranbaxy** deal, he said.

Opposition health spokesman Peter Dutton and Health Minister Tanya Plibersek would not comment yesterday.

Chemists said only those chemists who had signed up to a long-term contract with **Ranbaxy** were being offered the free stock. Some pharmacies are offering consumers $15 discounts on Trovas, which sells for $19.19 instead of the usual $35.40 under the PBS.

Medicines Australia said its drug company members needed time to adjust to new market pressures when a medicine came off **patent**.

``There needs to be a balance,'' its chief Brendan Shaw said.

**LOAD-DATE:** May 28, 2012

**LANGUAGE:** ENGLISH

**PUBLICATION-TYPE:** Newspaper

**JOURNAL-CODE:** AUS

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[Return to List](#cite_id_15)

15 of 200 DOCUMENTS

The Australian

**May** 28, 2012 Monday

1 - All-round Country Edition

**Free drugs costing taxpayers $410m GENERIC SUPPLY EXPOSES FLAW IN SUBSIDY SCHEME**

**BYLINE:** SUE DUNLEVY

**SECTION:** LOCAL; Pg. 3

**LENGTH:** 579 words

EXCLUSIVE

GENERIC drug company **Ranbaxy** is giving chemists free supplies of its anti-cholesterol pill Trovas, rival to the nation's biggest-selling medicine Lipitor, in a move that means taxpayers are wasting about $410 million a year subsidising the drug.

Although the medicine is being supplied for free, taxpayers still pay up to $73 every time a script is dispensed under the nation's drug subsidy scheme. The money goes to the chemists.

Lipitor is the nation's biggest-selling drug, with more than 10 million subsidised scripts supplied every year. The cholesterol treatment came off **patent** this month and the **Ranbaxy** offer is part of a strategy by the generic company to build its market share before nine new generic competitors enter the market next month.

**Ranbaxy** is offering chemists $14,650 worth of free supplies and has told pharmacists it will sell future supplies at a 90 per cent discount on the government's set price when the freebies run out.

The free supply of the drug has exposed once again how the nation's drug subsidy scheme is paying too much for generic medicines and is unable to secure taxpayers the best price on a range of cheap generic drugs.

University of Melbourne health economist Philip Clarke said the overpayment compared with the cost to the British government of as low as $3.64 per script for the 80mg strength.

``The high degree of discounting only demonstrates how out of line the current prices the government is paying with its actual market price,'' he said.

La Trobe University's public health expert Ken Harvey has complained to the Generic Medicines Industry Association that **Ranbaxy's** discounts breach two codes of practice in the medicine industry by offering a gift or pecuniary advantage that acts as an inducement to dispense the product.

But he says that because **Ranbaxy** belongs to neither Medicines Australia nor the GMIA, which oversee the codes of practice, it is unlikely any action can be taken.

The core of the problem is that the government sets the price it pays for medicines under the Pharmaceutical Benefits Scheme.

In many cases this set price can be up to 70 per cent higher than the market price because pharmacy wholesalers and drug companies offer chemists huge price discounts.

The government is trying to capture some of this discounting through its price disclosure process and it automatically cut the price of Lipitor by 16 per cent on April 1 when it became subject to generic competition.

However, that price drop is well short of the 90 per cent discount being offered by **Ranbaxy** and it will be another 18 months before the lengthy bureaucratic price disclosure process captures the **Ranbaxy** offer and delivers savings to taxpayers. In the meantime taxpayers will be spending $456m a year subsidising the anti-cholesterol treatments that only cost $45.6m.

The chemists will be the winners. They pay less for Trovas but get to charge the government the full PBS set price of up to $73 a script. The government is reviewing the prices it pays for Lipitor and another anti-cholesterol treatment, Crestor, and this could be an opportunity to capture further price savings.

On April 1, the government cut the price it pays for 1000 different generic drugs, which will drop by as much as $15 a packet for patients. Professor Clarke said at the time that the new lower prices were still up to 80 per cent higher than the market price, and the government could save as much as $1 billion a year if it better managed the PBS.

**LOAD-DATE:** May 27, 2012

**LANGUAGE:** ENGLISH

**PUBLICATION-TYPE:** Newspaper

**JOURNAL-CODE:** AUS

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[Return to List](#cite_id_16)

16 of 200 DOCUMENTS

Australian Financial Review

**May** 7, 2012 Monday

First Edition

**Ranbaxy moves in as patents expire**

**BYLINE:** Carrie LaFrenz

**SECTION:** COMPANIES AND MARKETS; Pg. 17

**LENGTH:** 463 words

India's largest pharmaceutical group, **Ranbaxy**, is looking to quadruple sales in Australia this year to more than $56 million by selling generic versions of big-selling drugs.

**Ranbaxy** Australia chief Alex Evans said half of Australia's pharmacies already stocked its generic version of the world's top-selling drug, the cholesterol-reducing Lipitor, since it came off **patent** on April 1.

This year "has been a year of large **patent** expiries, in both volume and dollar terms," Mr Evans said.

"Rambaxy has filed 12 molecules to the Therapeutic Goods Association which will drive the sales engine through 2014."

**Ranbaxy** has already launched seven molecules this year, including Trovas, the generic version of Lipitor.

Well known drugs such as Pfizer's Viagra and AstraZeneca's Crestor, which is used to treat high cholesterol, and Esomeprazole, used to treat peptic ulcer disease, are all close to coming off **patent**.

There are $US2.4 billion in drugs coming off **patent** over the next four years, representing a big opportunity for generic manufacturers.

While Rambaxy and Pfizer began selling their generic versions of Lipitor, last month, rivals can't offer deals to pharmacists until mid-May.

Pfizer offered to discount its generic by up to 75 per cent for those who order a year's supply of Lipitor and its generic.

**Ranbaxy** is making similar offers. **Ranbaxy** has one more month to maximise sales before other generic manufacturers can start selling their versions of Lipitor from June.

"We expect penetration to continue," Mr Evans said.

"Pfizer has been very aggressive in protecting this best selling molecule.

"We have a different structure to our larger competitors. We have not linked Trovas to other products or services," he said.

"We price competitively on every product, whether you buy one molecule or 50 molecules."

**Ranbaxy** Australia was established in 2004 and accounts for roughly 1 per cent of its parent's global sales which reached $2.1 billion in the 2011 financial year.

Mr Evans said Australia was an attractive market because it was highly regulated, resulting in a high barrier to entry.

"It's a well developed market in generics. Global generic companies want to be seen as playing in the well developed markets of the US, Australia and Europe," he said.

"If your products are passed by the regulatory authority TGA , that is also seen as an endorsement for the global company in places like Asia."

Mr Evans said that Australians were increasingly accepting of generic forms of medicine over branded products.

For every molecule available in generic form, three of four units dispensed is a generic in Australia, he said.

"Using generics reduces overall healthcare expenditure costs.

"Then that money can be used for future, more expensive molecules as they are developed," he said.

**LOAD-DATE:** May 6, 2012

**LANGUAGE:** ENGLISH

**GRAPHIC:** Photo:

**PUBLICATION-TYPE:** Newspaper

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[Return to List](#cite_id_17)

17 of 200 DOCUMENTS

Weekend Australian

**March** 31, 2012 Saturday

5 - Weekend Professional Edition

**We pay a heavy price for patent absurdities**

**BYLINE:** SUE DUNLEVY

**SECTION:** REVIEW; Pg. 8

**LENGTH:** 415 words

AS the government struggles to produce a budget surplus in 2012-13, academics, senators and the generic medicine industry have identified hundreds of millions of dollars that could be saved by better management of the medicines subsidy scheme.

Taxpayers spent about $600 million more than necessary on subsidies for just one clot-busting medicine because a lax **patent** system is protecting high-cost drugs from generic competition, a Senate committee has been told.

At the same time the government pays chemists 80 per cent more than the market price for one of the nation's biggest-selling anti-cholesterol pills, pushing up the cost of the Pharmaceutical Benefits Scheme.

And the generic medicine industry says $500m a year could be saved if the government lowered the $5.80 pensioner co-payment to encourage a switch to cheaper generic drugs.

Liberal senator Bill Heffernan told the Senate estimates committee last month that the 10-year extension of a **patent** on the anti-clotting medicine Plavix by Intellectual Property Australia had cost the PBS up to $600m in the past seven years. The extended **patent** was challenged by generic drug company Apotex in 2007, but an injunction prevented a generic version of the drug being sold in Australia while the court case was heard.

The **patent** was revoked by the full bench of the Federal Court in 2009 and the High Court denied an appeal and lifted the injunction in 2010.

According to Heffernan, the injunction meant the PBS had to keep paying a higher price for Plavix, which avoided generic competition until 2010.

Between the time the injunction was issued in 2007 and its removal, the PBS paid out $60m more than it needed to for the drug.

The Department of Health is launching legal action to recover the $60m in losses. But Heffernan claims the full seven-year cost to the PBS of the **patent**, now found to be invalid, was between $480m and $600m.

In another blow, from next month taxpayers will pay 80 per cent more than the market price for a top-selling anti-cholesterol medication.

Generic drug company **Ranbaxy** has announced it will sell its simvastatin pills to chemists for 80 per cent less than the set price the government pays chemists for the medicine.

While the taxpayer will pay chemists $22.68 a month for the 40mg version of simvastatin from tomorrow, chemists will pay just $2.83, costing the government $55m.

In the US, 78 per cent of medicines dispensed are generic; in Australia, generic medicines are used by only 36 per cent of patients.

**LOAD-DATE:** March 30, 2012

**LANGUAGE:** ENGLISH

**PUBLICATION-TYPE:** Newspaper

**JOURNAL-CODE:** AUS

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[Return to List](#cite_id_18)

18 of 200 DOCUMENTS

Australian Financial Review

**March** 27, 2012 Tuesday

Second Edition

**Pfizer reaches for painkillers**

**BYLINE:** Carrie LaFrenz and Emma Connors

**SECTION:** COMPANIES AND MARKETS; Pg. 12

**LENGTH:** 1578 words

The drug maker faces a critical year as it loses **patent** protection on the world's top-selling drug, Lipitor, write Carrie LaFrenz and Emma Connors.

The head of Terry White Chemists, Anthony White, reckons the largest drug company in the world has one hell of a fight on its hands.

From April 1, Pfizer has just three months to fill the pipeline with as many orders as possible for its blockbuster cholesterol fighting drug Lipitor before generic versions of the medicine flood the market.

Lipitor is the top-selling drug of all time. Often dubbed the "wonder drug", sales reached $US9.57billion in fiscal 2011, accounting for about 14.2 per cent of Pfizer's total global revenue of $US67 billion.

White, whose father Terry founded the eponymous 165-store chemist chain back in 1959, says Pfizer will have trouble securing a big chunk of the looming generic market for Lipitor before the bulk of its competitors enter the market.

White says pharmacists want to see all the offers on the table before committing to Pfizer. After all, when a drug loses **patent** protection, it opens the door for generic copycats that can be cheaper by as much as 90 per cent.

The dreaded "**patent** cliff" has arrived on many drugs, with some $2.4 billion in Pharmaceutical Benefits Scheme medicines to lose their **patent** protection between now and 2016. Pfizer lost about $US5 billion last year due to loss of product exclusivity. Originator drugs are big money. There are $US2.4 billion in drugs coming off **patent** over the next four years, of which Pfizer has $US1 billion.

While Indian generics manufacturer Rambaxy Laboratories and Pfizer can sell their generic versions of Lipitor, called Trovas and Atorvastatin Pfizer, from next month, rivals can't offer deals to pharmacists until mid-May for drugs that will list on the government's Pharmaceutical Benefits Scheme (PBS) from June.

Pfizer has offered to discount its generic by up to 75 per cent for those who order a year's supply of Lipitor and its generic, as long as the generic order is placed by April 30. **Ranbaxy** is making similar offers. It's not enough to tempt, says White.

"Pfizer were asking for a 12-month order. The bulk of pharmacists have negotiated a shorter time frame, as we have. Come June, we will want to have the full pressure of the market and see what others have to offer. I expect Pfizer will respond more competitively in June."

Industry, government and other major pharmaceutical companies will be watching Pfizer closely in coming months to see the take up of generics and see whether its audacious direct model installed 12 months ago in this country will pay off. Under the direct model, Pfizer is the sole distributor of its medicines, cutting out wholesalers like Australian Pharmaceutical Industries, Sigma Pharmaceuticals and Symbion Health.

Pfizer Australia managing director and chairman John Latham says the decision to go direct dates back to 2009 as Pfizer nutted out what to do when Lipitor came off **patent**.

"Lipitor being our biggest product, [we thought] how do we compete? Generics are a very competitive market. It became obvious to us the only way to compete was to go direct and we believe it's working. But the proof is in the pudding and that is; how are the pharmacists taking up our offers and deals? The focus last year was about proving we could deliver," Latham tells The Australian Financial Review.

He says Pfizer will focus on growing its generics business, valued at roughly $300 million a year and representing about 3 per cent of the total generics market in Australia.

Once entry is open to all, a bonanza of generics will seek to snare some of the $650 million in annual sales that went to Pfizer under the PBS. So far, there are 32 generic versions or additional trade names of Lipitor (atorvastatin) registered on the Australian Register of Therapeutic Goods. The price for Lipitor will be cut by 16 per cent overnight and the drug maker will also be selling its own generic product at a big discount to its branded product.

Reports from New York point to a 50 per cent drop in sales just one week after the release of generic competition in the US for Lipitor, despite an aggressive push by Pfizer to keep patients on its pill. Lipitor coming off **patent** is just the beginning of a sea change for Pfizer.

Latham declined to discuss strategy for other molecules coming off **patent** but the loss of well known names such as antipsychotic Geodon and erectile dysfunction drug Viagra will deeply affect the company.

One industry source said with **patent** "lives" shrinking from an average of about 12 years to eight, some big pharmaceutical companies are starting to think about the end of **patent** protection at the start of the drug's life.

Shrinking **patents** are a problem for the originator of the drug, cutting short the time available to recoup large research and development costs and allows generics to come to market sooner.

The price disclosure rules negotiated between industry and the Commonwealth government mean the first month after a generic enters the market is crucial.

The government collects price information during this time but it is not used in the price disclosure calculations. So any orders pharmacists make for Pfizer's generic Lipitor before April 30 don't count for price disclosure.

After 18 months, this data is used to remove trade discounts by bringing the price government pays in line with what wholesalers and pharmacists are charged.

**Ranbaxy** Australia managing director Alex Evans says many pharmacies already have Trovas on their shelves. "We have heard that the Pfizer generic will only be available at the last minute prior to the PBS listing on April 1. We assume this is to protect the price of Lipitor to the very last moment," Evans says. He says **Ranbaxy** is structured so that it offers the best possible terms and conditions to pharmacies on each product individually.

"We see the practice of making pharmacies buy 'the whole range' to get favourable terms as being outdated and unsustainable in 2012," he says.

And there's history. Anthony White describes the relationship between Pfizer and chemists as "strained" given the direct model installed by Pfizer.

"People are still bitter over losing 2 per cent discount over the past year," he says.

Patrick Davies, the head of SymbionHealth and National Pharmaceutical Services Association president, agrees. He says pharmacists are angry about the complexity Pfizer has added to their business. "Under the direct model, pharmacists have no choice but to access Pfizer's medicine only through Pfizer," he says. "They removed competition. There is concern about this. Pharmacists are not big corporations, they are small-business owners."

While the introductions of generics is a major blow for Pfizer, for pharmacists the bigger issue is the government's reforms to the Pharmaceutical Benefits Scheme.

About 75 drugs will have their prices slashed by between 25 per cent and 35 per cent on average from April 1 under the reforms.

These include names such as antibiotic Amoxicillin and Alendronate Sodium, and Fosamax, used for post-menopausal symptoms, White says.

"The industry is under extreme stress," White adds. "Over the past year, the number of pharmacies in administration has been more than the number over the past 10 years."

White says as much as he doesn't like Pfizer not using wholesalers, the drug maker has "acted responsibly". "It has not abused their market power. But I still wish it was using the wholesale channel. I don't agree that a drug should come only from one source," he says.

While the industry battles the government over funding, Macquarie Securities believes more reform remains a risk given Australia still pays too much for generic drugs compared with other countries. While the price of Lipitor will be cut by 16 per cent from April 1, the generic cost of a 40 milligram script will be $50, dwarfing the cost of the same script in Canada, which is $16, and New Zealand, at $5. Macquarie analyst Craig Collie says Australia has the second highest generic drug spend behind Japan, which highlights the real risk of further price reform in the space.

Government subsidises over 3950 medicines through the PBS. With the government looking for more cost savings, Collie believes more cuts might be on the cards.

Pfizer's Latham warns there should be "no knee-jerk changes" in policies that will hurt those investing in the sector. Latham is frustrated by the government's move a year ago to defer listing new drugs on the PBS that were recommended by its own expert committee.

"The MOU [memorandum of understanding signed in Sept 2010 by the Commonwealth Government and Medicines Australia] was an attempt to get stability.

"You want the investment? You want the $1 billion of R&D to continue? We punch above our weight when it comes to medical research and you would hate for that to stop because of what the government does."

Despite these words, Latham said industry would not hold a gun to the government's head. Still, holding back on new subsidies will have a longer term impact, he said. "I'm expecting the government to stick by what it signed. It was a breach of faith."

Other multinational pharmaceutical companies such as Britian's AstraZeneca and France's Sanofi are waiting to see how Pfizer goes in the next six months.

Symbion Health's Davies says if other large pharma companies mirrored Pfizer's direct model, it would be a disaster for wholesalers, the government and pharmacists.

**LOAD-DATE:** March 26, 2012

**LANGUAGE:** ENGLISH

**GRAPHIC:** Pfizer's Australian chief, John Latham, says the decision to go direct to pharmacies dates back to 2009 and the drug giant will focus on growing its generic business. Photo: Michel O'Sullivan

**PUBLICATION-TYPE:** Newspaper

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[Return to List](#cite_id_19)

19 of 200 DOCUMENTS

Canberra Times (Australia)

**March** 22, 2012 Thursday

Final Edition

**Pharmacists attacked for subsidy rort;**

**Letter showed how to use system**

**BYLINE:** Melissa Davey

**SECTION:** A; Pg. 2

**LENGTH:** 500 words

Pharmacists attacked for subsidy rort HEALTH Letter showed how to use system By Melissa Davey Pharmacists have been accused of pursuing profits at the expense of patients after their industry body distributed detailed instructions on how to attract hundreds of millions of dollars of government subsidies using a funding loophole.

In the four-page document, obtained by Fairfax, the Pharmacy Guild advises pharmacists to make deals with suppliers immediately after popular medicines lose their **patent** protection to lock in discounts - up to 90 per cent - while still receiving government reimbursement at artificially high rates.

The letter, sponsored by the drug maker **Ranbaxy** Australia, shows pharmacists how they can manipulate government price controls on new generic versions of the cholesterol-lowering blockbuster Lipitor - Australia's biggest-selling drug, which goes off-**patent** on April 1 - to "mitigate the impacts" of subsidy cuts to older off-**patent** drugs, reducing overall taxpayer savings.It counsels pharmacies to "increase generic substitution rates as quickly as possible" and "take advantage of introductory deals on any new generics", telling them they can buy medicines at massive discounts without lowering the price they will later be bound by.

Purchases in the month after **patent** expiry are excluded from a "weighted average" price the government uses to revise subsidies after the start of supplier competition.

This average, calculated using 18 months of wholesale sales data, is intended to protect pharmacists from sudden income crashes. During that period the government continues to pay for medicines at 16 per cent less than before the market was opened.

Chief executive of the Consumers Health Forum of Australia, Carol Bennett, said the guild "should concentrate on serving the best interests of Australian consumers rather than pharmacists' profits".

She said the document showed the government should institute tougher rules for the sector.

"Anyone looking at this latest information would have to question the future arrangements for ongoing subsidies to pharmacy owners," Ms Bennett said.

But a guild spokesman, Greg Turnbull, said while **Ranbaxy** had paid for the production of the document, there was no other connection to the supplier.

"It is not unusual for drug companies to pay for the distribution of these kinds of materials," he said.

"However, we have no commercial association with them." Pharmacies stand to profit to the tune of $540 million this year alone from the combined effect of new supplier deals and inflated government subsidies, a senior industry source said, as several blockbuster medicines come off **patent**.

"Pharmacists are crying poor while experiencing a cash bonanza," the source said.

A Department of Health and Ageing spokesman agreed drug makers offered pharmacists incentives but said bulk buying in the first month "rarely occurred". The 18-month grace period for subsidy revisions was to allow for seasonal variations in medicine use, he said.

**LOAD-DATE:** March 21, 2012

**LANGUAGE:** ENGLISH

**PUBLICATION-TYPE:** Newspaper

**JOURNAL-CODE:** CT

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[Return to List](#cite_id_20)

20 of 200 DOCUMENTS

Canberra Times (Australia)

**March** 22, 2012 Thursday

Final Edition

**Pharmacists attacked for subsidy rort;**

**Letter showed how to use system**

**BYLINE:** Melissa Davey

**SECTION:** A; Pg. 2

**LENGTH:** 500 words

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**LOAD-DATE:** August 15, 2013

**LANGUAGE:** ENGLISH

**PUBLICATION-TYPE:** Newspaper

**JOURNAL-CODE:** CT

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[Return to List](#cite_id_21)

21 of 200 DOCUMENTS

Sydney Morning Herald (Australia)

**March** 22, 2012 Thursday

First Edition

**Pharmacists 'putting profits before patients'**

**BYLINE:** Melissa Davey HEALTH

**SECTION:** NEWS AND FEATURES; Pg. 1

**LENGTH:** 646 words

PHARMACISTS have been accused of pursuing profits at the expense of patients after their industry body distributed detailed instructions on how to attract hundreds of millions of dollars of government subsidies using a funding loophole.

In the four-page document, obtained by the Herald, the Pharmacy Guild advises pharmacists to make deals with suppliers immediately after popular medicines lose their **patent** protection to lock in discounts - up to 90 per cent - while still receiving government reimbursement at artificially high rates.

The letter, sponsored by the drug maker **Ranbaxy** Australia, shows pharmacists how they can manipulate government price controls on new generic versions of the cholesterol-lowering blockbuster Lipitor - Australia's biggest-selling drug which goes off-**patent** on April 1 - to "mitigate the impacts" of subsidy cuts to older off-**patent** drugs, reducing overall taxpayer savings.

It counsels pharmacies to "increase generic substitution rates as quickly as possible" and "take advantage of introductory deals on any new generics", telling them they can buy medicines at massive discounts without lowering the price they will later be bound by. Purchases in the month after **patent** expiry are excluded from a "weighted average" price the government uses to revise subsidies after the start of supplier competition.

This average, calculated using 18 months of wholesale sales data, is intended to protect pharmacists from sudden income crashes. During that period the government continues to pay for medicines at 16 per cent less than before the market was opened.

The chief executive of the Consumers Health Forum of Australia, Carol Bennett, said the guild "should concentrate on serving the best interests of Australian consumers rather than pharmacists' profits".

She said the document showed the government should institute tougher rules for the sector - which provoked outrage last year when the guild, which represents 94 per cent of Australia's 5200 pharmacies, signed a deal with Blackmores to promote dietary supplements when patients filled prescriptions. It later dropped the arrangement.

"Anyone looking at this latest information would have to question the future arrangements for ongoing subsidies to pharmacy owners," Ms Bennett said.

But a Guild spokesman, Greg Turnbull, said while **Ranbaxy** had paid for the production of the document, there was no other connection to the supplier.

"It is not unusual for drug companies to pay for the distribution of these kinds of materials," he said. "However, we have no commercial association with them."

Pharmacies stand to profit to the tune of $540 million this year alone from the combined effect of new supplier deals and inflated government subsidies, a senior industry source said, as several blockbuster medicines come off **patent**.

As well as Lipitor, the antipsychotic Zyprexa, reflux medicine Pariet, and Seroquel, an antidepressant, will lose **patent** protection during 2012.

But as the Herald revealed last week, some pharmacists have threatened to run down drug stocks to protest at relatively small subsidy cuts as the government prepares to enforce new weighted average prices on older medicines from next month. "Pharmacists are crying poor while experiencing a cash bonanza," the source said.

A Department of Health and Ageing spokesman agreed drug makers offered pharmacists incentives but said bulk-buying in the first month "rarely occurred". The 18-month grace period for subsidy revisions was to allow for seasonal variations in medicine use, he said.

But Philip Clarke, a professor of health economics at the University of Melbourne, said subsidy reductions should be introduced faster.

"This is taxpayers' money and the government needs to provide its rationale as to how this benefits consumers," Professor Clarke said.

Do you know more? mdavey@smh.com.au

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documents online

**LOAD-DATE:** March 21, 2012

**LANGUAGE:** ENGLISH

**GRAPHIC:** Graph: BIG FAT SUBSIDY

**PUBLICATION-TYPE:** Newspaper

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[Return to List](#cite_id_22)

22 of 200 DOCUMENTS

Australian Financial Review

**February** 18, 2012 Saturday

First Edition

**Bitter pill for consumers**

**BYLINE:** Emma Connors

**SECTION:** NEWS; Pg. 10

**LENGTH:** 455 words

Pharmaceutical companies and pharmacists are working to ensure that prescription medicine prices stay high, even when popular drugs are replaced by identical generic versions.

The **patent** covering Australia's biggest selling prescription medicine, cholesterol-lowering Lipitor, will end soon. It is pharmacists, not patients, who will reap most of the benefits from competition from generic variants for at least 18 months.

Drug companies are rushing to lock in pharmacists with large discounts on their copycat versions of Lipitor that go on sale on April 1.

What happens next will be a test of Canberra's plan to reduce the prices it pays for older medicines through the $9¬ billion Pharmaceutical Benefits Scheme, which provides subsidised medicines for all Australians.

Pfizer and **Ranbaxy** are offering pharmacists big incentives to order stock before April 30, when the government will begin to use the prices paid for drugs by pharmacists to work out how big a gap there is between those prices and the official ones that guide its subsidies.

Drug companies are using a loophole that exists because Canberra has been persuaded that the prices paid by pharmacists in the first month should not count.

It could take 18 months for the price cuts to be enforced because prices will be monitored for one year first. As the professor of health economics at the University of Melbourne, Philip Clarke, noted, there is a striking difference in attitude towards banks and pharmacists when it comes to passing on changes in wholesale costs.

"With banks, people expect changes to their mortgage costs within days, but with pharmaceuticals it can take 18¬ months or more for discounts from manufacturers to flow through to consumers," he said.

The government subsidised 10.4 million Lipitor scripts to the tune of $597.8 million last year, and will benefit in April from a 16¬ per cent price cut for Lipitor.

The cut will be invisible to anyone outside the highly protected world of community pharmacies and the pharmaceutical supply channel.

The pharmaceutical industry points to price cuts that will come through for 75 older medicines on April 1 as proof that the system can lead to lower prices. The price disclosure regime agreed to by the industry in 2010 will cut those prices by an average of 28 per cent.

Canberra has indicated that it will monitor volumes come April 1, to ensure forward orders of Lipitor and its new competitors don't defeat price disclosure.

Price transparency for pharmaceutical drugs is a hot political issue. The chemists work under pharmacy agreements that last for five years, the latest of which runs until 2015. Greens senator Richard Di Natale is pressing for a review of how these accords work and are negotiated.

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**PUBLICATION-TYPE:** Newspaper

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[Return to List](#cite_id_23)

23 of 200 DOCUMENTS

Australian Financial Review

**February** 18, 2012 Saturday

First Edition

**How chemists beat customers to cheaper drugs**

**BYLINE:** Emma Connors

**SECTION:** PERSPECTIVE; Pg. 46

**LENGTH:** 1940 words

The cost of some medicines were due to fall in April, but they won't as chemists exploit a loophole.

Come April, Australian customers should be pleasantly surprised with their pharmacy bills as the price of some commonly used prescription medications will drop substantially.

That's the good news. The bad news is the cost of one of Australia's most popular medicines, Pfizer's cholesterol-lowering Lipitor, will also fall but not by enough to make any difference to what you pay your pharmacist.

Australians will pay far more than many other countries for this hugely prescribed drug - 10.4 million scripts in Australia last year - for some time to come. This is because the chemists will grab the discount, using a loophole that allows them to put in forward orders with the manufacturer at the cheaper, post-**patent** price while still attracting a large government subsidy.

So why are some prices coming down and others not? To understand this highly complicated landscape it is necessary to appreciate how profoundly regulated it is and why.

Australians spend an estimated $11 billion-plus on prescription drugs a year and the federal government subsidises them to the tune of $9 billion. The bulk of that goes to drug manufacturers but more than $2 billion a year goes to pay pharmacists to dispense medicines and provide various other programs and services.

When a blockbuster drug like Lipitor goes off **patent**, it opens the way for competition from copycat products made by companies that don't have huge research and development costs. In most markets, increased competition means lower prices but in this country it takes a while for the big benefits to filter through.

In other markets where Pfizer has already lost some degree of **patent** protection for Lipitor the price paid has fallen far and fast.

In Canada, for example, the ex-manufacturer price fell 75 per cent. In New Zealand, the price for a standard, generic prescription is now $NZ6.51($5.08). Even in the US, home of the most expensive drugs in the world, many of Lipitor's regular customers are paying up to 80 per cent less than in Australia.

Here, if you don't have a concession card, you will keep paying the standard script price of $35.40.

If you like to keep track of where your taxes go, you can factor in a 16 per cent cut on the price we - that is we, the taxpayers, and Lipitor users combined - pay into the pharmaceutical supply chain for that medication.

That saving is no small change, given this one medication accounted for $597.8 million of the government's $9 billion medicine bill last year.

But it will only take the price paid for a 40 milligram, 30-tab pack from $61.41 to $51.58. Add on wholesaler mark-ups and various payments to pharmacies and you get to a dispensed price of $67.43, of which the government pays $32.03 and consumers pay $35.40.

It won't be until the end of next year, at the earliest, when that dispensed price of Lipitor falls below the co-payment of $35.40 under the current regime.

This is mainly because the government has agreed, for the first six months, to monitor the size of the trade discounts pharmacists get once generic drugs come on the market.

Remember that's the discount the pharmacist gets, not what you the customer receives.

Past experience suggests sometimes these trade discounts are very big indeed (see box). What happens is manufacturers and wholesalers sell the drugs to pharmacists for less, often a lot less, than the list price. Pharmacists get to keep the difference.

At the end of the 12 months, the numbers are crunched. Six months after that, if there is more than a 10 per cent difference between what pharmacists pay and the list price, that list price comes down. Pharmacists argue this is a good idea as it can take them a long time to convince someone who has taken a drug like Lipitor for 10 years to try a generic.

Others believe the 18 months could be a lot shorter, and point to another loophole that pharmacists and drug manufacturers could use to further delay big price cuts.

Recent correspondence from Pfizer to pharmacists demonstrates how this works.

Pfizer has offered to discount its generic product by up to 75 per cent for those who order a year's supply of Lipitor and the Pfizer generic, as long as the generic order is placed by April 30.

That first month after a copycat drug enters the market is crucial. The government collects price information during this time but it is not used in the price disclosure calculations.

So any orders pharmacists make for Pfizer's generic Lipitor before April 30 don't count for price disclosure, even if that order is for a 12-month supply.

**Ranbaxy,** which will have a generic ready to go on April 1, is making similar offers. Other generic suppliers that enter the market in coming months are expected to follow suit.

Such orders can partially defer the price disclosure regime that is the government's main tool in reducing the trade discounts on older drugs so there's money to pay for new medicines.

A long-term advocate for pharmaceutical pricing reform, Philip Clarke, says the drug companies' offers demonstrate the weakness of the current system.

"After **patent** expiry, the Australian government pays around $50 per script for a typical dose of atorvastatin [Lipitor], compared with around $5 in New Zealand," says Clarke, professor of health economics at the University of Sydney.

"Price disclosure is a very slow system to bring down prices, and the practice of purchasing forward will make it even slower. This system needs to be reviewed to ensure it will deliver price cuts as quickly as possible for Australian taxpayers and consumers," he says.

For its part, Pfizer Australia says its commercial arrangements are confidential but they reflect common industry practice and the company has many different offers pharmacies can choose from.

A company spokeswoman notes the 16 per cent price cut that will take effect on April 1 and says the price disclosure rules should generate further price reductions in 2013 and beyond.

"We have confidence that price disclosure will create a competitive market. It is delivering savings to the Pharmaceutical Benefits Scheme," the spokeswoman says.

The government says it has seen no evidence that the one-off, one-month exclusion has skewed the outcomes from price disclosure.

It notes data collected in the past four years suggests bulk buying in the first month has rarely occurred, and there have been no instances of a product only being sold in the first month.

It will, however, continue to monitor sales and volume data provided to ensure it does not become an issue.

Given the large sums of money involved, it is no surprise pricing arrangements between drug companies and the government are hard fought. Last year, for example, AstraZeneca went to court to oppose (unsuccessfully) a new arrangement that pegged the price of its statin to Lipitor.

Similarly, the agreement with industry, aimed through price disclosure to generate big savings in the next few years, was bitterly opposed by generic manufacturers.

Both the innovative pharmaceutical companies that are trying to get new medications on the subsidy list and the generic suppliers have signalled they don't believe the industry can absorb any more cuts, come the May budget.

Pharmacy owners also fight hard. The Pharmacy Guild of Australia negotiates various mark-ups and fees every five years, and the current Community Pharmacy Agreement is set in stone until mid-2015.

The Pharmacy Guild has spent the past few months making this perfectly clear. The guild represents the owners of the 5000-odd community pharmacies scattered across the country. The pharmacy agreements affect to some degree 20,000 or more pharmacists, as well as pharmacy wholesalers, but it's the guild that leads the negotiations every five years.

But last year was not a stand-out for the organisation. Not even the guild can control the weather. In 2010-11 its insurance business, Guild Group Holdings, posted a $3 million loss, although it still managed to pay a $5 million dividend to its parent organisation.

Also last year the guild did - and then quickly undid - a questionable marketing and promotion deal with Blackmores. The infamous "cokes and fries" agreement called for pharmacists to recommend supplements with scripts.

It added fuel to the fire of other pharmacist groups calling for reform. It also attracted unwanted attention from the Greens, who called for a Senate inquiry into the community pharmacy agreement.

Specifically, the Greens wanted a Senate committee to probe "how the interests of taxpayers, consumers and pharmacists themselves could be better represented in the negotiation process".

The proposal was backed by the Consumers Health Forum, which noted that any other agreement with industry worth $15.4 billion over five years would be subject to similar taxpayer scrutiny.

It also found favour with some pharmacists who believe the time is right for an examination of the evolving role of the community. They want the cash-strapped public health system to make better use of pharmacists, particularly given the rising rates of chronic disease.

The guild is vehemently opposed. "The time for an examination of the evolving role of community pharmacy is at the end of the agreement, which could assist to shape the next agreement," says guild president Kos Sclavos.

It's a turf war, according to the pharmacists' division of the Association of Professional Engineers, Scientists & Managers Australia (APESMA) and the Society of Hospital Pharmacists of Australia.

APESMA chief executive Chris Walton says the guild simply doesn't want anyone else "playing in its sandpit". "There is a fascinating tension here between professional interest and financial concerns," Walton says.

Few in Canberra would be unaware of the guild's views on the inquiry. Or, indeed, of the opposing views of other pharmacists, as letters on the topic have flown thick and fast in recent weeks.

Sclavos met Greens health spokesman senator Richard Di Natale in late January, the week before the motion for the inquiry was due to be put to the Senate.

A few days later Di Natale was surprised when he discovered a lobbying organisation employed by the guild was emailing other Green senators about the inquiry and seeking to line up separate meetings between them and the guild.

Di Natale was not impressed.

"The guild clearly had not done their homework. I don't know how it works in other parties but all of those approaches were simply pushed straight back to me."

A few days later, as Canberra was riveted by the off-again, on-again passage of the health insurance rebate means test, new Health Minister Tanya Plibersek let it be known Labor would not support Di Natale's motion calling for an inquiry in its current form.

A revised motion, with new terms of reference, is due to be put to the Senate by the end of this month. While the government has said the community pharmacy agreement will be left to run its course, Sclavos is not taking any chances.

"There are no surplus funds in the federal health budget and the federal government fiscal position is well documented," he says.

"Funds in the agreement are allocated to programs via a signed agreement. It is for this reason the whole industry is very concerned that any Senate review has the agenda of changing the agreement, which we do not support."

For his part, Di Natale is still hopeful an inquiry will proceed.

"No one likes picking fights with health professionals in white coats but the difference this time is there is disagreement within the profession," he says.

"There are a number of groups in pharmacy who seek reform."

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[Return to List](#cite_id_24)

24 of 200 DOCUMENTS

The Straits Times (Singapore)

**January** 27, 2012 Friday

**Indian drugmaker reaches deal with FDA;**

**Ranbaxy to review India and US plants, change way it operates**

**BYLINE:** Nirmala Ganapathy, India Correspondent

**SECTION:** ASIA

**LENGTH:** 622 words

NEW DELHI: India's largest drugmaker has taken a step towards resolving its problems in the United States, where it is facing allegations that it violated practices in manufacturing drugs. It has agreed to change the way it operates its plants there and in India. Still, the problems are far from over.

Under a settlement reached on Wednesday, **Ranbaxy** Laboratories will hire an external expert to conduct a thorough internal review at affected facilities and audit past drug applications, the US Justice Department said. It will also hire an external auditor for future applications.

'Today's announcement is the next step in the process of finalising our agreement with the Food and Drug Administration to resolve this legacy issue,' said **Ranbaxy** chief executive Arun Sawhney in a statement.

However, a federal court in Maryland must approve the deal before it can go into effect.

**Ranbaxy** originally announced the agreement last month, but did not provide details, and set aside US$500 million (S$634 million) for any liabilities related to the case.

The US Justice Department said a long-running probe had found that the 'numerous problems' at the pharmaceutical company's facilities included not keeping written records and not preventing contamination of sterile drugs, and submitting false data in applications to the FDA.

In 2008, the same year that Japan's Daiichi Sankyo bought a majority share in **Ranbaxy** for US$4.6 billion, the US found manufacturing defects at **Ranbaxy's** India plants in Dewas, Batamandi and Paonta Sahib. As a result, the FDA banned the import of 30 generic drugs from these plants. The drugs treat ailments ranging from diabetes and cholesterol to allergies.

The FDA has now included the US plant in the action.

If the Maryland court approves the settlement, **Ranbaxy** will not be allowed to make drugs for the US market until it resolves its problems.

'This action against **Ranbaxy** is groundbreaking in its international reach - it requires the company to make fundamental changes to its plants in both the US and India,' said Mr Tony West, the Assistant Attorney-General for the Justice Department's Civil Division, in a statement.

**Ranbaxy** is part of India's pharmaceutical success story. Indian firms, including **Ranbaxy**, have been able to make generic versions of brand-name drugs that have benefited millions of the world's poor. Generic drugs are non-branded and can be made and sold more cheaply when the exclusive **patents** of their original manufacturers expire.

For instance, **Ranbaxy** successfully introduced a generic version of the cholesterol-lowering Lipitor, the biggest-selling drug of all time, in the US on Dec 1 last year.

Although this drug is not affected by the current action, **Ranbaxy** will have to comply with FDA standards to resume reviewing drug applications containing data or other information from the affected facilities.

'In fact, the surprising element is the addition of the US plant. The Indian plants were under import alert. Thus, if they are not able to meet standards in time, they will have to forfeit future launches,' said analyst Hemant Bakhru at broker CLSA.

'This is a gradual resolution process. It will be long-drawn-out. Those 30 products banned in 2008 are not going to come back in a hurry. **Ranbaxy** will continue to spend money on data verification and independent audit. They will have to do a lot of things afresh. It will take them a good amount of time and resources, and management will be occupied.'

Even with its problems in the US, **Ranbaxy** has been expanding its sales there. It said its US sales reached US$334 million in 2009 and US$600 million in 2010.

**gnirmala@sph.com.sg**

**With additional information from Reuters**

**LOAD-DATE:** January 26, 2012

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[Return to List](#cite_id_25)

25 of 200 DOCUMENTS

PR Week (US)

**January** 19, 2012

**Pfizer promotes 'Lipitor for You' program**

**BYLINE:** Virgil Dickson

**SECTION:** NEWS

**LENGTH:** 396 words

NEW YORK: Pfizer is focusing on promoting the Lipitor For You program after recently losing **patent** exclusivity for the cholesterol-lowering drug.

The program provides consumers with a co-pay card to get the drug for as low as $4 per monthly prescription with the rest of the cost typically absorbed by an employer's insurance plan. The program will run through the end of this year.

Three million patients were using the drug before **patent** exclusivity ended November 30, 2011. The generic versions of Lipitor include atorvastatin pills from **Ranbaxy** Laboratories and an authorize generic from Watson Pharmaceuticals, which is manufactured by Pfizer and marketed by Watson.

Pfizer has used press outreach to make sure the media is aware of the program and to ensure information about the brand is accurate. Pfizer also teamed up with restaurateur Joe Bastianich, a judge on Fox's *Master Chef* and owner of 22 restaurants around the country, to encourage consumers to ask physicians about Lipitor as a treatment choice.

The drugmaker also launched the site HeartInTheKitchen.com to promote the partnership.

"Our goal is to support patient choice in an effort to advance their own healthcare," said MacKay Jimeson, a press officer at Pfizer. Ketchum is assisting Pfizer with its media strategy for Lipitor.

Pfizer has also continued to invest in direct-to-consumer advertising to promote Lipitor, "which is not typical for a drug that has lost exclusivity," Jimenson said. He added that the company "will continue to promote Lipitor as long as we get positive returns."

Twenty-nine days before exclusivity ended, Pfizer reported that the drug made $2.6 billion worldwide during the third quarter of 2011, up 3% compared with the same period of the prior year. Pfizer will report post-exclusivity earnings for Lipitor on January 31. Sales for the drug have averaged $11 billion a year, one-sixth of Pfizer's total sales.

Even before the release of the company's fourth-quarter earnings, Kipp Davis, an analyst at Barclays Capital, doubted the success of the Lipitor For You program. "It's tough to say that the strategy is working particularly well given the data," he said. Figures from pharmaceutical intelligence firm IMS Health show that Lipitor's market share has dropped 67% from the end of November, with the drug maintaining less than 33% of market share at the beginning of January.

**LOAD-DATE:** January 30, 2012

**LANGUAGE:** ENGLISH

**PUBLICATION-TYPE:** Magazine

**JOURNAL-CODE:** PRWeek US

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[Return to List](#cite_id_26)

26 of 200 DOCUMENTS

The Advertiser (Australia)

**January** 14, 2012 Saturday

1 - State Edition

**Lipitor takes up drug fight**

**SECTION:** FINANCE; Pg. 76

**LENGTH:** 275 words

SALES of Lipitor, the top-selling drug in history, have levelled off after a steep plunge following the start of US generic competition.

New figures from data firm IMS Health show that at the end of December, sales of Pfizer's Lipitor were at just above a 37 per cent market share.

Two new generic versions of the cholesterol-lowering drug came on the market at the beginning of December, and in the first full week of the month they had siphoned off a combined 59 per cent of sales. By the last week of December, atorvastatin pills from **Ranbaxy** Laboratories and the authorised generic from Watson Pharmaceuticals . - manufactured by Pfizer and marketed by Watson - only picked up another 4 per cent between them.

That's because Pfizer is fighting hard to retain branded Lipitor sales, with big discounts to patients and insurers.

Lipitor lost its US **patent** protection on November 30.

Pfizer, the world's largest drug-maker, has been offering patients discount cards if they keep taking Lipitor rather than defecting to a cheaper generic version.

New York-based Pfizer generates nearly $US11 billion ($10.7 billion) in annual sales worldwide and has elected to pull out all stops to hang on to sales for as long as possible.

The strategy, closely watched because most other big drug-makers have their own blockbusters facing generic competition in the next couple of years, appears to be paying off.

Normally, sales of a brand name drug continue to fall over the weeks and months after the start of generic competition.

``It's been pretty stable after the first few weeks,'' said Michael Kleinrock, head researcher at the IMS Institute for Healthcare Informatics.

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**PUBLICATION-TYPE:** Newspaper

**JOURNAL-CODE:** ADV

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[Return to List](#cite_id_27)

27 of 200 DOCUMENTS

Daily Deal/The Deal

**January** 11, 2012 Wednesday

**Watson chief pledges more deals**

**BYLINE:** by Ben Fidler In San Francisco

**LENGTH:** 501 words

**Watson Pharmaceuticals Inc.** hasn't been as active lately on the M&A front as some of its competitors, but its CEO said Wednesday that it will look to expand its breadth and become more balanced through acquisitions. Speaking at the J.P. Morgan Healthcare Conference in San Francisco Wednesday, the specialty pharmaceutical company's president and CEO, Paul Bisaro, indicated that the company is eyeing a large-scale acquisition. "I think our appetite for a larger transaction is there," he said. "It's finding the right transaction." Watson produces both branded and generic drugs, but Bisaro indicated that the company wants to bolster its ability to be a balanced drugmaker, and use acquisitions as a tool to do so. Bisaro declared that Watson is "one or two large transactions away on the generic side" from where he'd like the company to be in terms of its generic capacity. Part of that generic expansion is taking place through a pact with **Amgen Inc.** to develop biosimilars, which are generic biologic drugs.

He also noted that the company is looking at some opportunities on the branded side, and though he didn't name names, he said that there are "some opportunities that are intriguing for [Watson]." "We see our company changing into a company with a more balanced approach," he said. "In the short term, we'll do tuck-in kinds of acquisitions - but we'll look at something bigger once we find the right fit." Watson made just one acquisition in 2011, when it paid at least $561.8 million for Greek rival Specifar Pharmaceuticals SA in May. The deal brought Watson a portfolio of off-**patent** medications and a sales network in Europe and Greece. Its last truly large-scale purchase came when it struck a deal to acquire generic drugmaker Arrow Group plc for $1.75 billion in 2009. Bisaro also addressed one of Watson's biggest prospects over the next few months - its generic version of **Pfizer Inc.**'s cholesterol pill Lipitor. Lipitor went off **patent** on Nov. 30, and Watson and **Ranbaxy Laboratories Ltd.**'s American subsidiary, **Ranbaxy** Pharmaceuticals Inc., are the only two companies free to produce generic copies during the 180-day window they get to exclusively market the drugs. While Bisaro said that Watson was "very pleased" with the launch of its generic Lipitor and predicted that the company would take in roughly 50% "or greater" of the drug's market share during the 180-day window, he noted that the unique moves Pfizer has taken to hold on to Lipitor's revenue - which include reported agreements with pharmacy benefit managers that prevent customers on certain health plans from getting access to generic Lipitor - are taking its toll. "They're probably the most aggressive we've ever seen in this space," Bisaro said of Pfizer's moves, noting that they've enabled the New York drug titan to retain between 38% and 39% of the market. "That number will go down, but how fast will depend on the pricing in the generic space. We'll see how it plays out the rest of the way."

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[Return to List](#cite_id_28)

28 of 200 DOCUMENTS

The Advertiser (Australia)

**December** 21, 2011 Wednesday

1 - State Edition

**Generics strip protective coating off Lipitor's sales**

**SECTION:** FINANCE; Pg. 61

**LENGTH:** 205 words

SALES of cholesterol blockbuster Lipitor plunged by half barely a week after the world's top-selling drug got its first US generic competition, new data shows.

That's despite a very aggressive effort by Lipitor-maker Pfizer Inc to keep patients on its pill, which generated peak sales of $13 billion a year, through patient subsidies and big rebates to insurers.

Lipitor lost **patent** protection on November 30 in the US, where the drug was still generating about $7.9 billion in annual sales.

Two generic versions costing about a third less hit the market right away, one made by India's **Ranbaxy** Laboratories Ltd and the other an authorised generic, made by Pfizer and sold by its partner, Watson Pharmaceuticals Inc.

Lipitor's **patent** loss has been closely watched across the pharmaceutical industry, where most firms face generic competition.

Figures from data firm IMS Health on prescriptions for Lipitor show the number of Lipitor prescriptions filled in the seven days ended December 9, the first full week when generic rivals were available, plunged to 359,235.

That's down from the 724,799 Lipitor prescriptions filled a month earlier. Lipitor's share of statin prescriptions dropped to 9.7 per cent from 20.9 per cent over that period.

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[Return to List](#cite_id_29)

29 of 200 DOCUMENTS

Daily Deal/The Deal

**December** 2, 2011 Friday

**Lipitor goes, but not without a fight**

**BYLINE:** by Ben Fidler

**LENGTH:** 713 words

The king of the pharmaceutical world relinquished its throne this week, as **Pfizer Inc.**'s mighty Lipitor - the cholesterol pill with more than $100 billion in combined sales, the highest of any drug of all time - went off **patent**. The moves that the pharmaceutical titan is making to hold onto as much revenue as it can from its crown jewel have come under Washington's scrutiny. Responding to deals Pfizer reportedly has made to give discounts to pharmacy benefit managers in exchange for blocking prescriptions for Lipitor's generic equivalents, Senate Finance Committee Chairman Max Baucus, D-Mont., senior Finance Committee member Chuck Grassley, R-Iowa, and Senate Special Committee on Aging Chairman Herb Kohl, D.-Wis., have sent letters to Pfizer, three PBMs and two insurance companies requesting more information about the transactions. Baucus and Grassley sent letters to PBMs **Medco Health Solutions Inc.**, **Express Scripts Inc.** and **Catalyst RX** and insurance companies **Coventry Health Care** and **UnitedHealth Group**, concerned that the agreements will send ripple effects through the industry, leading more drug companies to make such arrangements and hinder access to generic drugs. "By working with manufacturers to push brand-name drugs, drug benefit companies may be abusing Medicare to boost their profits and denying generic alternatives to patients - a practice that needs to end immediately," the senators said in a statement. The U.S. Food and Drug Administration cleared **Ranbaxy Laboratories Inc.**on Thursday to manufacture and market a Lipitor copy, but Pfizer has made several plans to maximize Lipitor's revenue during the 180-day period given to **Ranbaxy** to market a Lipitor copy exclusively in the U.S. following the **patent** expiration.

Pfizer cut a deal with **Watson Pharmaceuticals Inc.** to split the revenue it reaps from its so-called authorized generic version of Lipitor. What really caught the attention of the Senate are the deals Pfizer reportedly has made with Medco and Catalyst, which would prevent customers in certain drug plans from getting the Lipitor copies. The senators said that while the co-pays for plan members would be equal and potentially lower than the cost of a generic, they are concerned that the PBMs and insurance companies may charge health plan sponsors full price for Lipitor during the 180-day window while "pocketing" the discount they get from Pfizer - in addition to discouraging generics companies from churning out products. "In what's been reported, just about everyone wins except consumers and taxpayers," Grassley said. "That's cause for scrutiny, and these letters reflect a commitment to looking at how to prevent the system from being manipulated so that access to generic drugs is restricted and taxpayers are forced to unnecessarily pay brand-name drug prices." Baucus and Grassley want Pfizer to provide a list of all the agreements it has with PBMs or health insurance plans in which either the PBM or plan favors a Pfizer drug over a generic, and all documents pertaining to the agreements, by Dec. 21. Pfizer didn't respond to calls seeking comment, but released a statement claiming that the initial report revealing the agreement, which appeared in the New York Times on Nov. 11, contained "incomplete and incorrect information" about its Lipitor programs. "Our intent is to offer Lipitor to payers and patients at or below the cost of a generic during the 180-day period," Pfizer said in the statement. "As a result, patients receive Lipitor at co-pays comparable to generics. Participation in Pfizer's programs by a health plan is entirely voluntary. It is not imposed on any plan either by Pfizer or their PBM." The pharmaceutical sector, as a whole, faces significant **patent** expirations over the next two years. Many of the world's best-selling drugs, including blood-thinner Plavix (**Bristol-Myers Squibb Co.** and **Sanofi**), antipsychotics Zyprexa (**Eli Lilly & Co.**) and Seroquel (**AstraZeneca plc**), will all encounter generic competition by the end of 2012. "This heightens our concern that these types of arrangements will become a trend, ultimately compromising access to generic drugs and increasing overall health care costs," the senators wrote in a letter to Pfizer CEO Ian Read.

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**DOCUMENT-TYPE:** Article

**PUBLICATION-TYPE:** Web Publication

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[Return to List](#cite_id_30)

30 of 200 DOCUMENTS

The New Zealand Herald

**December** 2, 2011 Friday

**Generic Lipitor for launch**

**SECTION:** BUSINESS; General

**LENGTH:** 74 words

India"s biggest maker of generic drugs will launch a generic version of cholesterol blockbuster Lipitor, which lost US **patent** protection yesterday.

**Ranbaxy** has had major manufacturing quality deficiencies since 2006, leading the US Food and Drug Administration to hold up approval of **Ranbaxy**"s version of generic Lipitor.

Lipitor"s maker, Pfizer, is splitting revenue from an authorised generic version being sold by partner Watson Pharmaceuticals.

**LOAD-DATE:** December 1, 2011

**LANGUAGE:** ENGLISH

**PUBLICATION-TYPE:** Newspaper

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[Return to List](#cite_id_31)

31 of 200 DOCUMENTS



The Independent (London)

**December** 1, 2011 Thursday

First Edition

**Watson launches first generic Lipitor**

**BYLINE:** STEPHEN FOLEY

**SECTION:** BUSINESS; Pg. 60

**LENGTH:** 361 words

Watson Pharmaceuticals, the New Jersey-based drug manufacturer, did not even wait for dawn before trumpeting its first shipments yesterday of Lipitor, the cholesterol-lowering pill that became the world's biggest selling medicine.

After years of legal and scientific battles, Lipitor's creator Pfizer yesterday relinquished its stranglehold over production of the pill, as its **patent** on the drug in the US finally expired. And at 5.30am, Watson announced it "began shipping the product today," and called it the "largest generic product launch in US history".

That claim is certainly true, since Lipitor, the brand name for atorvastatin calcium, still had $7.8bn (£5bn) sales in the year to September, after peaking at $10.7bn last decade. Millions of Americans pop the pills to keep their cholesterol under control and to reduce the risks of heart attacks and strokes.

But as well as being the biggest generic product launch, this is also proving to be the most unusual, as Pfizer works to maintain as big a chunk of Lipitor sales as possible. For starters, it is serving as the exclusive supplier of the medicine to Watson, at least until 2016, and it has also adopted a range of novel tactics to keep another rival, India's **Ranbaxy,** from taking market share. Since drugs with an estimated $80bn of sales will be going off-**patent** in the next two years, Pfizer is being closely watched by other pharmaceuticals giants, including GlaxoSmithKline and AstraZeneca in the UK.

Pfizer has tied up a series of deals with American health insurers and pharmacy chains to supply branded Lipitor at a discount. Generic copies typically price slightly lower than the original drug for a few months after **patent** expiry until additional manufacturers emerge. In deals with Medco and Express Scripts, two big pharmacy benefits managers, Pfizer has agreed to match the generics' prices.

It is also subsidising the amount consumers have to contribute to the cost of the medicine, so that Americans on Lipitor are not encouraged to switch. However, Pharmacists United for Truth and Transparency says it is a "blatant attempt" to keep health insurers paying for more expensive branded drugs.

**LOAD-DATE:** November 30, 2011

**LANGUAGE:** ENGLISH

**PUBLICATION-TYPE:** Newspaper

**JOURNAL-CODE:** IA

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[Return to List](#cite_id_32)

32 of 200 DOCUMENTS

The International Herald Tribune

**December** 1, 2011 Thursday

**With patent for best-selling drug expiring, Pfizer raises hurdles for rivals**

**BYLINE:** DUFF WILSON

**SECTION:** FINANCE; Pg. 14

**LENGTH:** 1336 words

**DATELINE:** NEW YORK

**ABSTRACT**

The company's aggressive strategy may offer lessons for drug makers facing similar losses of **patent** protection for blockbuster drugs over the next few years.

**FULL TEXT**

For the past year, Pfizer has been laying the groundwork to combat the looming competition against Lipitor, forging deals with U.S. insurers, pharmacy benefit managers and patients to meet or beat the price of its generic replacements.

With the U.S. **patent** for Lipitor, the top-selling cholesterol-lowering drug, set to expire Wednesday, Pfizer is completing deals and preparing discounts - like a reduced co-payment of $4 a month versus the $10 customers would pay for many generic prescriptions. Some deals require pharmacies to reject prescriptions for low-cost generics starting Thursday and to substitute a discounted name-brand Lipitor.

Others have blocked generic makers from mail-order services that account for an estimated 40 percent of all Lipitor prescriptions.

Pfizer's aggressive strategy may offer lessons for drug makers facing similar losses of **patent** protection for blockbuster drugs over the next few years and could chart a new path for shifts between big pharmaceutical companies and makers of generics.

Lipitor was the first drug to exceed $10 billion a year in sales, and it accounted for almost a quarter of Pfizer's revenue over the past decade.

With Pfizer's plans to try to maintain brand loyalty in the United States for the next six months becoming public, industry analysts have raised the company's earnings outlook 2 percent to 4 percent, and they now estimate that it could retain 40 percent of the market through next year. Pfizer officials declined to comment on that estimate.

Aiding Pfizer's chances are several stumbles by makers of generics. **Ranbaxy** Laboratories, the Indian subsidiary of the Japanese drug company Daiichi Sankyo, won the right to bring the first generic version of the drug to market. But **Ranbaxy** has disclosed that it is under investigation by the U.S. government and that it has not yet received Food and Drug Administration approval. **Ranbaxy's** president has said it will be ready by Thursday.

Watson Pharmaceuticals of New Jersey is a second competitor, with a generic version of the drug authorized and manufactured by Pfizer. But Watson has to give about 70 percent of its profits to Pfizer, according to the investment house Sanford C. Bernstein & Co. Pfizer's own deals are undercutting both Watson and **Ranbaxy** on price.

''Pfizer's tactic of dressing up as a generics company is pulling the rug under the incentive system created to foster the development of generic drugs,'' said David A. Balto, a lawyer for some makers of generics and a former policy director for the U.S. Federal Trade Commission.

So far, Pfizer's strategy is limited to the first 180 days after Lipitor goes off **patent** in the United States. The company will maintain exclusivity in the European Union until May 2012.

Under U.S. law, competition from generics in the initial six-month period is limited and the first entries have historically charged fairly high prices to recoup their costs. After that, any company can enter the generic market, and prices tend to plunge.

Although **Ranbaxy** and Watson have not yet announced prices for their drugs, a Pfizer official said Tuesday that its new discounts could be adjusted to beat any tit-for-tat reduction in prices.

''They are a set contract, but they could change,'' said David S. Simmons, president and general manager of Pfizer's established products unit.

Mr. Simmons said the intention of Pfizer's discount was to keep Lipitor ''at or below generics' cost to the health care system.''

The discount will also be extended to many prescription drug plans under Medicare, the U.S. government-subsidized health program for the elderly, that will dispense Lipitor even if patients ask for generics, according to a memo released by an advocacy group called Pharmacists United for Truth and Transparency.

The memo, from CVS/Caremark, a pharmacy benefit management company, and dated Monday, notified pharmacies that the generic form of Lipitor would not be covered for 29 prescription drug plans it managed for Medicare. Instead, any prescription claims for generic atorvastatin will be rejected with a notice saying, ''Brand Lipitor will pay at generic co-pay.''

The company's memo did not disclose the financial terms.

The U.S. government may receive the rebates that drug manufacturers pay to benefit managers and insurers if they are fully disclosed and characterized as rebates, not fees, according to a March report by the Office of the Inspector General for the Department of Health and Human Services. But benefit managers' records may not be accessible or auditable, it added.

Express Scripts, another large pharmacy benefit manager, is recommending that its clients not accept Pfizer's deals under the reasoning that it could cost more in the long run, according to F. Everett Neville, vice president for pharmaceutical strategy. ''They're 180-day deals, but no one knows what the price of the generic may be if they lower their prices in a month or two,'' he said.

Medco Health Solutions, another giant benefit manager, is also recommending that customers switch to the generic version of Lipitor.

At the same time, both Express Scripts and Medco say their own mail-order services will use Lipitor as a ''house generic'' because Pfizer has guaranteed to match the price and assured a supply.

With mail order increasingly dominant - accounting for an estimated 30 percent of Lipitor sales - those deals are important. Timothy Anderson of Bernstein Research estimated that Pfizer would maintain 90 percent of the mail order market.

Aetna is not taking Pfizer's offer. ''We decided not to participate in the rebate program because it doesn't support our generic-first philosophy,'' an Aetna spokesman, Matt Wiggin, said.

Kevin Hooks, managing partner of Virtuous Group, a benefits consultant in Las Vegas, also said: ''We don't know what the generic is going to be priced yet.'' He added, ''Right now we think it'll be a better deal for members to get Lipitor for the first six months, with discount, and then kill the deals.''

Consumers will benefit from the price wars. Pfizer has started a program called Lipitor for You that offers the $4 co-payment card and direct delivery of Lipitor. The program is limited to privately insured people, though, because government programs like Medicare say such discounts could violate anti-kickback laws and lead to higher health spending.

It is unclear how U.S. taxpayers will fare through the Medicare Part D drug benefit program, a prescription drug plan administered by private companies. Tony Salters, a spokesman for Medicare, said he could not comment.

Christine K. Cramer, a spokeswoman for CVS/Caremark, said its drug plans had already included the Lipitor rebates in its 2012 Medicare bids, thus lowering premiums for the government and Lipitor users.

Even at the lower price, Pfizer will have a huge margin because of the relatively low cost of materials to make Lipitor, Bernstein Research estimated.

Pfizer, the benefit managers and some insurers say that all of the new discount will be passed along to consumers, companies and other payers.

''Who knows who it's good for?'' said Dr. John Santa, director of health ratings for the independent nonprofit organization Consumer Reports. With all the companies involved, ''and they say consumers are going to be good here, I'd be skeptical,'' he added.

Adam J. Fein, a pharmaceutical consultant and blogger, said, ''It's kind of a forerunner of what's going to happen over the next two years as everyone battles for the incremental profit in the generic wave.'' He added: ''You have over $80 billion in drugs that are going to go generic. Say $80 billion settles to $10 billion eventually. That's $70 billion savings. But during that period going from 80 to 10, there's going to be a lot of money made by the various channel intermediaries, and they all want a piece of that pie.''

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[Return to List](#cite_id_33)

33 of 200 DOCUMENTS

The New York Times

**December** 1, 2011 Thursday

Late Edition - Final

**Senators Question Deals to Block Generic Lipitor**

**BYLINE:** By DUFF WILSON

**SECTION:** Section B; Column 0; Business/Financial Desk; Pg. 3

**LENGTH:** 516 words

Three senators on Wednesday asked the drug maker Pfizer and five other health companies to detail their agreements to block prescriptions of generic versions of the cholesterol drug Lipitor and sell only the Pfizer brand-name version.

The action came as the **patent** expired on Lipitor, the best-selling drug in history.

Pfizer has taken unprecedented actions to preserve market share during the next six months, while generic competition is limited and prices remain fairly high. Pfizer is offering discounts to companies that will reject generic prescriptions and substitute Lipitor.

While some companies say they will save money, others do not. The senators said they were concerned about longer term impacts on employers, Medicare and health care costs.

''We need to take a close look to ensure we're protecting both taxpayer dollars and access to the medicine patients need,'' Senator Max Baucus, the chairman of the Finance Committee, said in a statement released with the senators' letters.

The letters were signed by Senators Baucus, a Montana Democrat; Charles E. Grassley, an Iowa Republican; and Herb Kohl, the Wisconsin Democrat who is chairman of the Special Committee on Aging.

''Consumers and taxpayers foot the bill when drug benefit companies and insurers manipulate the marketplace to prevent access to generic drugs for millions of Americans,'' Senator Kohl said in the statement.

Pfizer, in a statement, said, ''Our intent is to offer Lipitor to payers and patients at or below the cost of the generic during the 180-day period.'' The senators' concerns are based on ''incomplete or incorrect information,'' MacKay Jimeson, a Pfizer spokesman, said in an e-mail. ''Participation in Pfizer's programs by a health plan is entirely voluntary,'' he said.

The letters said pharmacy benefit managers might pocket the Pfizer discounts while charging employers and Medicare the full price for Lipitor -- a situation the companies insist will not occur. The companies say they will pass the Pfizer discounts on to employers, Medicare and consumers.

''We are concerned that arrangements like this will hinder access to generic drugs today and in the future,'' the letters said.

Watson Pharmaceuticals shipped a generic to 28,000 pharmacies on Wednesday. **Ranbaxy** Laboratories is seeking approval for another, but **Ranbaxy** has been under federal scrutiny.

The letters went to the chiefs of Pfizer; the insurance companies UnitedHealthcare and Coventry Health Care; and the pharmacy benefit management companies Express Scripts, Medco Health Solutions and Catalyst Rx, which act as middlemen between manufacturers and insurers.

Express Scripts and Medco have recommended that their clients sell generics, not Lipitor, because they say the Pfizer offer, even with a discount, could cost more in the long run. But those two companies are also buying Lipitor at the generic price for their mail order operations.

United, Coventry and Catalyst have said the Pfizer discount will save them money until more generics enter the market in June. Lipitor will also match or beat the copayment rate for generic drugs.

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[Return to List](#cite_id_34)

34 of 200 DOCUMENTS



The Times (London)

**December** 1, 2011 Thursday

Edition 1;

National Edition

**Drug copycats stand by**

**BYLINE:** AFP

**SECTION:** BUSINESS; Pg. 61

**LENGTH:** 80 words

Pfizer's **patent** on the bestselling drug of all time, the cholesterol-lowering Lipitor, has expired, opening the way for generic competitors. Lipitor came on the market in 1997 and has raked in $100 billion for the American drugs group. Watson Pharmaceuticals immediately announced its launch of a generic version of Lipitor. The Indian-based **Ranbaxy,** which was expected to release a copycat drug in the next six months, still awaits the green light from American authorities. (AFP)

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**JOURNAL-CODE:** TIM

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[Return to List](#cite_id_35)

35 of 200 DOCUMENTS

The Philadelphia Inquirer

**November** 30, 2011 Wednesday

CITY-C Edition

**Top-seller Lipitor goes generic**

**BYLINE:** By David Sell; Inquirer Staff Writer

**SECTION:** BUSINESS; P-com Biz; Pg. A17

**LENGTH:** 700 words

A big slice of the U.S. prescription-drug market will change Wednesday, when Lipitor, the world's best-selling drug, gets generic competition.

Black Friday-like rushes on pharmacies are not expected, but the change, at least in theory, will lower prices for patients trying to lower their cholesterol.

The drug still requires a doctor's prescription. Ian Read, chief executive of Lipitor's maker, Pfizer Inc., said recently that the company hoped to create a nonprescription version. But that is at least several years away and would need approval from the Food and Drug Administration.

Lipitor, on the market since 1997, is among drugs called statins, which are meant to lower cholesterol and reduce the chance of heart attack or stroke. Lipitor's chemical name is atorvastatin calcium, and those words will appear on all generic pill labels.

Generic drugs must be approved by the FDA before they can be legally sold in the United States, but the process is shorter and cheaper than with original brand-name drugs. With **patent** protections in effect, brand-name manufacturers generally charge enough for the drug to recoup costs and make as much profit as possible. Once a **patent** expires, the generic manufacturer is essentially copying the formula, although shape, color, and inactive ingredients of the generic pills will differ from the branded version.

Pfizer, based in Manhattan, but with operations in Collegeville, had about $10.7 billion in global Lipitor sales in 2010 to about three million patients.

Several top-selling drugs will reach **patent** expiration in the coming months, but **patents** expire at different times in different countries. For example, Teva Pharmaceuticals, based in Israel, but with its Americas headquarters in North Wales, began selling generic Lipitor in Canada in 2010, as did Watson Pharmaceuticals.

Watson, based in Parsippany, N.J., has a deal with Pfizer to sell a Pfizer-manufactured generic Lipitor for the next 180 days, after which there might be five or six manufacturers. For now, the only independent generic seller, pending FDA approval, in the United States will be **Ranbaxy** Pharmaceuticals Ltd., an India-based company with U.S. headquarters in Princeton.

For patients wanting the brand-name product, regardless of cost, the best way is to have a doctor write the prescription specifically for Lipitor. Pennsylvania and New Jersey laws require that pharmacies use a lower-cost generic version, unless the prescription specifically says that the brand name is to be used.

Those laws assume the generic is lower-priced, but for the next six months, that might not be true.

Pfizer is offering a $4 coupon good for a 30-day supply, but it helps only those patients who don't have drug payments reimbursed by Medicare, Medicaid, other federal health-care programs, and many private insurance plans. Pfizer also contracted with Diplomat Specialty Pharmacy of Flint, Mich., to set up a mail-order business, which would ship pills to patients and then bill insurers.

Neither of those moves is especially good for retail pharmacists, especially independents, who make more money on generic sales. One pharmacists' group also objected to Pfizer's better-than-usual deals with some pharmacy benefit managers (PBMs) so that the brand-name drug would be dispensed. Even if patients get the drug for the same lower price, Dave Marley, a founding member of Pharmacists United for Truth and Transparency, said that, unless employers get some of that Pfizer money passed back to them through the PBM, the employers might be inclined to reduce benefits to patients in the future.

CVS/Caremark is both a pharmacy and a PBM. Either way, stores are getting ready for Wednesday, according to the chain's public-relations director, Mike DeAngelis.

"We plan to have a generic alternative available in our pharmacies as soon as possible after that date," DeAngelis said in an e-mail. "We intend to help our patients with Lipitor prescriptions take advantage of the savings that the introduction of generic atorvastatin will provide."

Contact staff writer David Sell

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[Return to List](#cite_id_36)

36 of 200 DOCUMENTS



St. Petersburg Times (Florida)

**November** 30, 2011 Wednesday

4 State / Suncoast Edition

**LIPITOR USERS TO SEE BANK BALANCE GET HEALTHIER**

**BYLINE:** IRENE MAHER, Times Staff Writer

**SECTION:** TAMPA BAY; Pg. 1B

**LENGTH:** 572 words

**HIGHLIGHT:** The generic version is expected to cost much less. Pfizer may also lower the cost of the brand name.

If you are among the nearly 10 million Americans who take the popular cholesterol-lowering drug Lipitor, get ready to save some money.

The U.S. **patent** on Lipitor expires today, allowing a generic version to be sold under its chemical name, atorvastatin. The look of the pills - their size, shape, markings and color - may also change, but so will the price. Insurance co-pays for the generic version are expected to drop from $30 to $50 per prescription to $3 to $10.

Without insurance, Lipitor, the world's largest selling drug, costs $115 to $160 a month, depending on dosage. Atorvastatin should cost 30 to 50 percent less.

And at least for a while, you may pay the cheaper price while still getting the brand name. In an unusual move, drugmaker Pfizer, eager to maintain brand loyalty to its most profitable product, is devising discounts and incentives that could keep the brand-name drug as cheap as generics for the next six months.

"It has been a tremendously successful product; it made $100 billion for Pfizer," said Dr. John Santa, director of the Consumer Reports Health Ratings Center, a research division of Consumer Reports magazine. "We now enter the phase where consumers get some return on their investment. It's their time to benefit."

Some insurance plans have temporarily arranged to continue patients on brand-name Lipitor at the generic price, while others are moving patients immediately to the generic version.

Lipitor has long been the first drug of choice for treating patients with seriously high LDL cholesterol and a history of heart attack or acute heart disease.

"We use Lipitor in patients who need a 30 percent or greater reduction in LDL," said Dr. Charles Lambert, medical director of Florida Hospital Pepin Heart Institute in Tampa and professor of medicine at the University of Florida. "But you can use alternative statins in most other patients, including generics."

Generic drugs must contain the same key ingredients as the brand-name drug, but the appearance and some inactive ingredients may be different.

Santa hopes that Lipitor's going generic will loosen Pfizer's hold on the statin market.

"We hope that this is the end of all the marketing around Lipitor and that consumers and physicians will be more open to the evidence we've been pointing to for years," said Santa.

"For the vast majority of people on a statin, Lipitor is no better than other generic statins that have been available for years for about $4 a month. They are just as good as Lipitor for 90 percent of people on a statin."

Less costly alternatives include lovastatin, pravastatin and simvastatin, but they may only be appropriate for patients whose LDL cholesterol is not high.

Will the generic version of Lipitor work as well as the original? Lambert said that most of the time, there is no difference. "Concern arises, however, when production goes overseas, where manufacturing facilities are not under the direct control of the FDA. Based on past experience, that's a real concern.''

Initially, two drugmakers will produce generic Lipitor: Watson Pharmaceuticals of New Jersey and **Ranbaxy** Laboratories in India.

Limited generic competition is permitted in the first six months after a drug's **patent** expires. After May 2012, other generic versions of Lipitor are expected to hit the market, which may lower prices even further.

The Associated Press contributed to this report. Irene Maher may be reached at imaher@tampabay.com

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[Return to List](#cite_id_37)

37 of 200 DOCUMENTS

Daily Deal/The Deal

**November** 22, 2011 Tuesday

**As Lipitor nears the cliff, Pfizer does deals**

**BYLINE:** by Ben Fidler

**LENGTH:** 423 words

With Lipitor's **patent** expiration fast approaching, **Pfizer Inc.**has again gone small to add to its pipeline. The New York pharma titan agreed on Tuesday, Nov. 22 - eight days before Lipitor is to lose **patent** exclusivity - to acquire privately-held, San Diego-based **Excaliard Pharmaceuticals Inc.** Pfizer didn't disclose the price of the deal, but said it will make an upfront payment and contingent payments if certain milestones are reached. That doesn't include a payment of at least $14 million going to Excaliard equity holder **Isis Pharmaceuticals Inc.**, consisting of $4.4 million upfront and $9.6 million in contingent payouts. Excaliard develops drugs that treat skin fibrosis, commonly known as skin scarring. Its lead product is EXC001, a compound designed to halt fibrosis that is currently in Phase 2 trials. Pfizer said there are currently no Food and Drug Administration-approved products on the market to reduce scar severity. Isis granted Excaliard an exclusive worldwide license for the development and commercialization of certain compounds, including EXC001, in 2007. Excaliard started up just four years ago with the help of $15.5 million in Series A financing co-led by **AltaPartners**, **ProQuest Investments LLC** and **RiverVest Venture Partners**. Isis and Excaliard co-discovered EXC001. Pfizer, meanwhile, struck the deal just eight days before cholesterol pill Lipitor, the world's best-selling drug, comes off **patent**.

Pfizer has been arming itself for the revenue loss through a variety of channels, including low-level M&A (it bought out painkiller maker Icagen Inc., for example, in September). On a large scale, it is moving toward a massive restructuring by either selling or spinning off its animal health and nutrition businesses, each multi-billion dollar enterprises. And it is looking to wring out dollars from Lipitor by cutting several deals to help ease the revenue loss. **Watson Pharmaceuticals Inc.**, for example, will begin selling a generic version of Lipitor on Nov. 30, but will split the revenue with Pfizer under a deal between the two companies. **Ranbaxy Laboratories Ltd.**will also have the right to sell a generic Lipitor on that date, though an issue with the FDA over two of its manufacturing plants in India may affect its plans. Pfizer has also made deals with pharmacy benefit managers such as **Medco Health Solutions Inc.** to sell Lipitor at generic prices during the 180-day period given to Watson and **Ranbaxy** to exclusively market a Lipitor copy in the U.S. following the **patent's** expiration.

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[Return to List](#cite_id_38)

38 of 200 DOCUMENTS

Africa News

**November** 15, 2011 Tuesday

**Africa;**

**The End of Cheap Medicine?**

**BYLINE:** This is Africa (London)

**LENGTH:** 2987 words

The Bric countries have redefined affordable drugs, making access to medicines possible for millions in low income regions. Yet changing priorities for major generic drug producers, such as India, could reshape the African pharmaceutical landscape.

Access to medicines has improved dramatically over the last decade, driven by the rise of cheap pharmaceuticals from Asia, domestic efforts by governments of developing countries, commitment from donors, and price cuts from brand producers.

Smallpox is eradicated, the end of polio is nigh, and the number of children dying from measles has dropped by over 80 per cent. HIV-Aids, once a hopeless diagnosis for most people in developing countries, is now treatable for as little as $87 per person each year, down from around $10,000 in the late 1990s.

Brazil, India and China have been essential in driving this transformation, pushing down the price of drugs and introducing new business models that have re-shaped how medicines are consumed in Africa. But their changing interests, and greater adoption of intellectual property rules, some warn, could unleash price rises. How African governments respond to this changing terrain will determine whether the progress of the last decade can be quickened.

To understand the global health revolution of the last decade, and the decisions that confront African governments now if they are to sustain that progress, it is necessary to step back to the 1980s when the Brazilian government helped public labs develop yellow fever vaccines that Western producers were not providing - becoming the first developing country to enable cheap copies of brand drugs, now known as generics.

A more assertive stance was taken in 1996 when, to tackle a potential Aids epidemic, policy makers passed a law guaranteeing free, universal access to treatment. Brazilian domestic manufacturers were allowed to make copies of patented antiretroviral (ARV) drugs, which delay the onset of Aids from the HIV virus, provoking at times hostile responses from some Western governments, particularly the US. Drug companies were pressured to lower their prices or have their products copied.

"Brazil changed the landscape by proving that treatment in resource-limited settings was possible, by forcing pharmaceutical companies to reduce prices, and by ushering in global policy changes to promote more equitable access to essential medicines" says Amy Nunn, assistant professor of medicine at the Division of Infectious Diseases, Brown University Medical School.

In 2001, the Doha Declaration globalized Brazil's innovation, allowing all developing countries to copy brand drugs - whose **patent** life is typically 20 years - if public health demands were serious enough, or to import generics if they did not have manufacturing capacity. India seized the opportunity, producing and later exporting cheap generics around the world. Africa became India's second largest market after the US, with Kenya, Nigeria and South Africa the biggest recipients. India also provides most essential medicines procured by global health funds.

China later emerged as an exporter of chemical raw materials - especially artemisinin for malaria. At the Sino-African Summit in 2006, President Hu Jintao pledged Africa $37.5m in grants for artemisinin, part of a broader charm offensive geared to boost pharmaceutical exports, says Yanzhong Huang, senior fellow for global health at the Council on Foreign Relations and an associate professor at Seton Hall University. "China wants to use health aid not just to expand political influence and improve its international image, but also to open the market for Chinese medicines and equipment," says Professor Huang. In its most blatant form, doctors dispatched to Africa are encouraged to dispense Chinese-made drugs.

In 2005, China joined a network promoting Aids prevention, pooling its chemical exports to Brazil s advanced infrastructure and Russia s scale capacity. While Beijing took interest in global rule-setting after the Sars crisis in 2003, it shows little appetite for a major advocacy role. The elite are sceptical about calls to take greater responsibility for global welfare issues, believing this a Western conspiracy to slow China s growth, claims Professor Huang. Beijing prefers bilateral health aid rather than playing too heavily into multilateral initiatives, he says. Expectations of major charitable efforts are unrealistic. Brazil, in contrast, is becoming a major donor; the first developing country to sign up to a bond-based financing facility for immunization programmes last June.

Perhaps China s most promising public contribution is in research. At a Shanghai Institute college, Chinese scientists are working on malaria, tuberculosis, African sleeping sickness and dengue fever treatments. Xinjiang Medical University also partners a South African company in developing implants for bone disease.

Changing priorities

Although the rise of these three countries pushed down the price of medicines in Africa, the engagement of India and China has become increasingly ambiguous. In 2005, India implemented the Trade Related Aspects of Intellectual Property Rights, or Trips, part of its subscription to World Trade Organisation rules, which enforces tighter rules on **patent** protection. The implication is that all new drugs produced in India are under **patent** for twenty years, with flexibility for emergencies so producers can set higher prices since they have a monopoly for a set period. Any treatment dependent on drugs or a vaccine is subject to price rises under Trips argues Michelle Childs, director of policy advocacy of MSF s Access Campaign.

Ninety-five per cent of essential medicines are already off-**patent,** and available generics will not be affected, so at first glance the regulation seems harmless. However, many diseases require continuous innovations. HIV patients, for example, develop treatment immunity over time, so second and third generation drugs are needed. Moreover, current drugs require improvements; pregnant women, for example, are often unable to take some due to high toxicity. India s new trade laws have already pushed up the price of newer medicines by between 7 and 27 percent, says Ms Childs. This is echoed by Emmanuel Mujuru, chair of the Southern Africa Generic Medicines Association, who testifies to a rise in Aids and anti-malaria drug prices in Africa since 2005.

These price rises may be accentuated by a 2016 deadline for African countries to implement their own Trips legislation, making the continent a less attractive export market for generic producers looking for countries where there is no risk of **patent** infringement, says Christoph Spennemann of the Intellectual Property Unit at Unctad. The concern is that a global roll out of Trips puts an end to the very flexibilities which transformed access. While Trips could potentially increase profits for Africa s domestic producers, the sector needs 10 more years to be ready to benefit, says SAGMA s Mr Mujuru, who anticipates major shortages if the deadline is not extended.

Voices from industry downplay these fears. The approaches that companies adopt in terms of pricing depend on the markets they are looking at, says Andrew Jenner, director of innovation, intellectual property and trade at the International Federation of Pharmaceutical Manufacturers and Association, which represents the brand industry. Companies will not generally take legal action against low income countries if producers manufacture decent quality copies, he says. GlaxoSmithKline has already offered free licenses for generic companies to copy a range of their drugs in 69 countries around the world, including all of Africa s low income states. If anybody is vulnerable to Trips, it is probably the poorest in large emerging economies such as India, where pricing is likely to be more competitive.

Most of Africa simply is not a business concern yet for big pharmaceutical companies, who are highly unlikely to sue governments after the public relations disaster in 2001 when a consortium took legal action against South Africa for its generics policies. The industry is also open to an extension to the 2016 deadline, says John Pender, vice-president of intellectual property and access at GlaxoSmithKline s government affairs office. I believe that the actions of the industry over the past few years have demonstrated that we can help address the health challenges of the developing world without weakening intellectual property, he says.

The changing commercial interests of pharmaceutical producers in India and China present a second set of dangers, according to Unctad. Indian companies are increasingly aiming their sights on richer markets, where several blockbuster drugs are coming off **patent**. Chinese companies want access too, and as the disease burden within India and China starts to resemble that of rich countries, with more diabetes and cancer for example, tropical diseases may move off the radar.

However, non communicable diseases are a growing problem in Africa too, so more research effort is not simply to the benefit of the rich. Secondly, higher exports to OECD markets may give Indian and Chinese producers more resources to subsidise pricing in Africa, and to invest in research. In 2010, India s Serum Institute, in partnership with a non-profit group, released a highly effective vaccine for the meningitis belt that stretches from Senegal to Ethiopia. With ambitions to be powerhouses of innovation rather than merely copy cats, the research contribution that India and China could make to diseases in developing countries is potentially enormous.

Perhaps the greater commercial concern may be not disinterest, but crowding out. Chinese firms are selling a particular form of monotherapy malaria drugs in Africa which, while cheap, are less effective than combination therapy because patients develop resistance. Yet attempts to get low income patients to buyhealthier combination therapy drugs are made difficult by the Chinese undercutting, says Amanda Glassman at the Centre for Global Development.

Domestic production

Worried about Trips and business trends, Unctad and Unido are calling for Africa to raise pharmaceutical output. South Africa has the largest industry, with some proposing a state-owned pharmaceutical company based on the Brazilian experience. South African firms have marketing collaborations with over 20 African countries, and strong linkages with Botswana, Namibia and Nigeria. Egypt is strong on distribution with 10 African partners and a steady flow of graduates, but lacks export drive, according to Unctad s Mr Spennemann. Morocco, Tunisia, Cameroon, Ghana, Tanzania, Nigeria and Zimbabwe have some production, with donors, especially Germany, offering support.

Yet most small economies face an uphill struggle. Countries need to be at a threshold of competitiveness in terms of energy supply, skills, infrastructure, and regulatory efficiency, which few in sub-Saharan Africa have attained. It is not, however, impossible. Prior to 1982, eight transnational pharmaceutical companies controlled up to 70 per cent of Bangladesh s local industry. Bangladeshi firms now take that share. In Indonesia between 1991 and 2010, the same reversal has taken place.

Foreign investment is one stimulus, and there are forays from the Brics. India s Cipla is a partner in Cipla Medpro, South Africa s fourth largest pharmaceutical company and third largest generics company, and has established a joint venture in Uganda with a Kampala-based manufacturer producing Aids and malaria drugs. **Ranbaxy,** the first international company to establish a presence in French West Africa when it settled in Cameroon in 1987, provides ARVs, anti-infectives, anti-inflammatory drugs and cardiovascular medications there, and distributes products through offices in Nigeria, CÙte d Ivoire, Egypt, Kenya and Morocco. Indian firms have supported Zimbabwe s efforts to produce Aids treatments through a Harare-based manufacturer, and Cadila recently announced a $65m joint venture in Rwanda.

Brazil and China have modest commitments. Brazil has significant pharmaceutical trade with South Africa, with minor investments in Angola and Mozambique. Chinese entities have made occasional investments in Zanzibar in the 1970s, joint ventures in Mali and CÙte d Ivoire in the 1990s and, recently, in drug capsule production in Ethiopia through Jianxi Corporation, but Chinese firms are unlikely to want African production to emerge since they see the continent as a potential export market for themselves.

Some helpful technology transfer occurring through public initiatives such as Expand-TB, which provides laboratory-strengthening in 10 African countries, can stimulate production. Technical assistance from Western universities can help too. Recently, a team of researchers from New York University, Columbia University, Kigali, and Amsterdam launched the mChip , a stamp-size, portable pad that can diagnose HIV for just $1.

These inflows could increase if Trips is fully implemented, says Mario Ottiglio, associate director, public affairs and global health policy at IFPMA. An innovation-friendly environment would encourage technology transfer by creating a level of trust, transparency and certainty for investors, he claims. A larger domestic skills base, with graduates in pharmacy, biochemistry and industrial production, is also needed. Such domestic talent was vital to India s rise.

One of the best ways to boost industry, says SAGMA s Mr Mujuru, is for African producers to be given preferential treatment by global procurement agencies who currently source most drugs from industrialised countries or emerging economies, especially India. But preferential purchasing is problematic since African producers are pricier than their Indian counterparts. Should public agencies be interested in the cheapest drugs, or the development of the drug industry?

From a public health perspective what matters is that medicines reach the person in need, on time, in the right place and at the right price, says Juergen Reinhardt at Unido. But the venue of production should not be ignored, he says. Continuity of supply, strengthening national regulation and readying for a period beyond charitable donation are all worthy goals, he says, but proposals to build the pharmaceutical industry are batted from ministries of health to ministries of industry, and back again, Reinhardt claims, identifying a tremendous disconnect between public health and industrial actors

Tax may further hamper industry. While pharmaceuticals are a strategic priority in Ethiopia, high tariffs on imported raw materials are stifling local production, according to public statements by the Ethiopian Pharmaceutical and Medical Supplies Manufacturers Association. Yet even if African producers were given preferential treatment, quality control could make that an empty privilege. Only a handful of companies in South Africa, Zimbabwe and Uganda are qualified by the WHO to sell into procurement funds.

While a business case needs to emerge in the long term, low purchasing power among low income groups means most interventions are going to be more public-initiated than private for the time being. Africa is out there as a market, but it is on the horizon, says Simon Friend, partner at PricewaterhouseCoopers.

If production looks overly ambitious, streamlining regulation across smaller economies could boost Africa s attractiveness as a destination to sell into. When US pharmaceutical company Eli Lilly developed two antibiotics for tuburculosis and sought generic companies to sell them on in Africa, those identified including South Africa s Aspen said the mountain to climb to secure regulatory approval in each country made it unviable. It may be more effective to build regional regulators, perhaps incorporated into existing regional economic blocs such as Ecowas. A smaller number of better-resourced agencies might also help tackle the corruption that dogs some nations. In 2006, almost a million Aids drugs delivered to the Democratic Republic of Congo went missing. The following year, Uganda had vaccines grants suspended for mass corruption.

Political will

While the price of final drugs is important, access to medicine depends on how well the entire health system works. It can often be costs along the supply chain from import taxes to handling fees which drive prices up. Fragmented distribution networks, meanwhile, hinder the transit of drugs. Even where you have medicines, getting them to people is difficult, both in pharmaceuticals and, more pertinently, in vaccines, says Stephen Rea, a spokesperson at GlaxoSmithKline.

Refrigeration facilities, good roads, detailed country maps and skilled staff to administer drugs are key parts of that puzzle. Security and public goods are critical too. If people don t have clean water, or there is a war, those will be huge factors in how health access works, says IFPMA s Mr Jenner. Water is particularly important for Africa s cholera burden which is rising, even as global incidences fall. While Indian firms are working on a $3 treatment, the solution lies in fixing sanitation systems.

While the sheer breadth of the challenge may seem overwhelming and costly there is no evidence that bigger economies necessarily have better health outcomes. Rwanda has among the highest rates of Aids treatment coverage in Africa, at around 95 percent, while in South Africa only 66 percent of those needing treatment receive it. Governments, not companies, emerge as the most important actors in ensuring wide access to medicines for their populations. Their policies, from intellectual property rules to public investments in higher education and roads, may prove more important than the whims of companies in Delhi, Geneva or Beijing.

**LOAD-DATE:** December 13, 2011

**LANGUAGE:** ENGLISH

**PUBLICATION-TYPE:** Newsletter

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[Return to List](#cite_id_39)

39 of 200 DOCUMENTS

The New York Times

**November** 12, 2011 Saturday

Late Edition - Final

**Plan Would Delay Sales Of Generic For Lipitor**

**BYLINE:** By DUFF WILSON.

James B. Stewart, whose Common Sense column normally appears on this page, is away.

**SECTION:** Section B; Column 0; Business/Financial Desk; Pg. 1

**LENGTH:** 845 words

The biggest introduction of a generic drug in pharmaceutical history is being met with tough business strategies by Pfizer and pharmacy benefit companies, according to recent letters to pharmacists.

Many drugstores are being asked to block prescriptions for a generic version of Pfizer's Lipitor starting Dec. 1, when the company loses its **patent** for the blockbuster cholesterol drug and generic competition begins.

Medco Health Solutions, among the nation's largest pharmacy benefit managers, is one of the companies issuing instructions, seeking to have pharmacists keep filling prescriptions with the more expensive Lipitor for six months.

Pfizer has agreed to large discounts for benefit managers that block the use of generic versions of Lipitor, according to a letter from Catalyst Rx, a benefit manager for 18 million people in the United States. The letters have not previously been made public.

A pharmacy group and an independent expert say the tactic will benefit Pfizer and benefit managers at the expense of employers and taxpayers, who may end up paying more than they should for the drug.

Pharmacy benefit managers are middlemen between drug companies (the sellers) and insurers and employers that sponsor insurance plans (the buyers).

''I'm stunned,'' said Geoffrey F. Joyce, an associate professor of pharmaceutical economics and a health policy expert at the University of Southern California, after reviewing the letters. ''This is just an egregious case. Clearly there's been some negotiation between Pfizer and the large P.B.M.'s saying we're going to make this cost-beneficial to them, but the plan sponsors are going to eat it.''

As for the people who actually take Lipitor, after Nov. 30, they will typically see their co-payment for a 30-day supply drop to the $10 level of the generic substitute, according to one of the pharmacy letters. The co-payment for Lipitor now is often $25 or more.

When patients submit a prescription for a generic version of Lipitor, though, they are to be given Lipitor instead.

Lipitor is the best-selling drug ever, accounting for $106 billion sales over the last decade, or almost one-quarter of Pfizer's total. Pfizer has told analysts it is preparing for the loss of Lipitor's **patent** with a variety of business moves to preserve market share.

Two generic drug makers are set to compete starting Dec. 1. Watson Pharmaceuticals is making a generic version authorized by Pfizer under a profit-sharing agreement. Pending federal approval, **Ranbaxy** Laboratories of India also plans to sell a generic version. When a drug's **patent** protection expires, the law permits only limited generic competition in the first six months.

After May 31, other generic versions of Lipitor are expected to flood the market, lowering prices sharply. Then, according to the letter from Catalyst Rx, the generic block lifts, Lipitor's co-payment rises and drugstores are told to fill Lipitor prescriptions with the cheaper generic versions.

Objections to the deal were raised publicly on Thursday in a news release from a group called Pharmacists United for Truth and Transparency, which opposes some tactics of pharmacy benefit managers. The statement called the move ''a blatant attempt'' by benefit managers to keep Pfizer's discount while employers still have to pay the full price of the brand-name drug.

David Marley, an independent pharmacist in Winston-Salem, N.C., and spokesman for the group, said the benefit companies and Pfizer would profit at a cost to employers, the government and health care overall.

''That's why this is unique: We're talking about blocking a truly less expensive drug, which is why the employers have got to be on top of this,'' Mr. Marley said. ''This is the most aggressive I've seen where they are trusting the employer is not going to figure out the whole game.''

Paul M. Bisaro, chief executive of Watson, said the Pfizer discounts would undercut its generic price and raise overall health care costs while enriching pharmacy benefit managers.

''It's not a good event,'' he said in an interview. ''And consumers are going to be confused. They're not going to understand why they can't get a generic.''

Raymond F. Kerins, a Pfizer vice president and spokesman, issued a statement saying Pfizer was committed to supporting patients' continued access to Lipitor. He declined to answer further questions Friday afternoon.

In another statement, Melissa Mackey, manager of public affairs for Medco, said its letter described ''a custom plan design, which is not a new concept,'' in which clients could ''tailor their formulary to maximize value.'' Asked in an e-mail specifically whether Medco would pocket the Pfizer discounts while employers and taxpayers paid more than the generic price for brand-name Lipitor, Ms. Mackey declined further comment.

James H. Golden, a spokesman for Catalyst Rx, said in a statement: ''As **patents** expire and generic forms of medications become available, Catalyst evaluates the market on a case-by-case basis to determine the appropriate measures to drive the lowest cost for our clients.''

**URL:** http://www.nytimes.com

**LOAD-DATE:** November 12, 2011

**LANGUAGE:** ENGLISH

**GRAPHIC:** PHOTO: Pfizer's **patent** for the best-selling cholesterol drug Lipitor will expire on Nov. 30. (PHOTOGRAPH BY J. B. REED/BLOOMBERG NEWS) (B4)

**PUBLICATION-TYPE:** Newspaper

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[Return to List](#cite_id_40)

40 of 200 DOCUMENTS

The Irish Times

**November** 2, 2011 Wednesday

**Pfizer squares up to competition**

**SECTION:** FINANCE; Business Today; Pg. 16

**LENGTH:** 153 words

Pfizer is planning to hold on to every Lipitor prescription it can as the company s biggest drug which is manufactured in Cork faces a first wave of US generic competition this month.

Chief executive Ian Read described his determination to at least temporarily protect the $10 billion (EUR 7.3 billion) a year cholesterol fighter from the steep sales declines that large medicines typically suffer when they lose marketing exclusivity in the United States.

Whether this is possible in a market like the US is very unpredictable, Mr Read said.

Lipitor s **patent** protection expires on November 30th, when new versions of the drug are expected to be sold by **Ranbaxy** Laboratories Ltd and Watson Pharmaceuticals Inc.

Pfizer earned $3.74 billion, or 48 cents a share in the third quarter, including a $1.3 billion after-tax gain on the recent sale of its Capsugel business.

Company revenue rose 7 per cent to $17.19 billion.

**LOAD-DATE:** November 2, 2011

**LANGUAGE:** ENGLISH

**PUBLICATION-TYPE:** Newspaper

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[Return to List](#cite_id_41)

41 of 200 DOCUMENTS

The New York Times

**November** 2, 2011 Wednesday

Late Edition - Final

**Its Sales Strong, Pfizer Increases a Share Buyback**

**BYLINE:** By DUFF WILSON

**SECTION:** Section B; Column 0; Business/Financial Desk; PRESCRIPTIONS; Pg. 2

**LENGTH:** 1422 words

Pfizer, the world's largest drug company, surprised Wall Street in a good way Tuesday with higher-than-expected quarterly sales and an aggressive plan to respond to looming generic competition to Lipitor, the top-selling drug in the world.

Pfizer also increased its huge share buyback program, and investors responded by bidding the stock up by 0.36 percent, to $19.33 a share, even as all 29 other stocks in the Dow Jones industrial average lost value on European debt concerns. The Dow fell 2.48 percent.

As the exception, Pfizer reported quarterly profits of 62 cents a share, excluding special items, easily beating the consensus analyst expectation of 56 cents a share. Especially strong were overseas sales and the animal and nutrition businesses, which Pfizer is planning to sell or spin off by 2013 as it focuses more on pharmaceutical drugs.

At the same time, Pfizer executives said they were negotiating with payers and pharmacy benefit managers to preserve branded Lipitor sales against generic competition. Lipitor loses United States **patent** protection on Nov. 30. The cholesterol drug had $10.7 billion in sales last year, more than 15 percent of Pfizer's total of $67.8 billion sales.

A letter from one benefit manager, Catalyst Rx, to pharmacies said they would receive a large point-of-sale discount on brand-name Lipitor to beat the price of generic competitors. The flier, an unusually aggressive posture toward new generic drugs, said pharmacies would be asked to block any sales of generic Lipitor and substitute the Pfizer version, with presumably a lower price, from December through May.

Pfizer is facing an approved generic from Watson Pharmaceuticals and a challenger from **Ranbaxy** Laboratories in India. Watson, in its quarterly earnings call on Tuesday, estimated Pfizer would keep about 40 percent of the market share. **Ranbaxy** says it expects to overcome Food and Drug Administration concerns with its India manufacturing plant and have plenty of its generic Lipitor, made in New Jersey, available by Nov. 30.

Ian C. Read, a 33-year employee of Pfizer who was named president and chief executive last December, has slashed research spending and employment while expanding a share repurchase program to please investors disappointed with a decade of declining stock value.

Mr. Read on Tuesday announced that the company bought $2.1 billion in common stock in the third quarter and $6.5 billion in the year to date, and that it raised its 2011 target for share repurchases to $7 billion to $9 billion. Such purchases buoy the stock price.

''We have a track record certainly this year of showing we are acutely focused on shareholder value,'' Mr. Read said in a conference call.

Catherine J. Arnold, an analyst for Credit Suisse, praised Pfizer's ''robust'' results and said its long-term plan looked good.

Pfizer, like many companies, has benefited from a weak dollar driving up the value of foreign sales. After adjusting for currency, overseas sales rose 4 percent in the third quarter while United States sales declined 3 percent.

The drug maker's total sales for the quarter were $17.2 billion, an increase of 1 percent after adjusting for currency. Sales were $770 million higher than consensus estimates of Wall Street analysts.

The nutrition business grew by an adjusted 24 percent over the year-earlier quarter and animal health grew by 15 percent. The company said in July it planned to sell or spin off those businesses.

Adjusting for currency, sales of Lipitor declined 2 percent to $2.6 billion. Prevnar, a pneumococcal vaccine for children and infants, rose 35 percent to $1 billion, and Pfizer has sought F.D.A. approval to market it to adults over 50. Lyrica, a pain and epilepsy drug, rose 19 percent to $961 million, and Enbrel, an injectable arthritis drug, rose 7 percent to $957 million. Viagra, an impotence drug, rose 2 percent to $493 million, and Chantix, aimed at helping smokers quit, dropped 10 percent to $156 million.

Profit was $3.7 billion, four times higher than the $866 million of the year-earlier quarter, but most of that difference came from the $1.3 billion gain from selling Pfizer's Capsugel unit this year and special charges a year ago, such as settling asbestos litigation. Pfizer, the world's largest drug company, surprised Wall Street in a good way Tuesday with higher-than-expected quarterly sales and an aggressive plan to respond to looming generic competition to Lipitor, the top-selling drug in the world.

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This is a more complete version of the story than the one that appeared in print.

**URL:** http://www.nytimes.com

**LOAD-DATE:** November 2, 2011

**LANGUAGE:** ENGLISH

**GRAPHIC:** PHOTO: Ian Read, Pfizer's chief executive, said the company is focused on shareholder value. (PHOTOGRAPH BY NEIL SELKIRK/PFIZER)

**PUBLICATION-TYPE:** Newspaper

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[Return to List](#cite_id_42)

42 of 200 DOCUMENTS

Daily Deal/The Deal

**September** 28, 2011 Wednesday

**Santen looks abroad with Novagali**

**BYLINE:** by Ben Fidler

**LENGTH:** 679 words

**Santen Pharmaceutical Co. Ltd.** has become the latest Japanese drugmaker to leap into international dealmaking, agreeing Tuesday, Sept. 27, to buy up a controlling stake in French venture capital-backed **Novagali Pharma SA** to harness the potential of its eye care pipeline. Santen will pay as much as Euro101.9 million ($139.1 million) for Novagali, an Evry, France-based entity that specializes in ophthalmology products. Shareholders and VC backers including funds managed by **Edmond de Rothschild Investment Partners**, **Auriga Partners**, **IdInvest Partners** and **CDC Innovation Partners** have agreed to sell their stakes - representing 50.55% of the company - for Euro6.15 per share, a 71.3% premium to the company's closing share price on Tuesday. Santen will then launch a tender offer to buy the rest of Novagali's stock at Euro6.15 per share. If it ends up with at least 95% of Novagali's stock following the tender offer, it will boost the payout to shareholders to Euro6.25 per share (a 74.1% premium to the Tuesday closing price). Japanese pharmaceutical companies have been increasingly seeking foreign acquisitions to help compensate for sputtering pipelines and more generic competition. The past few years have seen at least three large deals, including **Takeda Pharmaceuticals Co. Ltd.**'s $13.7 billion purchase of Switzerland-based **Nycomed International Management GmbH**, **Daiichi Sankyo Co. Ltd.**'s $4.6 billion buyout of India-based **Ranbaxy** Laboratories Ltd.

and Takeda's earlier takeover, an $8.8 billion acquisition of Cambridge, Mass., biotech Millennium Pharmaceuticals Inc. Santen's deal isn't a move to offset a looming **patent** expiration, but more of an expansion play, both of its portfolio and its international reach. President and CEO Akira Kurokawa noted in a Wednesday statement that the company is focusing on increasing its global presence. Santen, a 121-year-old company that itself specializes in prescription ophthalmics, believes Novagali is a perfect strategic fit. Such drugs account for about 82% of Santen's sales - and Novagali's pipeline of ocular disease products and technologies appear to fit seamlessly. Among Novagali's products are Eyeject, which administers compounds to the back of the eye, and Novasorb, which helps administer drugs to the surface of the eye. The company has only one major product on the market, over-the-counter mild dry eye treatment Cationorm - which **Jefferies & Co.**analyst Naomi Kumagai wrote in a research note Wednesday is the biggest reason it suffered a $10.35 million operating loss on just $789,641 in sales in 2010 - but has four major compounds in its pipeline, among them Cyclokat, a dry eye medication in Phase 3 trials. Kumagai hailed the acquisition, writing Wednesday that Novagali will strengthen Santen's portfolio and won't hurt the company's balance sheet. "Management has a good track record in making sensible decisions in expanding the business," she wrote, highlighting licensing agreements with **Merck & Co.** for glaucoma drug tafluprost and **Bausch & Lomb Inc.**for intraocular lenses, or lenses implanted in the eye. Kumagai believes that the market for dry eye syndrome - when the eye can't maintain a healthy layer of tears to coat it - is relatively untapped and expected to grow, a potential financial boon for Santen. The deal allows Novagali's VC investors, who have pumped Euro44 million into the company since its inception in 2000, to cash out. Novagali received Euro3.6 million in first-round financing from CDC and Auriga in October 2001; Euro14.2 million in two tranches of second-round funding from CDC, Auriga, **123 Ventures Ltd.**, **Fondation Canadienne des Jeunes Entrepreneurs**, Rothschild, **Siparex Ventures** and **Cr√©dit Agricole Private Equity** in 2003 and 2004; and Euro26 million in third-round funding from AGF Private Equity SA, CIPV, **Mercure Longue Epargne SA** and Bernard Chauvin in 2006 and 2007. Santen had &yen;110.6 billion ($1.45 billion) in net sales in 2010. About &yen;86.87 billion of those sales came from its ophthalmics.

**DEAL SIZE**

$ 50-250 Million

**LOAD-DATE:** October 20, 2011

**LANGUAGE:** ENGLISH

**DOCUMENT-TYPE:** Article

**PUBLICATION-TYPE:** Web Publication

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[Return to List](#cite_id_43)

43 of 200 DOCUMENTS

The Straits Times (Singapore)

**September** 17, 2011 Saturday

**Drug firm takeovers stoke fears in India;**

**Officials' worry: foreign firms may raise prices**

**BYLINE:** Nirmala Ganapathy, India Correspondent

**SECTION:** ASIA

**LENGTH:** 716 words

NEW DELHI: India is known for making generic drugs affordable, but a spate of takeovers of local manufacturers by global pharmaceutical firms is raising fears that they could ultimately raise prices.

Worried about the prospect of what it means for India's millions of poor, some health officials are demanding that new policies be enacted to regulate and even limit foreign ownership of Indian pharmaceutical companies - something a government panel is now looking into.

The calls come amid concerns that foreign firms could raise their prices as they shift their focus to more lucrative markets around the world.

Officials and some in the industry also worry that mergers and takeovers could reduce competition in India's highly competitive drug markets, giving drug companies more power to control prices.

The Health Ministry's assessment is that restrictions should be put up to keep drug prices low and prevent any reduction in production of essential medicines for the Indian market.

'The government does not fund health care and all people pay out of their pocket. A couple of more acquisitions and you can forget about low-cost generic versions,' said Mr D.G. Shah, secretary-general of the Indian Pharmaceutical Alliance, a grouping of more than 10,000 pharmacists.

India has limits on foreign ownership in many areas such as retail, but not in its rapidly growing pharmaceutical sector.

Said Mr Shah: 'You can have 100 per cent foreign ownership for new projects, but when they want to acquire the business of Indian companies, that should go to the Foreign Investment Promotion Board where the government can give certain conditions like not retrenching people or downsizing.

'Pharmaceuticals should be considered a sensitive industry.'

But others have dismissed suggestions for new laws, saying these barriers could ultimately hurt foreign investment and the inflow of new technology.

'We shouldn't come to a knee-jerk conclusion,' said Mr Arun Maira, a member of the Planning Commission which heads the government committee looking into the issue.

'The committee should not be doing anything like changing foreign direct investment rules, maybe later. Right now, what we are saying is let's examine it.'

The debate was triggered in part by the takeover of six well-known Indian firms by foreign multinationals that came one after another in the last six years.

In 2008, the country's largest drug manufacturer, **Ranbaxy,** was bought out by Japanese company Daiichi Sankyo for US$4.6 billion (S$5.7 billion). The following year, United States-based Sanofi-Aventis paid (EURO)550 million (S$941 million) for a stake in Shanta Biotech, a vaccine maker, and last year, US firm Abbott Laboratories took over Piramal Health Care for US$3.7 billion.

There were also takeovers of Matrix Lab by US firm Mylan, Dabur Pharma by Fresenius Kabi and Chennai-based Orchid Chemicals and Pharmaceuticals, by US-based pharma company Hospira.

What is drawing such players is India's lucrative drug industry, which is worth US$11 billion a year and is estimated to grow to US$30 billion by 2020.

Indian firms have been able to make cheaper formulations of generic drugs that have benefited millions of the country's poor, while at the same time fobbing off strong opposition from Western competitors.

Generic drugs are non-branded versions of drugs that can be made when the exclusive **patents** of their original manufacturers expire, and are much cheaper because of the intense competition to make them.

India is now a global player in the business, producing 20 per cent of the world's generic drugs. In 2008-2009, the country exported US$8.3 billion worth of drugs - 25 per cent more than it did in the previous period - and is a major supplier of affordable HIV/Aids drugs to Africa.

Some analysts believe that concerns about rising prices are a little overblown.

'India is a very fragmented market. A lot of companies are selling generic drugs under different brands, so prices are really low,' noted analyst Hemant Bakhru at brokerage firm CLSA.

'As and when consolidation takes place, and companies on top become larger and gain market share, prices could go up. But a lot more consolidation has to happen, and that is in the long term.'

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[Return to List](#cite_id_44)

44 of 200 DOCUMENTS

Daily Deal/The Deal

**August** 24, 2011 Wednesday

**Sanofi makes acquisition in India**

**BYLINE:** by Ben Fidler

**LENGTH:** 629 words

French drugmaker **Sanofi-Aventis SA**has become the latest Big Pharma entity to strike in India, using subsidiary Aventis Pharma Ltd. to grab a division of Mumbai's **Universal Medicare Private Ltd.** Aventis Pharma, an India-based entity in which Sanofi owns a 60.4% stake, announced Wednesday that it has agreed to acquire Universal Medicare's branded nutraceutical formulations marketing and distribution business.

Though financial terms weren't disclosed, reports have suggested that Sanofi is paying about $109.5 million for the business. Both companies' boards of directors have approved the transaction, which is expected to close during the fourth quarter. Through the agreement, Universal Medicare will manufacture products that Aventis Pharma will then acquire on mutually acceptable terms. Sanofi said the deal will allow it to reach a larger section of India's population by diversifying its product base there. The company's Aventis Pharma unit - one of its four subsidiaries in India, along with Sanofi-Synthelabo (India) Ltd., Sanofi Pasteur Pvt. Ltd. and Shantha Biotechnics Ltd. - already provides pharmaceuticals and vaccines, specializing in diabetes, oncology, cardiovascular and central nervous system treatments. And by bringing in Universal Medicare, Aventis Pharma will now add over-the-counter offerings such as antioxidants, vitamins and mineral supplements, anti-arthritics, anti-osteoporotics and other items to its portfolio. "India is one of our most important markets in the emerging world and this acquisition reinforces our commitment to invest and grow our presence [there]," Sanofi senior vice president Antoine Ortoli said in a statement. Universal Medicare produces, markets and distributes more than 40 branded nutraceuticals in India - among them cod liver oil Seacod, pain reliever Syndol and amino acid supplement Amino-fit - and its nutraceuticals unit had about 1.1 billion rupees ($23.96 million) of revenue for the 12 months ending March 31. While the deal advances Sanofi's already substantial presence in India, it also may be a harbinger for more M&A in a country widely recognized as one of the key emerging markets for pharma giants looking to create revenue streams to offset **patent** expirations. Pharma has keen interest in India given its increasing population and economic growth, and the proof has been seen in the dealmaking over the past few years. Japanese drugmaker**Daiichi Sankyo Co. Ltd.**made the biggest splash to date in India in June 2008 when it paid $4.6 billion for generics company **Ranbaxy** Laboratories Ltd. **Abbott Laboratories**followed suit in May 2010 when it snagged **Piramal Healthcare Ltd.**'s healthcare solutions business, which makes branded generics, for as much as $3.72 billion. Most recently, on a far smaller scale, **Par Pharmaceutical Cos.** paid $37.6 million for generics developer**Edict Pharmaceuticals Pvt. Ltd.** And reports have surfaced that Japan's largest drug company, **Takeda Pharmaceutical Co. Ltd.**, may be the next acquirer. The reports claimed that Takeda is in talks to acquire the pharmaceutical businesses of either **Lupin Ltd.** or **Cipla Ltd.**, though both potential targets denied the rumors Wednesday. Takeda significantly expanded its international presence in May when it agreed to pay $13.7 billion for **Nycomed International Management GmbH**. As for Sanofi, Wednesday's deal marks its first acquisition since it completed its $20.1 billion megadeal for Genzyme Corp. in April. Its most recent M&A move was the $425 million divestiture of its dermatology business, Dermik Laboratories Inc., to **Valeant Pharmaceuticals International Inc.** in July. Sanofi posted Euro9.22 billion ($13.3 billion) in net income on Euro30.38 billion in net sales in 2010.

**DEAL SIZE**

$ 50-250 Million

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[Return to List](#cite_id_45)

45 of 200 DOCUMENTS

The Nikkei Weekly (Japan)

**August** 1, 2011 Monday

**600 bln yen loan to fund Takeda's Swiss deal**

**LENGTH:** 513 words

600 bln yen loan to fund Takeda's Swiss deal

Takeda Pharmaceutical Co. plans to finance its 1.1 trillion yen acquisition of major Swiss drugmaker Nycomed A/S by borrowing 600 billion yen in short-term funds from Sumitomo Mitsui Banking Corp. and other financial institutions.

The Nycomed deal is prompting a major shift in strategy for Takeda, known for its ample cash reserves and light debt load. In pursuit of growth, the Japanese drugmaker is set to take on the most interest-bearing debt in its history.

The 600 billion yen will comprise funds maturing in one year or less, with Takeda's interest payments likely to come to almost 10 billion yen. Closer to maturity, the firm will consider rolling over the debt into longer-term funds or switching it to bonds. It will not issue shares or convertible bonds. Over five to six years, the plan is to shrink the debt by an annual 100 billion yen or so.

The Nycomed deal will also eat into Takeda's cash on hand, which stood at 870 billion yen at the end of March for a capital ratio of 75%. The cash pile is expected to contract to 370 billion yen, and the ratio to just over 60%, at the end of September after Takeda completes the acquisition.

Takeda has been effectively debt-free since the second half of the 1990s, with liabilities amounting to just a few billion yen.

With Nycomed under its umbrella, Takeda aims to fully break into emerging markets. Takeda rang up sales of 17.8 billion yen in such places as China, Russia and Brazil last year. Emerging-market sales are expected to balloon to 142.6 billion yen with the addition of Nycomed, which has a strong presence in the former Soviet bloc as well as Central and South America.

Shopping spree

Eisai Co., Astellas Pharma Inc. and other top pharmaceutical firms have made foreign acquisitions part of their growth strategies, even at added risk to their financial health.

Pharmaceutical firms had focused on developing treatments for lifestyle-related diseases, largely shunning cancer therapies. Facing difficulties expanding with their own resources, they began opting to use their funds to do so.

Spurring the takeovers were expiring **patents** on leading products around 2010, as well as a dearth of new-drug candidates.

Eisai ended its debt-free days and fully entered the cancer drug market with its purchase of U.S. firm MGI Pharma Inc. in 2008. Its borrowings swelled from just 200 million yen at the end of March 2007 to more than 400 billion yen a year later. Its capital ratio declined as well, from 70% to 40%. Even at the end of this past March, Eisai still had some 260 billion yen in loans, bearing interest of about 5 billion yen.

When Daiichi Sankyo Co. purchased Indian generic-drug producer **Ranbaxy** Laboratories Ltd. in 2008, its borrowings swelled to 210 billion yen and its capital ratio plunged from 84% to 58%.

Astellas acquired U.S. firm OSI Pharmaceuticals Inc. last year, financing the acquisition with its own cash. This reduced its cash on hand from more than 500 billion yen to less than 200 billion yen.

(The Nikkei Weekly 08/01/2011 Edition)

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[Return to List](#cite_id_46)

46 of 200 DOCUMENTS

Australian Financial Review

**June** 6, 2011 Monday

First Edition

**Bitter pill for drug industry**

**BYLINE:** Emma Connors

**SECTION:** NEWS; Features; Pg. 53

**LENGTH:** 1552 words

The global pharmaceutical industry stands on a financial precipice as its lifeblood products come off **patent** and governments change the rules on price and availability. Emma Connors reports.

AstraZeneca chief executive David Brennan is a hard man to rattle. The American head of the drug company headquartered in the UK is steering one of the world's biggest pharmaceutical brands through one of the most unsteady periods in the industry's history and he is clearly used to making tough decisions.

But mention a UK fund manager's description of the pharmaceutical sector as unloved and Brennan bristles.

There's big changes under way in the world of big pharma and Brennan, head of a top 10, is among those redrawing the battle lines.

This shift is best seen through a microscope, given this industry is all about the molecules that have hit pay dirt by successfully treating common health conditions like high cholesterol, generating billions of dollars in sales all over the globe.

Now the **patents** on many of those blockbuster drugs have or will soon expire. Big pharma has been at this point in the cycle before but this time the industry doesn't have replacements lined up in the wings.

Instead, it's sales by generic medicine makers that are taking off, with their low-cost manufacturing centres zeroing in to compete with branded drugs as soon as they are legally able. Led by the likes of **Ranbaxy,** India is getting ready to supply the globe with low-cost medicines where competition is all about price rather than expensive research and development.

The industry's old guard from the UK, the US, Europe and Scandinavia are circling the wagons, redrawing distribution lines, taking on governments to preserve pricing while they still can and, above all, hunting for the next blockbuster drug which is, they say, the best way to fund the costly innovation that might just, one day, cure cancer and other debilitating and/or fatal diseases.

You've probably already been asked by your friendly pharmacist if you are happy to pay less for your script if it's filled with a generic drug. That question is going to be repeated more often in the years to come.

AstraZeneca already faces generic competition for its breast cancer drug Arimidex, asthma treatment Pulmicort and heart drug Toprol XL. **Patents** will soon expire on heartburn pill Nexium and schizophrenia treatment Seroquel.

AstraZeneca has warned its shareholders to expect a low- to mid-single-digit decline in revenues this year, albeit balanced out to some extent by a 6 per cent yield, so it's not hard to see why the company doesn't have fund managers swooning right now.

Brennan explained the situation during a recent visit to Sydney. "We're losing exclusivity on some of our products and it is not offset yet by new products coming through. It takes them a while to get them on the ground. They are not magic bullets.''

Last year, the company, tired of the continued questioning about the looming **patent** cliff, took the unusual step of setting out its best guess plan for its revenue, cash flow and earnings per share for the next five years. In that period, shareholders were told, annual revenue would fluctuate between $28 billion and $34 billion after hitting $32.5 billion in 2009.

"That fund manger may say we are unloved but he will find it difficult not to buy into a 6 per cent yield,'' Brennan said. "We have a financial strategy to underpin this period.''

The company's **patent** on its top-selling drug, the cholesterol-lowering Crestor, will expire in a few years. In Australia, the accompanying revenue hit is going to be felt earlier, thanks to a pricing mechanism the commonwealth government recently successfully defended in the Federal Court.

AstraZeneca is not on its own. In this country alone, some $2.4 billion in sales of drugs on the government's pharmaceutical benefit system will come off **patent** over the next four years. Pfizer's Lipitor, the world's biggest selling prescription drug and Crestor competitor, comes off **patent** next year. Lipitor sales were $US10.7 billion ($10 billion) last year, including about $650 million a year in Australia.

When drugs go off **patent**, it's not just the onset of competition from generic copy cats that hits a company's bottom line; the price of the branded product will fall. Thanks to the complex rules surrounding the $8 billion the Australian federal government pays for prescription medicines, drugs off **patent** will, eventually, be priced according to their generic competitors. The new regime starts with an immediate 16 per cent reduction in what the government pays when the **patent** expires. A year later, after monitoring what pharmacies are paying for generic versions of the drug, that price is reduced again. The same process is repeated every 12 months until the drug gets to its resting price, which is likely to be a fraction of what it was while the **patent** was held.

At its peak, Pfizer's Lipitor generated annual sales of $US15 billion. That was the good old days, when pharmaceutical companies made headlines with record sales. Now it's job cuts they are becoming famous for. Earlier this year, Pfizer announced it was closing its research operation in Kent, in south-east England, where Viagra was created, with the loss of up to 2400 jobs. Last year, Brennan outlined AstraZeneca's plan to cut 8000 jobs worldwide, mostly in the UK and US, including 3500 from research and development as it outsourced slabs of its operation to China.

Across the globe, big pharma is slashing jobs in the West to reposition its operations toward the development markets that are the best source of growth. Much of the R&D spend is being redirected to focus on areas like Alzheimer's disease. As the population ages, this has emerged as one of the major areas of medical need that could result in another blockbuster.

No such prize has been discovered, or at least not yet, but still Brennan insists the model ain't broke.

"The go-to-market model with large sales forces, multiple contact with physicians, personal selling on a high-margin business, yes, that has started to change.

"This industry overbuilt capacity in sales and R&D. That leads to consolidation and people cutting out capacity.

"But I think our business model is very adaptable.''

Lifecycle management also plays a big role: proving a drug approved to treat one condition can successfully treat another. "The hardest part is getting a drug out; once you've done that, you can look at opportunities to grow. You don't get a $6 billion drug overnight.''

The company is also pulling out all stops to preserve the pricing it has on its best sellers as various countries take steps to reduce the price they pay. In Western countries at least, the pharmaceutical business is one with many customers but one big payer in the form of government.

In Australia, AstraZeneca took the government to court in a bid to reverse its view that Lipitor and Crestor were interchangeable. This interchangeability enabled the two to be grouped in a new therapeutic class that means Crestor would be subject to the same price cuts that will hit Lipitor next year, a ruling that will cost AstraZeneca millions of dollars.

Last month, judge Robert Buchanan dismissed the application with costs and, in his ruling, he noted the major commercial significance the pricing change would have for AstraZeneca.

Since the Labor Party came to power in 2007, Health Minister Nicola Roxon has repeatedly signalled she is ready to cut off as much fat from the PBS as possible. Last year, the industry, reeling after successive budget cuts, struck a deal: no more surprises in return for price cuts that will reduce the cost of PBS by $1.9 billion over four years. Those savings are helping to fund the government's health reform agenda and, the industry was told, would also help provide some head room for new listings on the PBS.

But a few months ago, the government suddenly announced it was deferring new listings on the PBS until the budget was back in surplus.

Pfizer Australia managing director John Latham is among those who feel the government has welched on the deal struck last year. He said explaining the deferral decision to Pfizer headquarters in New York was not difficult. Coming up with some reasons why was considerably harder.

"We were staggered by this move. We negotiated the memorandum of understanding to give us some certainty. We didn't want price decreases in every budget, or new therapeutic groups in every budget. That was driving us nuts.

"So for the first time in a long time, we sat down with the Department of Health and came to an agreement and all of a sudden it falls into a back hole.

"We have been planning for the loss of exclusivity on Lipitor for years; you can contract the sales field force, expand into other areas such as animal health and generics; you can flex in those areas.

"But you cannot flex when you are told, not only that you are not going to get new products but also we don't know when you are going to get them.''

Latham says the combination of the **patent** cliff and the PBS deferrals is most unfortunate.

"As a lot of products come off **patent**, we are looking for new products to come through and fill those gaps.

"Certainty is highly valued in this industry but particularly at this time when the business is in a state of flux.''

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**GRAPHIC:** PHOTO: AstraZeneca chief David Brennan ... 'the hardest part is getting a drug out; once you've done that, you can look at opportunities to grow'. Photo: Bloomberg

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[Return to List](#cite_id_47)

47 of 200 DOCUMENTS



The Washington Post

**March** 12, 2011 Saturday

Suburban Edition

**India casts a protective eye on its drug industry**

**BYLINE:** Rama Lakshmi

**SECTION:** A-SECTION; Pg. A13

**LENGTH:** 860 words

NEW DELHI - Global pharmaceutical conglomerates' recent acquisitions of Indian companies have alarmed health officials and patient advocacy groups who say that cheap generic drugs may no longer be available for millions of poor people in the coming years.

Now, the government is considering erecting barriers to foreign investment in India's booming pharmaceutical industry to prevent takeovers. Officials say they could introduce new caps on foreign investment and tighten the rules of entry into the industry.

"The recent acquisitions of Indian companies by multinationals are a cause of major concern for us. This will affect availability and affordability of generic drugs for India's poor," said L.C. Goyal, additional secretary in the Ministry of Health and Family Welfare. "Right now, our policy says anybody can walk in and acquire. We have to ensure that these acquisitions do not undermine our public health priorities."

Since 2008, global pharmaceutical giants have acquired six Indian drug companies. The Japanese company Daiichi Sankyo took over India's largest drug producer, **Ranbaxy,** for $4.6 billion, and U.S.-based Abbott Laboratories acquired the domestic business of Indian firm Piramal Health Care for $3.7 billion last year.

A health panel of lawmakers has called for new policiesto ensure that major Indian drug companies remain in domestic hands.

Last month, Commerce Minister Anand Sharma said that foreign investment in existing Indian drug companies will no longer be "automatic," and that future investors will have to apply to the Foreign Investment Promotion Board for approval.

India's $11 billion drug industryis likely to grow to $30 billion by 2020, a jump of 163 percent, analysts say. Indian firms produce 20 percent of global generic drugs, and account for almost 30 percent of the U.S. generic market.

Analysts say that the recent mergers and acquisitions of Indian companies are aimed at the $150 billion in business opportunities that will open up by 2014, when several drug **patents** expire. With research funds drying up, the economic slump and drug **patents** expiring, big companies are turning to the generic drug market.

"This kind of an opportunity for growth does not come very often. Indian drug companies are perfectly placed to tap this with our generic manufacturing expertise. This is why so many global companies are acquiring Indian firms," said Dilip G. Shah, chief executive officer of Vision Consulting Group, which advises pharmaceutical companies.

The U.S. Food and Drug Administration has approved119 Indian manufacturing sites, the highest number of any foreign country. Almost all of Wal-Mart's U.S. pharmacies source their medicines from India, Shah says.

Health officials say that the global takeovers will turn India into a low-cost manufacturing hub for richer nations, and weaken their domestic focus.

"The Indian industry was built to make cheap lifesaving medicines available for its poor. But the foreign takeovers may shift their focus toward exporting to developed nations," said Goyal.

Nearly two-thirds of Indians do not have access to essential medicines. On average, the cost of Indians' drug consumption is among the world's lowest, at less than $5 per year compared to $53 for Chinese and $680 for Americans. "We have a long way to go to meet their needs. But there is already a significant surge in exports in recent years," he said.

But Tapan Ray, director general of the Organization of Pharmaceutical Producers of India, says the government's apprehensions are baseless because foreign companies make up only 19 percent of the total share of India's pharmaceutical industry. He said that Indian companies have gained access to expertise and resources through the mergers.

"The limiting of foreign direct investment at this stage . . . will indeed be a retrograde step for the country," said Ray.

Many global drug companies left India in 1970 because of a restrictive **patent** law that allowed Indian companies to tweak the manufacturing process of globally patented drugs and produce cheaper drugs locally. But this also gave local companies expertise in formulations of drugs and turned India into a robust producer. Over the years, developing countries bought affordable drugs from India, including those used to treat HIV/AIDS.

India manufactures more than 84 percent of the HIV drugs used by the humanitarian organization Medecins Sans Frontieres (Doctors Without Borders) and more than 50 percent of medicines distributed by UNICEF.

But since liberalizing its economy in 1991, India passed a **patent** law after signing the World Trade Organization (WTO) accord in 1995, lifted the cap on foreign investment, and reduced from 354 to 74 the number of drugs under government price control.

Although the new **patent** law of 2005 complies with WTO rules on intellectual property, India put in some safeguards for its **patents**. It does not allow new **patents** for minor improvements of existing medicines called "incremental innovations." The government says this "incremental innovation" helps global companies extend the **patent** period of a drug and will delay the rollout of new generics.

lakshmir@washpost.com

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[Return to List](#cite_id_48)

48 of 200 DOCUMENTS

Investors Chronicle - magazine and web content

**February** 18, 2011

**Big pharma's report card**

**SECTION:** 0261-3115

**LENGTH:** 984 words

SECTOR FOCUS: Who's top of the class after the major drugs companies results season

It doesn't take big pharmaceutical companies long to count all the cash they've made over a year; they're typically among the first blue chips to report results. So with all the global majors having already presented figures for 2010, now is a good time to cast an eye over the key players' prospects.

Considering just the UK's two pharma titans, GlaxoSmithKline and AstraZeneca, makes little sense. This is an industry where the peer group is truly global, so we have imagined ourselves as headteachers in an exclusive international school and presented a report card for the pharma class of 2011. Collectively, our "students" under-achieved last year - the FTSE AllWorld pharma sub-index rose just 0.4 per cent per cent in 2010, compared to a rise of 15 per cent in the FTSE AllWorld index.

And 2011 promises to be tough as well, because all major drug companies face challenges from **patent** expiries and new drug pipelines. Indeed, changes in the structure of the industry mean the international school of pharma could soon be welcoming some new students. As existing elite students lose **patent** protection on key products, new upstarts such as Indian generic drug makers **Ranbaxy** and Dr Reddy's could soon pass their entrance exams into the academy.

Another potential pupil is looking to buy its way in. Swiss-French drugs group Sanofi-Aventis recently spent $20bn acquiring Genzyme, which competes with Shire in the specialist medicines arena. Genzyme had been something of a problem child, having experienced production difficulties with some of its medicines in 2010. Financially, Genzyme is quite a handful for Sanofi, whose credit rating has been downgraded as a result of the acquisition, but cash generation at drugs companies is usually sufficiently good to overcome such concerns.

Nevertheless, graduates from the international school of pharma still hold many attractions for prospective investors. As a bunch, they're good value for money and their dividend yields compare very favourably with those of other elite academies, such as mining. In a world dominated by low real returns on cash and other safe assets, that's an attractive feature, as Mr Batstone-Carr, chairman of the governors, points out (see broker view).

But who in the class deserves a gold star, and who is most likely to be seen waiting nervously outside the headmaster's office, and which pupils would benefit from some extra coaching?

AstraZeneca: "must try harder - "

One can't fault Astra effort, but it always seems to come up a bit short. **Patent** expiries have weighed on its performance - most recently it was the loss of **patent** protection on Arimidex that hit US sales. Also, it has little to show three years on from its costly acquisition of Medimmune. Having paid $15bn for the company, Astra has already taken impairment charges on two Medimmune biological medicines that failed phase III trials - the $445m charge for Motavizumab, a respiratory disease treatment, was particularly painful. Still, a $4bn share buy-back programme and a dividend yield of over 5 per cent should keep teacher happy for now.

Novartis: "top foreign student - "

Top marks for shrewd acquisitions go to Swiss visitor Novartis, which like many of our pupils, was itself formed by merger. It showed a particular aptitude for buying diagnostics companies after spending $470m in cash - a 30 per cent premium to the target company's share price - to buy Genoptix. That followed the purchase of the shares it did not already own in eye-care specialist Alcon . However, progress might not be as rapid this year if sales of blockbuster drug Diovan slow, or if there is no repeat of the 2010 swine-flu pandemic from which it profited handsomely. Still, Novartis started broadening its horizons earlier than everyone else, and it leaves many of the other pupils struggling to catch up.

Glaxo: "too much fighting"

A generally solid performance from GSK. But the company's copy-book has been well and truly blotted lately by a fondness for getting involved in fights, particularly with US lawyers. Its latest escapade has involved the company putting up a GBP2.2bn fund to cover legal costs related to sales of diabetes treatment Avandia, which some patients allege causes unpleasant side-effects such as heart problems. Away from pharmaceuticals, Glaxo has developed a nice line supplying the school tuck shop with products such as Lucozade, and Matron with things like Sensodyne and Panadol. It's looking to start selling these things overseas, too, especially in emerging markets. Glaxo has also cut back on its own costs, so returns to shareholders in the form of dividends and share buybacks should grow to between GBP1bn and GBP2bn.

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| |TOP OF THE CLASS

|Shire has shown remarkable progress in the past few years. Its patented treatments for attention deficit disorder, which helps depressed children to concentrate in school, have allowed it to add more strings to its corporate bow. Shire's range of hard-to-copy enzyme-replacement therapies have also enjoyed a boost from the production problems at rival Genzyme, although that competitor could be reinvigorated by it's new owner.|

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| |SCHOOL DUNCE?

|Did he leave, or was he expelled? Either way Jeff Kindler is no longer running US pharma giant Pfizer. He shocked Wall Street by announcing that he was retiring from a job he found "extremely demanding" late last year. Pfizer has been pharma's spoilt rich kid for years, relying rather too much on the fabulous riches generated by its Lipitor heart drug family, which contributes more than $14bn in annual revenue. Unfortunately, Lipitor will shortly be off-**patent,** and Pfizer has already started trimming its costs (including UK research jobs in Kent). |

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BROKER VIEW: Jeremy Batstone-Carr head of research at Charles Stanley here

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[Return to List](#cite_id_49)

49 of 200 DOCUMENTS

The Nikkei Weekly (Japan)

**August** 30, 2010 Monday

**Daiichi Sankyo takes four-pronged approach**

**LENGTH:** 729 words

Daiichi Sankyo takes four-pronged approach

By forging an agreement to place a vaccine production business affiliated with the Kitasato Institute under its wing, Daiichi Sankyo Co. has distinguished itself as the first Japanese drugmaker to be fully engaged in the four primary pharmaceutical fields: new prescription drugs, generics, over-the-counter drugs and vaccines.

The deal "will promote our vaccine business," Daiichi Sankyo President Joji Nakayama said when he announced the accord at a July 30 press conference.

Under the arrangement, Daiichi Sankyo and the Kitasato Institute will set up a joint production unit next April. Daiichi Sankyo will hold a majority stake in the new firm.

The spread of a new strain of flu caused the domestic market for vaccines to balloon to more than 100 billion yen in 2009, up 60% over the previous year. Vaccine-based preventive care is expected to become more common in Japan, and demand for vaccines is likely to increase in other Asian countries as well.

The Kitasato Institute, which has sold its drugs through Daiichi Sankyo, lacks the financial muscle needed to accelerate investment. With the virtual takeover of Kitasato's production section, Daiichi Sankyo hopes to be able to develop and produce various vaccines in a flexible manner.

"We will be able to lead (the joint venture's) operations comprehensively, from production to sales," Nakayama said.

In the global pharmaceutical industry, **patents** on blockbuster drugs that generate hundreds of billions of yen in annual sales are expiring one after another. As a result, top makers like Pfizer Inc. of the U.S. and sanofi-aventis of France are reducing their reliance on major new drugs in favor of alternative earnings sources.

Japanese drugmakers, which are smaller than the global leaders, cannot afford to keep relying on core new drugs. Daiichi Sankyo thus acquired Astellas Pharma Inc.'s OTC drug unit in 2006. And in 2008, it took over **Ranbaxy** Laboratories Ltd., a major Indian maker of generic drugs, for about 400 billion yen.

Waiting for results

The latest deal with Kitasato is a logical next step, based on Daiichi Sankyo's strategy of promoting operations in the four main pharmaceutical areas.

But Daiichi Sankyo has yet to receive a high appraisal from the stock market. Its stock closed at 1,674 yen on Aug. 27, lower than Takeda Pharmaceutical Co., Astellas and Eisai Co., which range from 2,900 yen to 3,850 yen.

Daiichi Sankyo is moving in the "right direction," as its strategy of diversifying its earnings sources is ahead of trends in the global pharmaceutical industry, said Kenji Masuzoe, an analyst at Deutsche Securities Inc.

The stock market is watching to see how Daiichi Sankyo leverages the benefits from the M&A deals, Masuzoe said.

**Ranbaxy** swung into the black on an operating basis in the April-June quarter, riding a 20% year-on-year increase in sales thanks to strong global demand for generic drugs. But the U.S. Food and Drug Administration is maintaining an import ban on **Ranbaxy** products due to concerns about quality control at two plants operated by the Indian unit.

In addition, **Ranbaxy** remains hobbled by management confusion, as its president resigned Aug. 19, citing differences of opinion with Daiichi Sankyo about the firm's future course. The move followed the sudden resignation in May 2009 of his predecessor, a member of the founding family.

Daiichi Sankyo limits its OTC drug business to the domestic market, posting a small 43.7 billion yen in sales in fiscal 2009. It has yet to develop overseas markets for vaccines.

The expiration of **patents** on Daiichi Sankyo's blockbuster drugs is not happening all at once, so it will not seriously affect the company's earnings for the time being. But the firm has fewer candidates for new cancer drugs than many other pharmaceutical companies, which are stepping up efforts to develop them.

Now that two years have passed since it acquired **Ranbaxy**, Daiichi Sankyo is starting to free up some financial elbow room, with its funds on hand totaling nearly 100 billion yen on a net basis after deducting debt.

Daiichi Sankyo has expanded through M&As, and now it needs to aim for steady growth in each segment. So going forward, the company will probably limit its use of funds to acquiring new drug candidates and other smaller undertakings.

(The Nikkei Weekly 08/30/2010 Edition)

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[Return to List](#cite_id_50)

50 of 200 DOCUMENTS

The International Herald Tribune

**August** 27, 2010 Friday

**Looking for fortunes in sickness and health;**

**Drug maker's ex-chief dreams of pan-Asian network of hospitals**

**BYLINE:** BY WAYNE ARNOLD

**SECTION:** FINANCE; Pg. 14

**LENGTH:** 1403 words

**DATELINE:** SINGAPORE

**ABSTRACT**

Malvinder Singh has spent almost $1 billion in the past two years buying up assets in health care and other sectors around the world, and is already scouting for new targets.

**FULL TEXT**

No matter how healthy Asian economies are, and no matter how rich they may become, one thing is certain: Asians will never stop getting sick.

That helps explain why Malvinder Singh left his home in New Delhi this year to move to Singapore. Having made a fortune in 2008 selling the generic drug giant his family built, **Ranbaxy** Laboratories, Mr. Singh, 37, is now trying to expand another of the family companies, Fortis Healthcare, from a string of hospitals around the Indian subcontinent into a pan-Asian health care network.

''There is a huge opportunity for growth in Asia for health care,'' Mr. Singh, the Fortis chairman, said in a recent interview. ''There are multiple markets which need investment that we would want to be a part of.''

Fortis suffered a major setback in July when its bid to acquire Parkway Holdings, a regional hospital operator based in Singapore, lost out to a higher bid from Malaysia's sovereign wealth fund. But Mr. Singh, a vegetarian teetotaler with a master's degree in business administration from Duke University in North Carolina, said he was undeterred.

Having spent almost $1 billion in the past two years buying up assets in health care and other sectors around the world, he said he was already scouting for new targets.

One might wonder why he is bothering: With a population of more than 1.1 billion, most with no access to formal health care, India represents one of the fastest-growing health care markets. And the country's relatively low costs are increasingly attracting patients from abroad - medical tourists.

''There's a good amount of opportunity for the business to be transferred from patients migrating from other countries to India for treatment,'' said Ranjit Kapadia, an analyst at HDFC Securities in Mumbai.

But Mr. Singh is after much more: not only a slice of China's 1.3 billion people and Indonesia's 227 million, but the emerging class of affluent Asian medical tourists, many of whom flock to Singapore for quality private care. By building a regional network of hospitals, moreover, he hopes to bring better care to the poorest parts of India.

''The challenge for the country and for us as health care providers is to see how to create a model where you're able to create infrastructure and investment in health care and bring it closer to the people, so it's more accessible,'' said Mr. Singh, a nattily attired Sikh who matches his faith's traditional turban to his suit's pocket square.

Many in India still wonder why Mr. Singh and his younger brother, Shivinder, decided to walk away from their drug-making company.

Two of Mr. Singh's great-uncles, Ranbir and Gurbax Singh, started **Ranbaxy** in 1937 as a distributor for the Japanese drug maker Shionogi. When the brothers ran into financial trouble, they turned to Mr. Singh's grandfather for a loan. In 1952, when they could not repay him, they made him a partner.

Malvinder's father, Parvinder, returned to India from the United States in 1967 with a master's degree in pharmacy from Washington State University and a doctorate from the University of Michigan and went to work at **Ranbaxy**, eventually taking it over and turning it from a distributor into a generic-drug maker.

When Parvinder Singh died in 1999, his two sons inherited his 33.5 percent stake in **Ranbaxy**. Mr. Singh rose to join the company's board in 2003 and in 2006 became managing director and chief executive.

Along with another Indian drug company, Dr. Reddy's Laboratories, **Ranbaxy** became known globally for overturning big drug companies' **patents** in court fights and then churning out lower-cost versions of their best-selling products.

By the middle of the decade, though, competition from cheap generics was proving as tough on generic drug makers as it was on Big Pharma. In 2005, **Ranbaxy's** profit fell by two-thirds and its share price by nearly a half.

So in 2008, the Singhs sought a solution by merging **Ranbaxy** with the Japanese drug maker Daiichi Sankyo. For Daiichi Sankyo, **Ranbaxy** offered low-cost manufacturing and access to 60 new markets, including key emerging markets like India, to offset falling sales at home.

''We had what they wanted,'' Mr. Singh said.

Selling their stake in the company to the Japanese earned the Singhs $2.3 billion, vaulting them to No. 13 on Forbes magazine's rankings of the richest Indians. Mr. Singh retained his position at the company's helm.

In September 2008, however, the U.S. Food and Drug Administration banned 30 **Ranbaxy** drugs made at two of the company's Indian plants, citing manufacturing problems uncovered earlier that year. **Ranbaxy's** stock dropped by two-thirds, and in May, the company replaced Mr. Singh as chief executive and paid him a severance of 480 million rupees, or $9.6 million.

Mr. Singh declined to discuss the F.D.A. case, or his departure from **Ranbaxy**. ''Once I left **Ranbaxy**, I've not spoken on what they're doing or what we've done,'' he said. He noted, however, that the company's fortunes, and its shares, had largely recovered.

Mr. Singh turned to another family company, Fortis Healthcare. Founded in 1996 and named after the Greek word for strength, Fortis has grown from a single hospital in northwest India into a network of 48 hospitals and clinics.

Last year, the Indian health care market was estimated at $38 billion, and given the country's fast-growing, increasingly affluent population, more and more Indians are suffering from lifestyle diseases common to developed countries. India already has the largest number of diabetics in the world after China, for example, yet Indians still spend only $55 a year on health care.

''There's a huge gap in India,'' said Mr. Singh. ''The health care market in India is very fragmented. The corporatization of health care is still emerging.''

While 70 percent of the country's hospitals are government-run, private hospitals treat 70 percent of all patients, he said. And most private hospitals are small, with fewer than 30 beds, providing a big opportunity for larger operators like Fortis to use economies of scale to lower prices and increase profits. By introducing more advanced treatment methods, Fortis also aims to lower the average stay per patient, allowing it to increase volume.

To achieve the advantages of size, Fortis embarked on an acquisition spree, acquiring three hospital chains in India between 2005 and 2009. The company now has 10 more hospitals under construction.

In March, Fortis leaped overseas, buying 24 percent of Parkway from the private equity firm TPG for $685.3 million. With hospitals in Malaysia, China and India, Parkway gave Fortis a foothold across Asia. The chain is also popular with medical tourists: A third of its patients in Singapore come from abroad, mainly from Indonesia.

Some analysts expressed doubt about whether Fortis could benefit from a pan-national network: Unlike the managers and engineers who follow manufacturing investments overseas, doctors and nurses often cannot work in countries where they are not licensed. ''I don't know who can add more value to whom,'' Lynette Tan, an analyst at the Singapore brokerage DMG & Partners, said of the Fortis-Parkway link.

But Mr. Kapadia at HDFC said the economies of scale came not from personnel but from purchasing. With more hospitals, Fortis stands to get lower prices for drugs, supplies and equipment, he said, adding: ''A hospital is not only its doctors.''

Losing out on its bid to take over the rest of Parkway, therefore, represented a blow to Fortis's strategy. The Malaysian investment fund Khazanah Nasional Berhad won Parkway with a bid just 4 percentage points higher than Fortis's. ''We were not keen to get into a bidding war,'' Mr. Singh explained.

Fortis instead reaped a profit of 116.7 million Singapore dollars, or about $86 million, by selling its share of Parkway to Khazanah. The problem for Fortis now is that there are few pan-Asian players as big as Parkway for it to buy. ''There isn't any other very obvious candidate,'' said Anni Kum, an analyst at Kim Eng Securities in Singapore.

As a result, Mr. Singh said, Fortis is now considering moving into hospital management as an alternative.

''An acquisition to get kick-started might be the way to start,'' he said. ''But that doesn't mean it's the only way.''

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[Return to List](#cite_id_51)

51 of 200 DOCUMENTS

The Business Times Singapore

**August** 14, 2010 Saturday

**The cerebral tycoon;**

**Fortis chairman Malvinder Mohan Singh has an investment banker's penchant for dealmaking. But he is also instinctively a step-by-step institution builder, a believer in creating systems, processes and frameworks, and raising efficiencies. By Vikram Khanna**

**SECTION:** RAFFLES CONVERSATION

**LENGTH:** 2194 words

'IT was purely a business decision,' says Fortis chairman Malvinder Mohan Singh, of the Indian healthcare company's decision to exit from the takeover battle for Singapore's Parkway Holdings on July 25. After a brief bidding war and weeks of speculation about who would gain control of Parkway, Malvinder and his team decided to sell out their stake of just over 25 per cent at S $3.95 per share to rival Khazanah, the Malaysian sovereign wealth fund. The Indian company had paid $960 million, or $3.56 per share just four months earlier, and walked away with a profit of $116.7 million.

For Fortis, Parkway was a strategic fit, which would have combined the operations and capabilities of a healthcare leader in India with a big player in Singapore and Malaysia, and provided an ideal platform for a pan-Asian healthcare business. 'But you need to marry strategic fit and economic value,' says Malvinder. 'There's no point me telling my shareholders that we've created this huge healthcare business, but economically, the returns don't work. So, it was a clear cut, rational, objective call. It's not about ego or emotions. It's not about winning at any cost. It's about doing the right thing from a business viewpoint and creating value for shareholders.'

Malvinder, 37, one of India's youngest billionaires, has made many such calls during his eventful 18-year business career, which has spanned both the healthcare and the financial services industries. Probably the biggest of them was to sell his family's flagship company, the Indian pharmaceutical giant **Ranbaxy**, to Japanese drugmaker Dai-ichi Sankyo in June 2008 for US $4.6 billion.

In the lead-up to the deal, **Ranbaxy** had been working in partnership with global pharmaceutical companies on R&D - an initiative Malvinder had spearheaded. 'As I began partnering with them, I built some strong relationships. Then I realised these companies had a lot of challenges,' he recalls. 'Their top lines were shrinking, **patents** were expiring, cost structures were high, R&D productivity was low, emerging market presence was a gap in their business. I thought, all of that is what I have at **Ranbaxy**: I have generics, I have emerging market presence, I have cost efficient, high quality R&D and manufacturing facilities in India. In other words, I had exactly what they lacked. So I thought, let's put it together. So companies approached me, we began talking, one thing led to another, and we ended up created a new model in pharma with the Daiichi Sankyo deal.'

'Many people had talked to us. All of them wanted basically the same thing - a hybrid model which focused on both developed and emerging markets together, and innovation and generics together, a 2 x 2 matrix. I was convinced it was going to happen, it was just a matter of time. We were the first to make it happen. And now, everybody's doing it - Glaxo, Merck, Sanofi, Pfizer, Abbott - they're all doing it.'

But for Malvinder, the price of creating a new pharma paradigm was to exit from **Ranbaxy**, a company his grandfather had built up from 1952. 'It was the first time that had happened in India - a large business family selling its flagship business,' he points out. 'It created a bit of a flap. People were saying, a crown jewel gone, India's first MNC sold, why did I do it, et cetera. I said, look, it was a business call. It was the right thing to do. Today, everybody's doing it.'

The deal also happened to be impeccably timed. It was done in June 2008, just months before the global financial crisis hit.

Educated at Delhi's St Stephen's College, and Duke University's Fuqua School of Business, Malvinder's approach to business is cerebral rather than emotional. Having worked briefly in Merrill Lynch after college, he has an investment banker's penchant for dealmaking, where he can be bold and audacious. But he is acutely mindful of value. He is also instinctively a step-by-step institution builder, a believer in creating systems, processes and frameworks, and raising efficiencies.

He learned a lot, he says, from his father, the late Parvinder Singh, who built **Ranbaxy** into a global player from the 1970s through the 1990s. Dr Singh, a US-educated PhD, was widely regarded as one of India's most visionary captains of industry, who believed in professionalism and globalisation long before most other industrialists. When Malvinder joined the business in 1993, his father made him start at the bottom and work his way up, like everybody else. Malvinder and his younger brother Shivinder became the main shareholders of **Ranbaxy** after their father's death in 1999, by which time Malvinder was a senior manager.

'One of the things I learned from Dad was the framework of the basic tenets of business,' he says. 'First, no matter what business you get into, you must be in the forefront of that business. You must look at that business from a global perspective. You must create institutions of excellence. You must operate with a clear set of values. And you must create value for your stakeholders. This is the framework we use, to run businesses or to look at entry and exit.'

Malvinder's talents for dealmaking and institution-building came to the fore in the transformation of Fortis into an Indian healthcare industry leader in less than 10 years. The group started with one hospital in Mohali in the state of Punjab in 2001. 'Initially, our focus was to get the learning and the experience and we concentrated on organic growth,' he says.

Four years later, Fortis acquired New Delhi's prestigious Escorts Heart Institute, which was double Fortis' size. After taking management control of Escorts in 2007, Fortis set about finding ways to create efficiencies. It reduced the number of beds from 330 to 280, cut prices by 10 per cent, trimmed headcount from 2,000 to about 1,500, shortened waiting-times for operations, cut the average length of stay from seven days to 5.2 days - which reduced costs for patients. The net result: Within two years, margins went up from 10 per cent to 24 per cent and revenues went up 30 per cent.

In August last year, Fortis acquired 10 hospitals from the Wockhardt group, which propelled it to the forefront of India's healthcare industry. Apart from size, the acquisitions have added to Fortis in other ways. 'Fortis is not even a 10-year story,' says Malvinder. 'But with Escorts, which is a 25-year story and Wockhardt which is 20 years plus, the capability, knowledge and experience, the management processes, all that came into our system.'

He points out that Fortis now has a total of 170 systems and processes for running hospitals. 'They are institutionalised, and systemised,' he says. 'Just one example: with a 92 per cent level of accuracy plus-minus 5 per cent, we will tell you when you enter our hospitals what your treatment will cost. And if it's minus 5 per cent, we look into it and ask ourselves, why wasn't it accurate? What didn't we understand about this case?'

Malvinder took a similarly systematic approach to building Religare, India's largest private financial services company, together with its CEO, Sunil Godhwani, a family friend and one-time client of a small stockbroking business that Malvinder's family controlled.

'I've always been interested in financial services,' he says. 'It's where I started my career and I understand the industry well.'

He also views financial services as 'a call on India's growth'. He explains: 'Financial services is a business that's going to be a backbone. If your economy is growing, your financial services will expand, there will be more transactions. Also, there are not many business families in financial services, nor any integrated, global financial services company out of India. And India is globalising. As it does that, Indian business will globalise too.'

Malvinder was clear from the start that he wanted Religare to be an international business, not just a domestic business. But he also believed that a prerequisite for going global was to build a strong domestic base.

'So at Religare, we started by creating a retail franchise across India. We did it quietly, without people realising. Now we have more than 2,000 outlets in about 600 cities. That retail base is stronger than most banks, in terms of reach. We will use that reach to pipe through other products and services.'

Religare also built other platforms, including life insurance, asset management and investment banking. This was partly done through acquisitions, which included the purchase of Temasek subsidiary Lotus Asset Management in 2008; the UK's oldest independent broking and advisory firm Hichens and Harrison the same year; and Northgate, a US-based fund-of-funds business, in 2010.

'One by one, we're building the blocks across different businesses in financial services,' says Malvinder. 'Today, we've got 10 verticals. They are a mix of asset-heavy businesses, such as consumer finance, housing finance, life insurance and health insurance; and fee-based businesses, which are asset-light, such as investment banking, asset management, private equity and broking. In the asset-heavy businesses, we want to focus on India, where there is huge potential. But in the fee-based businesses, we want to go global.'

Although Religare's global headquarters are in India, its investment banking headquarters are in London and it has offices in Hongkong and Singapore.

Singapore is where Malvinder has chosen to be based. Why Singapore?

'We want to be part of the healthcare business here,' he says. 'Singapore is known for its service excellence. One of the reasons why Parkway is successful is because of the capabilities and skill sets available in Singapore: high service quality, strong medical education, capable doctors, a strong public healthcare system, which is a feeder for doctors coming into the private system. Singapore is also a regional hub, a great place from which to conduct business in Asia. And we want to have a pan-Asia, integrated healthcare business.'

Parkway was supposed to serve as a vehicle for Malvinder's pan-Asian vision. 'The vision remains the same, but the vehicle will change,' he says. 'Our team is already up and running to explore possibilities.'

He emphasises that just because Fortis bowed out in the battle for Parkway doesn't mean it is back to square one in pursuing its regional ambitions - because it has learned a lot from the Parkway experience.

'It's the difference between somebody reading a book about a country and somebody actually travelling to the country with a rucksack and going into the towns and villages and meeting the people,' he explains. 'That is the difference between us not having been in Parkway versus having been there. Through the eyes of Parkway we have been able to understand more about Asia: the geopolitical issues, various countries' policies in healthcare, the regulators, and how they operate. This is not something you can easily learn from the outside. You have to experience it. Now we understand what the competition is in various markets.

'And we have built relationships in Singapore. All of that is soft, tacit knowledge. We have further got more clarity and understanding of what can and what cannot work in healthcare in Asia, and how to do it. So it's not back to square one.'

Looking forward, Fortis has many options for expansion, both in Singapore and Asia. 'It could be through an acquisition, through a partnership, or through doing something afresh,' says Malvinder. 'Also, healthcare is not only hospitals. It also makes sense to look at a Reit in healthcare. We have the largest pathology and diagnostics business in Asia outside of Japan - a private company in India, which we could bring in here. Asia also has a strong GP business, which is another opportunity to evaluate.

'We won't overstretch, and we won't look at everything at the same time,' he adds. 'But if you look seven to 10 years from today, you will see Fortis in different segments of healthcare across Asia.

But whatever Fortis does, or buys, Malvinder's ground rules are clear.

'It's not just about you, or your dream,' he says. 'Stakeholders count too, and you have to see things from their perspective as well. You can't be selfish and say: this is my vision, my passion, my dream, and at any cost I'm going to do it. Then you should do it on your own, not with other people's money and other people's careers. When you run an institution, you have to be disciplined.'

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Malvinder Mohan Singh

Chairman, Fortis Healthcare Ltd

1972 Born in New Delhi, India

1993 Degree in Economics from St Stephen's College, Delhi

1998 MBA from Fuqua School of Business, Duke University, USA

2006 CEO and managing director of **Ranbaxy** Laboratories Ltd

2008 Completes sale of **Ranbaxy** to Daiichi Sankyo for US $4.6 billion

2001-present Chairman, Fortis Healthcare Ltd

2007-2010 Chairman, Religare Enterprises Ltd

March-Aug 2010 Chairman, Parkway Holdings Ltd

Awards

2005 Rajiv Gandhi Award for Leadership

2006 Most Promising Young Corporate Leader and Best Young Corporate Leader

2008 Financial Chronicle Businessman of the Year

2008 Golden Peacock Business Leadership

2009 Dynamic Entrepreneur

2010 Indian Business Leader of the Year

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[Return to List](#cite_id_52)

52 of 200 DOCUMENTS

The Nikkei Weekly (Japan)

**August** 9, 2010 Monday

**Emerging markets draw drugmakers**

**LENGTH:** 397 words

Emerging markets draw drugmakers

Japan's top pharmaceutical companies are embarking on major expansion drives to build sales networks in emerging markets. The firms seek to offset an anticipated revenue decline in industrialized countries as **patents** for their key medicines expire there.

Eisai Co. will set up a marketing base in Russia by the end of fiscal 2010 and launch sales of an epilepsy drug as early as next spring. It will also establish sales bases in Turkey and Brazil within three years, offering drugs for epilepsy and cancer. In addition to these countries, the company has begun selling its products in Canada and plans to do the same in or after next fiscal year in Australia.

Eisai, which has recently begun production in India, plans to expand shipments from India to other emerging nations, where drug prices are so low that exports from Japan would probably not make economic sense. The company has already set up sales operations in China.

Takeda Pharmaceutical Co. aims to enter Russia and India by fiscal 2012. It covered 71% of the global market in fiscal 2008, with the goal to raise this to 90% by the end of fiscal 2012.

To this end, Takeda will establish this month a sales subsidiary in South Korea. As well, the drugmaker has created a dedicated department to oversee its Asian marketing operations in order to make a full-fledged push into emerging markets, an area where it has so far lagged behind domestic rivals. The department is headed by Haruhiko Hirate, former president at a subsidiary of U.S. firm Merck & Co.

Astellas Pharma Inc. is leading other Japanese drugmakers in exploiting emerging markets, establishing sales subsidiaries in Brazil, Russia, India and China by last year. It also has sales units in South Korea, Turkey and South Africa.

Daiichi Sankyo Co. obtained sales networks in about 30 countries in one stroke by acquiring Indian drugmaker **Ranbaxy** Laboratories Ltd. in 2008. As a result, Daiichi Sankyo is steadily expanding its sales, not only in India but across a wide range of markets, including Eastern Europe and South Africa.

According to research firm IMS Health Inc., the Japanese, U.S. and European pharmaceutical markets are expected to grow only by an average of 5% or so annually over the next five years, but the growth rate will likely reach around 15% in emerging markets.

(The Nikkei Weekly 08/09/2010 Edition)

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[Return to List](#cite_id_53)

53 of 200 DOCUMENTS

The International Herald Tribune

**July** 8, 2010 Thursday

**India seeks its place among top drug makers;**

**Local producers grow rapidly as those in West encounter higher costs**

**BYLINE:** BY HEATHER TIMMONS

**SECTION:** FINANCE; Pg. 1

**LENGTH:** 1583 words

**DATELINE:** HALOL, INDIA

**ABSTRACT**

India, seasoned in the basics of medicine making, is starting to take on a more mainstream role thanks to recent strengthening of **patent** law and cost pressures on name-brand drug makers in the West.

**FULL TEXT**

Below an ancient hilltop temple to Kali, the Hindu goddess associated with destruction and change, Sun Pharmaceutical Industries churns out generic versions of cancer drugs and epilepsy medications bound for the United States.

Business is so brisk that Sun, with revenue last year of 41 billion rupees, or $872 million, predicts that sales will grow 20 percent this year and is expanding its Halol factory.

''This site specializes in making difficult things,'' Sampad Bhattacharya, Sun's vice president in charge of operations, said during a recent factory tour. The blue and gray concrete building, which will cover nearly 75,000 square meters, or 800,000 square feet, after the expansion, would not look out of place in the pharmaceutical manufacturing centers of New Jersey, except for the herds of cattle and buffalo wandering nearby.

India's drug industry - on track to grow about 13 percent this year, to more than $24 billion - was once notorious for making cheap knockoffs of Western medicines and selling them in developing countries. But India, seasoned in the basics of medicine making, is now starting to take on a more mainstream role in the global drug industry as a result of recent strengthening of **patent** law here and cost pressures on name-brand drug makers in the West.

And while the Indian industry has had quality control problems, it nonetheless benefits from growing wariness about the reliability of ingredients from that other historically low-cost drug provider - China. The United States is India's top export customer for drugs.

India is becoming a ''base for manufacturing for the global market,'' said Ajay G. Piramal, the chairman of Piramal Healthcare, a drug maker based in Mumbai. Eventually, in Mr. Piramal's perhaps overly optimistic forecast, only the very first and very last steps of the business - molecular drug discovery and marketing - will be run by the West's global drug giants.

Those companies ''don't create much value'' in the steps in between, he said.

It is not only Indian executives, though, who are bullish about the pharmaceuticals industry here. Analysts, research groups and consultants have been making similar predictions in recent months.

Big pharmaceutical companies have come calling, too. This year, Mr. Piramal sold his generic drug business to Abbott Laboratories for $3.7 billion in the latest in a string of takeovers and joint ventures in India.

Daiichi Sankyo of Japan helped begin the foreign drug push into India in 2008 by buying a stake in **Ranbaxy** Laboratories, the country's biggest drug maker. Last year, among other deals, GlaxoSmithKline formed a partnership with Dr. Reddy's Laboratories; Pfizer tied up with Claris Lifesciences; Sanofi-Aventis took control of Shantha Biotechnics; and Bristol-Myers Squibb opened a research center in India with Biocon.

''There is a lot of good talent at a much lower price in India,'' said Jim Worrell, the chief executive of Pharma Services Network, a consulting firm in Charlotte, North Carolina, that is organizing tours of Indian factories for Western pharmaceutical executives who are considering outsourcing some of their business. ''What I see happening now is manufacturing and even packaging and even formulation are moving to India,'' Mr. Worrell said.

The shift to pharmaceuticals is part of a subtle, broader shift in the Indian economy. Moving beyond less sophisticated, outsourced services like telephone call centers, India has been advancing up the business value chain, particularly in law and medical diagnostics. Now it is showing a flair for manufacturing, particularly in goods demanding high-skill production and superlow prices.

Until recently, pharmaceuticals had been ''an incredibly arrogant industry that has never outsourced,'' said Sujay Shetty, an associate director with PricewaterhouseCoopers in Mumbai. But over the next several years, he predicts, ''everything in the value chain will move to different parts of the world that are cheaper,'' with India a major beneficiary.

The next opportunities for India could come at the more sophisticated end of the drug-making spectrum, including research and development for the world's drug giants and even development of proprietary medicines.

''We can crack the problem of patented drug discovery in India at a much lower cost'' than in the West, predicted Mr. Piramal, who held onto his research and development operation, Piramal Lifesciences, when he sold the rest of his company to Abbott.

At Piramal's main laboratory in north Mumbai, about 300 scientists are researching new drugs aimed at inflammation, metabolic disorders and cancer. Mainly because of lower wages in India, if it costs big pharmaceutical companies ''$1 billion to $1.5 billion to discover a new drug, we can do it in a tenth of the cost,'' Mr. Piramal predicts.

G.V. Prasad, chief executive of Dr. Reddy's Laboratories, said that Indian drug makers had the ability to handle product development on a large scale at a low cost. Dr. Reddy's original diabetes drug has completed Phase 3 clinical trials, the last step before seeking approval from the U.S. Food and Drug Administration - the furthest of any of its peers.

Meanwhile, at Sun's stucco-and-glass laboratory in Gujarat State, surrounded by white, pink and yellow bougainvillea, 650 scientists, backed by tons of expensive machinery and 10,000 animals in cages, are at work breaking down drugs with the aim of rebuilding them in cheaper ways with fewer side effects.

Revolutionary science is not only about developing a brand-new product, said T. Rajamannar, executive vice president of Sun Pharma Advanced Research. It also means learning how to make an existing drug ''very efficiently,'' he said.

For all the potential, though, India's drug industry has a long way to go to fulfill its promise.

India exported about 384 billion rupees in drugs and services for the pharmaceutical industry in the 2008-2009 financial year, according to government figures, up 25 percent from the year before.

Recent growth, though, has been shadowed by quality problems. The U.S. Food and Drug agency has cited **Ranbaxy** for manufacturing violations several times in recent years, and in February, it ordered a review of the company's global manufacturing operations.

In May, Sanofi-Aventis recalled vaccines made by Shantha Biotechnics that had been distributed to the World Health Organization after users complained about white sediment in the vials. In June, after floating matter was found in some plastic intravenous supply bags, Pfizer recalled injectible drugs made by Claris Lifesciences and sold in the United States.

Intellectual property is also an open question. Trying to change its outlaw image as a maker of illegal knockoffs, India toughened its **patent** laws in 2005. But dozens of intellectual property suits are still being fought between Indian and foreign companies in courts around the world. And big pharmaceutical companies still find securing protection of their intellectual property in India difficult.

Meanwhile, outright counterfeit drug-making remains rampant in India, executives and analysts here say. A study this year of pharmaceuticals from Indian wholesalers found that 3.6 percent of the products had no active ingredients whatsoever.

All of which is why some drug executives in the United States say that their Indian peers may be too optimistic about their industry's prospects.

''Cost is one issue, and yes, it is important, but there are two other critical factors: intellectual property and quality and safety issues,'' said Panos Kalaritis, the chief operating officer of Irix Pharmaceuticals, a contract research and manufacturing company in Florence, South Carolina, that competes with Indian laboratories and factories.

The Food and Drug agency, in response to India's growing influence, has opened two offices in the country - in Delhi in early 2009 and in Mumbai in June of last year. When fully staffed, the offices will have between them a dozen full-time employees, including inspectors and technical specialists, a presence comparable to that of the agency in China.

Among other measures, the Indian offices will enable the U.S. agency to ''verify that important products and the way they are manufactured meet U.S. health and safety requirements,'' an agency spokeswoman said in an e-mail message.

While China is the undisputed low-cost maker of a multitude of consumer goods, India may have a rare edge in the drug industry. India's long tradition of generics has fostered a robust educational system here for pharmaceutical scientists, as well as longer experience dealing with Western regulators.

The U.S. agency has issued about 900 approvals to plants in India to export drugs or raw materials for the industry to the United States, the vast majority in recent years, compared with more than 300 such approvals for China.

Indian companies have ''a lot to offer, and the cost advantage is huge,'' said Swetha Shantikumar, a research analyst in Chennai with Frost & Sullivan, who predicted more buyouts of Indian firms by global giants in the near future. Chinese firms ''don't have the technical capacity to produce sophisticated drugs,'' Ms. Shantikumar said.

''If you want to make simpler drugs like aspirin,'' she said, ''you manufacture them in China.''

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[Return to List](#cite_id_54)

54 of 200 DOCUMENTS

The Nikkei Weekly (Japan)

**June** 28, 2010 Monday

**Drugmakers reap bigger profits from foreign units acquired through M&A**

**LENGTH:** 309 words

Drugmakers reap bigger profits from foreign units acquired through M&A

Japanese drugmakers Eisai and Daiichi Sankyo Co. see the foreign units they purchased over the past few years making growing contributions to group earnings this fiscal year.

Eisai bought U.S. firm MGI Pharma in 2008 in order to offer cancer treatments and other drugs. The subsidiary clipped Eisai's profit by nearly 90 billion yen in the year ended in March 2008 as the parent recognized in-process R&D expenses and amortized intangible fixed assets.

As the burden of such charges diminished in fiscal 2009, the unit boosted Eisai's net profit by about 5 billion yen.

Such contributions by MGI, which has merged with an Eisai U.S. subsidiary, are seen doubling to just over 10 billion yen this fiscal year. And this is expected to partly offset the negative impact of expiring U.S. **patents** for its Alzheimer's drug Aricept this year.

With generic drugs waiting to hit the market, "the U.S. **patent** expiration will cut into its net profit by about 15 billion yen," says a securities analyst.

Daiichi Sankyo purchased Indian generic drugmaker **Ranbaxy** Laboratories Ltd. in 2008. Daiichi Sankyo's net profit took a roughly 260 billion yen hit in fiscal 2008 due to the related in-process R&D expenses and one-time goodwill amortization.

But **Ranbaxy**, which sells generic drugs worldwide, lifted the Japanese parent's net profit by 7 billion yen in fiscal 2009, and is seen kicking in nearly 10 billion yen this fiscal year, a 40% or so increase.

By contrast, Takeda Pharmaceutical Co. is expected to take a roughly 40 billion yen net profit hit due to expenses associated with the purchase of U.S. firm Millennium Pharmaceuticals Inc.

Astellas Pharma Inc. also faces net profit erosion of 25 billion yen due to the acquisitions of two U.S. start-ups.

(The Nikkei Weekly 06/28/2010 Edition)

**LOAD-DATE:** July 30, 2010

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[Return to List](#cite_id_55)

55 of 200 DOCUMENTS

Business Day (South Africa)

**June** 25, 2010

Business Day Edition

**Drug multinationals look to the global south**

**BYLINE:** Nick Wilson

**SECTION:** ECONOMY, BUSINESS & FINANCE

**LENGTH:** 656 words

THE BOTTOM LINE COLUMN

Drug multinationals look to the global south

THAT US drug maker Merck has entered into a co-promotion deal with local pharmaceutical firm Adcock Ingram should be no surprise.

With increasing price and regulatory pressure in North American and European markets, multinational pharmaceutical companies have begun pursuing deals with generic drug makers in emerging markets.

Two years ago, Japan's Daiichi Sankyo acquired a majority stake in India's biggest generic drug maker, **Ranbaxy.**

UK-based GlaxoSmithKline has tied up with Africa's biggest generic drug maker, Durban-based Aspen Pharmacare.

Faced with growing competition from generic drug makers, more and more blockbuster drugs reaching the end of their **patent** life, and a dwindling product pipeline, the multinationals have sensibly tried to broaden their global exposure with deals of this kind. The numbers say it all: research company IMS Health forecasts that emerging markets will grow at 14%-17% through to 2014, while markets in North America and Europe will grow at just 3%-6%, reversing the pattern of the past five years.

SASOL is stuck in a narrow trading range, between R280 and R330, where it has been for almost two years now. Gone are the heady days of early 2008 when a Sasol share would set you back just on R500.

The Oryx gas-to-liquid project in Qatar appears to be running more smoothly now, but so far the return on its $1bn investment appears uninspiring. Sasol has also sold off its interest in the Escravos gas-to-liquid project, so there are no mega-projects under way. The company is still underpinned by its local gas-to-liquids business. While returns are great, growth is somewhat lacking.

Sasol has this advantage in being able to arbitrage the price difference between gas and oil through its gas-to-liquids technology. Hence, it now highlights the fact that it is one of the few companies that can really take advantage of lower gas prices. Gas prices are down because new technology enabling extraction from natural shale gas has proved viable and huge new reserves have become available.

The result is that many liquefied natural gas projects will not be as profitable as first hoped, and this is where Sasol hopes to step in and take advantage of the new "shale-gale" context. A feasibility study is under way in Uzbekistan and consideration is being given to gas-to-liquids prospects in Australia and Papua New Guinea. This is great, but the possibility of an Australian project has been on the cards for five years or more.

IS ANOTHER interest rate cut possible? If so, Reserve Bank governor Gill Marcus will have to eat her words. Only two months ago Ms Marcus said interest rates would remain the same for "some time".

That time could be sooner than expected, given the announcement by Stats SA yesterday that the consumer price index (CPI) slowed to 4,6% last month, from 4,8% in April.

This is the fourth successive month inflation has been within its 3%-6% target range and economists suggest it might go even lower, perhaps as low as 4%. The result will be that the real repo rate has effectively increased now to 1,9%, and any further CPI declines will provide the Reserve Bank with plenty of latitude to trim rates by 50 basis points.

CPI is not the only criterion here. The other issues are the business cycle, credit extension, labour market developments, and the stability and competitiveness of the rand.

These criteria are weighted towards a cut: the business cycle moving upward but the recovery seems weak; job growth is terrible; credit extension is in the dumps, and the rand may have weakened against the dollar, but against the euro and pound it's still a bit perky. The joker in the pack is the de-pegging of the renminbi, which could help weaken the rand.

So if another cut is possible, when would it occur? The betting now is as early as next month, or perhaps September.

o edits The Bottom Line. (wilsonn@bdfm.co.za)

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[Return to List](#cite_id_56)

56 of 200 DOCUMENTS

The Business Times Singapore

**June** 11, 2010 Friday

**Big pharma eyes Indian drug firms;**

**But despite the sales of leading companies, the situation is not as grim as it might appear**

**BYLINE:** Yogi Aggarwal

**SECTION:** VIEWS AND OPINIONS; Opinion

**LENGTH:** 1102 words

INDIAN pharmaceutical companies that had grown in the past three decades to become a powerhouse of generic manufacturers have recently been feeling the heat of prolonged and difficult litigation in major Western markets.

Western pharmaceutical giants have also tried to protect their markets with other restrictive practices.

Now it seems that these Western companies have found another way to fight off the Indian threat: They have persuaded the Indians to take the easier and profitable route of selling out to pharma giants.

The latest case is the sale of Piramal's 18.2 billion rupee (S $546 million) formulations business with 350 branded generics to Abbot Laboratories for 170 billion rupees. This is at a premium to its present market capitalisation of 108 billion rupees and the sale is valued at a high nine times annual revenue.

Piramal retains its over-the-counter medicines range and special lines with sales of 17 billion rupees. But Abbot will now be the largest player in the Indian market with a 7 per cent share, something that would otherwise have taken a long time to achieve.

As India's fourth largest pharma, Piramal has got a much better price than the US $4.6 billion paid for **Ranbaxy's** full business by Japanese company Daiichi Sankyo two years ago.

It is also the latest in a series of seven mergers and acquisitions (M&As) in the past two years when Indian companies, or parts of them, have been acquired by big pharma, or their smaller cousins.

Of course, Indian pharmas are also taking over foreign firms. The largest case was Sun Pharmaceuticals' US $454 million proposed takeover of Israeli firm Taro which is locked in litigation.

Market supremacy

There have been several concerns about this. A major one, expressed by India's Health Ministry, is whether multinational drug majors, with increasing control over generic firms, will increase the price of medicines available in India, especially since 95 per cent of the medicines sold within the country are locally made generics.

If such acquisitions continue, multinationals will gain market supremacy and people may have to pay through their nose for essential medicines.

Further, the Indian Pharmaceutical Alliance (IPA), an association of the country's leading domestic drug producers, has warned of the consequences of foreign companies acquiring homegrown players. In a letter to the Department of Pharmaceuticals, IPA has said the paucity of funds and the enormous challenges faced by the domestic industry abroad have driven promoters to sell their companies. According to IPA, all the acquired companies were engaged in intensive research and were attempting international expansion.

The determination with which big pharma is going in for expensive litigation to thwart the entry of generic medicine companies into their markets shows their tenacity and desperation. One reason for the low morale in Indian pharma is the difficulty in cracking the legal cases that are filed against them the moment a medicine goes off **patent**.

Daiichui Sankyo found this to its cost after its purchase of **Ranbaxy**, when the US Food and Drug Administration banned 30 of its generic drugs, accusing **Ranbaxy** of faking data and test results. Since then, **Ranbaxy** has been more successful in US **patent** tussles. It entered the US market in late 2009 with a six-month exclusivity to sell its generic version of herpes drug Valtrex, having annual sales of US $1.3 billion.

In 2010-11, **Ranbaxy** might launch generic version of Pfizer's blockbuster cholesterol drug Lipitor, which recorded revenues of US $13 billion

Yusuf Hamied, the feisty chairman of Cipla, who pioneered a low-cost Aids vaccine and leads the fight against big pharma strategies to keep extending **patents**, said in a recent interview: 'This question of monopoly of drugs in the future - if the Americans, Europeans and Big Pharma get their way - could be a disaster for the Third World. I am not against **patents**, but India cannot afford them. I am against monopolies.'

The attractive valuations and the resistance to generics reflect the 'seismic change' in the global pharmaceutical market in the past decade and the still larger changes to come.

Over the next five years, drugs worth US $142 billion are to come out of **patent**, and as a consequence of patients shifting to generics will mean a cut in profits of around US $80 billion to US $100 billion to big pharma. Moreover, governments are cutting health budgets and shifting to generics.

IMS Health, a pharmaceutical consultancy firm, reports that the size of the global market for pharmaceuticals is expected to grow nearly US $300 billion over the next five years, reaching US $1.1 trillion in 2014.

This will mainly be propelled by a 14 to 17 per cent growth (or US $120 billion to US $140 billion annually) in the seven countries of what it calls the 'pharmerging markets' (China, India, Brazil, Russia, Turkey, South Korea and Mexico.)

For this, big pharma is adopting three key strategies:

Prevent the emergence of new generic players in the mature markets,

Enter into partnerships with developing markets to make generics to be marketed by big pharma in the mature markets, and

Set up manufacturing facilities either by M&A or by greenfield projects to cater to the demand in the 'pharmerging' markets.

A PricewaterhouseCoopers (PwC) report, titled Global pharma looks to India, highlights that India is likely to become a competitor of global pharma in some key areas, and a potential partner in others.

Indian companies are among the world leaders in the production of generics and vaccines and India now produces more than 20 per cent of the world's generics.

PwC thinks that India is capable of manufacturing a substantial share of generics.

In manufacturing, big pharma companies are already striking closer relationships with Indian generics to service global markets under marketing alliances such as GSK-DRL and Pfizer-Aurobindo.

Sujay Shetty, associate director, pharma & life sciences, PricewaterhouseCoopers India, believes: 'Global players in the pharma industry are seeing immense prospects in the Indian market due to its sheer demographic profile. The pharma industry's main markets are battling serious pressure. India could be the most populous country in the world by 2050 and is now making its mark as a growing market, potential competitor or partner in manufacturing and R&D, and as a location for clinical trials.'

So perhaps, despite the sales of leading companies, the situation is not as grim as it might appear. It's just that the strategy has changed from confronting the big brother to collaborating with a potential ally.

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[Return to List](#cite_id_57)

57 of 200 DOCUMENTS

The New York Times

**April** 16, 2010 Friday

Late Edition - Final

**F.D.A. Again Warns the Generic Maker Apotex About the Conditions at Its Plants**

**BYLINE:** By NATASHA SINGER

**SECTION:** Section B; Column 0; Business/Financial Desk; Pg. 6

**LENGTH:** 853 words

Federal regulators have raised another red flag about the quality of generic drugs, sending a warning letter to a leading maker about manufacturing violations.

In the letter, posted on the Food and Drug Administration's Web site late Wednesday, the agency cited lapses at Apotex, Canada's biggest drug company, that included charred particles in a diabetes drug; contamination of an antihistamine, and drug cross-contamination that resulted from inadequate cleaning of manufacturing equipment.

The letter also said the company had failed to notify regulators in a timely fashion about such problems.

Apotex, with headquarters in Toronto, was the eighth-largest provider of generics in this country last year, with $879 million in American sales, according to IMS Health, an industry research firm that tracks drug sales. In 2009, American pharmacies filled 94 million prescriptions with Apotex medicines, IMS said.

Apotex did not respond to a phone message or e-mail request on Thursday seeking comment about the letter.

The F.D.A. action comes as another well-known generic maker, **Ranbaxy,** has also come under the agency's spotlight for manufacturing and quality control problems at two of its factories in India and one in Gloversville, N.Y.

Those regulatory actions focus attention on generic quality at a time when Americans are increasingly turning to the medicines to save money on their prescription drugs. Generic drugs now account for 75 percent of the prescriptions filled in this country, according to the latest data from IMS.

Concerns about the quality and effectiveness of generics have become prevalent enough among doctors and patients that the F.D.A. held a public advisory meeting this week to discuss the issue and explore whether additional regulation of the drugs would increase public confidence in the products.

But in an interview last month, Gary J. Buehler, an F.D.A. official and former director of the agency's office of generic drugs, said that the F.D.A. ensured that generic makers adhere to proper manufacturing standards and produce high-quality products.

''Generic quality is good,'' Mr. Buehler said.

He added that people should not judge the entire generic industry by a few isolated incidents.

Indeed, the F.D.A. has periodically accused brand-name drug makers and generic makers of violating manufacturing or quality control standards. Typically, the companies have put the matters to rest by quickly correcting the problems to the agency's satisfaction.

The new F.D.A. letter is unusual because it is the second warning to Apotex in less than a year. The current letter, dated March 29, cites problems found at an Apotex factory in Toronto during an inspection last summer.

Last June, the agency warned Apotex about similar issues arising from an earlier F.D.A. inspection of another facility in Etobicoke, Ontario, in late 2008.

Taken together, the violations ''demonstrated a lack of adequate process controls and raised serious questions regarding your corporation's quality and production systems,'' agency officials wrote to Jack M. Kay, the president and chief operating officer of Apotex, in the March 29 letter.

''This warning letter is being issued because of serious and repeat violations from the 2008 and 2009 inspections and because your response,'' the agency wrote, ''is inadequate and lacks sufficient corrective actions.''

Since last August, the agency has prohibited drugs from the Etobicoke and Toronto sites from entering the United States, although Apotex has other plants it can ship from.

From July 2007 to August 2009, Apotex voluntarily recalled all products associated with manufacturing concerns -- about 659 batches of various drugs -- in the United States, the F.D.A. said.

Many Americans first heard the name Apotex in 2006 when the company briefly flooded the United States market with a generic substitute for the blood thinner Plavix before the name-brand drug's main **patent** had officially expired.

A federal judge later blocked Apotex from selling the generic until a court could rule on the **patent's** validity. The **patent** holders, Bristol-Myers Squibb and Sanofi-Aventis, eventually won on appeal.

Apotex produces more than 300 kinds of generic drugs in about 4, 000 dosages and formats, according to the company's Web site. Apotex, which is privately held, has annual revenue of more than $1 billion Canadian, the Web site said.

In a statement last September, Apotex said that the F.D.A.'s import ban applied to only two of the company's many factories and that the company was working with agency officials to resolve their concerns.

''We pride ourselves on being a leading maker of top-quality generic pharmaceuticals,'' Mr. Kay, the Apotex executive, said in the September statement.

But the F.D.A.'s recent letter said officials remained concerned about continuing manufacturing issues at Apotex.

Until Apotex corrects the problems to the agency's satisfaction, regulators will recommend that the F.D.A. withhold approval for any new products listing Apotex as the manufacturer, the letter said.

**URL:** http://www.nytimes.com

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**GRAPHIC:** PHOTO: A worker at Apotex in Toronto. The Canadian company was said to have $879 million in United States sales last year. (PHOTOGRAPH BY JIM ROSS FOR THE NEW YORK TIMES)

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[Return to List](#cite_id_58)

58 of 200 DOCUMENTS

The Australian

**March** 31, 2010 Wednesday

1 - All-round Country Edition

**Tough competition in generics game**

**BYLINE:** Tim Boreham

**SECTION:** FINANCE; Pg. 40

**LENGTH:** 727 words

Ascent Pharmahealth (APH) 34c

BARRING further delays, Sigma Pharmaceuticals should release today the gory details of its writedowns stemming from its $2.2 billion purchase of generics drugs house Arrow Pharmaceuticals.

As Sigma receives its well-deserved whipping, a smaller generics rival plans to make the competitive market even tougher under the 100 per cent ownership of Indian pharma Strides Arcolab.

On March 16, Ascent revealed Strides' non-binding offer of 35c a share for the 43 per cent of the company it does not already own. Central to the deal is retaining chief executive and founder Dennis Bastas as an equity partner.

Ascent has about a 7-8 per cent share of the generics market, dominated by foreign-owned Alphapharm and our friends at Sigma. On reasonable interpretation, the Strides purchase points to even stiffer competition in the sector, which is fast-growing but low-margin.

Generics are the no-name, chemically identical version of big-name drugs going off **patent.** According to Sigma, 155 brands with annual sales of $1.6bn have gone off-**patent** already, with a further 65 ($2.5bn) due to follow by the end of 2014.

This includes Lipitor, the biggest-selling prescription drug. RBS Morgans pharma watcher Scott Power says Strides' move is no coincidence given Sigma's woes. Power says past entrants such as India's **Ranbaxy** have failed to gain a foothold in the small Australian market.

Criterion had Ascent as a spec buy at 25c in October.

Punters should hold, but in view of cashing in. The generics game has ``too hard'' written all over it.

Clinuvel Pharmaceuticals (CUV) 27c

Living Cell (LCT) 24.5c

THE skin disorder outfit has taken a topsy-turvy regulatory route for its lead drug afamelanotide by seeking research approvals in Europe (and locally) before tackling the feared US Food & Drug Administration.

Clinuvel won FDA assent yesterday for phase-two trials, aimed at treating a rare sun intolerance that we'll abbreviate to EPP. Given the incurable EPP affects only 10,000 people globally, the burning question is how Clinuvel will generate enough revenue to justify a decade of investment.

Chief executive Philippe Wolgen is committed to the medical route, but the obvious market is to produce a glowing tan. But there's no talk of frivolous applications over at the Kiwi-based Living Cell, which is tweaking the use of pancreatic islets from pigs to treat diabetes via a cell implant. Living Cell received NZ approval yesterday to start phase-two trials, after the result of four patients replicated the findings of a wider trial in Russia. Mother Russia might have a glorious medical research heritage but chief executive Paul Tan says there have always been some doubts about data from there.

Criterion rates Living Cell a speculative buy, but the next few months look an unexciting slog.

Investor interest in Clinuvel has waned as quickly as a tan from a Pacific cruise, but Wolgen won't rush a regulatory application, saying: ``I would prefer a delay rather than rejection.''

The drug is worth more than $46m, so we ascribe a spec buy.

BHP Billiton (BHP) $44.41

Rio Tinto (RIO) $79.25

IT was a terse announcement imparting weighty gravitas: BHP has convinced a ``significant number'' of iron ore customers to move to short-term contracts at ``market clearing prices''. In short, BHP has repeated what it did with its coking-coal customers and has refused to play the old annual contract caper. In Brazil, rival Vale has also reached a tentative agreement with Asian mills that would raise the price by 90 per cent to $US105 a tonne. BHP doesn't mention a price, but the Vale deal implies a free on board (ex-freight) price of about $US114 a tonne, compared with the current contracted $US60 a tonne.

The news sends out feel-good vibes about putative Pilbara collaborator Rio Tinto, but we dare not send a congratulatory telegram to ex-Rio negotiator Stern Hu as he begins 10 years in jail.

The disclosures fired up BHP and Rio shares, but the pricing doesn't seem far off what analysts had factored in anyway. We rate both stocks as holds. On a cautionary note, the pricing precedent will only encourage BHP's and Rio's many emerging rivals.

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The Australian accepts no responsibility for stock recommendations. Readers should contact a licensed financial adviser. The author owns shares in BHP Billiton and Rio Tinto.

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[Return to List](#cite_id_59)

59 of 200 DOCUMENTS



Investment Adviser

**March** 22, 2010

**Focus: Healthcare - Finally, the prognosis looks good**

**SECTION:** 1361-1593

**LENGTH:** 1090 words

Healthcare stocks have been off investors' radar screens for a long time. There are, however, a number of reasons why they could be about to make a comeback.

Beneath the surface of an overlooked sector, underappreciated cash flows, strong emerging market growth potential and interesting corporate activity give investors a number of reasons to be bullish for the first time in several years.

The global healthcare industry is a diverse set of businesses that includes large pharmaceuticals with **patent**-protected drug portfolios, potentially fast-growing biotechnology companies, generic drugs manufacturers, and technology companies producing a range of medical devices.

The sector has endured a troubled time from its 'sweet spot' in the 1990s, when companies saw fast growth based on blockbuster products and healthy drug development pipelines. Despite high levels of research and development (R&D), new products failed to keep pace with investors' expectations. This, combined with the threat of expiring **patents** on leading drugs and growing competition from lower-cost generic manufacturers, sparked a sustained derating of the sector during the past decade.

Recently, however, there have been some very encouraging signs of a change in strategy among the large pharmaceutical companies. A wave of intelligent deals have been made that could transform the outlook for a number of companies and, indeed, the overall shape of the industry. Meanwhile, medical demands and demographic trends continue to present the industry with excellent long-term growth opportunities.

In recognition of the threat of generic competition and an upcoming **patent** cliff in 2011-12, when a high number of lucrative blockbuster drugs lose their protected status, many of the leading drug companies have began to fight back by establishing or buying their own generic drug distribution. There has been a series of deals within the sector to bolster flagging drug development pipelines and bring about R&D synergies.

Last year, Pfizer bought Wyeth, Roche completed its acquisition of Genentech and Merck merged with Schering-Plough. These purchases have significantly boosted the product pipelines of the enlarged firms and provided cost-cutting opportunities and free cash flows that are not yet reflected in share prices.

**Patent** expiries have been a major driver behind this wave of creative corporate activity. For example, Pfizer's multi-billion dollar revenue generator, Lipitor (an anti-cholesterol drug) goes off **patent** in 2011. The good news for investors is that depressed share valuations currently discount the loss of revenues from these **patent** expiries. The valuation of developed country healthcare stocks has fallen from a price/earnings ratio of 28x in 2004 to roughly 16x.

It was Novartis who made the initial move to take the low-cost manufacturers on at their own game by moving into generics in 2003 when it set up its Sandoz arm. Sandoz is now the world's second-largest seller of generic drugs.

In the following years, the rest of the industry followed Novartis' lead. Japan's Daiichi Sankyo bought India's leading generics manufacturer **Ranbaxy,** while Sanofi-Aventis acquired the Czech company Zentiva. GlaxoSmithKline signed a deal with South Africa's Aspen PharmaCare to sell generic products in fast-growing emerging markets. We can expect to see more of such deals in future.

It's not just about mergers and acquisitions. There are a number of other interesting drivers that make the outlook encouraging for healthcare stocks:

A Increased demand for healthcare

The World Health Organisation (WHO) estimates that the number of people aged over 60 is likely to treble from 600m in 2000 to 2bn in 2050, mostly in developed countries. Rapidly ageing populations, coupled with economic and population growth in emerging countries, is likely to increase the industry's customer base significantly as the proportion of income spent on healthcare rises. As people live longer, demand increases for orthopaedic products such as hip replacements, eye care and hearing aids.

AMedical needs

Chronic disease presents the largest growth potential for healthcare companies in developed markets. The WHO predicts that the incidence of death from diseases such as chronic obstructive pulmonary disease, cancers and diabetes/metabolic conditions will increase from less than 20 per cent in 2005 to almost 30 per cent by 2030. Half of the US population is set to be classified as obese by the end of this decade and the prevalence of diabetes has more than doubled over the last 25 years. In terms of R&D spending, pharmaceutical companies are increasingly focusing on chronic diseases.

AGrowth of generics

The generics industry has huge growth potential, with opportunities in both emerging and developed markets. Building on recent developments, the lines will become increasingly blurred between the traditional R&D-driven, large pharmaceutical companies and generic manufacturers.

We are already seeing the development of intermediate-branded generic drugs for distribution in emerging markets in Latin America, Asia and Europe. Since many drugs are paid for by consumers out of their own pockets in these markets, branded generics can build up consumer loyalty.

They carry the name of a trusted drugmaker on the package, which is seen as a sign of authenticity and quality control. For example, Pfizer markets its antidepressant, Zoloft, under its own brand name while marketing a generic version of the drug under its Greenstone label.

The Obama administration's healthcare reform proposals have had an impact on healthcare stocks. The aim of the reforms is to bring down costs and expand health care coverage. However, the Democrats' loss of a clear 60-40 super-majority in the Senate may mean that the reform proposals have to be watered down in order to be made into legislation. This would have a positive short-term impact on the sector, particularly on those firms that were deemed most at risk.

In summary, the healthcare industry seems to be undergoing something of transformation. Moreover, there seems to be limited scope for downside.

Amid the current uncertainty in stock markets, investors may want to de-risk their portfolios. If we were to see a period of market consolidation, the health care sector should outperform due to its safe haven status and relatively defensive earnings. Beyond that, the sector seems to be ripe for a rerating as investors realise risks are priced in and valuations are attractive in the light of many encouraging developments.

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[Return to List](#cite_id_60)

60 of 200 DOCUMENTS



The Times (London)

**March** 12, 2010 Friday

Edition 1;

Ireland

**AstraZeneca takes on generic drugs partner as patents fade**

**BYLINE:** Rhys Blakely

**SECTION:** BUSINESS; Pg. 45

**LENGTH:** 309 words

AstraZeneca moved to broaden its presence in the huge South Asian market yesterday when it signed a partnership with a generic drugs maker. The deal with Torrent Pharmaceuticals gives the Anglo-Swedish group access to a fresh portfolio of cheap medicines to sell in developing markets at a time when it faces the loss of **patents** on several of its blockbuster brands.

Torrent has two large manufacturing plants in India that can produce more than 6 billion tablets a year.

AstraZeneca will put its own name on those drugs to lure brand-conscious consumers and doctors in developing markets. The arrangement, the financial terms of which were not disclosed, will initially cover nine countries.

**Patents** on seven AstraZeneca drugs will expire in the next four years. They include its three biggest sellers: Nexium, an ulcer treatment; Seroquel, an antipsychotic; and Crestor, an anticholesterol drug. The company warned last month that this may lead to "a period of fluctuating earnings".

AstraZeneca wants to boost sales in emerging markets to 25 per cent of annual revenue by 2014, from 13 per cent last year - in part to minimise the impact of **patent** losses. It will hold an investor day on March 16 to highlight its plans for emerging markets.

AstraZeneca already sells some of its own medicines in emerging markets as branded generics. Crestor, its cholesterol drug, is priced to compete with a range of cheap copies in India, where it has no **patent** protection.

Emerging markets tie-ups

GlaxoSmithKline struck a deal with Dr Reddy's of India last June, and has bought 16 per cent of Aspen in South Africa.

Sanofi-Aventis's purchases include Medley of Brazil and Zentiva of the Czech Republic.

Pfizer, the world's biggest drugmaker, reached agreements with the Indian companies Aurobindo and Claris Lifesciences.

Daiichi Sankyo of Japan bought **Ranbaxy** of India 2008.

**LOAD-DATE:** March 13, 2010

**LANGUAGE:** ENGLISH

**PUBLICATION-TYPE:** Newspaper

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[Return to List](#cite_id_61)

61 of 200 DOCUMENTS

The Nikkei Weekly (Japan)

**March** 1, 2010 Monday

**IN BRIEF: Japan no longer machine tool king**

**LENGTH:** 405 words

IN BRIEF: Japan no longer machine tool king

Japan slipped to third place in the 2009 worldwide ranking of machine tool producers by value, dropping from the top spot it had held for 27 years.

The country produced $5.8 billion worth of machine tools last year, down 57% from 2008. No. 1 China's machine tool production rose 9%, to $10.9 billion, nearly double Japan's output.

Germany came in second at $7.8 billion, down 35%. Its plunge was milder than Japan's, thanks to the weaker euro.

The figures were compiled by U.S. research firm Gartner and the Japan Machine Tool Builders' Association.

Japan had been the world's largest machine tool manufacturer since 1982, when it seized the crown from the U.S.

Mitsubishi Heavy to build offshore windmill

Mitsubishi Heavy Industries Ltd. is getting into marine windmill production. The company has signed a memorandum of understanding with the U.K. Department for Business, Innovation and Skills to receive as much as 30 million pounds ($46 million) in subsidies for the development of a large offshore windmill, which Mitsubishi Heavy expects to complete by 2013.

Because these windmills can be installed without concerns about noise pollution, their output can be as large as 5,000 to 7,000kw, more than double the 2,400kw that Mitsubishi Heavy's land-based windmills can generate.

Mitsubishi Heavy will consider building a plant in the U.K. once it secures orders.

Daiichi Sankyo to sell generics domestically

Daiichi Sankyo Co. plans to co-develop generic drugs with Indian subsidiary **Ranbaxy** Laboratories Ltd. and begin selling them in Japan as early as this fall - the first full-scale entry into the domestic generic drug market by a major Japanese pharmaceutical firm.

Japan's third-ranked drugmaker plans to establish a company in April that will develop and sell generic versions of other firms' off-**patent** medicines. The unit will focus on lifestyle-related conditions, such as high blood pressure and cholesterol, by using ingredients not found in Daiichi Sankyo's drugs.

The unit will begin marketing the knockoffs as soon as they are approved for sale by the Health, Labor and Welfare Ministry.

Daiichi Sankyo is targeting annual generic drug sales of 10 billion yen or so in two to three years, with an eye on eventually boosting the figure to 40-50 billion yen - roughly equal to the sales of major domestic generic drug companies.

(The Nikkei Weekly 03/01/2010 Edition)

**LOAD-DATE:** August 12, 2010

**LANGUAGE:** ENGLISH

**PUBLICATION-TYPE:** Newspaper

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[Return to List](#cite_id_62)

62 of 200 DOCUMENTS



ICIS Chemical Business

**February** 15, 2010

**On a high INTRODUCTION: Nonbranded drugs are expected to continue their strong growth. But could the dearth of their new branded rivals cause the sector to hit a wall?**

**BYLINE:** Doris De Guzman

**SECTION:** FEATURES

**LENGTH:** 1412 words

THE GLOBAL generic drug industry has witnessed an almost decade-long sales euphoria and volumes and sales growth of prescription generic drugs continued to increase in 2009.

In the 12 months ended September 2009, global prescription sales growth of generic drugs climbed by 7.7%, up from 3.6% in 2008, according to US-based health care information and consulting company IMS Health. This compares with the 5.7% growth seen within the overall global pharmaceutical universe last year, says Doug Long, vice-president, industry relations at IMS Health.

During that 12-month period, global generic products generated $83bn (Euro59.8bn) in audited sales, according to IMS. US market data provider BCC Research estimates that the global market was worth $84bn in 2009.

"The global industry virtually had 10 years in a row of good growth - not only in prescriptions but also in sales," says Long. "All the dynamics of the generics industry were strong and it seems to have even prospered more during the economic slowdown."

Generics now account for 72% of the total US pharmaceutical market volume, reaching an all-time high in 2009, he adds. However, they still only account for 17% of total sales, despite generics sales having more than tripled since 2000. In the 12 months ended November 2009, the US generics market was valued by IMS at $31bn. BCC Research estimates the US market in 2009 at $34bn.

BCC analyst Paul Evers notes continued volatility. "The demand for generics is increasing steadily because of pressure to control health care costs. But at the same time, fierce price competition is resulting in slashed profit margins for participating companies," he says. "A major growth driver for the generics sector is that several blockbuster pharmaceutical brands are coming off **patent** and therefore open to generic competition."

BCC notes that Israel-based Teva Pharmaceutical Industries' (18% global market share), Switzerland-headquartered Novartis's US generics business, Sandoz (10%), and both US-based Mylan (6%), and Watson (6%) are leading generics manufacturers, already occupying 40% of the global market. IMS estimates that sales from the top 10 US generic players grew at an average of 13.2% last year.

AT THE TOP

The top four global generics manufacturers - Teva, Sandoz, Mylan and Watson - also accounted for 47% of the US market as of 2009, according to IMS. The top 10, which also includes Canada's Apotex, Pfizer's US-based generics business Greenstone, Qualitest Products, Mallinckrodt and Actavis US, all US, and Lupin Pharmaceuticals, the US subsidiary of India-based Lupin, accounted for 66% of the market.

"This means there are still many players out there that are pretty small and would be ripe for acquisitions or mergers," notes Long. "Everybody expects that there will be consolidation within the generic drugs industry as smaller producers are experiencing significant margin pressure in this environment."

At the same time, large companies are consolidating their operations in established markets and/or expanding into emerging ones through local acquisitions or partnerships.

In May 2009, Sandoz acquired the specialty generics business of Austria-based Ebewe Pharma, while Teva closed its acquisition of US-based Barr Pharmaceuticals in December 2008.

In December, Teva's Japanese joint venture, Teva-Kowa Pharma, acquired a 66% stake in generics firm Taisho Pharmaceutical Industries.

In Teva's 2010-2015 growth strategy announced in early January, the company says it will continue to acquire companies that will boost its market share in attractive geographies as well as enhance its branded business with niche specialty products.

"Only those who are agile and strong will survive in this business," said Teva president and CEO Shlomo Yanai during the company's investor meeting last month in Jerusalem. "About 15% of our business will come from acquisitions. We are taking the necessary steps and building our infrastructure by getting assets and know-how either internally, through acquisition or partnerships."

Teva estimates its 2009 global sales at $13.9bn, of which 70% are from generic products. Yanai is targeting $31bn in sales by 2015, of which 70% will still come from generics.

"There is still room to grow in generics," says Yanai. "Almost $150bn of branded drugs are going to be off **patent** in the next five years. This does not include the expiration of biologics, which is an additional $50bn potential." Teva projects that the global generics market will reach between $135bn and $150bn by 2015. BCC estimates the global market to reach $129.3bn by 2014, representing a 9% annual growth rate.

BOOMING MARKETS

While generics firms are eagerly awaiting the ticking **patent** expiration of several branded blockbuster drugs, manufacturers are also monitoring the increasing emergence of government health care reforms worldwide.

"In almost any given country in the world, you may see different kinds of initiatives or reforms on their own health care systems or even regulating their own pharmaceutical industry. This will increase the pace of generic drug penetration, especially in countries that are asking for better health care," says Yanai.

International markets are especially ripe for generics, says Evers. In the $59bn global generics market in developed countries, Japan only accounts for 6%, while the US holds 42%, and five major European national markets account for 23%.

China, India, Eastern European countries and Brazil are rising centers of generics activity in emerging markets, Evers adds.

Big pharmaceutical companies are even buying generics firms to get into these emerging markets, says Long.

He highlights examples including France-based Sanofi Aventis's acquisitions last year of Brazil's Medley and Mexico's Kendrick, and in 2008 of Czech Republic-based Zentiva. UK-based GlaxoSmithKline (GSK) acquired Aspen of South Africa in July 2008, while at the same time, Japan's Daiichi Sankyo acquired India's **Ranbaxy.**

US-based Pfizer is now also reportedly in a bidding war against Teva for the acquisition of Germany's Ratiopharm. In 2009, Ratiopharm held 3% of the global generics market, reports BCC.

Pfizer started increasing its activities in generics last year with an expanded relationship with Indian firm Aurobindo in March and a commercialization deal with Indian injectable generics specialist Claris Lifesciences. Last month, Pfizer announced a deal with US-based Strides Arcolab to commercialize off-**patent** sterile injectable and oral products.

"At this point, it looks like Pfizer is really geared up towards expanding more into the generics market," says Long. Still, not everything is expected to be rosy for the generics market, especially after 2013, when **patent** expiries will be significantly lower.

"The slowing growth in branded blockbusters being developed by research and development-based manufacturers will ultimately lead to fewer opportunities for generics companies," notes Long. "They are now looking ahead and trying to compete in a less crowded and less competitive market such as in biosimilars."

Biosimilars are generic versions of biotechnology-based drugs.

Generic and branded pharmaceutical companies are not always at each other's throats. Both the US Federal Trade Commission (FTC) and the European Commission announced their closer scrutiny of the so-called "pay-for-delay" deals, where branded drug companies pay generics firms to delay the market launch of their generic drugs for a certain period of time.

Last month, the Commission asked companies including AstraZeneca, GlaxoSmithKline and Niche Generics, all of the UK, Gemany's Boehringer Ingelheim, Novartis and Roche, both Swiss, and France's Sanofi-Aventis to provide information pertaining to generics settlement agreements in Europe between July 2008 and December 2009.

From now on, the Commission also plans to gather this data on an annual basis in the same way as the FTC, which produces annual reports detailing the type and frequency of settlement agreements undertaken by US pharmaceutical companies.

The FTC released a report in January that claimed that the number of pay-for-delay deals in the US increased from zero in 2004 to a record 19 in 2009. The deals are said to cost consumers $35bn (Euro25bn) over 10 years. The Commission, meanwhile, estimates that these kinds of deals could have cost European consumers Euro3bn ($4bn) between 2000 and 2007.

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[Return to List](#cite_id_63)

63 of 200 DOCUMENTS

The Nikkei Weekly (Japan)

**February** 8, 2010 Monday

**Pharmaceuticals aim at emerging markets**

**LENGTH:** 760 words

Pharmaceuticals aim at emerging markets

Japanese drugmakers are moving fast to bolster sales operations in emerging countries now that sales prospects in the U.S. are looking murky.

Takeda Pharmaceutical spent much of its time late last year developing new overseas sales bases. The firm set up companies in Mexico and three other countries in October, and decided to establish another sales firm in Brazil in December. At the same time, it began preparing to enter India, and also signed a deal with Pfizer Inc. of the U.S. to jointly market its Actos diabetes treatment in China.

"We are lagging in the fast-growing emerging markets and should not dwell on past successes," President Hasegawa said in explaining the firm's flurry of activity. The industry leader earns 55% of its sales outside the country but relies heavily on the U.S., with 75% of its overseas sales coming from North America.

Drugmakers used to be able to count on handsome profits by focusing on the U.S., a market that accounts for 40% of global sales which were worth $770 billion in 2008. But this long-standing business model is becoming a thing of the past due to critical changes in the U.S.

One change is the market slump. With the economic downturn unlikely to end anytime soon, consumers there appear to be buying less medicine. The market growth slowed from 4% in 2007 to just 1.5% in 2008 and likely remained at the 1% level in 2009.

The second change is that it has become more difficult to get approval for new drugs following the 2007 toughening of evaluation criteria by the health authorities in response to a series of headline-grabbing problems involving side effects.

The third change is the U.S. healthcare reform envisaged by the Barack Obama administration. Though the reform plan is still up in the air, the envisaged introduction of a universal health insurance system would likely drive up fiscal spending, which could spur the government to curb drug prices. The upshot, of course, is that drugmakers would see their earnings slide.

Against this backdrop, Japanese drugmakers have been accelerating efforts to reduce their dependence on the U.S. and tap new demand in emerging countries. They have high hopes for these markets, which account for just 20% or so of global sales but are growing at an annual rate of over 10%.

Eisai is putting its chips on India. In December, the firm brought onstream a new factory in Visakhapatnam, an industrial city in southern India that is better known as Vizag. This is the firm's first overseas base for developing and manufacturing drug compounds and ingredients. The aim is to create cost-competitive products and market them in India and other countries by taking the advantage of low labor costs there. The company hopes to hike its sales ratio for Asia from the current 3.6% to 5% within three years.

Meanwhile, Daiichi Sankyo Co. has been making the most of the extensive sales network of **Ranbaxy** Laboratories Ltd., a major Indian generics maker it bought in 2008. By the end of this year, the firm plans to file for sales approval in Nigeria and other countries.

"Forays into emerging countries, a primary goal in making the **Ranbaxy** acquisition, will soon begin in earnest," said President Takashi Shoda.

Use of low-cost generics in emerging countries has been widespread because **patent** systems have not been well-established in these markets. Extra attention needs to be paid to customer relationships and regulations unique to each country. Given these unknown factors, it is unclear whether the expansion strategies of Japanese drugmakers will work as planned.

Nogimori, president of Astellas Pharma, is optimistic, saying, "Rising household incomes will drive up demand for nongenerics as well."

In fiscal 2008, Astellas saw its sales in Asia jump 20% thanks to strong sales of immunosuppressants in China. "Firms will see results if they are able to build solid sales networks and provide detailed explanations to customers" about the effects of their products, Nogimori said.

Foreign giants are also getting in on the action in emerging countries. Last year, GlaxoSmithKline Plc of the U.K. acquired a 19% stake in Aspen Pharmacare Holdings Ltd. of South Africa, Africa's largest generics maker. Meanwhile, Novartis AG of Switzerland bought a majority stake in a Chinese vaccine manufacturer.

To secure future growth, Japanese makers must come up with creative ways to compete against major foreign rivals, which have the absolute upper hand in funds and overseas know-how.

(The Nikkei Weekly 02/08/2010 Edition)

**LOAD-DATE:** August 12, 2010

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**PUBLICATION-TYPE:** Newspaper

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[Return to List](#cite_id_64)

64 of 200 DOCUMENTS

Daily Deal/The Deal

**January** 27, 2010 Wednesday

**Pfizer to cull 100 drugs from pipeline**

**BYLINE:** by Kenneth Bredemeier

**LENGTH:** 430 words

**Pfizer Inc.**, the world's biggest drugmaker, on Wednesday, Jan. 27, said it has dropped development of 100 of the 600 drugs in its pipeline, which ballooned with its $68 billion acquisition of Wyeth in 2009.

Additionally, Pfizer said it would withdraw for now its bid for U.S. government approval to market its pain drug Lyrica as an add-on treatment for anxiety. The drugmaker already generates nearly $3 billion in annual sales for the medication, which is approved for treatment of nerve pain and epileptic seizures, and said it would continue to study whether the therapy might have potential as a treatment for anxiety in the U.S., which would add to the revenue stream. It already has European approval for use as an anxiety therapy.

When Pfizer closed its deal to take over Wyeth in October it added 240 Wyeth drugs, most of them vaccines and biotech drugs in various stages of development and testing, to the 360 it already had in its development portfolio. In announcing the curtailed pipeline, Pfizer said it would concentrate on development of treatments in six fields: Alzheimer's disease, cancer, diabetes, inflammation, pain and psychoses. It said that 70% of its research projects and 75% of its late-stage portfolio are in these areas.

Cutting costs and focusing the pipeline is especially important to Pfizer as it faces the daunting task of eventually replacing the $13.1 billion in revenue generated by its cholesterol-fighting Lipitor, the world's biggest selling medication. Pfizer's exclusive **patent** on the drug expires in March and Indian firm **Ranbaxy Laboratories Ltd.** already has approval to sell a cheaper generic copy of the medication in the U.S. beginning late November 2011.

Mikael Dolsten, one of Pfizer's two top research chiefs, told The Deal that the cuts were made after "the best [scientists] of the two companies' laboratories made their priorities" about the prospects for the investigational drugs. He said the cuts came from across various medical areas and that the firm needed to "make strategic decisions for cost savings." He declined to say what the split was between drugs that had come from Wyeth or were already under development by Pfizer.

After the 100-drug cut, Pfizer now has 133 drugs in various stages of testing, including six for which it is seeking Food and Drug Administration approval.

With the Wyeth acquisition, Pfizer said it now has six vaccines and 27 biologics in development, up from one vaccine and 16 biologics. In all, Pfizer said it has 30 cancer compounds in development, 10 for Alzheimer's and 11 for inflammation.

**LOAD-DATE:** February 2, 2010

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**DOCUMENT-TYPE:** Article

**PUBLICATION-TYPE:** Web Publication

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[Return to List](#cite_id_65)

65 of 200 DOCUMENTS

Daily Deal/The Deal

**January** 22, 2010 Friday

**That Wile E. Coyote moment**

**LENGTH:** 141 words

For a dozen years, **Pfizer Inc.**has ridden high-cholesterol counts around the globe to financial success, selling more than $80 billion worth of its Lipitor pills to help it become the world's biggest pharmaceutical company.

Last year, the oval white pills generated 28% of Pfizer's revenue. At its peak, in 2006, the company sold nearly $13 billion of the pills, and when all is tallied for 2009, sales could reach $11 billion.

But the end of the financial success of Lipitor is nigh. Pfizer's exclusive **patent** on the blockbuster drug expires in two months, and by the end of November 2011, an Indian firm, **Ranbaxy Laboratories Ltd.**, will be able to sell a cheaper, generic form of the medication in the U.S. That's good for patients, but Pfizer says it could "lose a major portion of the revenue in a short period of time," perhaps within a year.

**LOAD-DATE:** January 28, 2010

**LANGUAGE:** ENGLISH

**DOCUMENT-TYPE:** Blog

**PUBLICATION-TYPE:** Web Publication

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[Return to List](#cite_id_66)

66 of 200 DOCUMENTS



The Independent (London)

**January** 8, 2010 Friday

First Edition

**AstraZeneca makes peace with Teva to protect Nexium sales**

**BYLINE:** Alistair Dawber

**SECTION:** BUSINESS; Pg. 48

**LENGTH:** 259 words

ASTRAZENECA HAS settled a row with the Israeli generics drugs maker Teva, which will protect its blockbuster heartburn drug Nexium from competition for at least the next four years.

It is the second time the Anglo-Swedish group has reached an accord with a generics company over Nexium. Two years ago, it did a similar deal with the Indian company **Ranbaxy** Laboratories. Both Teva and **Ranbaxy** will now be able to start marketing a copy of Nexium in May 2014, the date on which AstraZeneca's first **patent** is due to expire.

US sales of the drug reached $2.1bn (£1.3bn) in the first nine months of last year. Although the deal does not cover other generics firms, analysts said the agreement with Teva has afforded AstraZeneca some breathing space.

"AstraZeneca's announcement this morning of settlement with Teva on Nexium is welcome and reduces risk to earnings in 2011 because Teva could have been prepared to launch generic Nexium," said Savvas Neophytou, a pharmaceuticals analyst at Panmure Gordon.

"Although not all generic threat has been removed (Dr Reddy's, Lupin and Sandoz are still there), the court case [which had been set for this month] will now need to be rescheduled ... and pushes out further generic risk."

Pharmaceutical giants have struggled in recent years as the generics groups have moved to aggressively challenge their intellectual property rights over blockbuster earners. Several have responded by drastically cutting research and development spending and concentrating efforts in areas such as niche medicines and consumer healthcare.

**LOAD-DATE:** January 8, 2010

**LANGUAGE:** ENGLISH

**PUBLICATION-TYPE:** Newspaper

**JOURNAL-CODE:** IA

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[Return to List](#cite_id_67)

67 of 200 DOCUMENTS

Pharma

**January** 8, 2010 Friday

**Brokers say AstraZeneca's US patent settlement with Teva positive**

**LENGTH:** 232 words

7 January 2010 - Today's US **patent** settlement between Anglo-Swedish

pharma major AstraZeneca (LON: AZN, STO: AZN) and Israeli generic drug

maker Teva Pharmaceutical Industries Ltd (TLV: TEVA) is positive for

AstraZeneca, according to analysts.

On Thursday, AstraZeneca granted Teva a licence to enter the US market

with its generic version of AstraZeneca's ulcer drug Nexium

(esomeprazole magnesium) on 27 May 2014, subject to regulatory

approval, or earlier in certain circumstances.

Nexium are delayed-release capsules for the treatment of

gastroesophageal reflux disease (GERD).

Bank of America (BofA)/Merrill Lynch expects that the agreement with

Teva will reduce the direct generic threats against AstraZeneca.

According to Deutsche Bank, the settlement shows that the Nexium **patent**

is robust and decreases the risk of **patent** infringement in the USA by

2014.

In April 2008, AstraZeneca and India-based **Ranbaxy** Laboratories Ltd

(BOM: 500359) entered a similar agreement about Nexium.

However, the Anglo-Swedish major and its ulcer drug are still facing

threats from other generic makers, such as Indian Dr Reddy's

Laboratories (BOM: 500124) and Lupin Ltd (BOM: 500257), and Sandoz Inc,

the US arm of Swiss giant Novartis AG (VTX: NOVN).

By 14:14 CET today, AstraZeneca's stock was down 0.39% to SEK331.60

(USD46.6/EUR32.5) on the OMX Nordic Exchange in Stockholm.

(SEK1 = USD0.140/EUR0.098)

**LOAD-DATE:** January 11, 2010

**LANGUAGE:** ENGLISH

**PUBLICATION-TYPE:** Newsletter

**JOURNAL-CODE:** M2EUROPHARMA

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[Return to List](#cite_id_68)

68 of 200 DOCUMENTS



The Times (London)

**January** 8, 2010 Friday

Edition 1;

National Edition

**AstraZeneca given shot in the arm by patent deal**

**BYLINE:** Catherine Boyle

**SECTION:** BUSINESS; Pg. 57

**LENGTH:** 327 words

AstraZeneca, the British drugs company, has gained ground in its fight to protect its best-selling drug from generic competition.

It said yesterday that it had reached an agreement with Teva, the world's biggest generic drugs company, which will stop Teva selling cheaper copycat versions of Nexium before the **patent** expires. The heartburn medicine brought in $5.2 billion in sales for AstraZeneca in 2008.

Under the agreement, which has headed off a court case challenging the **patent**, Teva, which is based in Israel, has been given the right to start selling a cheaper version of Nexium before all its rivals apart from **Ranbaxy**, the Indian drugs company. **Ranbaxy** struck a deal with Astra-Zeneca in 2008 to sell a version of the drug before other companies, in return for not challenging AstraZeneca's **patents** on it. **Ranbaxy** will have six months, starting in May 2014, to sell its version of Nexium exclusively.

The agreement will limit the cost of **patent** litigation for AstraZeneca and will also help to control the loss of sales that will inevitably occur once its **patents** on Nexium expire and generic drug makers flood the market.

**Patent** expiries are a growing threat to pharmaceutical groups as pipelines of new drugs have become less fruitful in recent years. Many groups are now taking a softer approach to the generic manufacturers to avoid long and expensive legal clashes. AstraZeneca's share price rose 1.3 per cent to £29.11 yesterday in reaction to the news.

The company has yet to reach an agreement with Dr Reddy's, the most likely of the remaining generic challengers to threaten AstraZeneca's sales before the first Nexium **patent** expires in 2014. But analysts expect a settlement by the end of the year.

As part of AstraZeneca's deal with Teva, the Israeli group has conceded that all the Nexium **patents** involved in litigation are "valid and enforceable", and six of them would be violated by the manufacture or sale of its generic version of the drug.

**LOAD-DATE:** January 9, 2010

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**PUBLICATION-TYPE:** Newspaper

**JOURNAL-CODE:** TIM

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[Return to List](#cite_id_69)

69 of 200 DOCUMENTS



The Times (London)

**January** 5, 2010 Tuesday

Edition 1;

Ireland

**Why piling eye drops high can make a lot of sense to Novartis**

**BYLINE:** Dominic Walsh

**SECTION:** BUSINESS; Pg. 45

**LENGTH:** 369 words

If Alcon is attractive to Novartis, it is because it sells stuff to ordinary customers, such as branded eye-care products. The great fear that causes hands to be wrung in pharmaceutical company boardrooms is that the customers are too few and much too powerful. In other words, instead of selling prescription medicines to the mean beancounters of the NHS, Alcon will stock shelves at Tesco with drops and solutions aimed at a rising population of elderly people with rheumy eyes.

The jury is out on whether Novartis will get a good return on the $50 billion cost of Alcon.

However, a quick glance at the likely **patent** expiries among the leading pharmaceutical companies in 2010 explains why Novartis may pay top-dollar for eye drops.

Many billions of dollars of sales will be lost this year from **patent** expiries. Among the victims will be GlaxoSmithKline (GSK) when, later this year, it loses the **patent** on Seretide, the asthma treatment sold as Advair in the US. Seretide has racked up sales of about $4 billion a year. Sanofi, the French company, is at risk from the loss of **patents** on Plavix, a hypertension drug, a **patent** it shares with Bristol-Myers Squibb, and on Taxotere, an anti-cancer drug that generated $3 billion in sales.

Merck's blockbuster blood-pressure treatment, Cozaar, loses protection in the first half of the year. The product earned Merck $861 million in the third quarter of 2009. AstraZeneca's billion-dollar breast cancer drug, Arimidex, comes off **patent** in June.

AstraZeneca is sticking to its knitting of developing exotic compounds to cure common ailments - the key to pharmaceutical riches. But others are hedging their bets.

Novartis has one of the world's biggest generic businesses, formed when its parents, Ciba-Geigy and Sandoz, merged in 1996. More recently, rivals have followed suit, buying up emerging market drugmakers. Daiichi Sankyo of Japan bought India's **Ranbaxy** in 2008 and in the same year Sanofi bought Zentiva, a Czech drugmaker. Last June, GSK announced a marketing agreement with Dr Reddy's, an Indian producer of generic drugs. It is a shift of belief, from faith in science to faith in the consumer dollar.

Online

Read Tempus online at lunchtime

timesonline.co.uk/markets

**LOAD-DATE:** January 7, 2010

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[Return to List](#cite_id_70)

70 of 200 DOCUMENTS

Daily Deal/The Deal

**December** 15, 2009 Tuesday

**Hospira buys Orchid unit**

**BYLINE:** by Andrew Bulkeley

**LENGTH:** 427 words

**Hospira Inc.**, a maker of generic drugs and intravenous application equipment, on Tuesday agreed to buy the generic injectable pharmaceuticals business of India's **Orchid Chemicals & Pharmaceuticals Ltd.** to broaden its portfolio and gain a foothold in India.

Hospira, of Lake Forest, Ill., said it would pay $400 million for the portfolio of drugs as well as an Orchid antibiotics plant and research facility in Irungattukottai, Chennai, India. The deal includes a long-term agreement for Orchid to supply active ingredients for the acquired business.

"This acquisition aligns perfectly with Hospira's strategy to improve our margins and cash flow by lowering our cost position for a key product line, and to invest for growth," said Hospira COO Terry Kearney in a statement.

Drugmakers the world over are snatching up generics companies to bolster sales and help fund development of **patent**-protected drugs. France's **Sanofi-Aventis SA** in February announced an agreement for Czech generics maker Zentiva NV that valued the target at $1.9 billion and followed in April with a $680 million acquisition of Brazil's Medley SA.

Swiss **Novartis AG** also paid $1.3 billion for the generic injectables business of Austria's **Ebewe Pharma GmbH** earlier this year.

Pharmaceutical companies are also eager to boost their presence in emerging markets where they can manufacture at lower costs and benefit from expanding economies that offer improved access to healthcare. In 2008, Japan's **Daiichi Sankyo Co. Ltd.** paid $4.6 billion for **Ranbaxy** Laboratories Ltd., India's largest generic-drugs manufacturer.

Hospira said it expects Tuesday's agreement to close in the first quarter of next year and, excluding the costs of the transaction, said it won't have an effect on 2010 earnings per share.

Investors appeared to approve of the transaction with the shares trading 1.6%, or $0.79, higher at $49.76.

Spun out of **Abbott Laboratories Inc.** in 2004, Hospira became the world's biggest supplier of injectable generics to hospitals with the $2.1 billion acquisition of Australian generic cancer drug company Mayne Pharma Ltd. three years ago.

Earlier this year it sold its critical care product line to San Clemente, Calif., vascular treatment device maker **ICU Medical Inc.** for about $35 million.

Hospira turned to **Morgan Stanley** for financial advice, while **Baker & McKenzie LLP** and **Khaitan & Co.** provided counsel.

Orchid took financial advice from **Citigroup Global Markets India Pvt. Ltd.** and received legal counsel from **Latham & Watkins LLP** and **Crawford Bayley & Co.**

**DEAL SIZE**

$ 250-500 Million

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[Return to List](#cite_id_71)

71 of 200 DOCUMENTS

The Nikkei Weekly (Japan)

**November** 2, 2009 Monday

**Drugmakers shifting their focus**

**LENGTH:** 614 words

Drugmakers shifting their focus

Profits sought in emerging nations as U.S. market expected to decline

YOSHINORI OGISO

Staff writer

Japanese drugmakers are taking a long, hard look at their North American-centered overseas approach. Not only that, but seeing the fog that is beginning to envelope the world's biggest pharmaceutical market, the U.S., some of them are stepping into promising emerging countries.

Referring to the healthcare overhaul pushed by the administration of President Barack Obama, Eisai Co. President Haruo Naito said that while U.S. sales volume will likely rise, "there is no doubt that the recent proposal would put downward pressure on the prices of patented and generic drugs."

Growing consensus

In the early 2000s, the U.S. medical product market expanded at an annual rate of nearly 10%. Business was lucrative for Japanese drugmakers, in part because, unlike in Japan, they were allowed to set their own prices there.

Those heady days could be over, though, as the U.S. market is projected to begin shrinking this year. The major reason is sluggishness in the wake of the financial crisis, but there are other factors:

--the proposed healthcare reform

--the so-called 2010 problem in which **patents** on popular drugs will start to expire

--steps by the U.S. Food and Drug Administration to toughen its review process for new drugs.

In part, the Obama administration's push to reform healthcare is aimed at bringing the country's nearly 50 million uninsured residents into a system that now shuts them out. If the administration succeeds, the government will likely be involved in some kind of pricing system - which, like in Japan, would probably keep drug prices down.

While more insured Americans would mean more people receiving medications, Naito is concerned that the likely result would not offset what he sees as probable price declines. Many other industry insiders appear to feel the same way, and there is a growing consensus that tapping new markets is vital for future growth.

Generic challenge

Astellas Pharma Inc., which will see U.S. **patents** on key drugs expire sooner than some of its rivals, has been making steady efforts to expand sales in Asia and emerging markets.

This includes actively rolling out core products in China and elsewhere in Asia. In July, it launched a sales subsidiary in Brazil, and established sales networks in Russia, India and China.

Generics are the name of the game in emerging countries, given that **patent** protection there is less robust. But Astellas also expects demand for patented drugs in these nations to sharply rise as spending power increases.

About a year ago, Daiichi Sankyo Co. began shifting its overseas focus to emerging countries, taking the big step of acquiring Indian generics giant **Ranbaxy** Laboratories Ltd. Its ratio of Asian and emerging market sales to total sales is now approaching 10%, the highest among the four major Japanese drugmakers.

Takeda Pharmaceutical Co., meanwhile, continues to invest in the U.S. In 2008, it turned a major sales subsidiary into a wholly owned unit and also bought a bioventure for nearly 1 trillion yen ($10.8 billion). Takeda is lagging its rivals in Asia and emerging markets - its ratio of non-U.S. and non-European overseas sales to total sales is the lowest among the four big players.

Not so fast

But for all the excitement over Asian and emerging nations, they remain less profitable than Japan, the U.S. and European countries. Most of the top-sellers in these up-and-coming regions are generics.

With this in mind, drugmakers might be wise to hedge their bets by having a presence in a variety of markets.

(The Nikkei Weekly 11/02/2009 Edition)

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[Return to List](#cite_id_72)

72 of 200 DOCUMENTS

Pharma

**October** 7, 2009 Wednesday

**Cipher starts Phase III study of acne treatment CIP-ISOTRETINOIN**

**LENGTH:** 309 words

7 October 2009 - Canadian specialty pharmaceutical company Cipher

Pharmaceuticals Inc (TSE: DND) said today it has enrolled the first

patient in the Phase III safety study of CIP-ISOTRETINOIN, its

formulation of isotretinoin, which is used in the treatment of severe,

nodular acne.

The study is a randomised, double-blind trial comparing the safety

profile of CIP-ISOTRETINOIN to an US Food and Drug Administration

(FDA)-approved, commercially available isotretinoin product. The study

will be conducted at 50 sites in the United States and Canada, and is

expected to enroll more than 800 patients over an 18-month period. The

study is being conducted under a Special Protocol Assessment (SPA) that

was granted by the FDA.

In the clinical studies that formed the basis of its New Drug

Application (NDA) with the FDA, CIP-ISOTRETINOIN demonstrated

significantly more consistent absorption under variable dietary

conditions compared with existing isotretinoin products on the market.

To achieve optimal absorption, current isotretinoin formulations are

prescribed to be taken with meals, which proves to be a compliance

challenge for many teenagers. CIP-ISOTRETINOIN uses the

**patent**-protected Lidose drug delivery system, which delivers

super-bioavailability for relatively water-insoluble compounds. Cipher

was issued a US **patent** for CIP-ISOTRETINOIN in 2008.

As previously announced, **Ranbaxy** Pharmaceuticals, a company of Indian

**Ranbaxy** Laboratories Limited (BOM: 500359), is reimbursing Cipher for

all costs associated with the clinical studies required to obtain FDA

approval, up to a predetermined cap. Any additional development costs

associated with initial FDA approval will be shared equally. Cipher is

responsible for all product development activities, including

management of the clinical studies required by the FDA to secure NDA

approval.

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**PUBLICATION-TYPE:** Newsletter

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[Return to List](#cite_id_73)

73 of 200 DOCUMENTS

The Business Times Singapore

**September** 24, 2009 Thursday

**West blocking India's generic drugs;**

**They block shipments at European ports and step up lawsuits to stop the sale of generics**

**BYLINE:** Yogi Aggarwal

**SECTION:** VIEWS AND OPINIONS; Opinion

**LENGTH:** 1057 words

INDIA'S growing presence in the international generic market for medicines has led to aggressive steps by European countries and the US to reduce what they see as competition.

The measures adopted range from stopping at European ports the onward transport of Indian generic medicines bound for other developing countries and an unprecedented scale of litigation to stop the sale of Indian generics.

A Dutch NGO Health Action International (HAI) says that 16 out of 17 consignments of medicines blocked in Holland last year, meant for other countries, were from India. The blockade of exports being trans-shipped through a region to another market is a non-tariff barrier and a violation of European Union (EU) regulations.

Citing information given by Dutch authorities, HAI told a news agency that the medicines seized were headed to Peru, Columbia, Ecuador, Mexico, Portugal, Spain, Brazil and Nigeria. And the seized consignments comprised drugs for heart ailments, dementia, schizophrenia and AIDS, it added.

The restrictive trade practised by European countries affects them as well. The European Commission in its report on competition in the pharmaceutical sector released last month says it intends to intensify its scrutiny of the pharmaceutical sector under EC antitrust laws, and said as market entry of generic drugs is delayed, costs to Europeans go up.

India is the largest and fastest growing producer of generic medicines. It already has 22 per cent of the world generics market and this, according to a KPMG study 'India Pharma Inc: An Emerging Global Pharma Hub', is expected to rise to 30 per cent. According to Pharmaceuticals Exports Promotion Council (Pharmexcil) - a governing body in India, overseas sales in the first nine months of 2008-09 went up by 21 per cent to US $8.44 billion from US $6.97 billion in 2007-08.

Besides this, the domestic market is close to US $12 billion. While this is just a small fraction of the total US $650 billion global pharmaceutical industry, it is a significant segment of the generics market because typically they are priced at around one-tenth of patented drugs.

The generics market itself is set to explode. The KPMG report estimates that in the US alone, medicines worth US $47 billion are expected to go off **patent** in the next three years.

Add another US $25 billion for Europe and US $10 billion for Japan, and the market would be huge even if generics are sold for a fraction of this amount.

The desire to contain Indian competition to European and US dominance also seems to be behind a spate of litigation aimed at curbing Indian companies. With a change in the Indian **patent** law in 2005, now recognising 'product' **patents** on medicines from the earlier 1970 law which only allowed 'process' **patents**, the pharma giants have rushed in to register **patents**, often frivolous.

A study by the intellectual property rights (IPR) law department of National University of Juridical Sciences (NUJS) at Kolkata, has revealed that 9,719 pharmaceutical applications were filed by multinationals between 2005 and 2008; of these 2,734 **patents**, or less than one in three, were granted.

The provisions under Indian law say that **patents** applied for by foreign companies can be opposed at the pre-grant stage, post-grant stage, and under a provision that prevents the issue of a **patent** for any known substance unless the new **patent** makes the product's efficacy substantially higher.

Although Indian **patent** authorities grant only one in three, the local drug makers don't seem to be alert to the European and American attempts to stifle competition.

Out of the several thousand **patent** applications only 58 **patent** applications were opposed between 2005 and 2008; of these, 41 were rejected. Most of the 25 **patent** applications rejected under the pre-and post-grant opposition category were made by foreign drug makers such as Novartis, Pfizer, Gilead Sciences and AstraZeneca.

Most of the cases were filed by Indian drug makers such as Cipla, **Ranbaxy** Laboratories, Sun Pharmaceutical Industries and Torrent Pharma.

Some of the prominent among them would include:

The Indian Supreme Court's dismissal of Roche's petition on a generic version of its erlotinib (Tarceva) from Cipla, which maintained that the **patent** was invalid and should be revoked.

Following the footsteps of Roche, Novartis has now appealed to the Supreme Court for refusing **patent** protection for its anti-cancer drug Glivec, after the Madras High Court rejected Novartis' challenge to a part of Indian **patent** law.

'One can see only a few Indian companies coming forward to oppose such frivolous **patents**. The local industry and the NGOs should be made more aware of these provisions to use these tools very effectively,' D G Shah, secretary general of the Indian Pharmaceutical Alliance told a local business newspaper.

Others who opposed these 'frivolous' **patents** were health based NGOs. The contention of Indian companies and NGOs is that the **patent** applications are often not defensible in law and are only filed to harass local companies. These companies claim they want compulsory licensing for patented medicines so that they can be made available at affordable prices for those who need them. This is reflected in the attitude of Medecins Sans Fronti√®res (MSF), whose spokesman told Intellectual Property Watch earlier this year: 'Everything that makes the grant of compulsory licensing more burdensome, threatens the life of our patients.'

India is also facing pressure from the US, which has been retaining it on the 'priority watch list', under which Washington can exert pressure on America's trade partners to improve their copyright and **patent** regimes. In the US and European markets, several Indian companies are arriving at a compromise with companies whose drugs are going off **patent** to avoid expensive litigation. The compromise often involves delaying the introduction of the generic version for a short time.

It is clear that in the battle to extend their profitable **patents**, big pharma is prepared to go a long way. But with the pressure from world opinion about the need for more affordable medicines and from Indian companies able to make this possible, it is a losing battle for big pharma. The sooner they see the writing on the wall, the better for all.

The writer is a Mumbai-based journalist who contributes regularly to BT

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[Return to List](#cite_id_74)

74 of 200 DOCUMENTS

The Nikkei Weekly (Japan)

**May** 18, 2009 Monday

**M&As loom as drug patents expire**

**LENGTH:** 688 words

M&As loom as drug **patents** expire

JO KAWAKAMI

Staff writer

The year 2010 will be critical for global drugmakers and is already compelling them to grow larger, with even the biggest firm, Pfizer Inc. of the U.S., acquiring Wyeth, also of the U.S.

Major drugmakers are heavily dependent on so-called blockbuster drugs, which can generate yearly sales of over 100 billion yen ($1.02 billion). Japanese pharmaceutical companies are not free from the pressure to become stronger, as **patents** for some of their key drugs are also set to expire in and around 2010, allowing cheaper generic alternatives to enter the market, possibly seizing a significant portion of their sales.

Takeda Pharmaceutical Co., for example, will see **patents** for its ulcer drug Takepron (sold as Prevacid in America) and diabetes treatment Actos expire in the important U.S. market this November and January 2011, respectively.

This would deal a heavy blow to the company because Takepron generated 224 billion yen and Actos 297 billion yen, having made the two products collectively generate over 40% of its group sales in the nine months through December 2008.

Defensive no more

Similarly, the U.S. **patent** expired for Astellas Pharma Inc.'s Prograf in April 2008, and is set to end for the firm's Harnal treatment in October. For Eisai Co., the U.S. **patent** will end in November 2010 for Alzheimer's remedy Aricept, the company's best-selling drug.

Pharmaceutical stocks are generally regarded as defensive issues, as they enjoy relatively stable demand and are less affected by economic cycles. However, in the medium and long run, they are seen as engaged in a high-risk, high-return business, given that major players rely heavily on a handful of blockbuster drugs for much of their sales - which can plummet once **patents** expire.

Against this backdrop, industry observers anticipate another round of M&A deals among Japanese drugmakers.

Daiichi Pharmaceutical Co. and Sankyo Co. merged in September 2005, launching Daiichi Sankyo Co., while Astellas was established by a merger between Yamanouchi Pharmaceutical Co. and Fujisawa Pharmaceutical Co. in April 2005.

The small size of domestic players - even Takeda, Japan's No. 1 drugmaker, was ranked a mere 16th in the world in fiscal 2007 - suggests they could be acquired by overseas rivals.

A prime target of such foreign acquisition would be Daiichi Sankyo, as it is seen as having the most promising pipeline among Japanese drugmakers. One hopeful product is antiplatelet agent Efient, which hit the British market in April and, according to President Takashi Shoda, "is expected to obtain U.S. approval in the April-June quarter."

Clinical tests showed that the medication has a greater efficacy than Plavix, the world's second-best-selling antiplatelet drug marketed by Sanofi-aventis. Sales of Efient are expected to grow in many countries, and Fumiyoshi Sakai, an analyst at Credit Suisse Securities (Japan) Ltd., said Daiichi Sankyo is least vulnerable to the "2010 problem."

But its stock price has dropped to less than half the highest level logged in February 2007, in part because the company took a massive charge for goodwill resulting from the decline of shares in **Ranbaxy** Laboratories Ltd., India's largest drugmaker, which it acquired last autumn. This makes Daiichi Sankyo an easier acquisition target for overseas pharmaceutical companies.

M&A expectations

In contrast, Astellas may be hit hardest by **patent** expirations. With no promising drugs in its pipeline and the recent failed acquisition of U.S. bioventure CV Therapeutics Inc., the firm's profits are expected to shrink unless it purchases another drugmaker - Japanese or foreign - using its ample cash on hand exceeding 400 billion yen.

Attention has also been focused on Takeda, as it still has about 600 billion yen in cash, even after last year's acquisition of U.S. drugmaker Millennium Pharmaceuticals Inc. President Yasuchika Hasegawa recently said that large Japanese pharmaceutical companies, which had sought to expand overseas, may turn their eyes to midsize drugmakers at home.

(The Nikkei Weekly 05/18/2009 Edition)

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[Return to List](#cite_id_75)

75 of 200 DOCUMENTS



ICIS Chemical Business

**March** 16, 2009

**INTRODUCTION:**

**BYLINE:** Kumar Amitav Chaliha

**SECTION:** FEATURES

**LENGTH:** 1347 words

Low costs shelter India's drug companies from the monsoon of bad news flooding the global economy, but profits will likely suffer

Kumar Amitav Chaliha/Mumbai

The pharmaceutical industry in India is going strong, despite global economic turmoil.

Global ratings agency Fitch said in February that it expects the Indian pharmaceutical sector to remain stable during 2009. Over 50% of the sector's revenues come from exports to the US and Europe, and the weak global economic environment, along with a weaker rupee, is likely to drive increasing exports of low-cost Indian generics as well as greater demand for low-cost contract research and manufacturing activities (CRAMS).

The situation is not without a downside. Fitch analyst Priyamvada Balaji says profitability for Indian firms is likely to fall, owing to pricing pressures, higher depreciation costs, increased interest costs, foreign exchange fluctuations and stricter regulations in developed markets.

"Despite the evidence of demand for Indian pharmaceutical drugs, absolute revenue growth and profitability would remain contained due to intense competition among generic players on the pricing front, expansion in the generic market, and stringent US Food and Drug Administration [FDA] and European Union regulations," Balaji said.

With products going off **patent** in the developed markets and demand for low-cost drugs rising, competition among Indian and Chinese generic players could become even more intense, resulting in cut-throat pricing pressures and a consequent decrease in operating profits.

Additionally, pharmaceutical firms could face liquidity pressures because of longer working capital cycles. The gestation period for Indian firms in the sector is long, and the time taken to develop a drug averages eight years. Companies with significant foreign currency debt would also remain exposed to refinancing risks in the medium to long term, she says.

The Indian players

Two firms - Gurgaon-based **Ranbaxy** Laboratories and Mumbai-based Cipla - have been battling over the top position in India's pharmaceutical market. In January, Cipla took the crown from **Ranbaxy** with a 5.32% market share, compared to **Ranbaxy's** 5.08%, according to Mumbai-based market intelligence firm ORG-IMS. Cipla first overtook **Ranbaxy**, as well as Mumbai-based GlaxoSmithKline India (GSK), as the domestic leader for the first time in May 2007. Analysts say Cipla's growth has been due mainly to its large domestic product portfolio, especially respiratory products.

Notably, neither Cipla nor **Ranbaxy** has any top-selling drug brands in the country. ORG-IMS says the cough and cold syrup*Corex*Corexof global leader Pfizer is the leading drug band.

**Ranbaxy's** top five brands - amoxicillin antibiotic*Mox,*Mox,with sales of rupees (Rs) 1.093bn ($20.8m), multivitamin*Revital*Revital(Rs880m), cephalexin antibiotic*Sporidex*Sporidex(Rs821m), ciprofloxacin antibiotic*Cifran*Cifran(Rs769m) and cardiovascular drug*Storvas*Storvas(Rs728m) - together contributed Rs4.290bn for the 12-month period ended November 2008.

Cipla's five best sellers - asthma medicines*Asthalin*Asthalin(Rs947m) and*Seroflo*Seroflo(Rs829m), amoxicillin antibiotic*Novamox*Novamox(Rs733m), abortion drug*MT Pill* MT Pill (Rs602m) and asthma/respiratory salbutamol combination medicine*Aerocort*Aerocort(Rs583m), together contributed Rs3.694bn during the same period.

**Ranbaxy's** strengths are new drug-delivery systems and anti-infectants. Cipla is a leader in HIV drugs, respiratory disease drugs and contraceptives. Both firms possess a good portfolio of over-the-counter drugs.

**Ranbaxy's** success, particularly in overseas markets, attracted Daiichi Sankyo, and in June 2008, the Japanese pharma major acquired a majority stake in the Indian firm for Rs150bn, the largest-ever merger and acquisition (M&A) deal for India's pharmaceutical industry.

However, **Ranbaxy** has been in trouble of late, reporting a net loss of Rs6.798b for the fourth quarter ended December 31, 2008. In part, the damage stemmed from the company's heavy hedging on foreign currency receivables and significant foreign currency-denominated debt.

But **Ranbaxy** has also drawn the ire of the FDA. In September 2008, the agency issued two warning letters to the company and barred the entry of all finished drug products and active pharmaceutical ingredients from **Ranbaxy's** Dewas, Paonta Sahib and Batamandi facilities owing to violations of current Good Manufacturing Practices. And last month, the FDA issued a report stating that **Ranbaxy** had falsified data and test results in approved and pending drug applications related to the Poanta Sahib plant.

"The FDA's investigations revealed a pattern of questionable data, raising significant questions regarding the reliability of certain applications, and this warrants applying the Application Integrity Policy," said compliance director Deborah Autor at FDA's Center for Drug Evaluation and Research.

Indian firms are not only targets of M&A. Firms like Dr. Reddy's and even **Ranbaxy** before its M&A have made some big-scale buys, both at home and overseas. Cash-rich Sun Pharma is currently rumored to be seeking an acquisition either within the country or elsewhere.

Besides **Ranbaxy**, Cipla and GSK, other top pharmaceutical companies include Dr. Reddy's Laboratories, Sun Pharma, Lupin Labs, Zydus Cadila, Sanofi Aventis and Aurobindo Pharma. Players not yet in the top rung yet making forays include Torrent Pharma, Glenmark, and Styrides Arcolab. Even newer firms like Mankind Pharmaceuticals make an occasional entry into the top bracket.

Leading contract research organizations in the country include Syngene, Sai Advantium, GVK Biosciences and Accutest. The top hybrid firms that offer contract services and also conduct their own drug discovery include Dr. Reddy's, Jubilant Biosys, Avra Laboratories, Advinus Therapeutics, Suven Life Sciences and Piramal Life Sciences.

Growth strategies

Indian drug firms are increasingly evolving growth strategies around India's rapidly rising middle class of 300m, with their surging income levels. With rapid changes in the lifestyles of this population, lifestyle-related ailments such as cardiovascular diseases and diabetes are rising at an alarming rate.

According to a report by India's Yes Bank, domestic drug firms like Sun Pharmaceuticals, Sanofi Aventis and Zydus Cadila are increasingly catering to the cardiovascular segment, with each holding around 8% of the Indian cardiac market. The diabetic market in the country is equally divided between the two top players, Abbott and USV.

Meanwhile, the export of low-cost generic drugs to the US and Europe remains a major growth market. Most of the bigger pharma companies have over half their revenues coming in from such exports. According to the Pharmaceutical Export Council of India, the global recession has had a marginal impact on the country's drug exports. It estimates India's medicine exports for the financial year 2008-2009 will come down to $8.25bn, compared to the earlier estimate of $8.97bn.

Global pharma R&D hub

India, along with China, is fast becoming a pharmaceutical research and development (R&D) hub. Multinational drug firms are increasingly outsourcing early-stage drug discovery to India. Although intellectual property issues remain, things are getting better by the day.

Several Indian drug firms, including Dr. Reddy's Laboratories, **Ranbaxy**, Sun Pharma and Piramal Life Sciences, have spun off their R&D units into separate entities from their manufacturing and marketing operations, mainly to catch the interest of Western companies.

Analysts expect the ongoing economic meltdown to affect R&D spending by Indian firms just as it has affected multinationals'. Already, Dr. Reddy's has slashed funds for new R&D. Even firms such as Piramal Life Sciences, Wockhard and Sun Pharma, which have not cut R&D spending yet, may opt for such measures if the financial situation does not improve, the analysts say. But by cutting such costs Indian drug makers could have problems with their R&D tie-up deals with overseas players.

Read Malini Hariharan's India Chemicals blog

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[Return to List](#cite_id_76)

76 of 200 DOCUMENTS



ICIS Chemical Business

**March** 16, 2009

**Beware thepatent cliff! INTRODUCTION: Blockbusters have been driving growth in the pharma sector, but looming patent expiries are forcing companies in new directions**

**BYLINE:** Anna Jagger

**SECTION:** FEATURES

**LENGTH:** 1420 words

FACED WITH **patent** expiries and pressure on prices, pharmaceutical companies are transforming their growth strategies. They are decreasing their reliance on blockbuster drugs, diversifying their product mixes and moving into emerging markets.

Almost all big pharmaceutical companies have a number of large **patent** expiries coming up between now and 2012, says Chris Stirling, European head of chemicals and pharmaceuticals at global financial consultancy KPMG. "It is clear that relying on a small number of blockbusters is more risky now than it was in the past."

It is also becoming more difficult to develop new products. The easy targets have been plucked, and markets for drugs to treat primary care diseases, such as hypertension, heartburn and depression, have been saturated.

The disease areas that companies are now looking at are more complicated to understand, says Andrew Jones, senior pharmaceutical analyst at global consultancy Ernst & Young. "Time and money is being spent now just to try and understand these diseases, before you can even begin to develop therapeutic agents that might have a benefit in treating patients."

The industry is in decline because key drugs have gone off **patent** and new products are not in place to replace them, says Jones. "The product throughput required to offset the lost revenues on **patent** expiry hasn't happened," he remarks.

Netherlands-based brokerage ING warns that some pharmaceutical companies will suffer a long-term earnings decline, starting in 2010, as a result of the **patent** expiries. In the US, 45% of branded pharma sales are expected to face generic competition in the next five years, according to IMS Health, a global provider of pharmaceutical market intelligence.

The timing of an intellectual property meltdown could not be worse, according to Craig Maxwell, pharmaceutical analyst at ING. A new US president and substantial budget deficits for US and EU governments will, he argues, lead to a significant erosion of pricing power for drug companies. At the same time, the regulatory environment has become more challenging. "The pharma industry is entering uncharted territory over the next few years," Maxwell remarks.

To maintain growth prospects in challenging conditions, the big pharma groups are taking steps to decrease their dependence on high-margin, high-risk blockbusters. While the industry will always be attracted to blockbusters, "there is a recognition that you can also make returns on products that are selling less than $1bn [?787m] a year, particularly in specialty markets where sales force overheads are smaller", says Jones.

As part of a strategy to diversify their product mix, companies are also increasing their focus on consumer products.

US-based Pfizer has acted decisively by announcing the purchase of compatriot rival Wyeth. The $68bn (?52bn) acquisition was driven by Pfizer's need to bolster its product pipeline ahead of the expiry of **patent** protection on its blockbuster cholesterol drug*Lipitor*Lipitorin 2011. The deal also enables Pfizer to diversify its product mix. "By buying Wyeth, Pfizer inherits a vaccines business, an animal health business and a consumer business," says Jones. "It also gains access to Wyeth's biologics capability."

Another US mega-deal was announced as*ICIS Chemical Business*ICIS Chemical Businesswent to press. Merck & Co. said it planned to acquire Schering-Plough for $41bn. "The combined company will benefit from a formidable R&D pipeline, a significantly broader portfolio of medicines and an expanded presence in key international markets, particularly in high-growth emerging markets," Merck chairman and CEO Richard Clark said in a joint press release.

Some other CEOs in the industry, such as GlaxoSmithKline (GSK)'s Andrew Witty, have stated their intention to avoid mega-mergers.

To fill gaps in their portfolios, Stirling suggests that companies seek to acquire individual products or biotechnology companies with promising drugs in late-stage development. Putting two large R&D organizations together can harm the atmosphere of innovation, he says, and the consensus view has been that the last major wave of consolidation in the pharma sector, resulting in the creation of AstraZeneca and the former Glaxo Wellcome, for example, did not work.

Witty has indicated that he would rather buy niche players, and plans to expand further into emerging markets in Asia, The Middle East and South America. In the past six months, UK-based GSK has announced the purchase of the Egyptian mature products business and the Pakistani business of US-based Bristol-Myers Squibb (BMS), in addition to more than 50 operations from Belgium's UCB.

"GSK and other companies are investing in the channels, infrastructure and routes to market in those countries," comments Jones.

AstraZeneca also says it is not looking for any major deals. The UK-based company says it is more likely to seek licensing partnerships and small-scale purchases. It is also conducting deals to share risks, such as its partnership with BMS for the development and commercialization of compounds under study for the treatment of Type 2 diabetes.

AstraZeneca is one of the companies highlighted by ING as facing a decline in earnings as a result of the expiry of a series of **patents**. In response, AstraZeneca says it is bolstering its pipeline. "Our goal is to have about 12 projects in late-stage development," says CEO David Brennan. "Each year, we hope to be launching two new treatments from the pipeline, starting in 2010."

Companies are combining a move into emerging markets with an increased focus on generic pharmaceuticals. This could be seen as a hedging strategy, but more interestingly, gives companies access to emerging markets, comments Jones. "In addition to diversifying their product mix, it's also about the opportunity to capitalize on the growth that is occurring outside Western markets. Increasingly, Western markets are coming under pricing pressure, growth is slowing, the marketplace is saturated and there is lots of competition."

GSK entered a deal with South Africa's Aspen Pharmacare last year that paved the way for it to sell generic medicines in emerging markets. Japanese pharma group Daiichi Sankyo bought a controlling stake in Indian generics company **Ranbaxy** last year, and Sanofi-Aventis is acquiring Czech generic drug maker Zentiva.

But ING questions whether companies' emerging market strategies will provide sufficient growth. "We have deep concerns over the new focus by Sanofi-Aventis on growth driven by emerging market generics and away from innovation," says Maxwell. He believes GSK's emerging market strategy could deliver modest earnings growth, "however, we believe a fundamental return to innovation is required."

As pharmaceutical firms implement cost-cutting exercises, it is essential that the cuts do not harm innovation. Companies are slimming down (see page 20) in preparation for the dramatic drop-off in revenue at the edge of the **patent** cliff, and in response to the global economic downturn.

To cut costs, players are looking externally to see whether they can operate more effectively via collaborations with third parties, observes Andrew Hill, head of the European pharma R&D group at Accenture. "Lots of companies are looking at how to get the best out of what they have in-house, and how they get the best out of other organizations, either through alliances, partnerships and outsourcing."

Companies are seeking opportunities outside their traditional boundaries, and are cooperating with different types of organizations such as biotechnology companies, continues Hill. They are reviewing the way they allocate capital, making decisions about which businesses are core and should be invested in and which are noncore and can be disposed or outsourced to third parties. Business areas that could be outsourced include manufacturing, clinical trials, distribution and packaging and sales.

As big pharma stares down the **patent** cliff, players agree that the blockbuster model needs to be adapted. They are already developing new growth strategies, but need to strike a balance between cutting costs and ensuring that the R&D operations are equipped to ensure future growth. "The R&D function is the engine room of the pharmaceutical business," stresses Jones. "If that isn't working, the business model isn't working."

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[Return to List](#cite_id_77)

77 of 200 DOCUMENTS



ICIS Chemical Business

**March** 16, 2009

**High hopes forbiosimilars INTRODUCTION: Once in doubt, the future of biosimilars is advancing along a path smoothed by European groundwork**

**BYLINE:** Cynthia Challener

**SECTION:** FEATURES

**LENGTH:** 1709 words

WITH an EU regulatory framework in place to address the safety of biosimilars - also known as follow-on biologics - the opportunity represented by these products has been proven, and it is growing. Japan and the US are both following suit and exploring legislative development.

Over 10 biosimilars have been approved in Europe, using the EU's specially adapted approval procedure. The first follow-on biologic has been submitted for review in Japan, and in the US, a legislative pathway is in sight.

Both generic drug manufacturers and large pharma companies are angling for a share of this expanding niche in the $75bn (?60bn) global market for biologics.

Biologics comprise the fastest-growing segment of the pharmaceutical market, according to US-based market research firm Decision Resources. Nearly one-quarter of the top 100 drugs in 2007 were biologics, and 13 of them achieved mega-blockbuster status of more than $2bn in worldwide sales, says the firm. Many of these drugs will reach **patent** expiry within the next 10 years, driving interest in follow-on biologics.

The Players

Generic drug company Sandoz, a business unit of Swiss innovator Novartis, has already taken the lead with three follow-on biologics approved in Europe -*Omnitrope*Omnitrope,*Binocrit*Binocritand*Zarzio*Zarzio. Sandoz also offers the only follow-on biologic on the US market. Approval of*Omnitrope*Omnitropewas possible, according to the US Food and Drug Administration (FDA), because the drug is relatively simple, well characterized and shown to be highly similar to Pfizer's branded drug*Genotropin*Genotropin. It was not approved as a generic, but as a new drug under the Federal Food, Drug and Cosmetic (FD&C) Act, a pathway that would not be an option for most major biologics.

Teva Pharmaceuticals, a leading generics producer, also intends to become a major player in biosimilars. It has one product on the European market (*Tevagrastim*Tevagrastim) and has improved its biologics capabilities through the recent acquisitions of Barr Pharmaceuticals and CoGenesys, both US.

More recently, Israel-based Teva formed a strategic partnership with Swiss custom manufacturer Lonza to jointly develop, manufacture and market biosimilars. "Our complementary capabilities will facilitate the drive to secure a leading position in this market and enhance our ability to offer safe and price-effective biopharmaceuticals," says Lonza media relations manager Dominik Werner.

Teva will be responsible for preclinical and clinical development, commercialization and intellectual property/legal activities. Lonza will manage process development, scale-up and manufacturing of clinical and commercial material. The cost and profitability of the joint venture will be shared equally.

Other generics companies are expected to enter Western markets in the near future. For example, Indian manufacturers such as **Ranbaxy,** Dr. Reddy's Laboratories and Biocon, which market products in India, hope eventually to gain approvals in Europe and, ultimately, the US.

Several large pharmaceutical innovators have also indicated interest. US-based Eli Lilly, having completed the $6.5bn acquisition of compatriot ImClone Systems, has launched an initiative to develop follow-on biologics. The UK's AstraZeneca is also considering participating in the biosimilars market.

The most proactive major pharma company, however, appears to be US-based Merck & Co, which recently established Merck BioVentures (MBV) and agreed to purchase a portfolio of follow-on biologics candidates and commercial manufacturing facilities from US-based Insmed, a developer of follow-on biologics and biopharmaceuticals. Merck has also been developing a humanized yeast technology platform since its 2006 acquisition of compatriot GlycoFi.

"By establishing MBV, Merck is able to harness the competitive advantage of this unique yeast technology platform for the cost-effective production of follow-on biologics," says MBV executive director Gillian Cannon. "The platform has the potential to enhance the therapeutic properties of conventional biologics, as well as improve quality, increase speed of production and potentially reduce manufacturing costs over currently employed methods."

Merck is gearing up to deliver yeast strains that will support a continuous stream of three preclinical candidates and three lead optimization projects per year.

"We have initiated development activities that expect to result in five or more follow-on biologics in late-stage development by 2012, and six or more follow-on biologics launched between 2012 and 2017," says Cannon.

Merck also anticipates launching its lead molecule in 2012, MK-2578 (pegylated erythropoietin), and is establishing a flexible biologics manufacturing network, including a commercial-scale*Pichia*Pichiacapacity in Elkton, Virginia, US, due on stream by 2012. Insmed's follow-on biologics portfolio includes INS-19, an investigational recombinant granulocyte-colony stimulating factor (G-CSF), and INS-20, a pegylated recombinant G-CSF.

"Our strategy to move rapidly forward with a complete clinical development program will allow Merck to potentially launch biosimilars into the US around the time of **patent** expiry of several current biologic medications, independent of a clearly defined regulatory pathway for biosimilars," asserts Cannon.

Many of Merck's products can be considered second-generation biologics, reformulated or improved versions of branded drugs.

According to Decision Resources, these products could potentially obtain **patent** protection and command premium pricing.

While they must be approved via the same pathways as other new drugs, they do not require the same extensive investment in drug discovery and development as an innovator drug, nor do they carry the same level of risk. The FDA has already approved several glycoprotein drugs that may be classified as second-generation biopharmaceuticals.

The Regulatory Situation

Of the developed regions, only Europe has an established regulatory approval system for biosimilars. In Japan, draft guidelines were published in September 2008. In November of that year, Kissei Pharmaceutical filed an application for an erythropoietin product as Japan's first biosimilar.

The European Commission created its legislative framework in 2004 and the European Medicines Agency (EMEA) issued general guidelines for applications in 2005. The agency has also published product-specific guidelines for certain types of biologics.

"The Europeans used an extensive public consultation process that included key stakeholders," notes Sara Radcliffe, vice president of science and regulatory affairs for the Biotechnology Industry Organization (BIO). "The success of this approach helps to demonstrate that a system for approval of biosimilars can be effective."

The requirements for biosimilars are extensive when compared with small-molecule generics. However, they do not include full Phase III clinical trials and thus offer an abbreviated pathway for approval.

The difference between small-molecule generics and follow-on biologics is that small-molecule generics are identical to their branded counterparts, while biologic drugs can only ever be similar. Biosimilar is therefore the preferred term, and not biogeneric, which implies equivalence. The EU definition does not consider biosimilars to be generics.

In the US, legislation has been under discussion since 2007. A key point of contention is the length of exclusivity provided for innovator drugs. BIO argues that a minimum of 14 years of data exclusivity is necessary to enable biotech firms to make a profit and reinvest in research and development, according to Sandi Dennis, deputy general counsel for health care at BIO. Some generics firms would prefer a much shorter period.

Legislation before the 110th Congress provides markedly different periods of data exclusivity, ranging from zero years in a bill introduced by Representative Henry Waxman (Democrat, California) to 14 years in a bill introduced by Representative Jay Inslee (Democrat, Washington).

Sandoz believes the exclusivity period in Europe - eight years of data exclusivity, plus two or three years of market exclusivity - provides a useful guideline for the US.

"The balance that must be achieved should provide certainty that the time period on the market for any biologic to gain a return on investment will be sufficient to maintain investment," says a company spokesperson. "At the same time, it must enable subsequent sponsors to reasonably anticipate when they will be able to offer competing products to patients and other [health care] consumers."

Safety must also be addressed. BIO wants requirements for clinical and immunogenicity testing, in addition to analytical testing for approval, according to Radcliffe. And a provision requiring physician authorization prior to switching from a branded biologic to a biosimilar is also important, because the follow-on products are not identical.

Several biosimilars bills are expected to be introduced into the 2009 Congress.

The Future

In the long term, it is unlikely that a large number of newcomers will enter the biosimilars marketplace.

"Only companies able to cost-effectively develop high-quality molecules that meet the standards defined by EMEA and the US will enter the market," remarks Cannon.

"Companies will need to be able to offer 'bio-comparable' and 'bio-better' products," says Bill Marth, president and CEO of Teva North America. "To do that, they will need to have multiple marketing platforms. And it's a big spend."

"A system for approval of biosimilars can be effective"

Sara Radcliffe, vice president of science and regulatory affairs, Biotechnology Industry Organization

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DEFINITIONS

Biologic: a large-molecule drug based on proteins.

Biosimilar (or follow-on biologic): a "copy" of a biologic that has lost **patent** protection. It is distinguished from small-molecule generic drugs

because its size and complexity

preclude the determinations of equivalence that are used in the approval of generics.

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[Return to List](#cite_id_78)

78 of 200 DOCUMENTS

Pharma Marketletter

**March** 2, 2009 Monday

**Agility and innovation, at Economistπs 15th annual pharmaceuticals conference**

**LENGTH:** 1735 words

A wide range of issues were covered at The Economist's 15th Annual Pharmaceutical Conference in London, UK, which was on the theme of "Agility and innovation in emerging markets." The one-day event covered the future growth prospects for the drug industry in the next 10 years, including in the European Union (previously reported: Marketletter March 2). There were also sessions dealing with discussions about which strategies to adopt in different markets, how the industry should be valued, how the health care needs of poor communities in developing countries can be met and how the structure of the sector is changing.

Andrew Hotchkiss, managing director of US drug major Eli Lilly's UK subsidiary, spoke about the need to remember that, although the pharmerging or BRIC countries (Brazil, Russia, India and China) would see high growth rates and, in the long term, represent a shift in the global market, the top eight markets of today (Canada, France, Germany, Italy, Japan, Spain, the UK and the USA) remain important. Mr Hotchkiss cited IMS Health estimates that, by 2012, these will represent two thirds (66%) of revenue.

$130.0 billion "mid-life crisis"

Angus Russell, chief executive of UK-based Shire Pharmaceuticals, examined the prospects for growth in the rare diseases, the BRIC countries and structural changes to business models. He noted that there was a sense of a "mid-life crisis" for the drug industry, with $130.0 billion in sales going off-**patent** in four years, reduced R&D productivity and challenges to the Big Pharma business model.

Following from these issues, the research-based firms are re-examining their business models to find more effective ways of expanding. M&A is perceived as "the panacea" by many firms, Mr Russell noted, with global behemoth Pfizer, Swiss drug major Roche and Japanese firm Astellas already active in 2009. For some majors, getting bigger is the approach taken; others, such as Japan's Daiichi Sankyo, are buying generics firms (**Ranbaxy**; Marketletters passim). In the copy drug sector, some companies are scaling up, eg Teva, while others establish an R&D component, Mr Russell noted, adding that vaccines are "hot again, but scale is required."

The Shire CEO told his audience that, rather than focussing on challenges, pharmaceutical companies should also take heed of opportunities. These, he argued, include: the growing economic and political clout of emerging countries; the aging population and associated conditions; the move towards personalized medicine (echoing Mr Hotchkiss' similar point); the growing diversity of drug-delivery systems; and the rising sophistication and relevance of diagnostics.

Specialty biopharma, the pharmerging markets and improvements in their structures represent the sources of major growth for the drug sector, Mr Russell predicted. There are about 7,000 orphan diseases, he explained, which are individually rare but affect one in 10 people collectively. In the USA, this translates into an estimated market of 25 million people, with a similar number, 25 million-30 million in the European Union, and half of patients being children with 85% of cases serious or life threatening. Orphan drug incentives are worth noting: seven years marketing exclusivity in the USA, rising to 10 years in both the EU and Japan; tax credits; waiver of fees; and development assistance from governments.

Shire aims to shift global revenue mix away from USA

Between 2008 and 2015, Mr Russell explained, Shire aims to restructure its global revenue mix from 74% in the USA, 20% in the five major EU countries and Canada, and the rest of the world making up the balance (6%). The aspirational goal is 50% from the USA, 25% from the EU five and Canada, but 25% from the rest of the world. One way of achieving this target is the intention to attain number one or two ranking in each of Shire's chosen therapeutic fields, by global market share.

The spread of revenue sources in geographic terms also applies to Shire's human genetic therapies, which last year stood at 56% for the EU five and Canada, 15% the USA and 29% the rest of the world. Again in 2015, the UK drugmaker's goal is to split 20% for the USA and 40% each for the EU five plus Canada and the rest of the world.

Christine Soden, the chief operating officer of UK-based drug development company BTG, provided a view of the small/mid-cap life sciences sector's context and opportunities. She noted that share price performance for the sector over the past two to three years "has been disappointing," with the small-cap biotechnology sector index in the UK falling about 45%. Ms Soden described how specialist health care investors are "disappearing fast," initial public offerings are "virtually non-existent," follow-on financings are not going ahead, venture capitalists are focussing their resources on existing projects rather than start-ups and companies are being allowed to fail.

In the case of BTG, the current investment climate has encouraged a focus for cash self-sufficiency, ie, its acquisition of Protherics (Marketletter September 22, 2008) which has on-market products and the creation of a specialty pharmaceutical franchise backed by the financial promise from out-licensed programs. Ms Soden explained that the advantages of such a strategy are that it is more comprehensible to investors, there is no need for follow-on financing to support operations, the ability to capitalize on opportunities as they arise and growth potential from development programs at no cost to the parent company.

BTG: smaller drugmakers can compete in niche therapeutic markets

Smaller drugmakers can compete in the current climate, the BTG COO argued, with products that are protected through complex biologics manufacturing and the coverage of niche therapeutic areas, with antidotes to snake bites for example. Future growth may come from life-saving medicines that can be sold in multiple territories without significant promotion costs or from the protection awarded to orphan drugs and intellectual property rights or manufacturing barriers to entry from potential competitors.

In addition, the smaller firms can access growth potential in a number of presently poorly-served therapeutic areas, Ms Soden said. These include: emergency medicines (eg, anti-infectives to counter drug resistance); oncology; and pain or neuroscience, with improved formulations for treating Parkinson's disease and other conditions, or the improvement of pain relief with fewer side effects.

500 million people on $20k per year or more

Patrick Flochel, Europe, Middle East, India and Africa life sciences leader for management analysts Ernst & Young, presented what he termed a "holistic approach" to emerging markets. He used a pyramid to describe the income levels of the different classes in developing countries. At the top of the structure are 500 million people with an annual income of $20,000 or more. These represent a population segment that can potentially purchase health insurance. In the middle are one billion citizens living on $3,000-$20,000 per year, with over four billion people at the base of the pyramid, who live on less than $3,000 yearly income.

In a developing country, the majority of the population is unable to pay full price for a drug, leaving pharmaceutical firms with the choices of philanthropy or tiered pricing. One potential problem caused by the latter tactic is the lower-price medicines may be re-exported to countries where the full price is being charged, disrupting supplies and presenting supply-chain security issues. The option of not pricing a drug using a differential criteria invites compulsory licensing under the World Trade Organization's agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs; Marketletters passim). Another issue comes from middle-income countries, according to the World Bank's definition, which includes such nations as Brazil and Thailand. The governments there have been able to exercise economic leverage to claim a "health emergency" to demand lower prices under threat of a **patent** grab, which a genuinely poor country cannot afford to do. However, Mr Flochel's pyramid model reflects conditions within emerging countries as much as it does the aggregate effect.

ABPI chief: high-priced blockbuster era is over

Richard Barker, the director general of the Association of the British Pharmaceutical Industry, argued that "no one should have expected the past model of high-priced blockbusters for lifetime treatment of big diseases, promoted to doctors on the basis of marketing creativity and sales muscle, to last forever. They shouldn't and it hasn't." He told the conference: "the business of life sciences - biopharmaceuticals - is reinventing itself. It is a painful process, but an unavoidable one."

Dr Barker described the shift in R&D from vertical integration, "with occasional outsourcing" to an "open innovation model." He described this as a system in which different elements of R&D are performed by individuals or organizations that are best equipped to do so, with a virtual network. The crucial distinction made by the ABPI director general is that outsourcing is largely concerned with performing often routine functions at lower cost than in-house, whereas the new model is designed to overcome the problems of "organizational complexity across multiple sites, often around the globe, by internal politics, by complex resource allocation decisions and by decision-making treacle," he said.

The networks combine university researchers, academic experimental medicine units, contract research organizations, small bioscience companies, Indian and Chinese laboratories or clinical trial networks. "We will see more company spin outs, taking people, money and products out from the mothership to develop them faster and then return some of them later," Dr Barker predicted, with risk-sharing partnerships a growing activity, he added.

The ABPI's DG noted that UK-based drug major GlaxoSmithKline has already made several moves in this direction, with one of the firm's centers of excellence for drug discovery "focused solely on how to source innovation from outside," he said. He also noted a discovery partnership with India's generics firm **Ranbaxy**, which is viewed by the latter as a major shift towards an R&D component. Dr Barker predicted that "we are just at the beginning" of this change.

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[Return to List](#cite_id_79)

79 of 200 DOCUMENTS



The Times (London)

**February** 27, 2009 Friday

Edition 1

**Need to know**

**SECTION:** BUSINESS; Pg. 52

**LENGTH:** 2111 words

Economics

House prices: Figures from Nationwide Building Society showed house prices dropped by 1.8 per cent in February, after a 1.3 per cent decline in January.

The annual fall in prices widened to 17.6 per cent.

Inflation: A YouGov survey showed consumers in February expect inflation to be at 1.5 per cent in the next 12 months, up from 1.1 per cent in January. Expectations for inflation over the next five to ten years averaged 2.9 per cent, from 2.8 per cent in January.

Eurozone economy: Growth in eurozone money supply fell to 5.9 per cent in January, from 7.5 per cent in December, according to the European Central Bank.

Page 56 German unemployment: Figures showed that German unemployment rose by 40,000 in February, taking the rate of unemployment to 7.9 per cent - the highest level in nine months.

German consumer sentiment: The GfK market research group's forward-looking gauge of German consumer sentiment rose for the sixth month in a row to 2.6 for March, from an upwardly revised 2.3 for February.

Icelandic economy: David Oddsson, chairman of Iceland's central bank, was forced to leave his post as the Parliament effectively abolished his position. Page 56 US durable goods orders: New US orders for long-lasting manufactured goods fell by 5.2 per cent in January to $163.8 billion (£114 billion), a six-year low. Orders for December were revised to a drop of 4.6 per cent, previously reported as a 3 per cent fall.

US new home sales: Sales of US new homes fell by 10.2 per cent in January to a seasonally adjusted annual rate of 309,000, the worst since records began in 1963.

US unemployment: New US jobless claims rose to a 26-year high of 667,000 in the week ending February 14. The unemployment rate was 3.8 per cent, up from 3.7 per cent in the week before.

Global economy: The International Monetary Fund said it could lend a further $150 billion, on top of the $50 billion already committed, but the slowdown required a great deal of caution.

Banking & finance

UBS: The troubled Swiss bank has appointed Oswald Gr¸bel, a former head of Credit Suisse, its rival, as chief executive to replace Marcel Rohner, who will leave after less than two years. Page 54 6 RSA: The insurer said that it plans to cut 1,200 jobs as it aims to reduce its cost base by £70 million.

Page 57 Royal Bank of Scotland: The taxpayer is to inject up to a further £25 billion into the ailing bank as it confirmed that it had lost £24.1 billion last year - the biggest loss in UK corporate history.

Construction & property

Liberty International: The shopping malls owner said that it may need to raise £350 million to avoid breaching its banking covenants as it is hit by retail insolvencies and declining property values.

Westfield: The Australian shopping centre operator reported fullyear net losses of $2A.2 billion (£1 billion), from a $3A.44 billion profit the year before, driven by writedowns of $3A.3 billion in the value of its malls, which include the recently opened Westfield London centre. Page 60

Consumer goods

Diageo: The Guinness owner has signed a ten-year deal with Namibia Breweries, in which it has a 14.6 per cent stake, to brew and distribute the African group's Windhoek beer brand on a global basis, with the exception of some African markets.

British American Tobacco: The cigarette maker reported a 20 per cent rise in full-year pre-tax profits to £3.7 billion, boosted by acquisitions in Scandinavia and Turkey and the weak pound, which inflated overseas earnings. Page 58

Engineering

GKN: The London-listed aircraft and motor engineer announced another 2,400 job cuts, bringing the total number of redundancies at the group in the past year to nearly 6,000, or 14 per cent of its global workforce. Page 57 General Motors: The US carmaker reported that it had lost almost $10 billion (£6.9 billion) in the past quarter and had lost almost $31 billion in 2008, as it awaited advice from its auditors on whether it remained a going concern. Page 61 6

Health

**Ranbaxy:** The US Food and Drug Administration said it had suspended reviews of new products from the factory in Paonta Sahib, northern India, run by **Ranbaxy,** the Indian generic drugs maker.

Industrials

Filtrona: The London-listed plastics group, based in Buckinghamshire, reported flat fullyear adjusted pre-tax profits of £58.2 million and said it expected business conditions to remain challenging during 2009.

BASF: The German chemicals group said it was expecting a sales decline in 2009 and an even greater drop in operating earnings as demand from key customers in the vehicle and construction sectors shows no sign of recovery.

Leisure

Rank Group: The bingo and casino operator reported a 12 per cent fall in full-year operating profits before exceptionals to £60.3 million, ahead of market forecasts. Page 55 Blanc Brasseries: The EISbacked restaurant operator reported full-year losses of £2.1 million but said it was considering raising fresh capital to take advantage of the trading climate by accelerating its development programme.

Orient-Express Hotels: The New York-listed luxury hotel operator reported a 16 per cent fall in fourth-quarter revenue per available after a 31 per cent decline in its European hotels. It wrote down the value of its 50 per cent stake in the Hotel Ritz, Madrid, by $23 million (£16 million) and is delaying plans to build a hotel on the site of the New York Public Library.

William Hill: The bookmaker is expected to launch a £350 million rights issue as part of a £1.2 billion debt refinancing. Page 55

Media

Trinity Mirror: The newspaper group cut its final dividend as it reported a 22 per cent fall in fullyear operating profits and said advertising markets were already down sharply this year. Page 51 Entertainment Rights: The owner of characters including He- Man, Casper The Friendly Ghost and Postman Pat said in an update to the City that it was in advanced negotiations with a number of bidders with a view to completing a transaction soon. Page 59

Natural resources

Dragon Oil: The exploration group, based in Dublin and focused on Turkmenistan, has begun an investigation into "possible irregularities" in its procurement procedures between former senior managers in its marketing and contracts departments. Page 58 Hunting: The London-listed oil and gas group reported a 25 per cent rise in full-year pre-tax profits to £58.9 million, from £47.3 million last time.

Mesopotamia Petroleum Company: The British oil and gas group has signed a joint venture agreement with the state-owned Iraq Drilling Company to drill new oil wells. It is the Iraqi Ministry of Oil's first joint venture agreement of its type with a foreign company since Saddam Hussein's regime fell in 2003. Page 58

Retailing

Carphone Warehouse: The retail chain and TalkTalk broadband operator admitted that it may shed 10 per cent of its head office and support service staff in Britain after a review. Page 57

JJB Sports: Christopher Ronnie, the suspended chief executive of JJB Sports, has resigned from the beleaguered retailing group after claiming to have reached a financial settlement with his employer, although JJB said no such settlement had been agreed. Page 50

Support services

Hays: The London-listed recruitment group reported first-half pretax profits down 18 per cent to £100.8 million, from £122.7 million last time, as the decline in the jobs market led to falling fees. It said it would maintain its 1.85p interim dividend. Page 55

Technology

TomTom: The Dutch navigation systems company said Microsoft, the US software group, had launched a **patent** lawsuit against it in the United States, but denied that it had breached any **patent** rights.

Yahoo!: Blake Jorgensen, chief financial officer of the US internet search engine, is leaving in a management shake-up by Carol Bartz, the new chief executive. Page 55

Telecoms

O2: The mobile phone operator reported a 10.6 per cent rise in fullyear sales as TelefÛnica Europe, its parent, delivered a 5.9 per cent rise in full-year sales to §4.3 billion (£3.8 billion). Page 57

Transport

National Express: The bus and train operator reported a 9.7 per cent rise in full-year pre-tax profits to £194.1 million, but will reduce its dividend per share to 22.72p, from 37.96p, which should help it to save more than £30 million, compared with last year. Page 53 BBA Aviation: The Londonlisted aviation services group said that it would cut 350 jobs as it reported full-year results in line with estimates.

Utilities

British Gas: The utility reported a 34 per cent fall in full-year profits to £379 million as Centrica, its owner, passed on only part of rising energy costs to consumers.

British Gas said the huge rise in the cost of wholesale gas had cut its profits from the £571 million recorded in 2007, but they were still well above the £96 million booked in 2006. Page 50

Bank of England and The Times Interest Rate Challenge

Winners of the Bank of England and The Times interest rate challenge area finals: Yorkshire & The Humber, East Midlands and North East England area Nottingham High School

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Results in brief Name Period Pre-tax figure Dividend Profit (+) loss (-) Alphameric (technology) Yr to Nov 30 -£2.2m (-£5.1m) 0p (0p) BlueBay Asset Management (banking & finance) HY to Dec 31 +£11.4m (+£29.6m) 1.7p (3.2p) p Mar 6 British American Tobacco (consumer goods) Yr to Dec 31 +£3.7bn (+£3.1bn) 83.7p f 61.6p (66.2p f 47.6p) p May 6 Capita (support services) Yr to Dec 31 +£226.6m (+£228.7m) 14.4p f 9.6p (12p f 8p) p May 18 Centrica (utilities) Yr to Dec 31 -£2.5bn (+£539m) 12.2p f 8.73p (11.57p f 8.59p) p June 10 Dunelm Group (retailing) HY to Dec 27 +£27.3m (+£27.2m) 2p (2p) p May 1 Filtrona (industrials) Yr to Dec 31 +£54.9m (+£51.7m) 7.78p f 5.08p (7.6p f 5.08p) p May 8 Genus (health) HY to Dec 31 +£17.9m (+£7.3m) 0p (0p) GKN (engineering) Yr to Dec 31 -£130m (+£199m) 4.5p f 0p (13.5p f 9.2p) Hansard Global (banking & finance) HY to Dec 31 +£12.7m (+£12.6m) 5.25p (5p) p Apr 1 Hays (support services) HY to Dec 31 +£100.8m (+£122.7m) 1.85p (1.85p) p Apr 17 Henderson Group (banking & finance) Yr to Dec 31 -£20.8m (+£132.2m) 6.1p f 4.25p (6.1p f n/a) p May 29 Hunting (natural resources) Yr to Dec 31 +£58.9m (+£47.3m) 9.9p f 7p (8.25p f 5.7p) p July 1 Liberty International (construction & property) Yr to Dec 31 -£2.7bn (-£125m) 16.5p f 0p (34.1p f 17.6p) National Express (transport) Yr to Dec 31 +£119.7m (+£105.6m) 22.72p f 10p (37.96p f 26.4p) p Jul 3 Rank (leisure) Yr to Dec 31 -£26.1m (+£7.1m) 0p (0p) Royal Bank of Scotland (banking & finance) Yr to Dec 31 -£24.1bn (+£7.3bn) 0p f 0p (n/a) RSA Insurance (banking & finance) Yr to Dec 31 +£759m (+£670m) 7.71p f 4.98p (7.01p f 4.53p) p Jun 5 Sinclair Pharma (health) HY to Dec 31 +£3.2m (-£0.9m) 0p (0p) Spring Group (support services) Yr to Dec 31 +£6.5m (+£7.1m) 0.3p f 0.2p (0.3p f 0.2p) p May 5 Trinity Mirror (media) Yr to Dec 28 +£124.2m (+£191m) 3.2p f 0p (21.9p f 15.5p) Wilmington Group (media) HY to Dec 31 +£2m (+£3.3m) 2.3p (2.3p) p Apr 7 6 Results in brief are given for all companies valued at more than £25 million. f = final p = payable Full results for all companies can be found in the company search online at www.timesonline.co.uk/business

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[Return to List](#cite_id_80)

80 of 200 DOCUMENTS



ICIS Chemical Business

**February** 9, 2009

**Beyondthe limelight INTRODUCTION: A modest domestic market constrains the ambitions of Korea's pharmaceutical fine chemical manufacturers**

**BYLINE:** Clay Boswell

**SECTION:** FEATURES

**LENGTH:** 1169 words

REX features

SOUTH KOREA, with its large, affluent population of 40m, has a sizeable pharmaceutical market, a large chemical industry and a technically sophisticated workforce, but the number of fine chemical companies capable of making active pharmaceutical ingredients (APIs) is relatively small.

Demand for drugs in Korea is high and growing. The market for prescription drugs, which has expanded at a combined annual growth rate (CAGR) of 10.4% since 2004, totaled a respectable $9.8bn (?7.7bn) in 2008 according to UK market research firm Datamonitor.

By comparison, the booming Chinese market, which boasted a CAGR of 21.1% during the same period, totaled $20.7bn in 2008. The relatively moribund Japanese market grew at a CAGR of only 2.4%, reaching $65.3bn. Although market growth in Korea will slow to a CAGR of 5.3% over the next few years, sales will total $12.7bn by the end of 2013, says Datamonitor.

There is, moreover, a potential customer base of roughly 781 Korean drug companies, about 570 of which actually manufacture finished drugs, according to Invest Korea, a government agency for the promotion of investment. Few of these companies do drug discovery, however, instead licensing innovative products from Western and Japanese companies or focusing on generic drugs, the APIs of which could largely be imported from low-cost producers in countries such as India and China.

IN THE SHADOW OF GIANTS

Competition from China and India has had an important impact on the development of Korea's own API industry, says Jaeyon Yoon, marketing director at SK Life Science, a division of Seoul-based conglomerate SK.

"Usually, Korean custom chemical manufacturers are small and not technology-based, so they cannot compete with Chinese and Indian producers," he explains. Most producers make standard intermediates and export - the domestic market for the pharmaceutical chemical sector being relatively small. Few companies export APIs or advanced intermediates. SK Life Science, the pharmaceutical arm of SK, Korea's third-largest conglomerate (or chaebol), is one of the exceptions.

"We are a technology-based company, with cutting-edge technology such as continuous processing and enzyme processing," says Yoon. "Most of our products - 95% - are pharmaceutical-related, and we are exporting all of the products. We are one of the largest custom chemical manufacturers in Korea."

The firm makes intermediates, advanced intermediates and APIs for clinical materials, he says. "We manufacture under cGMP. [current Good Manufacturing Practice]. Our site has not been audited by FDA and EMEA yet, [but] we are expecting an audit in 2010 from the FDA."

Other notable Korean firms manufacturing pharmaceutical fine chemicals include Daelim Chemical, Daesang, Dong Bang Future Chemical, Dongwoo Fine-Chem, Doosan, Estech Pharma, Hansol Chemience, Kolon Chemical, Kyung Dong Pharmacuetical, LG Bio Sciences, Samchully Pharmaceutical, Samsung Fine Chemicals,Yuhan and EnzyChem.

Seoul-based Celltrion , a relative newcomer, has quickly emerged as a global leader in the contract manufacturing of protein-based drugs, or biologics.

The company has 50,000 liters of cell culture capacity in place and another 90,000 liters on the way. Customers include Bristol-Myers Squibb, which awarded Celltrion a long-term supply contract for Orencia (abatacept), a treatment for rheumatoid arthritis.

Biotech-based Celltrion, like the country's giant electronics industry, reflects the enthusiasm of Korean investors for emerging high-tech markets. By comparison, fine chemical production by chemical synthesis is a mature market with relatively slim margins and many entrenched players. The situation affects the availability not only of investment, but also of manpower.

"It is very hard to find good chemists," says Yoon. "Many of them want to participate in other hot areas."

A combination of differentiating technologies, better market knowledge and customer relationships are necessary for Korea's fine chemical companies to succeed on the global scene, says Yoon. "This industry needs reliability and a track record," he observes. "However, not many companies have this."

CHANGING THE PREMISE

It is possible that the business case for Korean pharmaceutical fine chemicals could become more appealing in the wake of recent moves to liberalize trade, such as the Korea-US Free Trade Agreement (KORUS FTA), which would lift tariffs and provide additional protections for intellectual property.

The Korea Pharmaceutical Manufacturers Association has called the KORUS FTA, which has not yet been ratified, a "major threat" to domestic producers, in part because many of them will be prevented from selling drugs currently treated as generics. Korea's Health Ministry counters that the new environment will improve the competitiveness of domestic firms and encourage greater innovation.

"I am sure that in the long run, small losses will lead Korean medical firms to seek a larger market share," one senior ministry official has been quoted as saying. Indeed, after 1995, when Korea adopted IP protections consistent with TRIPS (the agreement on Trade-Related Aspects of Intellectual Property Rights), leading Korean drug firms began to focus on the potential for greater returns offered by novel, **patent**-protected drugs, and they placed new emphasis on drug discovery, according to Rob Bryant, director of the UK-based fine chemical consultancy Brychem.

Well-resourced chaebol such as SK and LG also recognized the opportunity and moved into the market. Several drugs discovered in Korea have since been licensed to Western firms. SK, for example, licensed carisbamate, an experimental anticonvulsant, to US health care giant Johnson & Johnson in 1998. Only last month, Dong-A PharmTech licensed udenafil, a treatment for erectile dysfunction, to US drug company Warner Chilcott.

At the same time, Korea's generics market could become less comfortable for established domestic players, as foreign firms target it more aggressively. The Swiss firm Sandoz, for example, recently broke ties with local partner Dong Wha in order to focus greater attention on the Korean market, while Israel-based generics leader Teva Pharmaceuticals and Indian majors **Ranbaxy** Laboratories and Dr. Reddy's Laboratories have expressed interest in entering the Korean market.

Non-Korean innovators are penetrating the market more deeply too. Korea's Health Insurance Review Agency reportedly found that the market share of foreign firms grew from 22.2% in 2000 to nearly 28% in 2006. Pfizer's interest in Korea has extended to plans to invest $300m in the country on research and development by 2012.

Korea's drugmakers can look for hope in a 2007 government plan that will plow Korean won 1 trillion ($7bn) into the industry over 10 years. Whether the fine chemical industry will also benefit is an open question.

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[Return to List](#cite_id_81)

81 of 200 DOCUMENTS



The Times (London)

**February** 2, 2009 Monday

Edition 1

**GlaxoSmithKline says coming personnel cuts are not related to downturn in the economy**

**BYLINE:** Patrick Loughran

**SECTION:** BUSINESS; Pg. 41

**LENGTH:** 585 words

GlaxoSmithKline (GSK) will join the growing list of companies announcing sharp job cuts this week.

The British pharmaceuticals group could shed about 6,000 employees globally as it faces competition from companies making cheaper, generic copies of its drugs and continuing pressure to shift away from developed economies to tap into the growth in emerging markets.

GSK employs 18,000 people in the UK in its manufacturing, corporate management and research and development divisions, but a spokesman for the company could not say how many of these jobs would be lost. The company said that the cuts were not related to the recession but were part of a broader restructuring in the global drugs industry.

Although cuts would be made across GSK's international operations, the spokesman said that it employed "disproportionately a higher number [of people] in the UK ... The UK represents 20 per cent of our 100,000- strong global workforce, but less than 10 per cent of sales," he said. "We don't announce big headcount reductions until we talk to the unions and work councils first. We have a good relationship with the unions and we've had ongoing consultations with them for the past two years." GSK started restructuring in 2007 to increase its exposure to developing economies.

The spokesman said that the company had made four acquisitions in emerging markets in the past six months. "We've bought firms in Egypt and Pakistan and, from the Belgian company UCB, we've acquired some brands in emerging markets. We're also expanding into consumer healthcare with the Biotine oral care brand." Analysts say that, in addition to the pressure to move into new markets, the pharmaceuticals sector generally needs to develop new drugs as **patents** run out on the big money-spinning products discovered 15 to 20 years ago.

A new "copycat" industry is growing around manufacturing less expensive, generic versions of the bestselling drugs, especially for sale in developing economies. Companies specialising in generic replicas include Teva, an Israeli company, and **Ranbaxy,** from India.

GSK said that it was not focusing on lobbying for changes or extensions to the **patent** laws, but on investment in new products. "We have 30 drugs in the pipeline now and, a few years ago, it would only have been only a handful," the spokesman said.

Market-watchers say that GSK is in a stronger position than AstraZeneca, its nearest British rival, which last week announced 6,000 job cuts. GSK has more drugs in late-stage development and fewer looming **patent** expiries, but nevertheless it faces a drop in revenues. **Patents** for two high-earning products - Imitrex for migraines and Lamictal for epilepsy - lapsed last year.

While Glaxo's spokesman would not comment on the British jobs toll, he said that the company's headquarters would remain in the UK for the foreseeable future.

The exact number and nature of the job losses will be confirmed when Glaxo's annual results are published on Thursday..

6 Electrocomponents, the electronic parts distributor, cut 340 jobs last week, The Times has learnt. The posts were based at RS Components (under which the business trades in Britain) in Corby, Northamptonshire, where 90 temporary workers were also let go.

The losses come after a cost-reduction plan the company announced in December and is aimed at reducing annual operating costs by £15 million. As well as the job cuts, salaries will be frozen.

'We have 30 drugs in the pipeline. A few years ago, it would only have been only a handful'

**LOAD-DATE:** February 2, 2009

**LANGUAGE:** ENGLISH

**GRAPHIC:** GlaxoSmithKline has bought pharmaceutical brands in emerging markets

GLAXOSMITHKLINE

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[Return to List](#cite_id_82)

82 of 200 DOCUMENTS

Chemical Week

**January** 19, 2009

**Drug Industry Flux Proves Good Therapy for Suppliers**

**BYLINE:** DEEPTI RAMESH

**SECTION:** COVER STORY; Pg. 19

**LENGTH:** 3130 words

**HIGHLIGHT:** The pharmaceutical industry is going through a period of transition with many major drug companies restructuring to cut costs. Fine chemicals and contract manufacturing service suppliers say this year will be challenging, but that they will benefit from growing opportunities, including an increase in outsourcing contracts.

The pharmaceutical sector continues to be in a state of flux as major drug companies restructure to cut costs, including closing some plants and laying off staff, as the global economy worsens. Many fine chemicals suppliers and contract manufacturers expect the year ahead to be tough, but contend that some of the changes made at big pharma firms will result in benefits for them, including increased outsourcing opportunities as well as plant sale offerings with long-term supply contracts. Meanwhile, concerns over manufacturing standards in China and India continue to cast a pall over the entire industry.

"The pharmaceutical fine chemicals industry has not been devastated by the global economic crisis," says Dave Feldker, v.p./Sigma-Aldrich Fine Chemicals (SAFC). "However, some pharma companies, especially smaller ones, may find it difficult to raise funds for their projects, and that may cause some projects to be delayed," Feldker says.

Lonza says it expects the year ahead to be challenging, though it has not yet felt an impact from the economic crisis. "The impact has so far been limited. Nonetheless, 2009 will pose many challenges as pharmaceutical and fine chemicals companies are not immune to cyclical global market forces. However, as smaller pharma companies become more cautious within the next 12 months, we also see larger pharma companies become more focused on outsourcing," a Lonza spokesperson says.

"Virtually all companies are undergoing rationalization of their assets and their core activities. For some this will mean drastic reductions in manufacturing capacities supplemented by even higher levels of outsourcing," says Andreas Stolle, head of pharma business line at Lanxess's Saltigo (Langenfeld, Germany), a custom synthesis and manufacturing services company. "Some others will refocus on filling of internal capacities while they review their business strategies.

Saltigo says it expects the economic crisis to have some impact on its business. "There will be threats and also opportunities for the life sciences industry as a general result of the downturn in the economy," Stolle says. "We have not seen strong effects yet. However, a more conservative approach is being taken by customers on how and when to spend money. Small pharma customers will eventually be strongly affected as venture capital money is drying up, and big pharma companies will continue their cost-cutting initiatives, which were initiated even prior to this crisis," he says.

Active pharmaceutical ingredients (API) and pharma intermediates manufacturer Hikal (Mumbai) says it has had an increase in the number of custom manufacturing contracts during the last year. Hikal, posted revenues up 29% to Rs.3 billion ($ 63 million) in its fiscal year ended March 31, 2008, compared with the previous year. Sales for the first half of the current fiscal year have already grown 40% and are expected to be maintained for the full fiscal year, Hikal says.

"We are one of the few industries that has actually benefited from the downturn and the global economic crisis," says Jai Hiremath, vice chairman and managing director of Hikal. "Large pharma companies have been under pressure to cut down their costs, as a result of this downturn. They have decided to outsource more of their manufacturing, and this has benefited the contract manufacturing industry."

Reflecting this trend, GlaxoSmithKline (GSK) announced plans in November 2008 to close its manufacturing facility at Dartford, U.K. by 2013 and transfer production either to contract manufacturing companies or to other GSK facilities. The closure will result in 620 job cuts, GSK says. The closure reflects the fiercely competitive environment in which the pharmaceutical industry operates, GSK says.

"GSK is constantly reviewing the balance between demand and capacity within its manufacturing network," a GSK spokesperson says. "The proposals to close the Dartford site were developed after taking into account a substantial decline in forecast demand for the site's two largest products which, prior to **patent** expiries, accounted for 60% of total volumes manufactured at the site." The two products are lamotrigine for epilepsy/bipolar disorder and valaciclovir for herpes. "The current level of manufacturing activity at Dartford is not expected to be replaced by the same level of new business, driving utilization at the site down to an unsustainable level."

The Dartford site also produces APIs, and production of many of these products along with lamotrigine and valaciclovir will be transferred to contract manufacturing companies. GSK also announced earlier in 2008 that it will reduce its workforce and focus production during the next two years only on final-stage drug manufacturing at its Ulverston, U.K. site *(CW, March 17, 2008, p. 27).* The measures would lead to a workforce reduction at Ulverston to 210, from 540, GSK says. The company says it will outsource pharma intermediates that were being manufactured at the Ulverston site to contract manufacturers.

AstraZeneca announced plans last November to permanently close three plants at Destelbergen, Belgium; Porrino, Spain; and Umea, Sweden and to cut jobs at its Macclesfield, U.K. and Sodertalje, Sweden facilities, which will result in a total of 1,400 job cuts by 2013. The announcement was not caused by the current global economic situation or made with the intention to outsource its manufacturing, AstraZeneca says.

"These changes are a continuation of AstraZeneca's program to improve the organization's productivity and efficiency, which was announced in 2007," an AstraZeneca spokesperson says. "We have stated in the past that we intend to outsource the production of all APIs over the next 5-10 years, and this remains our intention. Fully outsourcing supply and manufacturing activities is not part of our strategy; in fact, in some areas, we see competitive advantage in retaining the capability in-house," the spokesperson says.

"A high proportion of this restructuring by large pharma companies aims to address the impact of products reaching the end of their **patent** life in the next few years," Stolle says.

Industry executives say that any pharma industry restructuring will impact the contract manufacturing industry. "As the industry downsizes, contract manufacturers are likely to continue to acquire sites from major pharma companies," says Michael Kosko, president, Pfizer CentreSource (PCS; Kalamazoo, MI). PCS, which is a part of the Pfizer Global Manufacturing (PGM) group, produces APIs, intermediates and formulations.

"The large pharma companies are trying to reduce the number of their manufacturing plants," says Enrico Polastro, v.p. and senior industry specialist at Arthur D. Little Benelux (Brussels). "These companies are trying to sell their plants to fine chemicals producers along with long-term supply contracts," Polastro says. "Large pharma companies prefer this model to just shutting down a plant, so as to ensure employment for their staff at these plants," he says.

That trend has been a key feature of growth for Aesica Pharmaceuticals (Newcastle, U.K.), a supplier of APIs, formulations, and custom synthesis. Aesica acquired a manufacturing facility at Queenborough, U.K. from Abbott (North Chicago, IL) in September 2007 and a manufacturing facility at Ponders End, U.K. from Merck Sharp & Dohme, a subsidiary of Merck & Co. (Whitehouse Station, NJ), in October 2006.

"Through these acquisitions we gained new contracts, as each came with supply agreements and also capacity and new capabilities. The Ponders End site brought us a high-potency unit, and Queenborough took us into secondary manufacturing," says Robert Hardy, CEO of Aesica.

The overall trend toward outsourcing and divestment of sites from the bigger players will create opportunities, Aesica says. "By 2010, more than 50% of new drugs will come from emerging pharmaceutical companies rather than being concentrated in the hands of big global firms. As many smaller companies have limited or nonexistent manufacturing capabilities of their own, this presents another opportunity in the near and medium terms," Hardy adds.

However, some in the industry say that acquiring manufacturing facilities from large pharma companies brings with it a set of problems. "The assets that are for sale are very large and, even if they are priced low, the overhead costs are going to be very high," Feldker says.

There is also the danger of overcapacity, some analysts say. "Despite the fact that the acquired facility may come with a long-term supply contract, the fine chemicals producer may end up with an extra manufacturing plant that it does not really need," Polastro says.

Aesica, which seeks to acquire both fine chemicals and formulations facilities from pharma companies, says that it is important to ensure that any acquired facilities serve a clear function for the chemical manufacturer. "The facility would have to be in the right area, bring with it the right technology, and right partner and right supply contracts," Hardy says.

Aesica says it expects large pharma companies to continue to sell their facilities to fine chemicals suppliers. "We believe the trend will continue as 'big pharma' focuses increasingly on what it does best -- sales and marketing -- and not manufacturing. Of the $ 50 billion manufacturing sector that supports the $ 550 billion of finished products sales, some $ 15 billion is currently outsourced, and the forecast growth represents a huge opportunity for contract manufacturers," Hardy says.

Another trend is growth in the outsourcing of finished dosage formulation manufacturing. This is expected to be considerably higher than that of pharma fine chemicals, analysts say. "While the outsourcing of pharma fine chemicals is expected to grow at about 2%-3% in 2009, the outsourcing of finished dosage formulations is expected to grow at about 5%-6%," Polastro says. One reason for this could be the fact that the finished dosage formulations manufacturing is labor-intensive, he says. "By outsourcing the manufacturing of formulations, these companies are trying to reduce their labor costs," he adds. This will likely lead to a consolidation among contract manufacturing organizations that offer formulations manufacturing services, Polastro says.

Meanwhile, pricing issues have been a concern for pharma fine chemicals producers during the past year. "Manufacturers have absorbed a great number of cost increases during the past year, including energy, solvents, raw materials, and packaging materials. Passing on these increases is necessary to maintain the long-term viability of many suppliers," Kosko says. PGM has improved its operations and processes to counter cost increases on raw materials, he says.

Manufacturers across all market sectors were heavily impacted by significant increases in energy costs during 2008. This along with volatile oil costs have translated into higher costs of most raw materials, Saltigo says. "Wherever possible companies like Saltigo have attempted to offset some of these increases with improvements in efficiency. However, in many cases it has been necessary to pass on some of these cost increases," Stolle says.

"Cost variables like oil price, exchange rates, and capacity adjustment vary today much faster than in the past. The pressure will be on watching the overall cost of production on a continuous basis and making sure that the necessary price adjustments are applied if and where necessary," says Martin Widmann, group v.p./BASF's Pharma Ingredients & Services global business unit. "It is critical to make this process fair and transparent in order to make it understandable to our close partners with whom we seek exclusively sustainable business partnerships," Widmann says.

Investment reductions due to the recession may also cause a decrease in outsourcing volume in the biotech sector, BASF says. The long-molecules business especially "will be affected due to relatively higher development and production costs," Widmann says.

Still another trend is that pharma companies are shifting their focus away from developing blockbuster pharma products toward lower-volume, specialty drugs. These drugs target a smaller market, Polastro says. "What this means for the fine chemicals firms is that they will be producing smaller volumes. Instead of hundreds of tons, they will be producing only tens of tons," he says.

The market will always be open to accommodate blockbuster products; however, this model is no longer the main approach for big pharma companies, Saltigo says. "We see a trend toward smaller-volume products with niche applications, but the new product pipeline is smaller compared to ten years ago," Stolle says.

The market will require more product approvals to secure more contracts, Polastro says. However, less than 30 drugs reached the market in 2008, he says.

Non-blockbuster products require a different kind of capability, SAFC says. The company says it is well-positioned for these type of products, which are smaller volume and more potent compounds. "With these non-blockbuster products, the projects are becoming of smaller dollar value. But with more product approvals, we hope to see the smoothening of revenues," Feldker says.

Several pharma fine chemicals suppliers have recently invested in setting up or expanding their high-potency API (HPAPI) businesses. "The new pipeline of drugs has a growing percentage of high-potency molecules," Hardy says. Aesica, which is expanding HPAPI capacity at its Queenborough site, says that the global growth and expansion in the HPAPI business is driven by a lack of sufficient high-potency facilities in the market.

SAFC, which claims to be one of the world leaders in HPAPIs, has invested about $ 65 million during the past two years to further this business. This includes the announcement made last September to invest $ 30 million to build an HPAPI facility at its Madison, WI complex. "We expect double-digit growth for the next five years in the HPAPI business," Feldker says.

Some consultants say there are limitations to the possibilities in this business, however. "HPAPI is a growing field, but it is not a field with infinite growth possibilities," Polastro says. "Therefore, eventually we may see overinvestment in this segment," he says.

Meanwhile, ongoing incidents involving quality standards for manufacturing pharma products in China and India continue to raise concerns about the future of sourcing from these countries. Incidents of contamination of the blood-thinning drug Heparin in 2008 raised quality and consistency concerns relating to drug ingredients sourced from China *(CW, May 5, 2008, p. 33).* The U.S. FDA halted imports last fall of generics made at two of **Ranbaxy's** (Gurgaon, India) Indian plants, charging the company with deviating from U.S. GMP standards *(CW, Sept. 22, 2008, p. 4).* China and India, which have until recent years been attractive destinations for low-cost manufacturing and sourcing for pharma companies, continue to be scrutinized by U.S. and other regulators. Some suppliers say there is a possibility that pharma companies will begin to turn to European or U.S. producers, but others say that China and India will continue to play an important role in the supply chain.

"Pharma companies are looking for the lowest possible costs with the lowest possible risks. If these companies can find this in China and India, they will consider these locations," Polastro says. "The distance to Europe or the U.S. is always a problem, and the cost of manufacturing in China and India are also going up." The cost of labor has been rising in these countries, he says. Labor cost in 2007 increased in China by about 25% and in India by about 15%, but in Europe these costs rose only by about 4%, he adds.

"In the past twelve months we have observed that some products that were being bought from China are now being bought from SAFC's European and North American facilities," Feldker says. However, China and India are still crucial to the pharma industry, and "as the standards in these countries improve, manufacturing in these countries won't be a concern," he says. China and India are also important markets and to have a presence and a manufacturing facility in these regions is crucial, SAFC says.

"I believe that outsourcing to countries like China and India is a trend that will continue," Kosko says. "It is critical for pharma manufacturers to have the infrastructure necessary to evaluate, select, and manage a contract manufacturer, regardless of the locations to which they outsource," he says. "With the proper level of oversight, good quality and safety standards can be achieved in most locations around the world," he adds. "Companies without the necessary infrastructure and commitment to support an outsourcing initiative might end up focusing their efforts on established contract manufacturers in Europe and the U.S.," Kosko says.

China and India will continue to be attractive destinations for outsourcing of manufacturing, although companies will become "more careful in choosing their outsourcing partners and will do more checks," Hiremath says. "The cost advantage in these countries is very crucial. Therefore, these companies may set up offices in these countries, or the ones that already have offices will set up special sections to check the local suppliers and to have better coordination," he says.

Also, FDA is expected to soon set up an office in India, which in turn will bring about more checks on local facilities, industry executives say.

"Companies that have very good systems and regulatory standards in place will only survive," Hiremath says. Hikal has facilities in Bangalore and Panoli, India for manufacturing pharma ingredients. FDA has already approved the Bangalore facility, and the company expects the agency to approve the Panoli, facility in a year. "Hikal is tightening its quality systems and making sure that no shortcuts are taken," he says.

Dishman Pharmaceuticals & Chemicals (Ahmedabad, India), which manufactures APIs, intermediates, and fine chemicals, says it does not expect a business fallout from industry incidents such as **Ranbaxy's** alleged deviation from maintaining GMP standards. "There have been some stray incidents of quality or regulatory issues with some companies in India and China. But these stray incidents will not have any impact on our business," says VVS Murthy, finance director at Dishman. The company says it expects to have at least 25% growth in sales in the next financial year.

**LOAD-DATE:** January 23, 2009

**LANGUAGE:** ENGLISH

**GRAPHIC:** Picture 1, no caption; Picture 2, STOLLE: There are threats and opportunities for the industry.; Picture 3, HIREMATH: Benefit from the economic crisis and downturn.; Picture 4, FELDKER: Non-blockbuster contracts are of smaller dollar value.; Picture 5, HARDY: Any acquired facility must serve a clear function for the chemical manufacturer.; Picture 6, WIDMANN: Biotech sector to reduce outsourcing volume.; Picture 7, KOSKO: Quality and safety standards can be achieved anywhere.; Picture 8, ALL SYSTEMS GO: Hikal's U.S. FDA-approved facility at Bangalore, India.

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[Return to List](#cite_id_83)

83 of 200 DOCUMENTS

National Post's Financial Post & FP Investing (Canada)

**January** 7, 2009 Wednesday

National Edition

**Pfizer wins new protection on Lipitor**

**BYLINE:** Bloomberg News

**SECTION:** FINANCIAL POST; National Report; Pg. FP4

**LENGTH:** 191 words

Pfizer Inc. won new protection on the cholesterol pill Lipitor, the world's best-selling drug, after the United States agreed to reissue a **patent** that had been invalidated by an appeals court. The U. S. **Patent** and Trademark Office said yesterday it would reissue a **patent** that expires in June, 2011, after the company altered what an appeals court had called inconsistent language that made the **patent** invalid. New York-based Pfizer, the world's biggest drugmaker, can get the **patent** if it pays a US$1,510 fee, according to information on the agency's Web site. The decision bolsters Pfizer's efforts to prevent Toronto-based Apotex Inc. from selling a copy before November, 2011, when India's **Ranbaxy** Laboratories Ltd. is scheduled to enter the U. S. market. Apotex has challenged the **patent** to begin sales before that. Sales of Lipitor were US$3.1-billion in the third quarter, including US$1.6-billion in the United States, Pfizer said in October. When the appeals court threw out the **patent** in 2006, it cut 14 months of **patent** protection from the drug. Pfizer was able to recoup that time in a lawsuit settlement reached with **Ranbaxy** last year.

**LOAD-DATE:** January 7, 2009

**LANGUAGE:** ENGLISH

**GRAPHIC:** Black & White

Photo:; ;

**DOCUMENT-TYPE:** Business; Brief

**PUBLICATION-TYPE:** Newspaper

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[Return to List](#cite_id_84)

84 of 200 DOCUMENTS

Pharma Marketletter

**January** 7, 2009 Wednesday

**Pfizer gets clarified Lipitor patent**

**LENGTH:** 210 words

Global drugs behemoth Pfizer says that the US **Patent** and Trademark Office has issued a "Notice of Allowance" accepting the company's application to correct the technical defect in the '995 enantiomer **patent** for atorvastatin calcium, the salt form of atorvastatin sold as Lipitor, the firm's blockbuster cholesterol-lowering drug, which has generated peak annual sales of nearly $13.0 billion. The company noted that certain formalities must be completed before the re-issue **patent** will be granted. The new **patent** will have the same force and effect as the original, as well as the same June 2011 expiration date (including the six-month pediatric exclusivity period).

"This is a very positive development, not just for Pfizer but for all those who believe that defending intellectual property is vital to supporting the enormous investments required to develop life-saving new medicines," said Raymond Kerins, vice president, worldwide communications at Pfizer.

The USPTO decision strengthens Pfizer's efforts to prevent generics groups such as Apotex and Teva from launching copy versions of Lipitor before November 2011, when India-headquartered **Ranbaxy** is set to come to market with its product, which has 180-days exclusivity, following a settlement with Pfizer.

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[Return to List](#cite_id_85)

85 of 200 DOCUMENTS



The Times (London)

**January** 3, 2009 Saturday

Edition 1

**InterContinental Hotels rises as Guoco buys stake;**

**Market report**

**BYLINE:** Robert Lindsay

**SECTION:** BUSINESS; Pg. 55

**LENGTH:** 546 words

Although hoteliers across the world are nervous about this year's prospects, the gloom was lightened for InterContinental Hotels Group, which welcomed a new guest to its share register yesterday. Guoco, of Malaysia, declared a 3 per cent stake, triggering a 6 per cent rise in IHG shares.

Guoco, which bought the 8.5 million shares in an off-market deal on Monday, owns Thistle Hotels, the UK brand, and has built a 25 per cent stake in Rank, the bingo and casino operator, and so there was inevitable speculation that the purchase might lead to a bid. However, sources close to the Malaysian leisure group said that the deal was likely to be only a portfolio investment made because it believes IHG, up 35Ωp to 597Ωp, is cheap.

Guoco, which also owns the Clermont Club casino in the West End of London, will be hoping it has picked IHG's nadir. The hotelier's brands, including Crowne Plaza and Holiday Inn, are seen as a beneficiary of the weak pound, since most profit is made in America. However, IHG's development programme will be hurt by lack of credit and the US hotel industry is struggling with low occupancy rates.

Meanwhile, rebounding mining stocks helped London's leading index to a positive first day of trading for 2009. However, the FTSE 100's rise of 127.62 points, or almost 3 per cent, to 4,561.79 was widely seen as a false dawn.

Miners took up eight of the top ten positions, with Xstrata up 107Ωp at 747Ωp, Rio Tinto up 204p at £16.94 and Vedanta rising 82p to 693Ωp. Rio and Xstrata should be able to avoid rescue rights issues if demand from

China recovers by the end of next year, as industry bosses hope. Analysts say that this makes Rio and Xstrata a speculative buy for those who can stomach the risk.

However, the rebound bore all the signs of short covering - hedge funds closing short positions. Prices of nickel and copper gained on speculation that they would be given greater weighting in commodity indices, which will have their annual rebasing this month. But the fundamentals are poor, with mounting metal stockpiles. Ryan Kneale, analyst for BetsForTraders, the City bookmaker, said: "Today's rally lacks any real conviction." Profit-taking cut 18p off Glaxo- SmithKline, at £12.66Ω, despite reports from America that **Ranbaxy**, the Indian group, was last month unable to launch a copycat version of Imitrex, Glaxo's profitable migraine drug, as planned. The US regulator, the FDA, is investigating **Ranbaxy** for alleged data fraud and sub-standard manufacturing and has banned the import of some of its medicines. If Indian manufacturing issues are to blame, Glaxo would get a clear run until its **patent** ends in June, said Panmure Gordon.

Politicians calling for an extension beyond January 16 of the ban on the short-selling of shares in banks lifted Royal Bank of Scotland 3.1p to 52Ωp, and HBOS 3Ωp to 72Ωp.

A surge in flat-screen TV sales at John Lewis helped Kesa Electricals and DSG International both rise 1p, to 89ºp and 18Ωp, respectively, and Carphone Warehouse to gain 5ºp at 95p.

6 New York: Bleak economic data failed to dent mid-session hopes that 2009 will bring back buyers to the market after the worst annual sell-off since the Great Depression. The Dow Jones industrial average was up 149.90 points at 8,926.29 at midday..

**LOAD-DATE:** January 3, 2009

**LANGUAGE:** ENGLISH

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[Return to List](#cite_id_86)

86 of 200 DOCUMENTS



The Times (London)

**January** 1, 2009 Thursday

Edition 1

**Price-fixing in itself insufficient to establish conspiracy to defraud;**

**Law Report**

**SECTION:** NEWS; Pg. 49

**LENGTH:** 1408 words

House of Lords Published January 1, 2009

Regina v Goldshield Group plc and Others

Before Lord Bingham of Cornhill, Lord Rodger of Earlsferry, Lord Carswell, Lord Brown of Eaton-under-Heywood and Lord Neuberger of Abbotsbury Opinion March 12, 2008

An indictment alleging the offence of conspiracy to defraud by entering into secret agreements to fix and maintain the prices, and manipulate the supply of prescription drugs was defective unless it isolated and charged specific aggravating elements which would elevate price-fixing into an indictable conspiracy to defraud.

The House of Lords so held, allowing an appeal by the defendants: Goldshield Group plc with Nicholas Mark Foster and Luma Auchi; Norton Healthcare Ltd with John Stephen Clark and Michael John Frederick Sparrow; **Ranbaxy** (UK) Ltd with Anil Kumar Sharma; Generics (UK) Ltd with Denis William O'Neill and Jonathan Raymond Close, from the dismissal by the Court of Appeal, Criminal Division (Lord Justice Moses, Mr Justice Jack and Mr Justice Owen) ([2007] EWCA Crim 2659) of their appeal from the refusal by Mr Justice Pitchford at Southwark Crown Court on April 27, 2007, of their preliminary application for quashing an indictment containing two counts of conspiracy to defraud.

Lord Pannick, QC and Mr Thomas de la Mare for Goldshield; Mr Nicholas Green,

QC and Mr Peter Carter, QC, for Norton Healthcare; Lord Pannick, QC and Miss Clare Sibson for **Ranbaxy;** Lord Pannick, QC and Ms Bridget Petherbridge for Generics; Mr Richard Lissack, QC, Mr James Flynn, QC, Mr Nicholas Medcroft and Miss Maya Lester for the prosecution.

THEIR LORDSHIPS, delivering the opinion of the Committee, said that defendants consisted of several companies and individuals who were at the material times employees or directors of those companies.

The companies were concerned in the manufacture, sale and/or distribution to wholesalers and pharmacists of mainly generic drugs, which pharmacists then supplied to members of the public on National Health Service prescriptions.

Generic drugs were normally produced by several different manufacturers once the **patent** on a branded drug had expired. Suppliers provided list prices to the Prescriptions Pricing Authority, which calculated a drug tariff in reliance upon the lists of certain suppliers. The Department of Health did not regulate the prices of generic drugs, but stated that it relied on the competition between suppliers in an open market to provide prices which represented value for money.

Pharmacists purchased those drugs from the suppliers of their choice at their list prices and were reimbursed by the department at the prices contained in the drug tariff for the cost of the drugs when they were dispensed on

NHS prescriptions. The department claimed that the reimbursement system, to the knowledge of the suppliers, was predicated upon the existence of a genuine open competitive market, and contended that it was important that the list prices published by suppliers and furnished by them to the department should be a true reflection of the prices which should be charged in such a competitive market. Otherwise they would pay the pharmacists inflated prices in accordance with the drug tariff.

The statement of offence in count 1 of the indictment was "conspiracy to defraud contrary to common law". The particulars were that between April 1, 1998, and September 30, 2000, the defendants "conspired together and with others to defraud the Secretary of State for Health and others concerned with the provision of medicinal products by dishonestly fixing and maintaining the price of penicillin-based antibiotics to wholesale and retail suppliers of the said medicines".

The allegations in count 2 were in similar terms in relation to the generic drug warfarin and the branded drug Marevan.

The prosecution case statement in relation to count 1 was that the defendants sought to induce the Department of Health to make grossly inflated payments for the antibiotics; that they held secret meetings to exchange confidential information on pricing and sales in order to devise and implement the scheme to control prices and manipulate supply; that they held 15 meetings, the true purpose of which was disguised under the pretext that they were connected with packaging, and that false minutes were created retrospectively.

The statement also alleged that the defendants pre-determined allocations of the supply of antibiotics between themselves and increased prices in concert on five separate occasions. They disseminated false reasons for stock shortages and price increases in accordance with a script and lied when questioned by the Department of Health about price increases across the market. They falsely asserted that the generic market was competitive and identified several bogus reasons for the price increases.

It was also alleged that they paid competitor companies with the capacity to supply antibiotics to stay out of the United Kingdom market and concealed the purpose of the payments. They withheld stock and policed agreed prices and market allocations by auditing each other and imposing penalties on those undertakings which exceeded the agreed allocations. They published price lists with a two per cent variation on the agreed prices to disguise the fact that they were the product of collusion.

Prosecution witnesses said that some of the conspirators acknowledged that they were behaving dishonestly and ran the risk of imprisonment.

Their Lordships said that it could be seen from the prosecution case statement that its essence was that price-fixing when accompanied by secretive and misleading behaviour of the kind alleged, was dishonest by the standards of the ordinary citizen and was sufficient without more to found a prosecution for conspiracy to defraud.

The contrary submission advanced by counsel for the defendants was that price-fixing agreements, described as "cartel behaviour", were not in themselves criminal, even if made secretly and with an element of deception which might be widely regarded as dishonest. The mere entry into a secret cartel, it was submitted, was not criminal and was to be distinguished from positive action such as deceptive misrepresentation.

Their Lordships had considered those arguments in Norris v Government of the United States of America (The Times March 14, 2008; [2008] 1 AC 920) and concluded that the defendant's submission in that case, the relevant part of which largely mirrored that which was advanced on behalf of the defendants in the present case, was correct.

In Norris Lord Bingham of Cornhill said that unless there were aggravating features such as fraud, misrepresentation, violence, intimidation or inducement of a breach of contract, agreements in restraint of trade, even if they might be unreasonable in the public interest, were not actionable or indictable.

The prosecution case statement contained within it quite sufficient notice of aggravating elements, consisting of allegations of lies and positive deception..

The defendants could not possibly maintain that they were left without notice of the acts of that nature on which the prosecution could rely in putting forward a case of conspiracy to defraud on the basis of agreement to commit such acts.

The difficulty which the prosecution faced was that although they could very well charge the defendants with conspiracy to defraud so based, they had not done so as the indictment stood. It was necessary that the particulars should make clear to the defence the case which it must meet.

The thrust of the case as charged was that of price-fixing.

It went on the incorrect assumption that price-fixing when carried out in circumstances of secretive and deceptive behaviour was dishonest in itself and a sufficient basis for conspiracy to defraud.

The indictment did not isolate and charge any specific aggravating elements which would elevate price-fixing into an indictable conspiracy to defraud, and was therefore defective as it stood.

However, the indictment and case statement were in principle capable of amendment in suitable terms in order to accord with the views expressed by their Lordships in Norris. Any application to amend had to be made to the trial judge, Mr Justice Pitchford, and accordingly the matter was remitted to him.

Solicitors: Jones Day; Roiter Zucker, Kilburn; Norton Rose LLP, Southwark; Berwin Leighton Paisner LLP; Solicitor, Serious Fraud Office.

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[Return to List](#cite_id_87)

87 of 200 DOCUMENTS

Daily Deal/The Deal

**November** 10, 2008 Monday

**M&A briefly noted: Nov. 7, 2008**

**BYLINE:** Edited by Greg Johnson

**SECTION:** M AND A

**LENGTH:** 812 words

**HIGHLIGHT:** Panasonic confirms talks with Sanyo Electronics; Lafarge plans to expand asset sale program and more.

**Panasonic confirms talks with Sanyo Electronics**

Japanese electronics group **Panasonic Corp.**, the world's biggest maker of plasma televisions, said Friday it is in talks to buy electronic components maker **Sanyo Electric Co. Ltd.** News reports said Panasonic has already approached Sanyo's creditors. Panasonic said it hopes to make Sanyo, which has a market cap of •389.4 billion ($4 billion), a subsidiary, but will keep its options open. The duo promised to release the outcome of talks by the end of December. A merger would create the world's largest rechargeable battery maker -- ahead of **Sony Corp.** -- Andrew Bulkeley

**Lafarge plans to expand asset sale program**

**Lafarge SA**, the world's biggest cement maker, said it would extend its EUR1 billion ($1.27 billion) asset sale program and ruled out new acquisitions next year amid a slump in demand for cement. Spending at the French company would be limited to EUR2 billion in 2009, less than the EUR3 billion it spent this year on maintenance and new plants. The company also said it could not guarantee its 2010 profit target due to a deteriorating business environment. On Nov. 4, Lafarge sold its Italian cement to Italy's **Societa Per Azioni Centrale Cementiere Italiane SpA**, or Sacci, for EUR290 million. -- Paul Whitfield

**Cemex sheds division in the Canary Islands**

The world's No. 3 cement maker, **Cemex SAB de CV**, on Friday sold its Canary Islands operations to Spanish investment holding company **Cimpor Inversiones SA**. The deal is valued at about EUR162 million ($211 million). Cemex, once an avid acquirer, will use the proceeds to reduce debt as it continues to reel from its 2007 $16 billion acquisition of Australia's Rinker Group Ltd., which had 80% of its operations in the U.S. Cemex not only faces a battered U.S. housing market, but also a slowdown in key European markets such as Spain. The Canary Islands operations generated about EUR189 million ($260 million) in 2007 revenue. -- Baz Hiralal

**Ameriprise Financial gets J. & W. Seligman**

Minneapolis asset manager and insurance broker **Ameriprise Financial Inc.** announced Friday said that it has completed its $440 million purchase of privately held New York asset manager J. & W. Seligman & Co. The transaction should be add to earnings and return on equity in 2009, Ameriprise said. The target manages about $18 billion in assets and will strengthen Ameriprise's technology and hedge fund investment business. Seligman will operate under Ameriprise's RiverSource product portfolio. -- Thomas Zadvydas

**Vienna Stock Exchange acquires Prague bourse**

The Vienna Stock Exchange, **Wiener Bˆrse AG**, announced Friday the acquisition of the **Prague Stock Exchange** in a deal reportedly valuing the Czech institution at about EUR600 million ($764 million). The Prague Stock Exchange is one of the largest exchanges in Central and Eastern Europe, listing 29 companies with a total market cap at Sept. 30 of almost EUR40 billion. The transaction, which regulators must approve, puts Vienna at the helm of three Eastern European exchanges -- Prague, Budapest and Ljubljana in Slovenia. -- Jonathan Braude

**Japan's Daiichi Sankyo grabs India's Ranbaxy**

Japan's third largest drug company, **Daiichi Sankyo Co. Ltd.**,has completed its $4 billion acquisition of India's **Ranbaxy Laboratories Ltd.**, the companies said Friday, Nov. 7. In June, Daiichi agreed to buy a controlling stake in generic drug developer and has since acquired 63.92% of **Ranbaxy's** shares. Under the terms, Daiichi paid 737 rupees ($15.42) per share for its takeover of **Ranbaxy**, which is now India's largest drugmaker. According to industry sources, Daiichi Sankyo appears to have less exposure to **patent** loss than many of its rivals. -- Cheryl Meyer

**New French wealth fund to buy STX France stake**

France's new sovereign wealth fund will make its debut with a EUR110 million ($142 million) agreement to buy one-third of STX France Cruise SA, builder of the world's longest ocean liner, the Queen Mary II. The deal is the first for the fund. The 33.3% stake is being sold by South Korean shipbuilder **STX Shipbuilding Co. Ltd.** and French engineering group **Alstom SA**. The deal reduces STX Shipbuilding's stake in STX France from 75% to just over 50%, while Alstom's stake falls from 25% to 16.7%. -- Paul Whitfield

**Panasonic confirms talks with Sanyo Electric**

Japanese electronics group **Panasonic Corp.**, the world's biggest maker of plasma televisions, said Friday it is in talks to buy electronic components maker **Sanyo Electric Co. Ltd.** News reports said Panasonic has already approached Sanyo's creditors. Panasonic said it hopes to make Sanyo, which has a market cap of •389.4 billion ($4 billion), a subsidiary, but will keep its options open. The duo promised to release the outcome of talks by the end of December. A merger would create the world's largest rechargeable battery maker, ahead of Sony Corp. -- Andrew Bulkeley

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[Return to List](#cite_id_88)

88 of 200 DOCUMENTS

The New York Times

**November** 2, 2008 Sunday

Late Edition - Final

**The Safety Gap**

**BYLINE:** By GARDINER HARRIS.

Gardiner Harris, a correspondent in The New York Times's Washington bureau, reports on public health.

**SECTION:** Section MM; Column 0; Magazine Desk; Pg. 46

**LENGTH:** 5079 words

In the belly of an industrial district south of Lyon, France, just past a sulfurous oil refinery and a synthetic vanilla plant, sits a run-down, eight-story factory that makes aspirin, the first pharmaceutical blockbuster. The Lyon factory is the last of its kind. No other major facility in Europe or the United States makes generic aspirin anymore. The market has been taken over by low-cost Chinese producers. Even Bayer, the German company that created aspirin in the 1890s and has fought for more than a century to distinguish its product as the most trustworthy one, now has backup supplies from China.

The Lyon plant is owned by a French chemical giant named Rhodia that has been making aspirin since 1908 and still accounts for more than 25 percent of the world's aspirin market. But now a century after its entry into the business, the company intends to quit making aspirin altogether. The plant was last renovated in 1992, and it would need an upgrade to continue operating, an investment the company can no longer justify in what has become a cutthroat business. In fact, Rhodia is closing another factory about 40 miles to the south. This one makes the painkiller acetaminophen, which is found in Tylenol. It, too, is the last such facility in Western Europe.

In some ways, this is a nonevent. European factories close; Chinese ones open. Consumers like their commodities cheap, in the case of aspirin as with everything else. China now produces about two-thirds of all aspirin and is poised to become the world's sole global supplier in the not-too-distant future. But are the Chinese factories safe? Who knows? The U.S. Food and Drug Administration, the European Medicines Agency and other competent government regulators rarely, if ever, inspect them. (By contrast, Rhodia's plant was last inspected by the F.D.A. in July and is routinely inspected by one country or another.) Companies that import Chinese pharmaceutical ingredients, including aspirin, are required to test the supplies before using them, and some send private inspectors to China to ensure that suppliers use adequate controls. No pharmaceutical maker wants its name to become synonymous with disaster, and the vast majority of drugs that are consumed in the United States are safe. But some industry executives told me that price sensitivity in the generics industry makes it more difficult to fully vet their low-cost suppliers.

In China, where thousands of drug manufacturers sell products in the local markets, profit margins are razor thin, and counterfeiting and contamination are common. In 2002, the Pharmaceutical Association, a Chinese trade group, estimated that as much as 8 percent of over-the-counter drugs sold in China are counterfeit. Contaminated products extend beyond drugs, as was made tragically clear this fall when four Chinese babies died and 53,000 were sickened by melamine, a toxic chemical illegally added to watered-down baby formula to artificially increase the protein count and fool quality tests.

Though no melamine-tainted baby formula from China was found in the United States, it has shown up in other countries. This is the latest in a series of food- and drug-safety scandals. China has in recent years exported poisonous toothpaste, deadly dog food, toys made with lead paint and tainted fish. In one infamous example this spring, Chinese manufacturers substituted a cheap fake for the dried pig intestines used to make the drug heparin, which is given to dialysis and surgery patients to prevent blood clotting. As deaths among those taking the drug mounted, the F.D.A. discovered the taint and banned the contaminated drug. In the end, 81 people may have died from allergic reactions, and tens of thousands around the world were exposed to danger. F.D.A. officials admitted that the agency should never have approved the Chinese-made heparin for sale in the United States; the agency, it turned out, had never inspected the Chinese plant making it.

Concerns about Chinese drugs have become so intense that just three weeks ago, the Health and Human Services secretary, Michael O. Leavitt, announced that the F.D.A. would open an office in Beijing by the end of the year and offices in Shanghai and Guangzhou next year. The agency still plans to send inspectors to China from the U.S., but the offices will provide ''an infrastructure that will make those people more effective,'' Leavitt said at the time of the announcement.

China's leap to one of the biggest suppliers of pharmaceutical ingredients in the world happened over the last decade, as the Chinese government subsidized the construction of manufacturing plants that have undercut prices everywhere. Generic drug makers in the United States, where price competition is fierce, were the first to seek cheaper drug ingredients in China. Last year, generic drug applications to the F.D.A. listed 1,154 plants providing active pharmaceutical ingredients: 43 percent of them were in China, and another 39 percent were in India. Only 13 percent were in the United States. Branded drug makers, with their fatter profit margins, resisted buying ingredients from China for years, but with their businesses now suffering, even major pharmaceutical companies like AstraZeneca, Bayer, Baxter and Pfizer have announced deals to outsource manufacturing to China.

I have been writing about the drug industry for more than a decade, but I have rarely written about a subject that both branded and generic drug makers wanted to discuss less. Nearly all of the industry executives who spoke for this article did so anonymously. Even the Generic Pharmaceutical Association, a normally loquacious trade group, was largely silent on the issue. Not one of them, it seems, wants to talk too much about the difficulty of regulating factories across several times zones, 6,000 miles and a vast linguistic and cultural divide.

The F.D.A. regulates more than $1 trillion worth of consumer goods, which amounts to about 25 cents of every consumer dollar spent in this country. This includes $466 billion in food sales, $275 billion in drugs, $60 billion in cosmetics and $18 billion in vitamin supplements. The agency is responsible for monitoring a third of all imported goods, from eggplant to eyeliner, microwave ovens to monoclonal antibodies, slaughterhouses to cellphones. But with fewer than 500 import inspectors and computer systems so old that repairmen must be called out of retirement to fix them, the agency is increasingly beset by a sense of futility.

Even the F.D.A.'s staunchest defenders now acknowledge that something is terribly wrong. Among them is Peter Barton Hutt, who served as the agency's general counsel during the Nixon administration and is widely considered the dean of the F.D.A. bar in Washington. I've interviewed Hutt dozens of times over the years, and he has always defended the F.D.A. No more. ''This is a fundamentally broken agency,'' Hutt told me earlier this year, ''and it needs to be repaired.''

The breakdown is not simply about money. This summer 1,442 people around the country were sickened by tainted tomatoes -- or possibly jalepeno peppers. Such scares have become familiar, and the inability to quickly find the sources of contamination has been one of the agency's signal failures. A 2002 law requires produce processors and distributors to keep track of where food goes and comes from, but the government has yet to mandate standardized record-keeping. As a result, in response to a scare, investigators must pour over a blizzard of contradictory packing slips and incompatible computer programs as they race to save people.

To ensure the safety of imported drugs, the F.D.A. relies almost entirely on its own inspections of foreign plants. This was not much of a problem 30 years ago, when most medical products consumed in the United States were made here and F.D.A. inspectors could drive around to plants in their district. Most of those plants have since moved abroad, and now decades can pass between inspections. Testifying before Congress in April, Dr. Janet Woodcock, director of the F.D.A.'s drug center, spoke with rare frankness about the ability of the agency to do its job abroad. ''The F.D.A. of the last century is not configured to regulate this century's globalized pharmaceutical industry,'' she testified.

Other current and former F.D.A. officials I talked to echoed Woodcock's warning. Tim Wells, who was a field investigator and then a compliance officer for 24 years at the F.D.A., now does private audits of drug plants and sees the holes in the agency's safety net. ''A company I recently visited abroad hasn't been inspected for 10 years,'' he told me.

Besides being more frequent, domestic inspections are unannounced and more intense. And when inspectors find dangerous conditions at domestic plants, they generally return promptly to ensure that those conditions get fixed. Not so in foreign plants. In a report released Oct. 22, government auditors reported that between 2002 and 2007, F.D.A. inspectors found dangerous conditions in 15 foreign plants. Only one of those plants was reinspected within two years, the auditors found. In every other case, the agency took foreign managers at their word that promised changes were made.

The record is particularly bad in China. Over the past six years, the F.D.A. has managed to inspect annually an average of just 15 of the 714 Chinese drug plants that export to the United States. At its present pace, the F.D.A. would need more than 50 years to visit all of these Chinese plants. By contrast, the F.D.A. inspects domestic drug plants every 2.7 years.

Inspectors volunteer for the grueling overseas assignments, and, it turns out, they don't much like traveling to parts of Asia. ''I went to Taiwan once, and after initially spending a night in a very nice hotel, I was transferred several hours by car to a hotel closer to the plant,'' recalls DeVaughn Edwards, who worked as an F.D.A. inspector for 14 years until he left in 2006. ''The bed consisted of two mattresses on the floor. There was no lock on the door. You had to hope that no one came in. It was dark; there were no amenities, no TV that worked. There was a shared restroom down the hall. It was only one night there, but it was enough to make you not want to revisit the plant or spend too much time there.''

When inspectors do go to China, their reports sometimes read like a bureaucratic rendering of Mark Twain's ''Innocents Abroad.'' During a 2001 trip, for example, two F.D.A. inspectors visited a plant that was exporting acetaminophen to the United States. The plant had never been inspected. ''The F.D.A. inspection team was met at the hotel in Wenzhou by representatives from Wenzhou No. 3 Pharmaceutical Factory and . . . transported by public ferry and then company vehicle to the manufacturing facility on Dong Tou Island off the coast of Wenzhou,'' their report states. ''There is no street address or plot number, and the address of the facility is given only by the county and province.''

Once the team arrived in what seemed like the middle of nowhere, the inspectors learned the drug was being manufactured at another plant -- one that once had a similar name but had recently changed it. ''In fact,'' the report continues, ''inspection found that there were initially three separate and independent firms operating under the names Wenzhou No. 1 Pharmaceutical Factory, Wenzhou No. 2 Pharmaceutical Factory and Wenzhou No. 3 Pharmaceutical Factory. The location of Wenzhou No. 1 Pharmaceutical Factory was also determined by the F.D.A. inspection team during the visit to Wenzhou, and it was learned that the firm is operating under a new Chinese name; however, the English translation of that name was not available.'' So the two inspectors flew back to the

United States -- at taxpayers' expense -- never having inspected a thing.

The F.D.A.'s apparent inability to keep names straight is no trivial matter. One reason the agency failed to inspect the Changzhou plant that produced deadly heparin, for instance, was that someone mixed up the facility's name and concluded that the plant had already been inspected. Chinese plant names, a vestige of its once strictly controlled economy, are often very similar, and translations can vary. For instance, there are 57 separate drug master files -- the basic F.D.A. record of a plant's name, location and approved product -- with ''Shanghai'' in the name. Some are obvious repeats, like the ones for ''Shanghai No. 6 Pharmaceutical Factory'' and ''Shanghai Number 6 Pharmaceutical Factory.'' But others could be separate plants. Or maybe not. It's just too hard to tell.

Compounding the problem is the F.D.A.'s antiquated technology. Its computer systems are so awful that officials have no way of knowing which names, or which plants, are real. To determine which factories need to be inspected, agency investigators must consult two incompatible databases, one of which lists 3,000 foreign drug plants exporting to the United States and the other 6,800. Which number is right? Nobody really knows. Officials have told House investigators that their best guess for the number of foreign drug plants exporting to the United States is 2,967, while the Government Accountability Office recently guessed 3,249. Neither can the agency tell in many cases when the plants were last inspected (or, more important, which have never been inspected), where they are located or what products they make.

The combined ports of Los Angeles and Long Beach receive about 45 percent of all ship-borne trade that comes to the United States, or some 5.2 million containers a year. When I visited one day in May, giant cranes were unloading and loading more than 30 ships, each bearing about 2,500 containers. Some 40 to 50 of those containers -- a tiny fraction of the total -- were trucked to a gigantic warehouse about a half-mile from the ports. There the F.D.A. and Customs and Border Protection cracked open shipping containers that they considered suspicious and then emptied the containers into a large examination area in front of the bays, arranging the boxes and crates as if they were pathologists lining up organs from an autopsy.

Just about every crate I saw contained some kind of food product. One crate came from Indonesia, and its manifest said it contained products with chicken inside. Indonesia plus chicken suggests avian flu to F.D.A. officials. So they decided to take a look. The crate turned out to contain chicken seasoning, but no actual chicken. Still, the cans were sent off for testing. Deeper into the guts of the container were glass jars of sambal terasi, a hot sauce. They would probably be sent back because the F.D.A. requires makers of low-acid foods in jars or cans to register with the agency.

The labels on high-end olives from Italy were lacking the required nutritional information, so back to Italy they went. Jars of jam made of figs and tangerines indicated they were produced close to Ukraine, so an F.D.A. inspector said that he wanted to sample the product for radioactive fallout from the 1986 Chernobyl disaster.

As I wandered through this cornucopia, I realized that I had seen similar products at specialty grocery stores all over New York. My brother is a gourmet chef, and I bet an F.D.A. inspection of his kitchen cabinets would net a sizable seizure of improperly labeled food of suspicious provenance. The F.D.A., after all, inspects less than 1 percent of all imports.

This year, 18.2 million shipments of food, devices, cosmetics and drugs are expected to enter more than 300 U.S. ports; the F.D.A. had 454 investigators in 2007 -- one and a half per port -- to scrutinize them. Theirs is an almost hopeless task, made even more frustrating by the inability of one part of the F.D.A. to share even its most basic information with another. Inspectors in Los Angeles, for instance, have no way of knowing which Chinese drug or device imports really ought to be reviewed because they do not have access to records of F.D.A. plant inspections. If the agents knew, for example, that an F.D.A. inspector had found significant problems at a particular facility, they could be sure to check for the maker's name on a shipping manifest. But they have no way of knowing where to focus their attention. ''Our current nonautomated approach to entry screening cannot continue,'' Woodcock of the F.D.A. told Congress. ''We need to be able to assure that both the product and site of manufacture are acceptable before a drug gets into our country.''

I met Yusuf K. Hamied in the lobby of the Waldorf-Astoria Hotel, where he likes to stay when visiting New York City from his home in Mumbai. He greeted me warmly and turned quickly to the matter at hand. ''Let's go eat,'' he said, steering me to a nearby Chinese restaurant where the maitre d' greeted him by name and showed us to a quiet table.

Hamied is the chairman and managing director of Cipla, the giant Indian generic drug manufacturer. A small man with thinning white hair and well-tailored suits, Hamied has become something of an international public-health hero. In September 2000, Hamied walked into an international meeting on AIDS and other diseases and promised to sell a cocktail of AIDS drugs for about $600 per patient per year, a fraction of the price then being offered by large drug makers. ''Friends,'' he told the crowd, ''I represent the needs and aspirations of the third world. I represent the capabilities of the third world, and above all I represent an opportunity.''

Until Hamied's announcement, most leaders and even many charitable organizations had dismissed the possibility of treating impoverished Africans and Asians who were infected with H.I.V. Drug combinations that kept the infection at bay cost upward of $15,000 per year, a price even those in rich nations strained to bear. But by defying Western companies that held the **patents** on the medicines, Hamied, whose offer was later lowered to $350 and then to $80, changed everything.

Hamied certainly saved many lives and, in doing so, demonstrated just how cheaply effective drugs could be made. Today, as more and more drug makers are seeking out Chinese and Indian manufacturers, the prices for all kinds of generic drugs have dropped. A result has been lower prices in industrial nations as well as the developing world. The A.A.R.P. announced earlier this year that the prices of 185 widely used generic drugs dropped nearly 10 percent last year while those of the 220 most commonly used brand-name drugs rose 7 percent.

If not for the low prices from Chinese and Indian producers, millions of people around the world would likely go untreated. And in the United States, buying generic drugs produced abroad is one way to tamp down the exploding health care costs confronting companies and individuals. But there is a hazard: without proper regulation, some of those drugs could be either ineffective or dangerous. A 2006 study found that more than half of anti-malarial drugs sold in Southeast Asia contained no active ingredients. The World Health Organization has estimated that as much as 10 percent of pharmaceuticals sold worldwide are counterfeit or contaminated. In some poor countries, the share is more than 30 percent.

At lunch, Hamied said that his plants are inspected routinely, and he provided an extensive schedule of inspections. Indeed, international drug buyers say that getting a few days to audit a Cipla facility can be difficult because, as a crucial supplier to dozens of companies across the world, the Indian drug maker hosts a never-ending stream of inspectors and auditors. But like everyone else, Cipla acquires an increasing share of its drug ingredients from plants in China. ''Yes, I've heard all those stories about problems in Chinese plants,'' Hamied said. But he added that he trusted his Chinese partners.

Many international drug buyers said that they are far more comfortable buying from Indian companies than Chinese ones. Language is one reason, but another is that corruption is not as endemic in India. ''We haven't had the problems with the Indians that we've had with the Chinese,'' says William F. Haddad, chairman and chief executive of Biogenerics. ''There's something missing in China, and it has a lot to do with corruption.''

But a few weeks after my lunch with Hamied, the U.S. Justice Department announced that it had opened a criminal investigation of **Ranbaxy,** the largest Indian drug maker, with $390 million in annual sales in the United States. In a motion filed in federal court in Maryland, the Justice Department accused **Ranbaxy** of ''a pattern of systemic fraudulent conduct,'' including filing fabricated drug data to the F.D.A. and using drug ingredients from unapproved and uninspected plants. AIDS drugs purchased by the President's Emergency Plan for AIDS Relief were among the medicines implicated, the Justice Department charged. Leaders of a House committee sent the F.D.A. a letter in July saying that court documents showed that the agency's officials knew of the allegations for 18 months but did nothing. In September, the F.D.A. banned imports of more than 30 generic drugs made by **Ranbaxy,** citing violations that could lead to contamination and allergic reactions.

It was a hot day in June, but Dr. Andrew von Eschenbach, the commissioner of the Food and Drug Administration, was dressed as usual in a dark suit and tie with a monogrammed white dress shirt. His gold cuff links and the yellow ''Livestrong'' wristband from his ''good friend'' Lance Armstrong were visible. He was clearly excited.

I was following von Eschenbach on a visit to the John F. Kennedy airport international mail facility. When I visited the ports of Los Angeles and Long Beach in May, the agency agreed only at the last minute to send along its district director. Now I was getting an unusual ride-along with the agency's commissioner. In the intervening weeks, the agency went from defending its oversight of the nation's drug supply as effective to agreeing that the agency was overwhelmed. The reason for the change? A bipartisan chorus on Capitol Hill had been denouncing the agency's failings -- while at last promising more money.

We were herded into ''the cage,'' a 30-foot-by-20-foot area where customs and F.D.A. inspectors do their work. There are two to three F.D.A. inspectors assigned to police the flood of illegal drug shipments among the nearly 1.3 million pieces of foreign mail that flow through J.F.K. every day. Mail workers pull packages from countries that customs has decided are risky and dump them into ''the cage.''

Officer James Ng of Customs and Border Protection started the tour by putting a package from China through an X-ray machine. The pictures showed row upon row of vials. ''When it looks like this, it's usually anabolic steroids inside,'' Ng said. He opened the box, put on a pair of half-glasses and took out one of the vials, which was filled with a white crystalline powder. ''It says it's testosterone,'' Ng said and then handed the vial to von Eschenbach.

''It's an incredible example,'' von Eschenbach said, his eyes bright. ''It's a steroid from China, but the label is written in Spanish.''

Customs seizes any steroids and narcotics they find, but they give other drugs to F.D.A. inspectors, who laboriously fill out handwritten forms and send letters to intended recipients. If the recipient swears that the drugs are for his or her own personal use, the F.D.A. often releases the detained package. It takes an hour or two to process each package, ''an obstacle that makes their job functionally impossible,'' according to a 2003 Congressional investigation. Thousands of packages can pile up waiting for F.D.A. review, and the agency often releases packages without any investigation for lack of staff.

Even when there are inspectors on the job, they cannot be sure every ingredient in a medicine is safe. The F.D.A. confines nearly all of its regulations and much of its inspection oversight to the active part of most pills, which generally constitutes between 1 percent and 10 percent of a pill's volume. Much of a pill is fillers, binders, coatings, colorants and lubricants that are almost entirely unregulated.

The syrup in which cough and fever medicines are delivered has figured in at least eight mass poisonings around the world in the past two decades, with three of the four most recent cases originating in China. Hundreds died in Panama in 2006, at least 88 children in Haiti died in 1995 and 1996 and some 30 infants died in India in 1998 -- all from toxic syrup. In 1937, 107 people in the United States died because of similar toxic syrup. In fact, it was this incident that led to the creation of the modern F.D.A. But plants making fillers and other nondrug ingredients of pills and syrups are rarely, if ever, inspected by the F.D.A. or any other regulatory agency.

Providing money to finance the agency has been an issue through both Democratic and Republican administrations. The situation grew so dire in the early 1990s that drug makers, alarmed that it was taking up to three years for the F.D.A. to approve new drugs, agreed to pay fees to speed review times. But the companies put strict limits on how that fee money could be spent, and Congress went along with these limits. The parts of the agency that are not financed by fees, like the inspectorate and those charged with overseeing the safety of already approved medicines, began to whither. Indeed, the number of personnel financed by Congressional appropriations remained unchanged at the F.D.A. between 1992 and 2007. Since 1990, the volume of U.S. imports has increased by more than 900 percent.

Several independent assessments of the F.D.A. have called attention to the agency's poor organization and shortage of funds -- and to the hazard those shortfalls pose to the nation's supply of food and medicinal drugs. A board of scientific advisers to the F.D.A. released a report last year that concluded that nothing less than the lives of U.S. citizens were at stake.

In February of this year, the president asked Congress to provide the F.D.A. with $1.77 billion for 2009, which included an increase of $50.7 million over the prior year that was not enough to cover even normal salary increases. Over the ensuing months, von Eschenbach endured withering criticism from Congressional Democrats and Republicans. Repeated scandals involving tainted drugs and food led them to conclude that the F.D.A. needed to conduct far more foreign inspections. House Democrats held more than a dozen hearings to highlight the agency's shortcomings and to urge the administration to propose greater expenditures.

Eventually, after a bruising interrogation by Representative John D. Dingell, the Michigan Democrat who is the chairman of the Energy and Commerce Committee, von Eschenbach asked Congress in May for $275 million to ensure the safety of imported foods, drugs and medical devices. In June, Leavitt, the Health and Human Services secretary, urged speedy action by Congress, which soon gave the agency an emergency infusion of $150 million for this year and another $150 million for next.

This could be the moment to make a difference at the F.D.A. There is strong bipartisan support on Capitol Hill to beef up the agency and prevent another heparin scare. Come January, there will be a new administration in Washington, and no matter who wins the presidential election, change is likely: neither Barack Obama nor John McCain is apt to be as philosophically opposed to regulation as the Bush administration has been. Under Bush, the emphasis was on encouraging companies to hire private inspectors, which the F.D.A. has tried to do for some time with little success. That ethos has already changed in Congress. As Representative Joe Barton, the Texas Republican who is the ranking member on the House Energy and Commerce Committee, said recently, when it comes to reforming the agency to increase foreign drug inspections, ''there isn't any daylight between Republicans and Democrats.''

Unlike reforming Social Security or health insurance generally, fixing the F.D.A. won't mean allocating enormous sums or necessitate reconceiving the system. It just requires some money and will. There are already legislative changes in the works. Bills now circulating on Capitol Hill would require food, medical- device and drug makers to pay annual registration fees to the F.D.A. Those fees would be used to allow as many inspections of foreign firms as domestic ones.

There also seems to be agreement that our regulatory agencies can't rely on China to police its own factories. The Chinese have lurched between vows of reform and disregard for American concerns about the quality of the country's products. When melamine was first found in Chinese-made pet food, Chinese government officials denied that the taint originated in their country and then, when that claim was disproved, said melamine would not hurt pets. During the heparin scare, Chinese officials admitted the contamination but insisted it wasn't lethal. Last year, however, the Chinese government executed the former head of the agency entrusted with oversight of food and drug industries. He was found to have approved untested medicine in exchange for cash. The punishment shocked many at the F.D.A. but also led some to imagine that the Chinese were signaling a broader crackdown on unsafe foods and drugs, a hope that so far remains unrealized.

More inspectors will certainly help, but even regular inspections of Chinese plants cannot ensure safety. Inspectors can be hoodwinked; tests can be fooled. ''No matter how many F.D.A. inspections they do,'' says Senator Sherrod Brown, Democrat of Ohio, ''our safety is still at risk if the pressure continues to cut costs.'' Brown has introduced a bill to require labels disclosing the source country of key drug ingredients. Some lawmakers have gone as far as to suggest a ban on all drugs made with Chinese ingredients, but China has become such a crucial supplier that a ban would lead to the collapse of the U.S. health care system. And our dependence is only growing: when PricewaterhouseCoopers cited the best place for pharmaceutical outsourcing in the world in an October report to drug companies, its pick was China.

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[Return to List](#cite_id_89)

89 of 200 DOCUMENTS

The Nikkei Weekly (Japan)

**October** 27, 2008 Monday

**Generics no panacea, drug firms find**

**LENGTH:** 963 words

Generics no panacea, drug firms find

Access to **patent**-expired treatments no gold mine, but pharmaceutical majors still vying for market

Not all pharmaceutical companies are benefiting from the expanding generic drug market in Japan, as industry players are discovering that access to popular treatments whose **patents** have recently expired does not guarantee strong sales.

The challenge generic drugmakers face is finding effective strategies for expanding a market that, while getting slowly bigger, appears somewhat resistant to embracing a shift to non-brand-name products.

In what was a long-awaited development for generic drugmakers, generic treatments based on the amlodipine hypertension medicine went on sale in Japan in July. The widely used amlodipine had sales exceeding 200 billion yen ($1.98 billion) a year in Japan.

More than 30 pharmaceutical companies decided to market generic versions, hoping the drug would spearhead the expansion of Japan's generic drug market following the relaxation of rules in April for prescribing generics.

Three months later, it has become clear that their hopes were too high. Many generic drugmakers are struggling to sell amlodipine-based products.

Some argue that the stagnant sales are due to the fact that generic drug producers set their prices too high to avoid a discount war.

In contrast, brand-name drug producers, such as Meiji Seika Kaisha Ltd. and Aska Pharmaceutical Co., are enjoying strong sales of amlodipine drugs. Yuji Umeki, head of Meiji Seika's generics marketing department, said his company was accelerating production to meet increasing demand for the medicine.

Meiji Seika has mobilized its medical representatives to offer information on amlodipine to doctors and pharmacists, just like it does for new brand-name drugs. Umeki said his company decided to put resources into quelling doubts that some doctors and pharmacist have about generics.

Meiji Seika went so far as to compile data by administering amlodipine to laboratory animals and provided the test result to its medical representatives even though the process was unnecessary in the application for approval of generic drugs.

Meiji Seika also plans to compile a record of the effects of amlodipine use among 1,500 patients within two to three years.

The mixed results of amlodipine within the industry were a reality check for generic drug makers, which were expecting to use the drug as a way to broaden the domestic market.

The price of generic drugs, rather than detailed information about them, is often the key in the U.S. and European markets, where generics are more widely used and the medical systems are different from those in Japan. Some U.S. generics producers go so far as to not have their own sales forces in order to reduce sales and general administrative expenditures as much as possible. Because of these differences, foreign pharmaceutical firms sometimes have difficulty when applying their business models to Japan.

Joint venture

Recently, Teva Pharmaceutical Industries Ltd. of Israel, the world's leading maker of generic drugs, announced it will form a joint venture with midsize Japanese pharmaceutical maker Kowa Co. in early 2009.

Some in the industry express doubt about the prospects for the new venture, called Teva-Kowa Pharma Co. "We initially braced ourselves for the arrival of a nuclear aircraft carrier, but what we saw approaching was a landing raft," said an official at a Japanese pharmaceutical company.

Kowa is known for its Cabagin antacid and other over-the-counter products. Its operations for drugs used by medical professionals, such as its Livalo hyperlipidemia treatment, are relatively small, with sales of about 70 billion yen a year, and the company's capacity for this area is untested.

Teva CEO Shlomo Yanai said his company has produced business results in more than 60 countries and has plenty of information on the side effects of its products. However, some Japanese doctors think the effects of drugs on Asians may be different than those on Caucasians.

Teva-Kowa has set a bold target of achieving sales of 100 billion yen in 2015. To achieve this goal, the firm must prepare and implement the plan with great care.

According to Nihon Chozai Co., a leading operator of dispensing pharmacies, 29.4% of drugs that its patients received in August were generic. This figure is close to the goal set by the Ministry of Health, Labor and Welfare of boosting the market share of generics to 30% on a volume basis in fiscal 2012.

Small and midsize operators of pharmacies are more inclined to avoid stocking generics, which are less profitable, which may hamper the spread of such drugs. Still, there is no doubt that the generics market is expanding.

The next turning point for the market is likely to arrive around 2011. Shigeki Aratani, president of Taiyo Pharmaceutical Industry Co., noted that several **patents** for popular brand-name drugs will expire that year, boosting the generics industry. Those slated for **patent** expiration include the Lipitor cholesterol treatment, with annual sales of 100 billion yen, and the Aricept Alzheimer's treatment, with annual sales of 60 billion yen.

Pharmaceutical companies appear to be planning their future strategies based in part on lessons learned from the experience of marketing amlodipine.

The question many are asking is who will get the biggest chunk of the expanding generics market. Mitsubishi Tanabe Pharma Corp. entered the market by taking advantage of its name recognition in the brand-drug market. Daiichi Sankyo Co., for its part, is in the process of acquiring **Ranbaxy** Laboratories Ltd., India's biggest producer of generics.

The strategies these firms choose to take will decide the outcome.

(The Nikkei Weekly 10/27/2008 Edition)

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[Return to List](#cite_id_90)

90 of 200 DOCUMENTS

Weekend Australian

**October** 18, 2008 Saturday

5 - Careers / Health Edition

**Shot in the arm for generics**

**BYLINE:** Adam Cresswell

**SECTION:** REVIEW; Pg. 13

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Copycat medicines can help patients save money if they know where to look, writes Health editor Adam Cresswell

ASPIRIN is for many people synonymous with headache cure, or at least it was until the arrival of more modern painkilling drugs in the past 20 years.

It's cheap, available in umpteen different boxes and bottles from different makers, and in recent years has also been taken in low-dose form by millions of people with heart conditions to lower the risk of having a heart attack.

Aspirin has become one of the world's best-known generic medicines, but it started its life as a brand name. In 1899, the German company Bayer started supplying Aspirin in powdered form to doctors, with tablet formulations arriving in 1915.

No one has second thoughts these days about buying a bottle of aspirin made by another company. But for other medicines, generic versions -- which have the same amount of the same active ingredient, and are tested to ensure they affect the body in the same way as the original drug -- have yet to achieve the same degree of popularity.

A Deakin University study in 2007 suggested that in Australia, generic medicines account for just 18 per cent of Pharmaceutical Benefits Scheme expenditure, equivalent to 25 to 30 per cent of the nearly 170 million PBS prescriptions written each year.

Although that's up to 50 million scripts, it's still well behind other countries. The Deakin study found generics represented over 50 per cent of prescriptions in the US, 44 per cent in the Netherlands and about 70 per cent in Denmark.

In part, the lower rate in Australia has been due to the set-up of the PBS, which historically has kept a tighter lid on the prices of newly-invented brand-name drugs than elsewhere in the world. According to drug makers, this has meant prices fall less when their medicines come off **patent,** reducing generics' market appeal.

However, other research has suggested generic drugs overseas are cheaper than comparable generics here. A separate study published in the Medical Journal of Australia last year (2007;187:236-9) found that the cost of a generic supply of the blood pressure drug enalapril would have to fall by 68 per cent to match the price in New Zealand. The cost of a generic version of the anti-depressant fluoxetine would have to fall by 71 per cent to match the price across the Tasman.

Another reason for generics' poor uptake in Australia is that there has often been no cost saving to patients, and thus no incentive to request a generic, because the price reduction usually passes instead to the PBS. Even in cases where there is a saving, few members of the public know about them.

However, this is about to change.

The former government was long dissatisfied with the higher price and lower take-up of Australian generics, and pushed through reforms which led in August to price cuts for over 1000 medicines. To complement that policy, the independent National Prescribing Service (NPS) is about to launch a $4 million advertising and awareness campaign, which aims to boost generic uptake.

The campaign, involving posters, TV commercials and online publicity, will raise awareness that generic medicines are identical to their better-known equivalents -- and could even help people save money.

Drug makers are free to charge patients a ``brand premium'' on top of the base price that the PBS pays to buy the drug.

These premiums range enormously, from 9 cents to $76.86 -- although the latter relates to a highly specialised cancer drug used by few people.

The average premium is $2.88, and the vast majority lie somewhere between $1 and $4. In some cases, there is a generic alternative available with no premium, in which case the patient can save money.

Of the 2800 products on the PBS, about 360 have a brand premium. Because several of them are among the most commonly prescribed medicines, taken every day for various chronic diseases, the savings can mount up.

For example, the cholesterol-lowering drug simvastatin -- best known by the brand names of its top-selling versions, Zocor and Lipex, is available in more than 10 different generic versions. The cheapest of these cost $1.05 less than the brand-name products.

Likewise, patients can save $2.15 by choosing the cheapest generic version of omeprazole, which is sold under the brand name Losec and treats peptic ulcers. Generic versions of the beta-blocker atenolol (brand name Tenormin) cost up to $2.79 less, and generic versions of the anti-diabetes drug metformin cost $1.40 less.

``The savings are modest, but in these straitened times even a dollar here and there is important to people,'' says NPS chief executive Lynn Weekes.

``Other people will make a decision that they prefer having the brand they know, and they are prepared to pay that (brand premium) price.

``The main message in our generics campaign is to remind people that generics are an equal choice, that they have the same active ingredient as the branded product, and the Therapeutic Goods Administration has approved them as a reliable product in Australia. All of these generic products have to be shown to be bio-equivalent to the branded product, which means they work in the same way.''

Cost savings to the PBS are often considerably larger than for patients. Weekes says this is another important advantage -- easing cost pressures on the scheme, allowing it to afford new medicines which in some cases can cost tens of thousands of dollars per patient per year.

Not everyone has been so enthusiastic about generics. There has been criticism from Australian-based companies that generics allow a free kick to overseas companies, such as India's **Ranbaxy,** which can supply bargain-basement products without the need to reinvest in research or in Australian jobs.

The Australian Medical Association has also been cautious, arguing that profits from branded drugs support research and development of new medicines, and that patients risk becoming confused and taking a double-dose of two versions of the same product.

For that reason Weekes and the NPS are encouraging the public to be familiar with the drug's generic name, which is the same for all generic and branded versions based on that molecule. At the very least -- particularly in the cases where chemical names are utter tongue-twisters -- people should know where to look on the packet, to allow them to cross-check their medicines, she says.

Roger Millichamp, chairman of the Generic Medicines Industry Association, says the industry is ``playing a vital role in helping to deliver the whole central prophecy of the PBS, which is to give the widest possible access to medicines''.

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[Return to List](#cite_id_91)

91 of 200 DOCUMENTS



ICIS Chemical Business

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**The populationbomb INTRODUCTION: Demand for generic drugs in Japan is set to explode, with the collision of an aging population and skyrocketing drug costs**

**BYLINE:** John Richardson

**SECTION:** FEATURES

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PUT YOURSELF in the shoes of any Japanese politician or bureaucrat, and you should be chilled to the bone by rising health-care costs and the country's aging population. The two make up a demographic time-bomb that threatens unsustainable levels of national debt.

Japan's health care bill already totals yen 30 trillion ($279bn)/year, of which drugs account for yen 6 trillion, according to the Japan Generic Pharmaceutical Manufacturers Association (JGPMA), and the cost will only grow with the number of elderly. By 2050, 35-40% of Japanese will be over 65, says global consultancy Frost & Sullivan. Meanwhile, the total population will have declined from the current 127m to only 100m, very bad news for tax revenues.

As far back as 1993, politicians and government officials recognized that there was a pressing need to reduce the drug bill by promoting generics. This led to the introduction of a step-by-step policy to boost generic sales from the early years of this decade, including subsidies for doctors who merely explain the benefits of generic substitutes and further payments for actual prescriptions. Pharmacists also receive government cash for dispensing nonpatented medicines.

"This was a big step forward when you consider that many hospitals are in the red," says Nitin Naik, vice president of health care and life sciences at Frost & Sullivan. "As for incentivizing the drug companies to boost generics production, the prices that they can charge hospitals for drugs have been cut by 1.5-2%/year over each of the last four years."

Co-payments have also been raised to 30% from 20%, and company health insurance contributions have been increased.

But will Japan be able to do enough to prevent health care costs from crippling an economy already burdened by years of low growth and entrenched deflation?

The answer should be yes. There is a political consensus that the health care crisis has to be tackled, meaning no change in the overall objective no matter who is in power, Naik argues.

The corporate sector can only gain by containing health care costs, resulting in initiatives such as that taken by Toyota. The Japanese auto giant has opened two medical centers providing the annual medical checks mandatory for employees over 40. This is cheaper than paying charges levied by hospitals.

Other companies, including the Mitsubishi industrial group, look likely to follow suit, and hospitals will be under pressure to improve cost efficiency if they want to attract business.

Japan's pharmaceutical companies also stand to benefit from boosting production of generic drugs, and they have some major competitive strengths, which include the ability to achieve Pharmaceutical and Medical Device Agency and other regulatory approvals 30-40% quicker than overseas rivals, says Naik. "When you consider that it can take seven to eight years to bring a drug to market, this is a considerable time and cost saving. "This puts the companies in a strong position to compete in 'branded' generic drugs which have big potential in Japan because of concerns over the efficacy of standard generics," Naik says.

Blockbuster drugs are few and far between - and very expensive to develop - so generics need to be part of any balanced strategy, he adds.

Boosting competitiveness

Competitiveness can be further improved through sourcing active ingredients from overseas. Labor costs, also very high in Japan, are not a significant drag on profitability, as they represent only a small percentage of any pharmaceutical company's overall expenses.

The government provides a good package of investment incentives, resulting in the establishment of pharmaceutical parks outside the major cities.

As a result of all these advantages, generics will account for 30% of total sales in 2050, as against 14% in 2007, Frost & Sullivan predicts.

Japan's pharmaceutical sector presents a great opportunity to overseas players that want to benefit from the growing off-**patent** medicines business by establishing local joint ventures, the consultancy notes.

As for the local players themselves, Daiichi Sankyo is acquiring **Ranbaxy** of India for as much as $4.7bn (?3.2bn). The move could help Daiichi boost its generics business, although the takeover is part of a much wider strategy.

Some Japanese players are already very well established in generics, most notably Sawai Pharmaceuticals.

"The company's sales rose by 28.9% in the financial year ending 31 March 2007, spurred by the government's progeneric drug reforms," says Naik. "Saiwa is at the forefront of the Japanese generics markets and is involved in the export and import, manufacturing and sales of pharmaceutical products and health-care products."

Japanese producers are also in a great position to benefit from the growth of the generics industry overseas, as well as at home. Many other developed countries face their own health care funding crises.

The struggle with perception

However, some serious hurdles need to be cleared if the generics market is to grow to Western levels.

Not least of these is the very high standard of health care in Japan. In the minds of patients and doctors, a big reason for long life expectancy is the immediate use of expensive drugs to treat illnesses and long, complex and expensive drug therapy programs. The JGPMA and Frost & Sullivan, however, say that drug consumption is unnecessarily high.

distribution adds to costs

Complex and multilayered distribution systems can greatly add to costs. As a result, the JGPMA is encouraging companies to sidestep small community wholesalers in favor of the cost savings to be made using big national distributors.

Another barrier is wealth. Despite the increase in co-payments to 30%, Japan's rich workers and often even wealthier retirees can easily afford to pay their share of medical bills, and still insist on branded drugs.

Major generic companies are responding with media campaigns explaining that off-**patent** does not mean poor quality.

The JGPMA has distributed 300,000 "Generic Drug Consultation Cards" free of charge to patients in order to prompt discussions between patients and doctors about generic alternatives.

The ease with which **patents** can be extended multiple times is another obstacle. Extensions are for five years beyond the standard 20 years of all **patents**.

Drugs to treat typhoid and paratyphoid fever have had their **patents** extended on three occasions. Regulators are also considering an application for a fourth extension for a drug taken to combat Legionaires' disease, says the JGPMA.

When Japan makes its mind up

A Japanese friend once said: "We spend a lot of time considering all the options, but once we've made our mind up on something, that's it - we go for it. Look at the way we rebuilt our economy from the 1950s to the 1980s."

The government and the pharma companies have made their minds up on generic drugs as a vital ingredient of the solution to Japan's health care dilemma.

Once the majority of the public, doctors and medical health care practitioners also agree, the sky could be the limit for one of the world's most valuable drugs markets.

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[Return to List](#cite_id_92)

92 of 200 DOCUMENTS

The Nikkei Weekly (Japan)

**September** 22, 2008 Monday

**Firms alter tactics amid changing U.S. market**

**LENGTH:** 686 words

Firms alter tactics amid changing U.S. market

When launching new products, Japanese and foreign pharmaceutical companies usually focus on the U.S. market, the largest in the world, seeking to maximize their profits. However, changes are afoot in America that could force these firms to alter their business models.

This summer, Takeda Pharmaceutical and its U.S. partner temporarily suspended clinical trials of a drug to treat cancerous anemia because they could secure only two participants, far short of the 100 volunteers they hoped to have.

The U.S. has traditionally offered a favorable research environment for pharmaceutical companies because recruiting trial participants has been easier there than in Japan. However, the attitude of the U.S. Food and Drug Administration toward drug tests is changing, as reflected in the difficulty the two companies had in recruiting people for their trials.

The FDA issued an unprecedentedly strict order regarding the use of the new drug after the agency heard that a similar drug had the possibility of exacerbating cancer symptoms.

Not only Takeda, but the pharmaceutical industry as a whole, has a growing sense of crisis over the increasing difficulty in obtaining approval to produce and market drugs in the U.S. The biggest reason for the FDA's stricter stance was the risk of potential lawsuits.

U.S. drugmaker Merck & Co. spilled red ink in the October-December quarter of 2007 mainly because it had to settle lawsuits for side effects of a pain-killer. It is possible that the FDA may bear the brunt of criticism if this type of lawsuit occurs often.

As a result, the FDA has been increasingly cautious about approving drugs, delaying approval in some cases. A U.S. subsidiary of Eisai received a rejection letter from the FDA in late July in response to its application for a sedative. The FDA appears to have rejected the application because the drug required specially qualified doctors to administer it.

According to U.S. market research firm IMS Health, the North American pharmaceutical market grew only 4% in 2007, compared with 13% in Asia outside Japan, and 7% in Europe. The FDA approved 12 world-first drugs with new compounds, down 37% from the previous year.

The North American pharmaceutical market accounts more than 40% of global drug sales. However, if the FDA slows its pace of approving new drugs, drugmakers may need to adopt strategies less dependent on the U.S. market.

Daiichi Sankyo Co. is acquiring top Indian pharmaceutical firm **Ranbaxy** Laboratories Ltd. Daiichi Sankyo President Takashi Shoda said his company plans to focus not only on new drugs and advanced markets but also on long-sellers and emerging markets.

Generic drugs, or long-sellers, have thin profit margins because they use ingredients whose **patents** have expired. However, they involve lower risks and prop up drugmakers because they do not require research and development costs.

**Ranbaxy's** sales networks were another key factor behind Daiichi Sankyo's decision to acquire the Indian company. The drug markets of the so-called BRICs (Brazil, Russia, India and China) were worth $37.4 billion in 2007. They are expected to grow to $278-361 billion in 2030, about the size of the current U.S. market.

Previously, makers of generic drugs were seen as threats to conventional pharmaceutical companies. However, with global pharmaceutical markets having changed dramatically, these companies are increasingly joining hands.

Daiichi Sankyo plans to invest as much as 500 billion yen to acquire **Ranbaxy**. In general, markets have regarded the purchase of overseas drugmakers by major Japanese pharmaceuticals as being overpriced. However, when the planned acquisition of **Ranbaxy** by Daiichi Sankyo was reported on June 11, the Japanese firm's share price closed 4.9% higher from the previous day's close.

Fumiyoshi Sakai, a senior analyst at Credit Suisse Securities (Japan) Ltd., said that if Daiichi Sankyo can take advantage of **Ranbaxy's** sales networks in emerging economies, Daiichi Sankyo's business model will be of great interest.

(The Nikkei Weekly 09/22/2008 Edition)

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[Return to List](#cite_id_93)

93 of 200 DOCUMENTS

National Post's Financial Post & FP Investing (Canada)

**September** 12, 2008 Friday

National Edition

**The drug hunters; Acquisitions are the prescription for Big Pharma**

**BYLINE:** Ben Hirschler, Reuters

**SECTION:** FINANCIAL POST; Pg. FP13

**LENGTH:** 705 words

Existing drugs aren't paying off, so big pharmaceutical companies are set to step up the hunt for assets to buy in promising fields like biotechnology, as well as non-prescription areas of health care.

The risk is they could end up overpaying.

Screening for acquisitions will be high on the "to do" list of Chris Viehbacher, newly appointed chief executive of Sanofi-Aventis, when he takes the helm at the French drugmaker on Dec. 1, industry analysts and bankers say.

He is not alone. Glaxo-SmithKline -- the company Mr. Viehbacher is leaving-- is also expected to strike one or more significant deals to boost its consumer health business as part of a new growth strategy.

Roche and Bristol-Myers Squibb, meanwhile, are locked in multi-billion-dollar battles for two prime biotech assets, Genentech and Im-Clone Systems.

News this week of a second bid for ImClone, topping an earlier offer from Bristol, suggests competition is fierce.

The identity of the new bidder is unknown, but analysts said ImClone could attract the likes of Pfizer, Novartis, Glaxo and Sanofi-- but it might be too big a bite for Merck KGaA, its partner on cancer drug Erbitux.

"I think it's the natural way of things that Big Pharma is going to take over the biotech world sooner or later," Carl Icahn, ImClone's billionaire chairman, told the company's annual shareholder meeting on Wednesday.

Japanese companies, too, are flexing their muscles on the global scene, with Takeda splashing out for U. S. biotech firm Millennium this year and Daiichi Sankyo buying India's **Ranbaxy.**

"The large guys worldwide are looking really aggressively for assets wherever they can find them, and diversification is a strong theme," said one banker, speaking on condition of anonymity.

The ousting of Gerard Le Fur as Sanofi's CEO after less than two years in the job and the appointment of an outsider signals radical change inside a group that has suffered worse than most from an inability to get enough new drugs to market.

With shareholders demanding action, dealmaking is an obvious way forward.

"We see this option as a practicable way to shake things up quickly," said Morgan Stanley analyst Andrew Baum.

Just what Mr. Viehbacher might decide to buy is less clear. A brief statement from Sanofiannouncing his appointment on Wednesday highlighted overhauling drug research, growth in emerging markets and diversification as key priorities.

The last two both imply acquisitions, according to Amit Roy and colleagues at Citigroup.

French financial daily Les Echos reported that Sanofi was planning to diversify even more widely than most of its peers into health foods, vitamins and mineral supplements.

And Deutsche Bank analyst Michael Leuchten says a mega-merger could also be back on the cards for Sanofi, with its powerful chairman, Jean-Francois Dehecq, likely open to the idea.

Sanofi has long been tipped as a buyer for its U. S. partner Bristol-Myers, which has a market value of around US$43-billion.

The risk for investors in all these cases is that drug company executives, desperate to reinvigorate anaemic sales, may end up overpaying.

Roche stock has been capped in the past two months by worries it will have to offer substantially more than US$44-billion for the rest of Genentech, while Bristol-Myers fell on Wednesday on fears of a costly bidding war for Im-Clone.

In the case of Sanofi, Citigroup's Mr. Roy said likely competition for assets with other pharmaceutical or consumer companies clearly raised the risk of overpayment.

So far, though, the biggest player in the pharmaceutical industry has been surprisingly quiet. Pfizer's failure to buy another big rival has surprised many, given its need to find new products to offset the 2011 loss of U. S. **patent** on its US$13-billion-a-year blockbuster Lipitor.

The combination of growing generic competition, major research problems for particular drugs, and fears of a tougher U. S. regulatory and political climate mean drug stocks have been a poor investment overall this year.

Yet since June, the American Stock Exchange's pharmaceutical index, which includes leading U. S. and European companies, has outperformed the broader market by 13% as fears for the global economy have fuelled demand for defensive stocks.

**LOAD-DATE:** September 12, 2008

**LANGUAGE:** ENGLISH

**GRAPHIC:** Black & White

Photo: Bloomberg News File Photo; A researcher works in a **Ranbaxy** Laboratories Ltd. lab in Gurgaon, India. Japanese drugmaker Daiichi Sankyo is acquiring a controlling stake in **Ranbaxy,** as big pharmaceutical companies go on a buying spree. ;

**DOCUMENT-TYPE:** Business

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[Return to List](#cite_id_94)

94 of 200 DOCUMENTS

Daily Deal/The Deal

**September** 3, 2008 Wednesday

**Shionogi grabs Sciele for $1.4B**

**BYLINE:** by Renee Cordes

**SECTION:** M AND A; Deal International

**LENGTH:** 328 words

**HIGHLIGHT:** The acquirer is one of several Japanese pharmaceutical companies looking for overseas acquisitions.

Japanese drugmaker **Shionogi & Co. Ltd.**agreed Monday, Sept. 1, to buy **Sciele Pharma Inc.**for about $1.42 billion, including debt.

The Osaka maker of the Crestor cholesterol pill will offer $31 for each Sciele share, or 61% above the Atlanta target's closing price Aug. 29.

Shionogi is one of several Japanese pharmaceutical companies looking for overseas acquisitions to compensate for declining domestic drug sales and expiring **patents.** In June, **Daiichi Sankyo Ltd.**unveiled plans to buy a majority stake in Indian market leader **Ranbaxy Laboratories Ltd.**, while in January, **Takeda Pharmaceutical Co. Ltd.**paid $8.1 billion for MGI Pharma Inc. of Bloomington, Minn.

"Through the Sciele acquisition, along with its existing operations under Shionogi USA, Shionogi will increase its efforts to strengthen its pipeline of drug candidate and to accelerate overseas development," the buyer said in a statement.

Shionogi announced the deal after the close of trading in Tokyo. Its shares finished Monday down •15 at •2,460. That equates to a market value of •863.8 billion ($7.9 billion), up 48% on the year.

On Aug. 29, Sciele shares fell nearly 2% on Nasdaq to finish the week at $19.27, for a market value of $609.7 million. The $1.42 billion total price includes $325 million to redeem senior convertible notes.

Sciele, founded in 1992, is involved with medicines for cardiovascular disease, diabetes, women's health and pediatric products. Its 2007 sales rose 30% to $382.2 million.

Sciele CEO Patrick Fourteau and other managers will remain in place, and its new owner has no plans to cut the group's 920 staff.

Shionogi employs 4,920 and reported •214.3 billion in sales for the year ended March 31.

The company plans to launch the tender offer within 10 days and close it within 20 days. **Goldman, Sachs & Co.** was financial adviser to Shionogi, and UBS advised Sciele.

**Davis Polk & Wardwell** was Shionogi's law firm, and **Paul, Hastings, Janofsky & Walker LLP** was legal adviser to Sciele.

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[Return to List](#cite_id_95)

95 of 200 DOCUMENTS

Pharma Marketletter

**August** 29, 2008 Friday

**Denmark upholds two of Pfizer's Lipitor patents**

**LENGTH:** 134 words

Global drugs behemoth Pfizer reported that the Eastern Division of the High Court in Copenhagen, Denmark, has ruled in the company's favor in challenges to two of its **patents** covering atorvastatin, the active ingredient in Lipitor, its blockbuster lipid-lowerer which generated nearly $13.0 billion in sales last year. The basic (DK 171,588) and enantiomer (EP 409,281) **patents** were challenged by India-based generics manufacturer **Ranbaxy**. The court ruled that the basic **patent**, which expires in November 2011, would be infringed by **Ranbaxy's** generic atorvastatin product. It also declared that the atorvastatin enantiomer **patent**, which expires in July 2010, is valid. The decision, which is subject to possible appeal, prevents **Ranbaxy** from launching its generic product before November 2011, noted Pfizer.

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[Return to List](#cite_id_96)

96 of 200 DOCUMENTS

Investment Dealers Digest

**August** 11, 2008

**Private Equity GetsHeated In India: India's homegrown funds tackle their country's PE market with a vengeance**

**BYLINE:** Kelly Holman

**LENGTH:** 1666 words

When news surfaced this past week that Indian business mogul Anil Ambani's Reliance Capital was planning to raise $1 billion for a new India-focused private equity fund and Tata Capital had appointed banking veteran Shailendra Bhandari to run its private equity operations, the developments reinforced how much interest India's corporations have in investment prospects in their own backyard.

It also illustrates that the Republic of India's homegrown private equity business is flourishing, pitting a number of India-based private equity investment funds-some backed by deep-pocketed business executives like Wipro Ltd. chairman Azim Premji's $1 billion PremjiInvest investment vehicle, for instance-against a host of foreign alternative asset investors. Among them are TheBlackstone Group, Carlyle Group, Kohlberg Kravis Roberts and London's 3i Group and Candover, which is reported to be establishing an office in Mumbai that will be headed by Goldman Sachs banker Harsha Raghavan.

Besides Reliance, other Indian corporate-related or executive-backed investment ventures that are jockeying for deal flow include Dabur Group's Promethean investment venture, Premji's committed $20 million towards HealthCare Global Enterprises in May, Aditya Birla Capital Advisors, Tata Capital, TVS Group's TVS CapitalFunds and Indivision by the Future Group, according to Venture Intelligence, a Chennai, India-based provider of India private equity data.

"The trend among Indian corporate houses to set up a private equity practice of their own is picking up," says Arun Natarajan, chief executive of Venture Intelligence.

In essence, Indian investors are establishing investment vehicles that draw their capital from third party sources like US and European private equity partnerships.

US private equity interest in India, of course, isn't new. Both Warburg Pincus and General Atlantic Partners have plied their trade in the nation for years, while other sponsors including groups known as middle market investors, have been putting their money to work more recently. To wit, First Reserve Corp., a Houston private equity firm focused on the energy sector, made an investment of undisclosed size in Indian industrial conglomerate Kalyani Group's wind turbine maker Kenersys in April.

But, the gravity that India's corporate investment houses are bringing to the deal business is hard to ignore. Reliance Capital, for instance, grabbed headlines this week when itwas rumored to be interested in acquiring famed UK soccer club Newcastle United for 260 million pounds, a rumor that the Indian company later denied.

Private equity funds sponsored by corporate groups have an advantage over foreign financial sponsors partly because of their long-standing local business ties and capability to add value to investee companies from their other business holdings, according to Natarajan. That doesn't mean, though, that they're likely to run roughshod over independent private investor groups, which also include local Indian powerhouses such as ICICI Ventures, India's largest private equity firm that is in the midst of raising a new fund, says one source.

"We feel it is not a given [corporate sponsors] will have a superior edge over pure financial private equity funds, who are increasingly headed by executives with long-standing corporate experience. Another challenge for the corporate PE firms would be the way in which interests are aligned between the parent and the professionals managing the fund," Natarajan says.

One independent that is involved in a financial services deal and poised to make a splash in India's private investment market is New Silk Route Partners, which just finished raising $1.4 billion for its debut fund. A firm whose founders are based in New York, but one with offices in Mumbai, Bangalore and Dubai and a 20-investment professional strong team, aims to make growth equity and control-oriented investments in Indian companies in the consumer services, financial services, infrastructure, manufacturing and telecommunications industries, according to Parag Saxena, chief executive of New Silk Route Partners and a 26-year investment veteran.

He acknowledges that family businesses in India have an edge when it comes to information and knowledge of the local business territory, but adds that these same groups also face their own unique set of challenges that include intra-corporate rivalries that can impede deal execution. "The independent groups tend to do better," he says, adding "we have great relationships with corporations, which we hope will be very valuable. We are looking to purchase the equity of companies that are growing rapidly," he says, noting that many traditional buyouts are carried out with companies that only generate moderate revenue growth.

India's opportunities aren't lost on large banking houses like Morgan Stanley. In May, Morgan Stanley Private Equity set up shop in India with the hiring of former ICICI Venture investor Aluri Srinivasa Rao as managing director to lead its Indian private equity investment effort. The private equity arm of the investment bank will fund its deals in India with equity from its $1.5 billion Asian-focused private equity vehicle, Morgan Stanley Private Equity Asia III Fund, which is run by Chin Chou, a managing director and chief executive of Morgan Stanley Private Equity.

India's private investment activity has historically revolved around growth capital investments, though buyout transactions are expected to play a larger role in India's deal business as US and European private equity houses open offices in the nation. The stage was set three years ago when Warburg Pincus generated a highly profitable realization by selling a $560 million stake in Bharti Tele-Ventures.

KKR invested $250 million in Bharti Infratel, a subsidiary of Bharti Airtel Ltd., in February, a deal which marked the country's second largest investment but also reflects the traditional growth capital-style investments executed in India. In 2006, KKR made its first investment in India when agreed to buy a software unit of Flextronics International for $900 million.

Whether it's buyouts or growth capital infusions what is certain is that money is being put to work in India.

Private equity firms invested about $2.8 billion in 77 Indian companies in the second quarter, compared to 74 deals totaling $1.9 billion in the second quarter of 2007 and accounting for $6.3 billion worth of investment in the first half of the year, according to data released last month by Venture Intelligence, which is sponsoring an IT Services and business processing outsourcing conference in India on Aug. 28.

Meanwhile, the fundraising train for India-specific funds shows little signs of slowing down. In fact, it is picking up speed based on data from Washington industry trade association Emerging Markets Private Equity Association. India-centric funds raised $3 billion in the first half of the year, marking a 357% increase from the same period last year, according to the EMPEA.

The attraction of the country's business sector was highlighted earlier this month in a big cross-border strategic M&A deal: Japanese pharmaceutical company Daiichi Sankyo's agreement to acquire a substantial stake in Indian drug manufacturer **Ranbaxy** Laboratories.

With a GDP growth rate expected to total 8% in 2008, according to the International Monetary Fund, and large Indian companies generating 30% annual growth rates, it's no wonder that private investment firms want to get in on the action. Moreover, the country has a well developed stock market system with the Bombay Stock Exchange and other exchanges offering exit and additional capital-raising opportunities.

One area that is drawing a lot of investor interest within India is infrastructure. In April, 3i announced it had secured $1.2 billion for its India infrastructure fund. A year earlier, the UK firm established a partnership with the Indian government-owned India Infrastructure Finance Corporation Ltd. in order to work jointly on the financing of infrastructure projects like road improvements, airport construction, ports and other projects in India. The country expects that it will require at least $500 billion in infrastructure investment to meet its needs by 2012.

Meanwhile, political concerns and the recent bomb attacks in Bangalore and Ahmedabad have done little to diminish private equity interest in the country, say industry observers.

"Such incidents are not new to the country. Bombay, India's key financial center, has faced several such attacks and bounced back every time," says Venture Intelligence's Natarajan.

When it comes to where private equity firms find the staff to fill their ranks most foreign investment firms operating in India have brought their personnel talent from overseas, though they generally recruit locally to build their investment teams and generally come from outside the private equity industry itself, according to Sanjay Kapoor, country manager for New Delhi, India at Russell Reynolds. "Most recruitment has been from investment banks. There are a handful of [private equity] people who have gone through a whole business cycle and been through bull and bear markets, they're not easily available."

Kapoor, who recruits senior executives across various industries including financial services, professional services and outsourcing, real estate, private equity and venture capital funds, says there is strong demand for personnel slots in the infrastructure and real estate investment space in India. He also says that the interest to get into the private investment business is strong on the part of investment banking professionals in India. "Most investment professionals on the sell-side want to get into private equity or private equity-backed companies."

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[Return to List](#cite_id_97)

97 of 200 DOCUMENTS

Africa News

**July** 31, 2008 Thursday

**Africa;**

**Daily HIV/Aids Report**

**BYLINE:** Kaisernetwork.org

**LENGTH:** 3939 words

Politics and Policy

President Bush Signs PEPFAR Reauthorization Bill

[Jul 31, 2008]

President Bush on Wednesday signed into law legislation (HR 5501) that reauthorizes the President's Emergency Plan for AIDS Relief through 2013, the Washington Post reports (Eggen, Washington Post, 7/31).

The House last week approved the measure 303-115. The legislation allocates a total of $50 billion -- $48 billion of which goes to PEPFAR and $2 billion of which goes to American Indian issues. The bill also includes an amendment intended to increase oversight of the Global Fund To Fight AIDS, Tuberculosis and Malaria and encourage cost-sharing and transition strategies as part of agreements with countries that receive PEPFAR aid. The bill does not mention family planning programs.

The measure also includes a provision that more than half of the program's aid go toward HIV/AIDS treatment and care. In addition, it overturns an existing law that requires one-third of prevention funds be spent on abstinence and fidelity programs, instead requiring a report to Congress if countries do not spend half of prevention money on such programs. The bill also directs 10% of funding to programs for orphans and vulnerable children, as well as allocates $2 billion for the Global Fund in fiscal year 2009. The legislation contains an existing requirement that organizations receiving PEPFAR aid have a policy that opposes commercial sex work. The bill creates links between HIV/AIDS and nutrition programs and sets a target of recruiting 140,000 health care workers. In addition, the measure allocates $5 billion for malaria programs and $4 billion for TB initiatives (Kaiser Daily HIV/AIDS Report, 7/28).

Although the bill also includes a provision that eases U.S. HIV/AIDS travel restrictions, it is "unclear" whether HHS plans to address the restrictions in the near future, the Los Angeles Times reports. HHS in 1987 placed HIV on a list of diseases barring entry into the U.S., according to the Times. Although that prohibition is separate from the congressionally imposed travel restrictions eased in the PEPFAR bill, federal health officials are "no longer bound by law to keep HIV on the list," the Times reports.

An HHS spokesperson did not return a call for comment on Wednesday. CDC -- which is under the jurisdiction of HHS and would make recommendations about the travel restrictions -- also could not be reached for comment, the Times reports. However, advocates of repealing the ban are "hopeful," according to the Times (Patel, Los Angeles Times, 7/31).

Bush, White House Comments

Bush at the signing ceremony said, "Defeating HIV/AIDS once and for all will require an unprecedented investment over generations. But it is an investment that yields the best possible return -- saved lives." He added that "HIV/AIDS is still one of the world's greatest humanitarian challenges, no question about it. But it is a challenge we're meeting" (Dunham, Reuters, 7/30). Bush noted that the goal for the new funding level is to prevent 12 million new HIV cases, provide more than two million people with antiretroviral drugs, support care for 12 million people and train at least 140,000 new health care workers (Euphrat, AP/Google.com, 7/30). "We are a compassionate nation," Bush said, adding, "And that's what this bill says loud and clear" (Washington Post, 7/31).

The White House in a statement said PEPFAR is "the largest commitment by any nation to combat a single disease in human history." When Bush "launched [PEPFAR] in 2003, about 50,000 people in all of sub-Saharan Africa were receiving antiretroviral treatment," the White House said, adding, "Today, PEPFAR supports lifesaving antiretroviral treatment for nearly 1.7 million people in the region and tens of thousands more around the world, from Asia to Eastern Europe" (AFP/Google.com, 7/30).

Other Reaction

Rep. Howard Berman (D-Calif.), who sponsored the bill, said its passage is a "tribute to what we can achieve in foreign policy when the cause is right and all parties work together in goodwill" (Washington Post, 7/31). House Speaker Nancy Pelosi (D-Calif.) praised the bill for taking the global fight against AIDS, TB and malaria "from the emergency phase to the sustainability phase." The new legislation "is our compact with developing nations across the globe," Pelosi said in a statement, adding, "It says that America stands with them in this fight, that our commitment will not waver and shows them America's true face of compassion." Eric Friedman, senior global health policy adviser for Physicians for Human Rights, said the legislation is "the boldest act of any wealthy nation in ameliorating Africa's disastrous health worker shortage." He also praised the bill for lifting the HIV/AIDS-related travel restrictions but criticized the legislation for not linking HIV services with family planning. "That allows HIV to go unprevented and undetected for years, until a whole family is infected," he said (AFP/Google.com, 7/30).

UNAIDS Executive Director Peter Piot said, "The generosity of the U.S. government has helped to truly transform the global response to AIDS and the course of the epidemic" (Reuters, 7/30). Bill and Melinda Gates, co-chairs of the Bill & Melinda Gates Foundation, in a statement said, "We congratulate President Bush and leaders in Congress for their achievement in getting PEPFAR reauthorized at an unprecedented level." They added, "This bill renews and strengthens America's commitment to the global fight against AIDS, TB and malaria." They noted that they are "encouraged by the act's strong emphasis on preventing new HIV infections," as well as lifting the travel restrictions (Gates Foundation release, 7/30).

Michael Weinstein, president of the AIDS Healthcare Foundation, also praised Bush for signing the reauthorization bill. "Passage of this historic legislation is a crucial turning point in the battle to control AIDS around the world," Weinstein said. He added, "We take our hats off to everyone who helped ensure that this lifesaving global AIDS bill became a reality" (AHF release, 7/30). Pamela Barnes, president and CEO of the Elizabeth Glaser Pediatric AIDS Foundation, said the signing of the bill into law "is a beacon of hope to millions around the world living with HIV/AIDS. It is an unmistakable signal of the United States' continued commitment to preventing new HIV infections in the countries most affected by the pandemic." She added that one of the "most significant challenges for the next five years is to scale up the delivery of [the prevention of mother-to-child HIV transmission] services, and to ensure that all infected children receive urgently needed antiretroviral treatment," adding, "We are committed to achieving the target in the PEPFAR legislation of reaching 80% of these women in the next five years" (Elizabeth Glaser Pediatric AIDS Foundation release, 7/30).

Serra Sippel, executive director of the Center for Health and Gender Equity, welcomed passage of the legislation; however, she said the group will "continue to be disappointed that despite the findings and recommendations issued by U.S. government agencies, a Democratic-led Congress is continuing to impose arbitrary funding directives to encourage abstinence-only programs over effective, comprehensive prevention interventions." She added, "With the amount of work that so many prevention advocates put into the reauthorization process, it is disheartening to see global AIDS prevention policy continue to emphasize ideology in the guise of political expediency" (CHANGE release, 7/30).

Wall Street Journal Examines Role of Generic Drugs in PEPFAR

In related news, the Wall Street Journal on Thursday examined how generic drugmakers, many of which are based in India, now "dominate" PEPFAR. Generics accounted for 57% of the $131 million the U.S. spent on PEPFAR in FY 2007, according to the Office of the U.S. Global AIDS Coordinator. Generics in 2005 accounted for 11% of PEPFAR's funding. In 2005, the U.S. had approved few generic drugs for PEPFAR, so "most of the money went to buy brand-name drugs that are often more expensive," according to the Journal. Some of the largest generic contributors to PEPFAR include Aurobindo Pharma, **Ranbaxy** Laboratories, Cipla and Aspen Pharmacare. PEPFAR's "shift to generics" during the past two years follows a Bush administration "decision to set up a special approval" at FDA for the medicines, which cannot be marketed in the U.S. because of **patent** and exclusivity regulations, the Journal reports. "It's pretty clear that the system is working well, and it protects African families just like American families are protected," Ambassador Mark Dybul, the U.S. global AIDS coordinator who administers PEPFAR, said. He added, "We pretty methodically did what we said we were going to do." **Ranbaxy** spokesperson Chuck Caprariello said that the "key is having affordable and accessible medicines, and I think the generic industry has made a contribution in a very positive way to PEPFAR."

PEPFAR's spending on brand-name drugs totaled about $56 million in FY 2007, a decrease from the $106 million spent in 2005. Some of the largest contributors of brand-name drugs to PEFPAR are Merck, GlaxoSmithKline and Abbott Laboratories, according to the Journal (Lueck, Wall Street Journal, 7/31).

The Christian Science Monitor on Thursday examined how PEPFAR is impacting other issues, such as food security, in Ethiopia. The Lancet also recently examined issues in the PEPFAR reauthorization bill.

Link to this story.

Global Challenges

HIV/AIDS Advocates Protest Stigma, Discrimination Ahead of AIDS Conference

[Jul 31, 2008]

HIV/AIDS advocates in Mexico City have begun protesting the problems of stigma, discrimination and a lack of access to antiretroviral drugs in Latin America ahead of next week's XVII International AIDS Conference in Mexico City, Agence France-Presse reports (Rosenthal, Agence France-Presse, 7/29).

According to VOA News, 17 people at the conference are expected to lead discussions that address issues -- such as stigma and discrimination -- that discourage people from being tested and accessing treatment. South African Justice Edwin Cameron is scheduled to lead a plenary session about the criminalization of HIV-positive people in some countries, which is fueling stigma against people living with the virus, according to VOA News.

According to the South Africa Supreme Court of Appeals, 11 African countries -- including Kenya, Liberia, Sierra Leone and Uganda -- have laws in place to prosecute HIV-positive people who do not disclose their HIV status to their partners, even if they do not transmit the virus (Eagle, VOA News, 7/29). In addition, although most countries in Latin America have laws that prohibit HIV-associated discrimination, people who violate the laws rarely are prosecuted, Agence France-Presse reports (Agence France Presse, 7/29).

Cameron said that such laws discourage people from being tested for HIV. "The point I will make at the conference is that those statutes, apart from their very broad and vague wording, are very bad for the central issue of the epidemic, which is getting treatment to people," Cameron said.

In addition, Adeeba Kamarulzaman, president of the Malaysian AIDS Council, is expected to host a discussion on legal obstacles to fighting the spread of HIV among injection drug users. Kamarulzaman said a lack of needle-exchange programs and methadone programs, as well as criminalization of injection drug use, are fueling the spread of HIV among IDUs and discouraging them from receiving HIV tests.

Pedro Cahn -- president of the International AIDS Society, which is convening the AIDS conference -- said the conference also will address criticism that efforts to increase HIV/AIDS prevention and treatment activities have taken away from efforts to build health systems in developing countries. Cahn said some people have claimed that the international community has put "too much money into the AIDS struggle" and is "weakening health care systems." Cahn said, "African health care systems were not OK before (the AIDS epidemic) and have become better after the opening of clinics," adding that the accusations are "absolutely not true."

Cahn added that advocates attending the AIDS conference likely will call for the integration of reproductive health services and treatment for tuberculosis and sexually transmitted infections into HIV treatment programs. Advocates have said such efforts would help meet the United Nations Millennium Development Goal of providing universal access to HIV prevention and treatment by 2010 (VOA News, 7/29).

Kaisernetwork.org is the official webcaster of the XVII International AIDS Conference in Mexico City. Click here to sign up for your Daily Update e-mail during the conference.

Link to this story.

Kenya's HIV Prevalence Increases to 7.8% in 2007, Report Finds

[Jul 31, 2008]

HIV prevalence in Kenya increased to 7.8% in 2007, a slight increase from the 6.7% prevalence recorded in 2003, according to a survey released by the government on Tuesday, the Associated Press reports. According to the Associated Press, the increase in the percentage of the population living with HIV likely is because of wider access to antiretroviral drugs.

The survey, titled "2007 Kenya AIDS Indicator Survey," was conducted by several organizations, including CDC, the World Health Organization and the Kenya Medical and Research Institute (Associated Press, 7/29). The survey cost about 400 million Kenyan shillings, or about $6 million, Kenya's Daily Nation reports (Gathura/Okwemba, Daily Nation, 7/29). The survey is based on tests conducted among 18,000 people between ages 15 and 64 for HIV and other sexually transmitted infections from August 2007 to May 2008 (Associated Press, 7/29).

According to the survey, about 1.4 million Kenyan adults are living with HIV/AIDS. In addition, four out of every five HIV-positive Kenyans are unaware of their status, and about two-thirds of the country's 37 million people have never been tested for the virus, the survey found. Fifty-seven percent of HIV-positive people reported that they had never taken an HIV test, and 26% said they were HIV-negative but later tested positive. Ibrahim Mohammed, chief of Kenya's National AIDS and Sexually Transmitted Infection Control Program, said that 16% of those tested did not want to know their status, 14% were unaware of the HIV test or where to receive one and 5% indicated that distance to testing clinics was a "major barrier" (AFP/Google.com, 7/29). Mohammed added that three out of five HIV-positive people are women and that uncircumcised men are three to five times more likely to contract the virus, compared with circumcised men.

Prime Minister Raila Odinga said the survey's finding that 50% of Kenyans used condoms and only 20% used a condom during their last sexual encounter is "alarming," the Associated Press reports. "There are now nearly 1.5 million Kenyans living with [the virus]. ... This is nothing less than a national crisis," Odinga said. He added, "The only way to reverse this epidemic is through prevention" (Associated Press, 7/29). Kenya's Health Minister Beth Mugo said, "We have made notable progress; however, HIV/AIDS rates among our families and communities remains unacceptably high and the impact severe" (AFP/Google.com, 7/29).

Link to this story.

Universities in East Africa To Take Part in Study Examining Impact of HIV/AIDS on Community

[Jul 31, 2008]

A study aimed at examining the effects on HIV/AIDS on universities in East Africa is scheduled to start in October, Tanzania's The Citizen reports. According to officials at the Inter-University Council for East Africa, the project initially will target 18 universities in Kenya, Tanzania and Uganda. The project -- which will cost about $700,000 -- will involve the East African Community through the Lake Victoria Basin Commission. It is receiving funding from the Swedish International Development Agency. According to the project's manager Doreen Othero, the African Medical and Research Foundation also will be involved with the study.

Othero said that the study will run for two months and that it is aimed at examining the severity of HIV/AIDS in university communities in the region. The study will focus on the Lake Victoria basin, which has a higher HIV/AIDS prevalence compared with other parts of the region, according to The Citizen. In addition, the basin has a high population density and is home to numerous cross-border activities, according to Othero. "The survey will provide relevant contextual information, which will be used for determining intervention mechanisms for improvement of management of the problem in the university communities in terms of all aspects of the pandemic," Othero said. IUCEA Executive Secretary Chacha Nyaigotti-Chacha said there are concerns that university communities, particularly students and teachers, are highly affected by HIV/AIDS. He added that the project might be expanded to more universities in the future.

Universities currently involved in the study are the universities of Dar es Salaam, Mzumbe, Sokoine, Tumaini, St. Augustine and Muhimbili in Tanzania; the universities of Makerere, Mbarara, Gulu, Islamic, Kampala International and Nkumba in Uganda; and the Jomo Kenyatta University of Agriculture and Technology, and the universities of Nairobi, Baraton, Moi, Masinde Muliro and Maseno in Kenya (Ubwani, The Citizen, 7/28).

Link to this story.

Vietnam Should Prioritize HIV/AIDS Prevention Programs, Deputy Prime Minister Says

[Jul 31, 2008]

Vietnamese local governments should prioritize HIV/AIDS prevention measures, particularly education and communication programs that target injection drug use among young people, Deputy Prime Minister Truong Vinh Trong said on Tuesday at a symposium on HIV prevention and drug detoxification in Hanoi, Vietnam, the Vietnam News Agency reports.

Trong -- who also serves as chair of a committee to combat and prevent HIV/AIDS, drug addiction and sex work -- encouraged the Ministry of Health to "upgrade" the prevention of HIV/AIDS to a national target. According to Health Minister Nguyen Quoc Trieu, about 55% of HIV-positive injection drug users in Vietnam were found to have contracted the virus through needle sharing. According to the Vietnam News Agency, rates of HIV in Vietnam have declined during the last six-month period compared with the same period one year ago. Six times more men are diagnosed with HIV compared with women in Vietnam, and people between ages 20 and 39 account for 83.7% of those people with the virus, according to the Vietnam News Agency (Vietnam News Agency, 7/29).

Link to this story.

Opinion

Responses to PEPFAR Reauthorization

[Jul 31, 2008]

Several newspapers and a journal have published commentaries in response to legislation to reauthorize the President's Emergency Plan for AIDS Relief. Summaries appear below.

Opinion Pieces

Rep. Barbara Lee (D-Calif.), San Francisco Chronicle: The PEPFAR reauthorization bill is a "landmark achievement that will save millions of people from certain death and prevent millions of new HIV infections in the developing world," Lee writes, adding, "Sadly, our commitment to fighting AIDS globally has not extended to the fight against AIDS here at home." It is "past time our government stopped turning a blind eye to our national AIDS epidemic," according to Lee, who adds, "Far greater support is needed for community responses to the epidemic in Black America, especially through the Minority AIDS Initiative." In addition, the U.S. "must develop a national AIDS strategy and fund HIV prevention initiatives designed for African-Americans," Lee writes. She concludes that HIV/AIDS is "not just a foreign policy issue. If we wish to show real global leadership on AIDS, then we must keep our commitments abroad and take care of our epidemic here at home" (Lee, San Francisco Chronicle, 7/30).

Wafaa El-Sadr and David Hoos, New England Journal of Medicine: "Since its inception, PEPFAR has faced criticism," El-Sadr of the Mailman School of Public Health and the College of Physicians and Surgeons at Columbia University and Hoos of the Mailman School write in an NEJM perspective piece. According to the authors, PEPFAR's "most vocal critics have focused on some of its prevention strategies," but "critics have also questioned PEFPAR's focus on HIV care and treatment." In addition, the program was "criticized for creating a vertical program with disease-specific goals, as well as a single-donor driven structure and strategy," the authors write. They add that despite PEPFAR's "verticality, the program has also been reasonably well integrated with the global and national responses to the HIV epidemic." The "key challenge for PEPFAR will be to maintain its sense of urgency and its razor-sharp focus on results -- factors that have resulted in remarkable achievements in the face of enormous challenges," the authors write, concluding, "The advances have been dramatic, but much remains to be done" (El-Sadr/Hoos, NEJM, 8/7).

Michael Gerson, Washington Post: The "bipartisan expansion" of PEPFAR, as well as the President's Malaria Initiative, is "significant in a number of ways," columnist Gerson writes in a Post opinion piece. The legislation is the "congressional affirmation of a major legacy of" President Bush, Gerson writes, adding that the bill's passage "displayed the reviled Democratic Congress at its best." In addition, the legislation "served to isolate and discredit that element of American politics that refines hatred of government to a toxic purity," according to Gerson, who adds that the "largest significance of this bill, or course, is human." Without the "amazing generosity of America, the challenge faced by" many families worldwide "would be a private holocaust of abandonment, mourning and despair," Gerson writes (Gerson, Washington Post, 7/30).

Letter

Rick Santorum, Washington Times: The PEPFAR reauthorization bill "preserves the PEPFAR program's successful founding principles, and it deserves the wide support it has achieved," Santorum, senior fellow at the Ethics and Public Policy Center, writes in a Times letter to the editor in response to a recent Times editorial. According to Santorum, it is "worth noting that the bill includes new ... accountability and transparency benchmarks" for the Global Fund To Fight AIDS, Tuberculosis and Malaria (Santorum, Washington Times, 7/30).

Link to this story.

Recent Releases in HIV/AIDS

GlobalHealthFacts.org Posts Latest Global, Country-Level HIV/AIDS Data; New Latin America, Mexico HIV/AIDS Fact Sheets Available

[Jul 31, 2008]

"Latest Global and Country-Level HIV/AIDS Data Now Available on GlobalHealthFacts.org," Kaiser Family Foundation: GlobalHealthFacts.org has been updated with country-level HIV/AIDS data to reflect the latest information released in the UNAIDS 2008 Report on the Global AIDS Epidemic. The Web site includes data on people living with HIV/AIDS and AIDS-related deaths displayed in tables, charts and color-coded maps, which can be downloaded for custom analyses. In addition, GlobalHealthFacts.org's new custom data sheet tool can be used to compare data across countries. Updated regional HIV/AIDS statistics also can be found on GlobalHealthReporting.org. Several Kaiser Family Foundation fact sheets have also been updated with the new data, and the Kaiser Family Foundation has produced new fact sheets on HIV/AIDS in Latin America and Mexico in preparation for next week's XVII International AIDS Conference (KFF release, 7/30).

Link to this story.

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[Return to List](#cite_id_98)

98 of 200 DOCUMENTS



The Guardian (London) - Final Edition

**July** 19, 2008 Saturday

**Israel's Teva buys US copycat drug rival for $7.5bn: Acquisition gives group extra European presence: Patent expiries heating up cut-price medicine market**

**BYLINE:** Andrew Clark, New York

**SECTION:** GUARDIAN FINANCIAL PAGES; Pg. 39

**LENGTH:** 600 words

The global leader in copycat drugs, Teva Pharmaceuticals, is taking over a US rival, Barr Pharmaceuticals, in a $7.5bn deal which continues a rapid spate of consolidation in the crowded industry for generic medicines.

The Israel-based company's purchase of Barr will put it further ahead of the pack as the world's biggest maker of generics - drugs for which developers' **patent** protection has expired, allowing rivals to fill the market with cut-price versions.

"We believe we are paying a fair price for a very good company with a great strategic rationale which will provide benefits for many years to come," said Teva's chief executive, Shlomo Yanai. He added that there was "minimal overlap between the two companies", although the deal is likely to be scrutinised by competition regulators.

Generics is a hot area in the drugs industry because a spate of blockbuster medicines are reaching the end of their **patents**. Among them are Merck's osteoporosis drug Fosamax, AstraZeneca's cancer treatment Casodex and Glaxo SmithKline's asthma medicines Advair and Serevent.

At the same time, there is intense political pressure to reduce the cost of healthcare, particularly in the US where retailers such as Wal-Mart are driving increasingly hard bargains for cut-price drugs.

Buying New Jersey-based Barr will give Teva an increased presence in central and eastern Europe, which are considered promising areas for healthcare spending.

Teva will also inherit Barr's expertise in women's healthcare - its products include two oral contraceptives, Seasonique and Seasonale, and a version of the morning-after pill.

The company became a global generics powerhouse two years ago when it bought another US business, Ivax. But it has suffered several setbacks recently including disappointing trial results for a new version of a multiple sclerosis drug, Copaxone.

Yoav Burgan, a drugs analyst at Leader Capital Markets in Tel Aviv, said: "Businesswise, the acquisition makes tons of sense for Teva."

Teva lost out recently in a struggle to buy Merck's generics business and Burgan said its management was under pressure to deliver: "All these circumstances intensified the incentive of Teva management to show off a very substantial and high quality acquisition such as Barr."

Several other deals have taken place recently between makers of copycat drugs. Japan's Daiichi Sankyo bought a stake in India's **Ranbaxy,** while Germany's Fresenius struck a deal to buy US firm APP Pharmaceuticals. Merck sold its generics business last year to Mylan Laboratories for euros 4.9bn (£3.9bn).

At present, the industry is relatively fragmented. Prices for drugs typically fall by as much as 80% once **patent** protection ends, as manufacturers fight to deliver the lowest price. But larger players are beginning to flex their muscles through acquisitions which suck up market share.

Ricky Goldwasser, an analyst at UBS, described Teva's purchase of Barr as "both strategic and operationally sound". In a research note, he said: "The combination allows Teva to even further establish its position in both the US and eastern European market, and boost its pipeline."

The purchase price for Barr of $7.5bn (£3.75bn) includes $1.5bn of debt. It valued Barr at $66.50 a share, sending the company's stock price leaping by 10% to $63.25.

Teva said the deal was likely to close by the end of the year. It suggested that the acquisition would enhance its earnings within three months of completion. The combined company will have operations in 60 countries employing more than 37,000 people. Between them, they generated sales of $11.9bn last year.

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[Return to List](#cite_id_99)

99 of 200 DOCUMENTS



The Independent (London)

**July** 19, 2008 Saturday

First Edition

**Teva to create generic drug giant in $7.5bn Barr buyout**

**BYLINE:** Alistair Dawber

**SECTION:** BUSINESS; Pg. 50

**LENGTH:** 460 words

The increase in merger deals involving generic drug companies has continued apace after Israel's Teva Pharmaceuticals announced it was buying its American rival Barr, the fourth-biggest group in the sector, for $7.5bn (£3.75bn).

The friendly deal will combine the generalist group Teva with Barr, which specialises in female healthcare, giving the merged company more than 500 products and sales worth $11.9bn. Teva will pay $66.50 for each share, which represents a 32 per cent premium to Barr's average share price over the past two years and 42 per cent above where the stock closed on Wednesday. The acquisition price also includes Barr's debt.

Teva hopes the deal will cement its place as one of the leading off-**patent** drugs producers in the US, as well as establishing its position in Europe. The combined group has as many as 70 **patent** challenges in the pipeline. "The combination of our two companies provides an outstanding opportunity strategically and economically: it will enhance our market share and leadership position in the US and key global markets," said Teva's chief executive Shlomo Yanai.

Andreas Theisen, an analyst at WestLB in Germany, said the deal comes as something of a surprise. "We would not have thought that Teva was interested in the US operation where it has undoubtedly been attracted to Barr's very specialised oral contraceptive business. The price looks pretty cheap at a multiple of just 12.7 times Ebitda, most deals in the past three or four years have come at around 15 to 16 times. This certainly leaves the door open for others to bid for Barr." According to Mr Theisen, the agreement includes a$200m break clause, which is payable to Teva if Barr withdraws from the merger.

Generic drugs companies operate by producing treatments that were originally developed by the branded sector, but where **patents** have lapsed. Increasingly, generics groups are challenging **patents** in the courts. Earlier this month, Teva was dealt as blow when a New Jersey district judge awarded Astra-Zeneca a summary judgment in a case where Teva had sought to set aside the **patent** protecting the schizophrenia drug Seroquel. Teva conceded it had breached AstraZeneca's copyright, but claimed the branded group had acted inequitably.

Yesterday's deal is the latest in a line of merger deals involving the generic drugs industry. Last month, Japan's third-biggest pharmaceuticals group, Daiichi Sankyo, bought a 35 per cent share in India's largest generic drugs maker, **Ranbaxy,** for $4.6bn. One analyst in London said that the latest wave of deals was nothing new. "We have been here before and historically these deals do not work very well," said the analyst. "The only merger that has succeeded in recent times was Novartis' buyout of Sandoz."

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**PUBLICATION-TYPE:** Newspaper

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[Return to List](#cite_id_100)

100 of 200 DOCUMENTS

Pharma Marketletter

**July** 17, 2008 Thursday

**Access to Medicines: index praises GSK, as Sanofi-Aventis argues commercial case**

**LENGTH:** 927 words

The issue of drug access in the less-developed parts of the world has provoked some discussion, especially in the run-up to the early-July G8 Summit in Japan. The Netherlands-based Access to Medicines Foundation has launched an index to encourage "socially responsible" financial institutions to invest in drugmakers on the basis of their compliance with certain criteria. Meanwhile, France's drug major, Sanofi-Aventis, has also provided the Marketletter with details of its own program to make pharmaceutical products more readily available in poorer countries.

The two biggest factors in determining a pharmaceutical company's score in the Access to Medicines Index each carried 20% of the overall tally. These were accountability combined with ethical policies and research into neglected diseases. Equitable pricing and the quality of manufacturing processes as well as of the finished product were each worth 15%. Licensing and **patent** policies, public policy advocacy, drug donations and philanthropy between them were worth 30% of the total.

Wim Leereveld, the Index' founder, said that social pressure will "prompt laggards into action." He claimed that cultural differences between Europe and the USA led to better scores for firms based in the former region.

The company with the best Index score of 4.5 was UK-based giant GlaxoSmithKline, with Denmark's diabetes specialist firm Novo Nordisk and three drug majors tied in second place on 3.9: the USA's Merck & Co, Switzerland's Novartis and France's Sanofi-Aventis. No Japanese firms were included in the Index, which was notable in ranking two India-based companies: Cipla (14th) and **Ranbaxy** Laboratories (16th) both with 2.7 points.

Methodology and data accuracy challenged

Teva, the world's biggest generic drug firm, responded by noting that some of the data used in the index were derived from non-governmental organizations that the Israeli firm donates its products to, ignoring some contributions. Teva's spokeswoman added that "most of the pharma companies listed are branded and, as such, their donation dollars will typically be much higher since generic prices are lower."

Jeremiah Norris, the director of the Center for Science in Public Policy at the US think-tank the Hudson Institute wrote to the Financial Times to raise questions about the valuation method used by the Index' compilers. He said: "it isn't obvious from [Mr Leereveld's] methodology whether he has been able to separate monetary value of products from their clinical value." One example of this is the relatively inexpensive Merck vaccine against river blindness, ivermectin, which has been donated at low cost for 20 years and led to benefits for millions of people. Dr Norris also countered Mr Leereveld's claim that drug firms score badly in terms of neglected disease R&D. Drug majors have invested considerably in the R&D and manufacturing for essential and new drugs in previously-neglected areas, he said.

Sanofi-Aventis' Access to Medicines program

Robert Sebag, Sanofi-Aventis' vice president for access to medicines, spoke to the Marketletter about the work undertaken by the French drug major worldwide. He believes the three best firms in this field are currently GSK, Novartis and Sanofi, partly reflecting their strength in vaccines research. Dr Sebag, who has extensive field experience of working with NGOs was keen to put across the two messages that, "the pharma industry is a mandatory partner" in helping to bridge the health care gap between the North and South, and the firm's Access to Medicines program "is not a philanthropic activity." Sanofi has selected seven areas for its program in which to press ahead: malaria; tuberculosis; sleeping sickness; leishmaniasis; epilepsy; mental health diseases; and vaccines.

Dr Sebag stressed that his financial target is to achieve neither profit nor loss and the unit should be considered one of three tiers in the French company's overall structure, the other two being patented and off-**patent** drugs. Sanofi inherited 24 projects in developing countries from its predecessor firms, which have been reorganized to ensure that the right facilities are in the optimal location and to ensure both economies of scale and a degree of economic generation in the targeted regions. For example, Dr Sebag noted, the main site for malaria research is now in Morocco.

In order to meet the World Health Organization's recommended target for the first-line treatment of malaria with artemisinin-based combination therapy, Sanofi developed a co-blister pack of amodiaquine and aretsunate for use in 20 African countries. However, despite being a drugmaker foremost, Dr Sebag explained that the basic problem was often the means of delivering or monitoring treatments. He acknowledged that, for some disease areas such as malaria, actual results of interventions are hard to measure. Insecticide-treated mosquito netting has been used for catching fish in some places, Dr Sebag said, but the donor, based on numbers distributed, may claim unwarranted successes.

However, a good example of a program where measurable results had already been achieved was sleeping sickness. In addition to distributing drugs at an accessible price, Sanofi committed $25.0 million over five years in 2001 to include surveillance and disease control. Dr Sebag said 14 million diagnostic procedures were carried out and 110,000 lives saved from the disease. He concluded that the entry of new business-like funders such as the Bill & Melinda Gates Foundation, would lead to better outcome measuring.

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[Return to List](#cite_id_101)

101 of 200 DOCUMENTS

The Age (Melbourne, Australia)

**July** 12, 2008 Saturday

First Edition

**Will this save millions of lives?;**

**HEALTH**

**BYLINE:** Simon Mann - Simon Mann is a senior writer

**SECTION:** INSIGHT; Pg. 3

**LENGTH:** 2917 words

Malaria is one of the world's most inexorable killers, claiming about 1.3 million people a year. Now a new drug, partly developed in Melbourne, may revolutionise the fight against the disease.

IT WOULD not be the first time that the Boeing 747 has been used to illustrate a point. But the analogy used by Melbourne scientist Professor Bill Charman is confronting - the number of children under five years of age who die from malaria daily could fill more than seven jumbo jets. That's the equivalent of a child dying every 30 seconds.

"Just terrible," says Charman, shaking his head.

Malaria kills about 1.3 million people a year. Many millions more become infected, mostly Africans and populations across Asia and South America. Right now, as many as 5 million people in Tanzania and Mozambique have the disease, caused by the bite of an infected female anopheles mosquito. Nearly 2 million people have it in India, 400,000 in Brazil, 200,000 in Indonesia.

Malaria, by numbers, is a nightmare. But in the hunt for a cheap and easy cure for one of the world's most relentless killers, the numbers 277 and 439 have assumed monumental significance and look to be cardinal signposts to a new way of battling global diseases.

Both numbers refer to variations of a stunning anti-malarial drug part-developed in the laboratories of Monash University, an ozonide dubbed "OZ" whose design started from the proven malaria fighter artemisinin, which is extracted from the wormwood plant Artemisia annua, used for centuries by the Chinese as a herbal remedy.

But the OZ compounds have been forced onto diverging paths by a combination of economics and necessity.

OZ277, launched with international fanfare in August 2004 with the promise of a simple three-day oral treatment for sufferers, continues through laborious human trials conducted by the big Indian pharmaceutical company **Ranbaxy**.

Now OZ439, developed as a next generation drug candidate and not yet paraded publicly, could well supersede its talented older sibling and provide medicine's silver bullet - a combined one-shot treatment and preventative drug, costing less than $1, a breakthrough that stands to revolutionise the fight against malaria.

Though the scientists who created OZ are deliberately cautious about 439's prospects, their new incarnation offers a compelling case for optimism. "Our confidence is high," says Charman, the head of the Monash Institute of Pharmaceutical Sciences and a driver of the project. "How you quantify (that optimism), I don't know."

Adds Professor Susan Charman, a partner scientist who specialises in drug design and development chemistry: "We're four years further on. We've got four years more knowledge. Right now, based on all the available data, OZ439 looks better than OZ277 . . . but there's a long way to go."

The wonderful story of OZ typifies the highs and lows of major drug discovery and development, and also the glacial speed at which such enterprise progresses.

It is a narrative in which science, philanthropy and big business intersect, one whose principal cast includes a unique partnership of scientists from Melbourne, Nebraska in the US and Basle in Switzerland, as well as a Geneva-based non-profit organisation that is a go-between for science and Big Pharma, and global donors headed by Microsoft founder Bill Gates, whose altruism comes in multimillion-dollar licks and who has sounded a clarion call for malaria's eradication.

OZ is also a story that challenges the convention of pharmaceutical behemoths spending billions of dollars on drug research in the hope of a once-in-a-lifetime lollapalooza: think Pfizer and the cholesterol-buster Lipitor, Ely Lilly and the anti-depressant Prozac. That model might be tolerated by developed economies seeking drugs to treat Western disorders. But it's unlikely to support the search for a cure for the ills of the world's poor, in communities that survive on a pittance and where drugs need to be supplied dirt-cheap.

Enter the Medicines for Malaria Venture, a non-profit "start-up" that carries the blessing of the World Health Organisation as well as some of the globe's biggest drug makers. Established at the start of the decade, MMV uses innovative public-private partnerships that connect academia with industry on a single-minded mission to beat malaria. It has 30 projects on its books.

"Last year just 17 or so new drugs were approved in the world," says Bill Charman. "Given the billions of dollars the pharmaceutical industry spends on research, that's a pretty ordinary return. I'd suggest the model isn't working." But MMV, spending just $50 million a year on its collaborative works, is providing a counterpoint.

Part of MMV's raison d'etre was growing concern that the world's anti-malarial weaponry was being steadily depleted by the malaria parasite's powerful ability to mutate and build resistance. Cheap, accessible medicines such as chloroquine, the synthetic quinine that for years led the fight, have all but lost their sting and health authorities have become increasingly protective of artemisinin lest it go the same way.

A dictum issued a few years ago by the world's leading public health body raised the stakes: WHO insisted that artemisinin-based treatments must be combination therapies - that is, delivered with a compatible second drug similar to treatments for AIDS and tuberculosis - thereby making it tougher for the parasite to fight back.

But the OZ project was largely driven by price and availability. Therapies using artemisinin derivatives were costing up to 10 times as much as standard medicines and were in short supply due to the vagaries of artemisia production. (The plant, which takes about 18 months to grow, is farmed mostly in China and Vietnam.) With demand for artemisinin-based treatments rising towards 200 million a year, what the world needed was a synthetic version that could be mass-produced.

"What we wanted was something that was completely synthetic," says Anna Wang of MMV. "Something that mimicked what artemisinin does. Otherwise you are left dependent on the weather, on farmers . . . and the cost is unstable."

MMV contrived a suitable partnership to crack artemisinin's code, its "arranged marriage" putting Bill and Susan Charman of Monash University together with renowned researcher Jonathan Vennerstrom of the University of Nebraska Medical Centre. The team included scientists from the Swiss Tropical Institute in Basle, with input from experts at neighbouring Hoffman-La Roche and from Fulcrum Pharma in the UK.

A complex partnership strung out across the globe might not have been manageable even 10 years ago. "Without email and FedEx I think it would be next to impossible," laughs Vennerstrom now.

The partnership was as careful a construction as a molecule itself, drawing on complementary expertise: Vennerstrom built the synthetic molecules that would be the foundation of OZ, the Swiss tested them in cultures in which the parasite was growing, while Monash University's Parkville laboratories worked on the drug's chemical and metabolic properties, fine-tuning the compound to make it more effective.

The scientists were never going to replicate the whole molecule that is artemisinin "because there were 12 or 13 steps and it was just not practical," Susan Charman says. "It would be far too expensive and too difficult."

What the team did learn was how to replicate in just a few steps the key part of artemisinin that delivers its anti-malarial clout, something that chemists call an endoperoxide bridge where two oxygen molecules link together. In the body, the oxygen atoms in the OZ drugs are programmed to react with iron that is released when the parasite feeds on infected blood cells, destroying the parasite in the process.

But this type of molecule is typically unstable, something the researchers had to overcome with their copy compound. Their end product, delivered after 277 painstaking attempts, was a synthetic peroxide that was stable and an ultra-efficient killer of the Plasmodium falciparum parasite, responsible for the most lethal strain of malaria.

The result drew worldwide acclaim. OZ277 immediately entered trials conducted by **Ranbaxy**, passing safety and toxicology tests with flying colours, before being tested on healthy human volunteers. "And it was terrific," Bill Charman says. "There were no adverse effects at doses much higher than we expected to be needed. It was a very safe, clean molecule.

"And phase one is where a lot of compounds will fail, because you can test them on mice and rats and dogs but, ultimately, there's only one species that you've got to get right. But we went through phase one and there weren't any serious issues at all."

OZ277 was headed for phase two, where it would be tested on malaria sufferers.

Meanwhile, the OZ team kept working on their potential world-beater "because drug discovery never stops", Susan Charman says. "You can always improve certain properties. It's just a continual process."

This is also where MMV's public-private model of drug development digresses from the general practice of Big Pharma. Producing a next-generation follow-up compound is not always the inclination of Big Pharma, whose research efforts are often diverted once a first compound becomes its candidate for clinical trials.

Being first out of the blocks can be critical in securing windfall returns. But being first can also mean rivals can track a new drug's progress through **patents,** allowing them to work quietly on copy compounds while the original drug is being trialled.

Pfizer's erectile dysfunction wonder-drug Viagra is an example. It was the first of its type, delivered in the late 1990s, but a next-generation version, Eli Lilly's Cialis, was on the market within four years.

"The problem is Pfizer had already invested in the Viagra brand," Bill Charman explains. "It doesn't want to have to come along later and say, 'Actually, we've got a better one'. So you don't tend to get 'Viagra 2', for instance. The company moves on looking for the next big thing."

But MMV doesn't work like that, because the profit motive is largely absent and its enterprise is partly supported by universities such as Monash and Nebraska that are looking for impact and a different kind of kudos from their research. Getting a prototype into the clinic allows its creators to watch for deficiencies and then correct them by creating superior compounds. In the case of the OZ program, 277 did, ultimately, have a few problems.

"We came to a crossroads," MMV's Anna Wang says. "We were fast-tracking 277 because we desperately wanted the synthetic version and because we didn't know when we would encounter resistance to the artemisinin class of drugs. I think at that point, around 2004, we were thinking that maybe by 2010 we could have this next-generation drug.

"But drug development is a risky business. When we got to phase two, where you actually test the drug on patients with malaria, we hit some hurdles. Basically, we thought we needed a certain amount of the drug to beat the malaria. In fact, it looked like we might need more, which would obviously have implications for the cost of the drug."

Because of the ongoing nature of their investigations, the OZ researchers were already looking at ways of ensuring that their new drug stayed in the bloodstream longer so that it could kill more of the parasites, more quickly.

But about the same time, the multinational team assembled in India for meetings with **Ranbaxy**. Almost by accident they had an epiphany.

One of the difficulties of treating malaria sufferers in Third World conditions is getting patients to complete a course of treatment. A seven-day program is fraught: nomadic people can lose track of their drugs, and sometimes adults who start feeling better after a few doses save the rest of the course in case their child gets sick.

OZ277 was promising to deliver that regimen in just three doses, a big improvement on the prevailing standard for most anti-malarial medicines. But the research team asked themselves why they hadn't gone all-out for a one-day cure.

"It was pretty obvious," Bill Charman says. "The issue for refugees is that some are arriving in camps already with malaria. But if you had a single oral dose . . . there's no compliance issue."

The two events conspired, and more than 100 compounds later, Susan Charman's team of 20 or so scientists in Melbourne had found a way of prolonging the life of the OZ compound, paving the way for a one-dose treatment. Further, the team was able to reconstruct the OZ molecule so that it also carried prophylactic qualities that were as effective as some of the widely marketed brands, but faster acting - something that the original artemisinin-based treatments did not have.

"We got our so-called Viagra-2," says Bill Charman with a laugh. And how!

The breakthrough upped the ante, creating an immediate dilemma for MMV, which was funding much of the OZ research and had awarded OZ277 its "project of the year" in 2001. Reluctantly, it withdrew support for 277 and **Ranbaxy's** trials, focusing its energy - and donor funds - on the new generation of ozonides that the research team was now producing, and by the end of 2006 the OZ team had won "project of the year" for a second time.

In the end, the team looked to be spoiled for choice. Several of the next-generation compounds looked terrific, but in March they finally chose number 439 as their new candidate for trials.

"I think for Susan and Bill, picking 439 was really difficult," MMV's Wang says. "There were at least two other compounds that looked similar but were a little bit different. But for them to say 'OK, we'll take this one', that's a bit like picking a horse in a race. You'd like to be able to pick two or three to be sure, but we're just not in a position to be able to (fund) that."

RIGHT now, 439 is being put through its - very preliminary - paces, being tested for safety in animals. But the team has already conducted early toxicology tests "and those have looked very good", Susan Charman says. But the switch to 439 means the researchers have lost time: they do not expect the new drug to be tested in malaria sufferers before 2010. All going well, it could hit the market by 2014.

Meanwhile, **Ranbaxy** is pushing ahead with OZ277, now coded RBx-11160. In a statement issued to The Age, it confirmed that phase-two trials were progressing in Thailand and India, and that regulatory approval had been sought for trials involving children in Kenya and Tanzania.

The scientists say it is possible that the two OZ therapies will both succeed. OZ277 could be destined for India's middle class if it does end up costing more than originally hoped, while a dirt-cheap 439 could be the hope of sub-Saharan Africa.

"Drug discovery is not an exact science," says Omaha-based researcher Jonathan Vennerstrom. "It's a bit like weather forecasting. Sometimes you're way off, sometimes you're somewhat accurate . . . but if you're getting good communication and good data sharing then that helps a lot."

Nor is it inconceivable that an even better OZ compound could emerge down the track. "One never knows," adds Vennerstrom. "And that depends upon the people who fund this MMV project. What their opinion would be if something goes wrong with 439. Do we view it as a serious liability to the whole class of compounds?"

Though the future can never be certain, that outcome seems unlikely. Says Anna Wang: "The whole class of compound is very, very potent. That we're sure of . . . I would say we are quite sure that something will come out of this class."

Simon Mann is a senior writer.

A Relentless Killer

IN THE BEGINNING

The word "malaria" is derived from the Italian for "bad air", reflecting ancient belief that it was caused by fetid air from swamps. Symptoms of the disease were first recorded more than 2000 years ago by Chinese therapists, but the parasite causing the illness was not identified until 1880, by a French army surgeon.

BREAKTHROUGH

Nearly 20 years later, a British officer in the Indian Medical Service worked out that the parasites were transmitted by mosquitoes.

First treatments for malaria were herbal, mostly. But Spanish missionaries in South America in the 17th century became aware of a tree bark used by indigenous Indian tribes that became the source of the anti-malarial medicine quinine. Many of the older, quininebased treatments are now less effective because of the parasite's ability to mutate.

THE CHALLENGE

Artemisinin, a comparatively new drug, based on a chemical extracted from a plant, remains a formidable opponent.

But it is expensive and in short supply.

More than 300 million people are infected with malaria each year. Malaria is responsible for more than 10% of all children's deaths in developing countries. It kills an estimated 1.3 million people a year.

HOW MALARIA KILLS

Malaria is caused by a parasite that is passed from one person to another through the bite of infected anopheles mosquitoes. The parasites migrate to the liver, where they mature before entering the bloodstream.

They then target red blood cells, which eventually rupture.

Symptoms including fever, headache, general aching, chills and vomiting appear 10 or so days after a person is infected. Left untreated, malaria can lead to seizures, lost consciousness and organ failure.

There are four types of human malaria but Plasmodium falciparum, one of the most common, is also the most deadly. It can be fatal within hours of the first symptoms emerging.

**LOAD-DATE:** July 11, 2008

**LANGUAGE:** ENGLISH

**GRAPHIC:** FIVE PHOTOS: Wonder vial: OZ439, a synthetic anti-malarial medication being developed at Monash University; BELOW: Monash researchers Bill Charman, Julia Morizzi, Francis Chiu and Susan Charman. PICTURES: PAT SCALA; Spotted mosquito Anopheles maeulipearis ; The malaria parasite spreading through blood and infecting red blood; Malaria parasites attacking red blood cell cells; BLOOD ILLUSTRATIONS BY DREW BERRY, THE WALTER AND ELIZA HALL INSTITUTE

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[Return to List](#cite_id_102)

102 of 200 DOCUMENTS

Investors Chronicle - magazine and web content

**July** 9, 2008

**AstraZeneca wins admirers**

**SECTION:** 0261-3115

**LENGTH:** 451 words

ANALYSIS: Favourable court decisions have made AstraZeneca's shares one of the best performers over the past four months. But analysts are divided on the shares.

While growing fears of a severe economic slowdown have hit stock markets in recent months, shares in pharmaceutical giant AstraZeneca have risen strongly. Its shares have returned 33.5 per cent in the past four months, compared to a 2.2 per cent dip in the FTSE All-Share Index.

Investors believe that AstraZeneca will continue to generate massive amounts of cash no matter what the economic conditions, while worries over generic competition have also diminished after important court decisions. Earlier this month, its shares shot up as much as 7 per cent on the day it secured a **patent** win for its $4bn (GBP2.02bn) a year anti-psychotic drug, Seroquel.

The ruling from Judge Pisano of the District Court of New Jersey protects AstraZeneca from generic drugs producers, Teva Pharmaceutical Industries and Sandoz (an arm of Swiss pharmaceutical, Novartis), which now won't be able to achieve US regulatory approval for their copies of Seroquel until the **patent** expires in 2011. It follows a favourable decision by the courts to protect AstraZeneca's **patent** on its $5bn a year ulcer treatment, Nexium.

Citigroup's view

Buy. We expect Teva and Sandoz to appeal Judge Pisano's ruling, but the case now seems heavily skewed in AstraZeneca's favour. Our current forecasts are based on settlement with Teva and a generic launch in early 2011, and we predict 2008 Seroquel sales of $2.9bn for the US and $4.4bn worldwide (14 per cent of group turnover). Overall revenues for the current year will hit $31.2bn, rising to $32.3bn the following year, which translates to EPS of $4.77 in 2008 and $5.22 the year after. Our price target is 2,550p.

Charles Stanley's view

Reduce. Ostensibly, this ruling, coming hard on the heals of the earlier favourable settlement with **Ranbaxy** over its Nexium product, should remove a potentially significant uncertainty and drive the share price higher as near-term sentiment improves. However, we retain our view that the news has no impact on earnings expectations. Longer term, Astra's operational issues remain undiminished by this development. Its late-stage product pipeline is insufficiently robust to make good the pressure on the top line as products move off-**patent** over the next decade.

We believe that AstraZeneca's safe haven status is secured by recent court decisions in its favour, and its 5 per cent dividend yield is outstanding value compared to the 3 per cent average of the market. At 2,352p, shares trade on a forecast PE of just under 10 - a 30 per cent discount to the sector - which is good value.

GoodValue

**LOAD-DATE:** July 16, 2008

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[Return to List](#cite_id_103)

103 of 200 DOCUMENTS



ICIS Chemical Business

**July** 7, 2008

**Land ofdiscovery INTRODUCTION: India is pushing into fresh territory by evolving from a commodity-driven drug market into a research-driven development center. But challenges abound**

**BYLINE:** Feliza Mirasol

**SECTION:** FEATURES

**LENGTH:** 1509 words

India's reputation as a hub for pharmaceutical research and development (R&D) is growing. The country's drug industry is famous for its skill in copying products developed elsewhere, but Indian companies, prompted by new **patent** laws, have begun discovery programs of their own and set their eyes on the global market for innovative drugs.

"There are Indian companies that are engaged in the discovery of their own products, and are offering these for licensing to third parties, even at very early stages," observes Enrico Polastro, vice president of global management consultancy firm Arthur D. Little. "These types of companies are 'active' in their own discovery activities."

"There are also other various Indian companies engaged in CRAMS [contract research and manufacturing services]," he adds.

An interesting move being noticed recently is that some Indian drug companies are spinning off their discovery activities from their manufacturing and marketing operations.

"Examples are Nicholas Piramal, Dr. Reddy's Laboratories, and **Ranbaxy**, which have spun off their discovery divisions in an effort to capture the interest of Western companies. This has been quite fashionable since the end of last year," says Polastro.

In addition, there are also service providers that are focusing only on contract development, medicinal chemistry, toxicology, and other narrow areas.

"I think most Western generic players are already doing a significant amount of bioavailability studies in India because it's cheaper, and it's easier if you want to do these studies during the period of **patent** exclusivity," Polastro says.

Innovators that once would source only raw materials from Asia are becoming more comfortable with the region.

"Global pharmaceutical companies are increasingly outsourcing early-stage drug discovery to China and India," says UK-based consulting firm Decision Resources. "This trend is not simply a matter of cost. Relocating these functions to China and India helps to gain access to enormous emerging markets."

The intellectual challenge

However, intellectual property (IP) protection remains a sticky, and often complicated, issue.

India's drug industry has historically been driven by the dynamics of the generic drug market. Now it must prove that it can respect **patent** exclusivity and protect the IP of innovator partners. So far, the results are mixed.

"**Patents** in India are still being overruled in the interest of affordability for the general population," Polastro notes, pointing to Roche's cancer drug Tarceva (erlotinib). The Swiss pharmaceutical company had applied for an Indian **patent** for Tarceva in 1996. In 2005, Indian regulatory authorities granted Roche the right to market the drug, and in 2007, Roche was granted an Indian **patent**. So when Mumbai-based Cipla launched Erlocip, a generic version of Tarceva, this past January, Roche immediately sued. In March, however, the Delhi High Court overruled Roche's Indian **patent** on Tarceva, clearing the way for the copy. Another hearing is scheduled for August 6.

"The argument [in India] is to make the product more affordable for the general population. As a result, originators are not comfortable with IP in India," Polastro explains. "Another issue is that there is a lot of labor turnover, and this puts IP at risk."

The situation is evolving. Regulatory authorities began recognizing drug **patents** in January 2005 to meet the terms of its membership in the World Trade Organization, (WTO) and Indian drug firms increasingly have an interest of their own in the international norms of IP protection.

In principle, at least, the country has a new **patent** plan and a promise to better protect IP rights. In practice, this has been difficult, as the Tarceva example demonstrates.

"India's development is entrepreneurial and market-driven [but] it must continue improving IP protection to attract additional global pharmaceutical company investment," says Decision Resources.

Indian contract research organizations (CROs) have benefited from trust engendered by the government's new IP protection laws. However, each firm on its own will still need to demonstrate that respect for intellectual property is part of its culture and ensured by its systems.

"Intellectual property protection in China and India is improving. Both countries are now bound by the WTO's IP rules, however global pharmaceutical companies (GPCs) continue to face IP hurdles. The development of local life sciences industries will help to improve the IP environment," says Decision Resources.

Attractive shores

Pharmaceutical companies have been moving R&D functions and operations to India, as well as China, only in recent years. In some cases, companies began offshoring their business, either relocating internal operations to these countries or establishing joint ventures with Indian or Chinese partners, but they are also outsourcing as well.

Driving these choices is the need to improve pharmaceutical R&D productivity and bring a larger number of drugs to market more efficiently, states Decision Resources.

Western pharmaceutical companies have typically tapped into CROs in both China and India to perform specific tasks in clinical development, data management, and preclinical toxicology studies. Now these CROs are moving upstream in the R&D value chain. They are increasingly offering their services in chemistry, assay development and even target identification, according to Decision Resources.

"This trend is a consequence of higher government investments in basic research and improved technology transfer between universities and industry," says the consultancy.

Both India's and China's governments are striving to create outsourcing opportunities. More importantly, they want to establish domestic high-tech industries and a high-value research base in lucrative therapeutic areas.

The nature of the relationship between Western pharmaceutical companies and Indian drug discovery service providers remains tentative, as drug discovery outsourcing to India is still in the early stages.

"I think the jury is still out," says Polastro. "And the same applies to China. I think at this stage, everyone is still searching their own way for the best solutions, feeling their way through the R&D dilemma."

He adds: "Another issue with IP, for example, is that everybody is moving into new territory, everybody is talking the game, but not many people have actually done it. So it remains somewhat theoretical."

Polastro also notes that some companies, such as European-headquartered pharmaceutical research firms Sanofi-Aventis and Novartis, have their own R&D activities in both China and India. "They are setting up shop with their own facilities and their own employees," he says.

Who's on the table

Leading Indian CROs include GVK Biosciences, Syngene, Sai Advantium and Accutest. Meanwhile, leading Indian hybrid companies - those offering contract services as well as conducting their own internal drug discovery - include Advinus Therapeutics, Avra Laboratories, Dr. Reddy's Laboratories, Jubilant Biosys, Suven Life Sciences and Nicholas Piramal, according to Decisions Resources.

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In May, GVK and Wyeth signed another research agreement to discover and develop drug candidates from prediscovered targets.

Also in May, US-based Merck established an alliance with India's **Ranbaxy** Laboratories for drug discovery and clinical development for new candidates in the antiinfectives therapy market. The deal, which has an initial five-year term, is potentially worth over $100m (?64m).

In June, **Ranbaxy** agreed to sell a majority stake to Japan-based Daiichi Sankyo in a transaction valued at roughly $8.5bn. **Ranbaxy** is known to be in Phase II clinical testing of what some are calling the next important antimalaria drug.

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The growing outsourcing markets of China and India are attracting Western companies such as Switzerland-based RCC Pharma and US-based Albany Molecular Research, Covance, and Charles River Laboratories.

Indian players have been getting more play in early drug discovery, giving them an edge over their Chinese peers. India is said to have far more experience from selling generic drugs and from having a track record of meeting the US Food & Drug Administration's standards, lending it a more mature market reputation for chemistry and drug discovery activities.

"Some Indian companies seeking to enter Western markets are contracting with Western CROs. This situation offers significant opportunities for Western CROs able to comply with US or European regulations," states Decision Resources.

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[Return to List](#cite_id_104)

104 of 200 DOCUMENTS



ICIS Chemical Business

**July** 7, 2008

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**SECTION:** FEATURES

**LENGTH:** 1558 words

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PARA::

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[Return to List](#cite_id_105)

105 of 200 DOCUMENTS

Birmingham Post

**July** 3, 2008, Thursday

1ST Edition

**AstraZeneca gets shot in the arm as court backs it in 'copies' case;**

**PHARMACEUTICALS**

**SECTION:** BUSINESS; Pg. 24

**LENGTH:** 331 words

Drugs giant AstraZeneca yesterday celebrated its latest victory in the battle to protect its most valuable medicines from cheaper, unauthorised copies.

The company sued two firms for trying to market generic versions of Seroquel, a treatment for schizophrenia and bipolar depression.

The drug was the Macclesfield-based firm's second best selling drug last year, generating revenues of EUR4 billion (pounds 2 billion). Astra brought the case against Israel-based Teva Pharmaceutical Industries and US drugs firm Sandoz, which both specialise in making generic medicines.

They were both seeking to produce versions of Seroquel before a **patent** ran out in 2011, Astra said, but the US District Court for the District of New Jersey granted the company's motion complaining its **patent** had been infringed.

The decision means Astra avoids a potentially costly and time-consuming trial scheduled to start next month.

The ruling comes three months after Astra settled with Indian pharmaceutical giant **Ranbaxy** over an attempt to make copies of Astra's best-selling ulcer pill Nexium. **Ranbaxy** also wanted to market cheaper versions before the firm's **patent** expired in 2014.

News of the Seroquel settlement boosted Astra's shares by six per cent yesterday.

Astra chief executive David Brennan said: "We are pleased with the court's decision to uphold our valid intellectual property.

"Seroquel remains an important part of our company's portfolio benefiting patients and physicians throughout the world."

Astra is understood to be pursuing dozens of similar cases at the moment. Panmure Gordon analyst Savvas Neophytou said: "AstraZeneca had suffered in recent years from the overhang of unexpected generic competition against its two biggest products, Nexium and Seroquel.

"We have been positive on the prospects of AstraZeneca prevailing against challenges, and welcomed the settlement with **Ranbaxy**.

The Seroquel decision today removes a second big overhang from the stock."

Astra's profits fell four per cent.

**LOAD-DATE:** July 2, 2008

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**PUBLICATION-TYPE:** Newspaper

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[Return to List](#cite_id_106)

106 of 200 DOCUMENTS

Chemical Week

**June** 23, 2008

**Pfizer and Ranbaxy Settle Lipitor Patent Dispute**

**BYLINE:** DR

**SECTION:** PHARMACEUTICALS & FINE CHEMICALS; Pg. 25

**LENGTH:** 284 words

Pfizer (New York) and **Ranbaxy** Laboratories Ltd. (Gurgaon) say they have settled their **patent** dispute involving Pfizer's Lipitor, the largest selling cholesterol-lowering drug worldwide with sales of $ 12.7 billion. The agreement provides **Ranbaxy** with a license to sell Atorvastatin, the generic version of Lipitor, in the U.S. starting November 30, 2011, and in Australia, Belgium, Canada, Germany, Italy, the Netherlands, and Sweden starting at various dates, the firms say. The agreement follows unconfirmed media reports earlier this month regarding the possibility of Pfizer making a hostile bid for **Ranbaxy** to stop **Ranbaxy** from launching generic Lipitor, a move that the agreement now makes unnecessary, recent reports say.

"This agreement provides certainty and visibility to the launch of **Ranbaxy's** Atorvastatin, with 180-day market exclusivity in the U.S. and an early entry in other markets," says Malvinder Singh, CEO and managing director of **Ranbaxy**. "This will make the world's largest-selling drug more accessible to patients, who will gain from the timely availability of an affordable quality option."

Pfizer has been defending Lipitor **patent** challenges by **Ranbaxy** worldwide since 2003. The agreement pertains solely to **Ranbaxy** and does not cover legal challenges to the Lipitor **patents** involving other generic manufacturers, Pfizer says.

"This agreement is a win-win-win because it is pro-patient, pro-competition, and pro-intellectual property," says Ian Read, president of Pfizer's Worldwide Pharmaceutical Operations.

However, litigation relating to Lipitor will continue between **Ranbaxy** and Pfizer in Denmark, Finland, Portugal, Romania, and Spain, the companies say.

**LOAD-DATE:** June 30, 2008

**LANGUAGE:** ENGLISH

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[Return to List](#cite_id_107)

107 of 200 DOCUMENTS

The Sunday Telegraph (LONDON)

**June** 22, 2008 Sunday

**India's generic prescription for Big Pharma CITY PROFILE Malvinder Mohan Singh's family has sold its stake in Ranbaxy, India's largest pharmaceuticals company - but not sold out on its dream of selling cheap, effective drugs to the world's poor. Andrew Cave reports**

**BYLINE:** Andrew Cave

**SECTION:** CITY; Pg. 7

**LENGTH:** 1596 words

'I HAVE always believed in a model of co-operation and competition at the same point in time,'' smiles Malvinder Mohan Singh. I'm not sure that's how his rivals in the world's pharmaceuticals industry would describe it.

**Ranbaxy** Laboratories, the Indian generic pharmaceuticals group where Singh, 35, is the youthful chief executive, has built its business success on finding ways past the **patents** that protect the world's most valuable drugs.

Is there a major drugs group in the world that hasn't had to contend with a **Ranbaxy** attempt to produce a cheaper generic version? He shrugs and doesn't think so. "We're very aggressive,'' he admits.

Hmm, co-aggression? Maybe this model is shaped on Singh himself. Sitting in his business suit, stripey tie and turban and talking about his philanthropic efforts to provide healthcare to under-served parts of India, one of the world's best-known Sikh businessmen seems the epitome of modern, caring capitalism.

There again, here he is talking about his sporting philosophy. "I play to win,'' he declares, citing his passions for tennis, hockey, football, cricket as well as athletics, in which the 35-year-old was a 100m runner and high jumper in his younger days.

Then there's his passion for collecting Indian art, which he is incredibly competitive about as well. "There was an auction at Christie's the other week where I was very keen to buy something, but at that time I was announcing our major deal,'' he confides. "It's a shame because I would really have liked to do it.''

At least the deal that got in the way was a piece of history itself as India's largest corporate transaction: the sale of the Singh family's 34.8 per cent stake in **Ranbaxy** to Japan's second largest drugs group, Daiichi Sankyo, which is making a tender offer for another 20 per cent stake, making the deal worth up to $4.6bn ( pounds 2.4bn). Singh, who is pledging to stay on as chief executive for at least five years, believes the deal creates a new corporate animal in the shape of a hybrid between a traditional pharmaceutical company and a generics manufacturer.

His thesis is this. The pharmaceutical majors are facing huge pressures of **patent** expiries of their multi-billion dollar blockbuster drugs. Research and development expenditure is rising but drugs groups are struggling to make up for **patent** expiries.

There are no new huge blockbuster products coming on to the market, which is denting revenues and profits of Big Pharma and prompting restructuring programmes and heavy erosion in market capitalisations.

The healthcare deficits of most Western economies and the enormous demand from markets in Africa that want affordable access to major drugs are adding to the pressure. At the same time, there's been rapid growth in the generics industry, where **Ranbaxy**, India's largest drugs group, now ranks amongst the world's top 10 companies and is capitalising on India's low-cost base and high research and development capabilities.

The natural answer, according to Singh, is for co-operative and collaborative arrangements between the traditional big pharmaceutical groups and the generics companies that have been busy nibbling their lunches.

"Big pharmaceutical and generic companies clearly have an avenue where they can partner and collaborate and leverage each other's strengths,'' he says.

"There's an opportunity to create a business model where you bring together innovation, over-the-counter medicine, branded genetics and commodity generics and have a much stronger presence in developed markets, emerging markets and underdeveloped markets.

"That's the logic and rationale and the commonality or thinking and vision between the chief executive of Daiichi Sankyo and me that led to the creation of a new business model.''

Gosh. He really does seem to want to co-operate with the kind of company he has been targeting for years. He does not see the irony in that. "I've always believed that we will continue to compete with generic companies and with innovation-based companies,'' he says, "and at the same time there is a significant opportunity to leverage each other's strengths to co-operate.

"**Ranbaxy** is probably the leading generics company that has formed multiple

risk-reward R&D partnerships with Big Pharma, so while we compete with them when we challenge their **patents**, we also do joint R&D together in discovery and development. **Ranbaxy** has also done many **patent** settlements.''

It certainly has. Over the past 18 months, it has settled five **patent** cases, including this year's deal with AstraZeneca over Nexium, the $5.2bn-a-year ulcer treatment that is the world second best-selling drug.

Then last week, **Ranbaxy** announced a settlement of its five-year-long **patent** lawsuit against Pfizer, maker of cholesterol-lowering Lipitor, the world's biggest drug with $12.7bn of sales last year.

The deal will keep the US drugs giant free from generic competition to Lipitor for three years, after which **Ranbaxy** will have

six-month exclusivity on a generic version of the treatment in the US. **Ranbaxy** also gets a licence to sell its version in seven other countries but litigation between the companies will continue in Finland, Spain, Portugal, Denmark and Romania.

Singh speaks about **patent** protection as precisely as his company's lawyers have sliced open **patent** agreements. He says he is a big believer in the sanctity of intellectual property, claiming that **Ranbaxy**, which sells its drugs in nearly 150 countries, operates 20 manufacturing plants in 12 countries and has a global workforce of 12,000, is India's largest R&D spender in India.

**Ranbaxy's** attacks on **patents** in the past, he says, related to a period before 2005 when India did not recognise **patent** protection on pharmaceuticals, while **patent** challenges by **Ranbaxy** since then are justified on the basis of exposing weak arrangements in the interests of making affordable healthcare accessible to all.

"I think those who would logically understand what the facts are would probably say that if there is a **patent** that's weak, if there is a **patent** that should not be there and a generic company comes in and proves that and invalidates that, they're doing a service to the consumer by bringing in a generic earlier, which is right,'' he argues.

"However, if a **patent** is strong and it is valid and it's right, it should be protected for a defined period of time. India is today completely globally compliant with what has to be done to respect intellectual property.''

Would he have formed his new

co-operative approach without that having happened? "Absolutely'' - Singh is adamant - "because this is the future model of what we believe will succeed at a global level.

"It's because we are a global company focused on generics and there's another company that's an innovative company and aligning their two strengths is a very substantial opportunity to create a model that will be far more successful in the future.

"Daiichi Sankyo is the 22nd largest pharmaceutical company in the world and **Ranbaxy** is around 50th. Together, we become the 15th largest pharmaceutical in the world.

"This is a defining moment for the industry because here onwards, the business model will change. Over the next few years, we will see more mergers between pharmaceutical companies and generics.

"Will all pharmaceutical companies therefore be hybrids in 10 years' time? He raises his eyebrows. "I wouldn't wait 10 years,'' he says ominously. "I would say that in three years, maximum, you will see this model.''

Nonetheless, the deal has aroused passions, both in Singh's family and in India. "It was highly emotional in India,'' he concedes. "**Ranbaxy** is the torchbearer seen as Indian's first multinational company. There was a sense of surprise. There has always been a huge sense of pride in **Ranbaxy** being Indian.

"My comment is that **Ranbaxy** was Indian, is Indian and will remain Indian. Our headquarters are there, most of our people are there and our facilities are in India. We remain listed in India. None of that changes.''

There is still a chance that the deal could come unstuck. Singh says there are no poison pill arrangements but won't comment on break fees if someone else comes in with an offer or on the extent to which **Ranbaxy's** individual partnerships with other drugs groups contain break clauses in the event of a change of control.

Neither is the crystallisation of about half the Singh family's $5bn fortune likely to mean the eldest son retiring to spend more time with his money.

The family still has two other businesses in private hospitals and financial services and Singh says he is considering setting up a private equity company with his brother Shivinder, who he says is so like him that the two often turn up to meetings wearing matching clothes.

"This is my passion, this is what I enjoy doing,'' he says. "This is what I have lived and have seen my grandfather and father do every day of my life. This is in my genes - it's in my blood.

"My grandfather started it [**Ranbaxy**] in 1961, my father took it global and I want to transform this company, taking it to a completely different level and making it stronger.

"Yes, it was an emotional decision to let go of the equity of the family because this is the third generation that I am leading. But at the same time, it was so imperative for the company that it made eminent sense to do it.''

Malvinder

Singh

**Ranbaxy**

Age: 35.

Married to: Japna with three daughters.

Homes: two houses in Delhi.

Interests: music, dancing, Indian art, photography.

Drives: Mercedes SC50 and Mercedes SC20.

Favourite Book: The Art of War.

Favourite Author: John Grisham

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**LANGUAGE:** ENGLISH

**PUBLICATION-TYPE:** Newspaper

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[Return to List](#cite_id_108)

108 of 200 DOCUMENTS

The International Herald Tribune

**June** 20, 2008 Friday

**Pfizer deal stalls sale of cholesterol generic**

**BYLINE:** Stephanie Saul - The New York Times Media Group

**SECTION:** FINANCE; Pg. 16

**LENGTH:** 790 words

For people with high cholesterol, the wait for a cheaper version of Lipitor has gotten longer. Pfizer has announced an agreement to head off generic competition for its flagship drug until November 2011.

The drug maker said Wednesday that it had settled **patent** litigation with **Ranbaxy** Laboratories, an Indian maker of generic drugs that had threatened to market its own version of Lipitor, the world's best-selling medicine.

The agreement delays **Ranbaxy's** generic version of Lipitor and is estimated to be worth billions of dollars in additional sales for Pfizer, which could have faced generic competition from **Ranbaxy** as early as March 2010.

Whenever it comes, a cheaper generic version of Lipitor would sharply cut Pfizer's sales of the drug, which were $12.7 billion last year.

Lipitor is priced at up to $3 a day, while a generic version might eventually sell for well below $1.

Pfizer did not disclose the terms of the agreement. But the company said it contained no provisions that would run afoul of the Federal Trade Commission, which has frowned on arrangements in which makers of name-brand drugs pay off generic manufacturers to keep them from entering the market.

The FTC has argued that such arrangements harm the public by inflating drug prices and has challenged them in court, with mixed results.

''We don't have any of the items that the FTC has identified as being of concern, such as reverse payments,'' said David Reid, acting general counsel for Pfizer.

In a conference call with investors and analysts Wednesday, Reid called the agreement ''pro-patient, pro-competition and pro-intellectual property.''

But Ronny Gal, a generic pharmaceutical analyst for the investment company Sanford C. Bernstein, said that the agreement clearly was not envisioned by the Hatch-Waxman Act, the 1984 law that meant to encourage generic drug competition.

''This is clearly a miscarriage of the law,'' Gal said, noting that the agreement will mean that consumers continue to pay branded pharmaceutical prices for Lipitor longer than necessary. Yet, Gal said, the agreement is probably fashioned in such a way that it will avoid FTC opposition.

Under terms of the deal, Pfizer also granted **Ranbaxy** the right to generic versions of Lipitor in seven countries, beginning at various times. Those countries are Canada, Belgium, the Netherlands, Germany, Sweden, Italy and Australia.

Reid said the company's agreements involved no payments to **Ranbaxy**.

But the deal also included another incentive for the generic manufacturer. Pfizer dropped its challenge to **Ranbaxy's** current sales of generic Lipitor in four other countries - Brunei, Malaysia, Peru and Vietnam - allowing those sales to continue.

The deal has the effect of extending Lipitor's market exclusivity by up to 20 months. The exact extension is unclear because the date of Lipitor's **patent** expiration has been a matter of dispute, with one **patent** expiring in March 2010 and another in June 2011.

The company had argued that Lipitor might be covered by **patents** extending into 2016, but analysts have said those are minor **patents** not likely to be upheld.

Either way, Gal said the extension would be worth billions of dollars to Pfizer, which has traded near decade lows this year.

The company has mounted an aggressive marketing campaign to defend its Lipitor brand against recent competition from simvastatin, a generic version of Zocor, a similar anti-cholesterol drug that lost **patent** protection in 2006.

Studies have shown that for many patients hoping to control cholesterol levels, simvastatin is a viable substitute for Lipitor, known generically as atorvastatin. A big difference between the two is that Lipitor costs $2.50 to $3 a day, while simvastatin can retail for 75 cents to $1 a day, or as low as 10 cents a day at some discount pharmacies.

As the first company to file with federal regulators to market a generic version of Lipitor, **Ranbaxy** has rights under the Hatch-Waxman Act to 180 days of generic market exclusivity. During that six-month period, the maker can price generic drugs fairly close to the brand-name version. Prices generally decline sharply when other generic competitors can enter the market.

The settlement agreement does not prevent other generic companies from challenging the Lipitor **patent**, but **Ranbaxy's** ''first filer'' rights in the United States eliminate much of the incentive to do so.

Pfizer currently faces a generic-Lipitor challenge in Canada from Apotex, a drug company in Toronto known for aggressively litigating **patent** cases.

Reid said that the settlement involved Lipitor and **Ranbaxy** **patent** disputes virtually worldwide with **Ranbaxy** and that it also covered Caduet, a Pfizer product that combines Lipitor with a blood-pressure medication, Norvasc.

**LOAD-DATE:** July 11, 2008

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**PUBLICATION-TYPE:** Newspaper

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[Return to List](#cite_id_109)

109 of 200 DOCUMENTS

Daily Deal/The Deal

**June** 19, 2008 Thursday

**Sanofi purchase of Zentiva hailed**

**BYLINE:** by Cheryl Meyer and Paul Whitfield

**SECTION:** M AND A; Deal International

**LENGTH:** 839 words

**HIGHLIGHT:** The Czech firm should help to shore up revenue for France's biggest drugmaker.

**Sanofi-Aventis SA**'s move Wednesday, June 18, to buy Czech firm **Zentiva NV** for $1.93 billion should help the company offset future financial losses caused by increasing generics competition.

"They are trying to shore up future revenue generation," said Damien Conover, equity analyst at Chicago's **Morningstar Inc.**, of Sanofi. "This is one area of growth because of its geographic location, and it should be pretty steady business for them, and helps offset some of the volatility they'll be facing."

Sanofi, France's largest drugmaker, bid about 30.032 billion Czech koruna for the three-quarters stake it doesn't already own of Czech generics group Zentiva, topping a rival offer by Czech financial firm **PPF Group NV**. Sanofi will offer Kcs1,050 per share in cash, 11% higher than a Kcs950 per share bid lodged May 1 by PPF. The offer values Zentiva at about $2.6 billion, almost 15% above its market value on April 30, the day before PPF made its offer.

The deal also values Zentiva at 1.8 times 2009 estimated sales and 18 times 2009 earnings per share estimates, according to **J.P. Morgan Securities Ltd.**analyst Alexandra Hauber. "At 18 times our 2009 EPS forecast, this is an expensive deal," she wrote in a Wednesday report. Still, she said, Zentiva, a maker of generic drugs to treat cardiovascular disease, pain and central nervous system disorders, should add up to 5% to Sanofi's sales. Zentiva employs about 6,500 people.

The French bid pitches Zentiva's two biggest shareholders against each other. Sanofi holds 24.9% of the group, a stake it bought two years ago. PPF and subsidiary Generali PPF Holding BV together hold about 19.2%.

Sanofi made its move a day after Anthiarose Ltd., another subsidiary of PPF, published details of its offer and said it could make a "more favorable" bid to win shareholder support. Zentiva, which trades on the Prague stock exchange but has headquarters in Amsterdam, said Tuesday it was considering PPF's bid and would hold a shareholder meeting to discuss the offer.

The following day, Zentiva acknowledged Sanofi-Aventis' announcement and said its board would meet to review it.

"Once the full details of the intended competing offer are published, Zentiva's board will issue its fully considered response in due course," it said. "In the meantime, shareholders are advised not to take any action in regards to the intended competing offer or the offer recently made by Anthiarose Ltd."

A Zentiva spokeswoman said the company would likely comment later Wednesday on Sanofi's offer.

Sanofi's move will help minimize losses on **patents** that are scheduled to expire within a few years. It will also give Sanofi a presence in Eastern Europe and Russia, where generics are popular due to their cheaper costs. Zentiva has operations in the Czech Republic, Slovakia, Russia, Romania, Poland and Turkey.

Recently, Sanofi received word that a generic anti-clotting drug manufactured by **Schweizerhall Holdings AG** was approved in Germany, pitting the generic against Sanofi's Plavix drug. Sources say the German approval likely means a generic in other European Union countries. Sanofi's anti-thrombotic drug, Lovenox, could also face generic competition when it goes off-**patent** in 2012. Generic competition has also dogged Sanofi's insomnia drug Ambien and cancer drug Eloxatin.

Sanofi might face further competition from rival drug giants. **Eli Lilly and Co.** could receive approval from the Food and Drug Administration on cardiovascular treatment Prasugrel this summer, and could take market share from Plavix, Conover said in a recent report. Plus, **Novartis AG** is expected to launch a meningitis vaccine to compete with Sanofi's Manactra.

Still, the company is in good shape, with dozens of products in its pipeline to address diseases with no current treatments, and 30 submissions of new products planned by 2010, Conover wrote. Its vaccine business is healthy, racking up sales of EUR2.8 billion ($4.4 billion) in 2007.

An acquisition of Zentiva would mark Sanofi's biggest move into the generic drugs arena, as the company now only receives 2% of its sales from generic products. In recent months, its major rivals, including **Daiichi Sankyo Co. Ltd.**, Japan's third-largest drug company by sales, have been expanding their generic drug operations. Daiichi in June said it would buy a majority stake in **Ranbaxy Laboratories Ltd.**, a generics firm that has built itself into India's largest drugmaker, in a deal valuing the target at around $8.5 billion.

Sanofi's offer values Zentiva at about 2.4 times its 2007 sales of Kcs16.67 billion. Daiichi is paying about 4.7 times **Ranbaxy's** sales.

Analysts expect completion of the Sanofi deal by January.

The company is receiving financial advice from French bank **BNP Paribas SA** and legal counsel from Paul Cronheim and Martin Van Olffen of Netherlands firm **De Brauw Blackstone Westbroek** as well as law firm **Glatzova & Co.** of the Czech Republic.

Zentiva is taking financial advice from **Merrill Lynch & Co.** and legal counsel from **White & Case LLP** and **Clifford Chance LLP**.

**URL:** http://www.TheDeal.com

**LOAD-DATE:** June 19, 2008

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[Return to List](#cite_id_110)

110 of 200 DOCUMENTS

The Globe and Mail (Canada)

**June** 19, 2008 Thursday

**Pfizer, Ranbaxy reach deal over U.S. generic version of Lipitor**

**BYLINE:** AVERY JOHNSON

**SECTION:** REPORT ON BUSINESS: THE WALL STREET JOURNAL; PHARMACEUTICALS; Pg. B13

**LENGTH:** 611 words

**Pfizer Inc.** struck a deal with Indian generic-drug maker **Ranbaxy Laboratories Ltd.** to keep a cheaper version of the blockbuster anti-cholesterol drug Lipitor off the U.S. market until November, 2011.

The agreement buys Pfizer chief executive Jeffrey Kindler about 20 additional months of full Lipitor revenue, currently running about $13-billion (U.S.) a year. **Ranbaxy's** challenge to Lipitor **patents** might have brought a generic competitor to Lipitor as early as March, 2010, causing sales of Lipitor to plummet quickly. The uncertainty over the **patent** expiration and Pfizer's lack of other drugs to replace Lipitor had sent the company's shares to their lowest level in more than a decade.

The settlement eases uncertainty for **Ranbaxy**, as well. Malvinder Singh, **Ranbaxy's** chief executive, said the pact both provides a firm launch date and ensures that his company will be the only one eligible to sell a generic version for 180 days after Lipitor's **patent** expires.

In return for delaying its launch until November ,2011, **Ranbaxy** secured the right to sell a copycat of Caduet - another subject of litigation between the companies - seven years before that drug's 2018 **patent** expiration. Caduet, a pill that combines Lipitor and the blood-pressure medicine Norvasc and had $568-million in 2007 sales, has been a disappointment for Pfizer.

The settlement also permits **Ranbaxy** to sell generic Lipitor slightly earlier than anticipated in some European countries; firms up launch dates in other big markets, including Canada and Australia; and resolves litigation between the companies in most other parts of the world.

But the agreement may still face significant hurdles, chief among them whether regulators will challenge the terms. The Federal Trade Commission may object to such deals if it determines they amount to payoffs by big drug makers to squelch generic competition. In recent years, the agency contested a pact between Bristol-Myers Squibb Co. and Apotex that delayed a copycat of the blood thinner Plavix, and moves by Cephalon Inc. that stalled generic challenges to the narcolepsy medicine Provigil.

Marc Brotman, head of Pfizer's antitrust group, said, "We do fully expect [the FTC] to take a look, as they should. But [this agreement] does not contain any of the things that the FTC has spoken out about recently regarding side deals, reverse payments, so this is simply a compromise on time of the **patent**."

Pfizer stock, which last week closed at its lowest price since 1997, crept up 5 cents in 4 p.m. composite trading on the New York Stock Exchange to $17.77 on yesterday's news.

Last week, Daiichi Sankyo Co., of Japan, announced plans to buy a majority stake in **Ranbaxy** for $3.4-billion to $4.6-billion. Ronny Gal, a generics analyst at Sanford C. Bernstein & Co., said **Ranbaxy** may have been motivated to settle with Pfizer to give the Japanese company more clarity about future sales of generic Lipitor. A **Ranbaxy** spokesman declined to comment on the speculation but said that the Daiichi Sankyo deal and the Pfizer settlement were negotiated separately and that the latter has been under way for a while.

David Reid, Pfizer's acting general counsel, hailed the deal as good for patients, competition and intellectual-property rights. In a call with investors and analysts, he said a much cheaper generic will now be available sooner than if **patents** protecting Lipitor through 2016 and 2017 had delayed **Ranbaxy's** hoped-for launch date.

But Wall Street analysts and intellectual-property experts largely discounted the importance of those later **patents**, which protect the processes for making the drug rather than its core composition.

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**LANGUAGE:** ENGLISH

**PUBLICATION-TYPE:** Newspaper

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[Return to List](#cite_id_111)

111 of 200 DOCUMENTS

The Irish Times

**June** 19, 2008 Thursday

**In short**

**SECTION:** FINANCE; Other Stories; Pg. 20

**LENGTH:** 517 words

Today's other stories in brief

**Icon surges 8% on bonus issue plans**

Shares in clinical research, pharmaceutical and biotechnology company Icon surged by nearly 8 per cent to EUR 47.50 yesterday following the company's announcement of plans to double its capital through a bonus share issue.

If the move is ratified by shareholders, the company will issue one new ordinary share for each ordinary share held by shareholders. Icon said that the bonus share issue would increase the liquidity and marketability of the stock.

**Bank chiefs in market for shares**

Bank of Ireland chief financial officer John O'Donovan spent EUR 67,500 buying 10,000 shares at EUR 6.75 each on Monday.

AIB non-executive director Stephen Kingon, chairman of Invest Northern Ireland, spent EUR 50,940 buying 4,500 shares at EUR 11.32 each on Tuesday.

**Northern Rock may take legal action**

Northern Rock confirmed yesterday that its new bosses have launched an investigation into whether legal action can be taken against the now nationalised bank's former board.

Executive chairman Ron Sandler has instructed the bank's lawyers, Freshfields, to review the previous board's conduct during its time presiding over Northern Rock and its near-collapse last autumn. **- (PA)**

**Equity groups in fundraising fall-off**

Fundraising by European private equity groups fell by almost a third last year, indicating that investors pulled back sharply from the buyout market for the first time in five years, according to a report published today.

Private equity groups raised EUR 79 billion ($122 billion) in Europe last year - **(Financial Times service)**

**Slowdown in sales at Sainsbury**

J Sainsbury, the third-largest UK supermarket chain, reported slower first-quarter sales growth as higher living expenses cut into spending on food and clothes.

Sales gained 3.4 per cent, excluding petrol, at stores open at least a year in the three months ended June 14th, the London-based company said yesterday. - **(Bloomberg)**

Sanofi-Aventis to bid for Zentiva

French drugmaker Sanofi-Aventis plans to make a 40.04 billion crown (EUR 1.7 billion) offer for Czech drugmaker Zentiva, trumping a bid from financial group PPF.

The move would take Sanofi deeper into the field of generic drug production, an area which has traditionally been shunned by large pharmaceutical companies. - **(Reuters)**

**Pfizer settles case with Ranbax**

Pfizer, the US-based pharmaceutical company, yesterday agreed a deal with **Ranbaxy** of India that ends the uncertainty over the **patent** expiry of Lipitor, the world's top-selling medicine.

**Ranbaxy** has settled most of its worldwide litigation with Pfizer. **- (Financial Times service)**

**Gazprom's EUR $64m European exports**

Russian gas export monopoly Gazprom expects to generate a record $64 billion on export sales to Europe in 2008, some 62 per cent more than in 2007, as energy prices beat new records, the company said yesterday.

In 2007, Gazproms export sales stood at $39.5 billion. Gazprom, the worlds largest gas producer, supplies a quarter of Europe's gas needs. The firm said it saw its average gas export prices at around $401 per 1,000 cubic metres this year.

**LOAD-DATE:** June 19, 2008

**LANGUAGE:** ENGLISH

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[Return to List](#cite_id_112)

112 of 200 DOCUMENTS

National Post's Financial Post & FP Investing (Canada)

**June** 19, 2008 Thursday

National Edition

**Lipitor monopoly to end in 2011; Indian drug maker Ranbaxy's settlement with Pfizer will lead to a flood of lower-cost generics on the U.S. market**

**BYLINE:** Ransdell Pierson, Reuters

**SECTION:** FINANCIAL POST; Pg. FP16

**LENGTH:** 850 words

**DATELINE:** NEW YORK

NEW YORK -Pfizer Inc. said yesterday that **Ranbaxy** Laboratories Ltd. can begin selling a U. S. generic form of its Lipitor cholesterol fighter by late 2011 under a settlement deal, some five months later than Wall Street expectations.

Industry analysts have long expected Lipitor's U. S. marketing exclusivity to lapse no later than June, 2011, and for cheaper generic forms of the world's bestselling drug to then immediately flood U. S. drugstores.

But under Pfizer's settlement with India's **Ranbaxy**, which has long challenged Lipitor's **patents** in the courts, U. S. patients will not have access to **Ranbaxy's** copycat product until Nov. 30, 2011.

Pfizer's shares rose 3.8% to US$18.40 in premarket trading. **Ranbaxy** closed up 2.9% at a three-year high of 598.20 rupees in Mumbai on speculation the company would reach a Lipitor settlement with Pfizer. Japan's DaiichiSankyoCo. last week said it would pay up to US$4.6-billion for control of **Ranbaxy**.

The delay in Lipitor generics would buy a little extra time for Pfizer, whose earnings are expected to plunge once a copycat form of its US$12-billion-a-year flagship product arrives and starts hammering away at Lipitor sales.

Asked if the delay could spark a backlash among patients and insurers who favour cheaper generics, David Reid, Pfizer's acting general counsel, said, "We're pleased with this settlement and we actually think it is pro-patient, pro-competitive and pro-intellectual property."

"It was best to bring certainty for both organizations," Malvinder Singh, **Ranbaxy** chief executive, said in an interview at **Ranbaxy's** London office.

"The biggest part for us is in the United States, where we will launch with certainty and without any risk."

Mike Krensavage, principal of Krensavage Asset Management LLC, said investors had been expecting Lipitor's marketing exclusivity to lapse as soon as March, 2010, but no later than June, 2011, depending on expiration times of two important Lipitor **patents**.

"Pfizer is a more attractive company today because this deal would delay Lipitor generics from five to 20 months, and spare Pfizer US$3-billon to US$11.7-billion in lost Lipitor sales over that period," Mr. Krensavage said, predicting the settlement would ease uncertainty among Pfizer investors.

Pfizer, whose shares are at a 10-year low due to anemic revenue from its other medicines and worries about Lipitor's looming **patent** expiration, also described the deal as a potential balm to its long-suffering shareholders.

**Ranbaxy**, as the first to seek approval of generic Lipitor, would be entitled under federal law to 180 days of marketing exclusivity before other generics could be introduced, Mr. Reid said in an interview.

U. S. prices of branded medicines typically fall 20% or more once the first generic hits the market, and can tumble 80% or more after other generics are launched.

The deal, while ending Pfizer's long-standing attempts to block **Ranbaxy's** product in the United States, would leave Pfizer free to eventually launch its own authorized generic form of Lipitor, Mr. Reid said.

Mr. Reid said the agreement would benefit consumers because some less-well-known Lipitor **patents** extend as far out as 2017, and could have blocked generics until then. Analysts, however, have discounted that possibility.

The settlement will also entitle **Ranbaxy** to begin selling generic versions of Caduet -- a Pfizer drug that combines Lipitor with the company's Norvasc blood-pressure treatment -- in the United States by November, 2011.

Although Pfizer will not pay **Ranbaxy** any monies under the deal, Mr. Reid said **Ranbaxy** would profit because its U. S. generic now has a guaranteed path and because Pfizer will drop efforts to stop ongoing sales of its Lipitor generics in Malaysia, Brunei, Peru and Vietnam.

The arrangement would also allow **Ranbaxy** to sell generic Lipitor in Canada, Belgium, the Netherlands, Germany, Sweden, Italy and Australia near the time of respective **patent** expirations in those countries.

**Patent** battles between the companies over Lipitor would continue, however, in Finland, Spain, Portugal, Denmark and Romania, Pfizer said.

The deal would also end ongoing U. S. **patent** disputes between the companies relating to Pfizer's Accupril blood pressure drug, and a dispute in Ecuador involving Pfizer's Viagra anti-impotence pill.

Although Pfizer will submit the deal to the U. S. Federal Trade Commission, Mr. Reid said it does not require the agency's approval.

The FTC in February filed suit against Cephalon Inc., alleging the U. S. biotechnology company broke the law by paying generic drug makers to keep copycat versions of its Provigil sleep-disorder medicine off the market.

The agency has been battling similar agreements among drug makers for years, arguing they violate antitrust law and keep drug prices high.

Mr. Reid said Pfizer's agreement with **Ranbaxy** should not raise such concerns at the FTC because it involves no payments and complies with all applicable laws.

Last week, India's Business Standard newspaper said Pfizer may bid for **Ranbaxy**, countering Daiichi's offer. Pfizer has declined to comment on the speculation.

**LOAD-DATE:** June 19, 2008

**LANGUAGE:** ENGLISH

**GRAPHIC:**

Color Photo: Manpreet Romana, AFP, Getty Images; **Ranbaxy** CEO Malvinder Singh, left, is in talks with Takashi Shoda, CEO of Daiichi Sankyo Co., over the Japanese company's US$4.6-billion bid for control of the Indian drugmaker. **Ranbaxy** has been cleared to market a generic version of Lipitor in the United States beginning in late 2011. ;

**DOCUMENT-TYPE:** Business

**PUBLICATION-TYPE:** Newspaper

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[Return to List](#cite_id_113)

113 of 200 DOCUMENTS

The New York Times

**June** 19, 2008 Thursday

Late Edition - Final

**Settlement Delays a Generic Lipitor For Many Months, a Boon to Pfizer**

**BYLINE:** By STEPHANIE SAUL

**SECTION:** Section C; Column 0; Business/Financial Desk; Pg. 1

**LENGTH:** 1026 words

For people with high cholesterol, the wait for a cheaper version of Lipitor just got longer. Pfizer announced an agreement Wednesday to head off generic competition for its flagship drug until November 2011 -- up to 20 months later than many analysts had been expecting.

The drug maker settled global **patent** disputes with **Ranbaxy** Laboratories, a generic drug maker in India that had threatened to market its own version of Lipitor. The cholesterol medication is the world's top drug, with $12.7 billion in sales last year.

By delaying **Ranbaxy's** generic version of Lipitor, which might have been sold as early as March 2010, Pfizer has won extra time for exclusive sales of Lipitor, potentially totaling billions of additional dollars. Lipitor's current price can exceed $3 a day, while a generic version might eventually sell for well below $1.

**Ranbaxy** said it had agreed to the settlement partly to avoid the uncertainty of continuing to fight Pfizer's **patent** claims in court after years of litigation.

''This brings closure to a number of ongoing **patent** lawsuits and provides certainty and visibility to the launch of **Ranbaxy's** generic atorvastatin,'' said Dr. Malvinder Mohan Singh, the chief executive, referring to generic Lipitor.

As part of the agreement, Pfizer granted licenses to **Ranbaxy** authorizing the company to sell generic Lipitor in seven other important pharmaceutical markets: Australia, Canada, Belgium, Germany, Italy, the Netherlands and Sweden.

The deal will let **Ranbaxy** sell its drug in those seven countries two to four months before **patents** expire, according to Chuck Caprariello, a spokesman for **Ranbaxy**.

That could potentially mean that generic Lipitor will become available in Canada earlier than in the United States. But the dates **Ranbaxy** will begin marketing in Canada and the six other countries were not disclosed.

Pfizer also dropped its challenge to **Ranbaxy's** current sale of a generic Lipitor in four other countries -- Brunei, Malaysia, Peru and Vietnam -- allowing those sales to continue.

Both companies said the agreement did not involve any payments.

Pfizer, based in New York, said the agreement contained no provisions that would run afoul of the Federal Trade Commission. The agency has frowned on arrangements in which makers of name-brand drugs pay off generic manufacturers to keep them from entering the market.

The F.T.C. has argued that such arrangements, called reverse payments, harm the public by inflating drug prices and the agency has challenged them in court, with mixed results.

''We don't have any of the items that the F.T.C. has identified as being of concern such as reverse payments,'' David Reid, Pfizer's acting general counsel, said in a conference call with investors Wednesday morning. During that call, Mr. Reid called the agreement ''pro-patient, pro-competition and pro-intellectual property.''

Jonathan D. Leibowitz, an F.T.C. commissioner who has voiced particular concern about agreements that drive up pharmaceutical costs, said the agency would review the settlement.

''Not every agreement between a brand company and a generic to settle a **patent** dispute is going to violate the antitrust laws,'' Mr. Leibowitz said, ''but we're certainly going to take a very close look at this deal.''

Ronny Gal, a generic pharmaceutical analyst for the investment company Sanford C. Bernstein, said such an agreement clearly was not envisioned by the Hatch-Waxman Act, the 1984 law meant to encourage generic drug competition.

Mr. Gal said that the agreement meant that consumers would continue to pay branded pharmaceutical prices for Lipitor longer than necessary.

Yet, Pfizer has been more cautious in antitrust matters than many of its competitors and Mr. Gal said the agreement was probably fashioned in such a way that it would avoid F.T.C. opposition.

Shares of Pfizer, which has recently traded near its lowest point in a decade, ended the day up 5 cents at $17.77.

While the deal has the effect of extending Lipitor's market exclusivity by up to 20 months, the exact extension is unclear. The date Lipitor loses market exclusivity has been a matter of dispute, with one **patent** expiring in March 2010 and another in June 2011.

The company had argued that Lipitor might be protected by **patents** expiring in 2016 and 2017 but analysts have said those are minor **patents** not likely to be upheld.

In any case, Mr. Gal said the extension would be worth more than a billion dollars to Pfizer. Analysts also said the deal probably means that Pfizer can preserve its 7 percent dividend for now.

''Inasmuch as Lipitor generics are delayed and this remedies the matter, its dividend should be secure for a bit longer,'' Dr. Tim Anderson, a pharmaceutical analyst for Sanford C. Bernstein, said in a note to clients.

Pfizer has mounted an aggressive marketing campaign to defend its Lipitor brand against recent competition from simvastatin, a generic version of Zocor, a similar anticholesterol drug that lost **patent** protection in 2006.

Studies have shown that for many patients hoping to control cholesterol levels, simvastatin is a viable substitute for Lipitor, known generically as atorvastatin. A big difference between the two is that Lipitor costs $2.50 to $3 a day, while simvastatin can cost 75 cents to $1 a day, or as low as 10 cents a day at some discount pharmacies.

As the first company to file with federal regulators to market a generic version of Lipitor, **Ranbaxy** has legal rights to 180 days of generic market exclusivity. During that six-month period, the maker can price generic drugs fairly close to the brand-name version. Prices generally decline sharply when other generic competitors enter the market.

The settlement agreement does not prevent other generic companies from challenging the Lipitor **patent**, but **Ranbaxy's** ''first filer'' rights in the United States eliminates much of the incentive to do so. Shares of **Ranbaxy** were up 2.6 percent Wednesday.

The settlement also allows **Ranbaxy** to market a version of Caduet, a Pfizer product that combines Lipitor with a blood-pressure medication, Norvasc.

**URL:** http://www.nytimes.com

**LOAD-DATE:** June 19, 2008

**LANGUAGE:** ENGLISH

**GRAPHIC:** PHOTO: The cholesterol medication Lipitor is the world's top drug, with $12.7 billion in sales last year.(PHOTOGRAPH BY PAUL SAKUMA/ASSOCIATED PRESS)(pg. C2)

**PUBLICATION-TYPE:** Newspaper

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[Return to List](#cite_id_114)

114 of 200 DOCUMENTS

Pharma Marketletter

**June** 19, 2008 Thursday

**Pfizer to settle patent disputes with Ranbaxy**

**LENGTH:** 143 words

Global drug giant Pfizer has entered an agreement to settle most of its **patent** disputes with Indian generics manufacturer **Ranbaxy**. This ends five years of legal disputes over Pfizer's principal drug, blockbuster cholesterol-lowerer Lipitor (atorvastatin). **Ranbaxy** will gain the rights to market the first legal copy-version of atorvastatin worldwide. Malvinder Mohan Singh, chief executive of **Ranbaxy** told the UK Financial Times that his firm may be able to begin marketing the drug in Canada by the end of this year. Best of all, **Ranbaxy** will gain 180-day exclusivity on its copy version in the US market as the first to produce the generic drug, once its license to do so begins in 2011. The Indian company is in the process of being acquired by Japanese drugmaker Daiichi Sankyo, but Pfizer is rumored to be considering a counter-offer (Marketletter June 16).

**LOAD-DATE:** June 19, 2008

**LANGUAGE:** ENGLISH

**PUBLICATION-TYPE:** Newsletter

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[Return to List](#cite_id_115)

115 of 200 DOCUMENTS

WALL STREET JOURNAL ABSTRACTS

**June** 19, 2008 Thursday

**pfizer buys more time for lipitor**

**BYLINE:** Avery Johnson

**SECTION:** Section B; Column 1; Pg. 1

**LENGTH:** 65 words

Pfizer Inc reaches deal with **Ranbaxy** Laboratories Ltd to keep cheaper version of its blockbuster cholesterol drug Lipitor of US market until November 2011; deal buys Pfizer about 20 additional months of full Lipitor revenue, currently about $13 billion annually; **Ranbaxy's** challenge to Lipitor **patents** might have brought generic competitor to market as early as March 2010; photo; chart (M)

**LOAD-DATE:** June 20, 2008

**LANGUAGE:** ENGLISH

**GRAPHIC:** Combination

**PUBLICATION-TYPE:** Abstract

**JOURNAL-CODE:** WSJ

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Information Bank Abstracts

[Return to List](#cite_id_116)

116 of 200 DOCUMENTS

Africa News

**June** 18, 2008 Wednesday

**HIV-Aids and STDs;**

**Daily HIV/Aids Report**

**BYLINE:** Kaisernetwork.org

**LENGTH:** 2185 words

Drug Access

Mexico Should Declare HIV/AIDS a National Emergency To Ensure Universal Access to Antiretrovirals, Coalition Says

[Jun 18, 2008]

The Mexican government should declare HIV/AIDS a national emergency to ensure "universal, permanent and sustainable" access to antiretroviral drugs, a coalition of about 60 nongovernmental organizations said Tuesday, EFE News Service reports. According to the coalition, antiretrovirals cost up to 30 times more in Mexico than in other countries with comparable per capita incomes.

In a letter to Health Secretary Jose Angel Villalobos, the coalition criticized the high price of antiretrovirals "set by the pharmaceutical industry." It added that declaring HIV/AIDS a national emergency would make it possible to "save the lives of nearly 180,000 Mexicans." It also would permit the government to "gain access to the mechanisms established by the World Trade Organization for obtaining better prices," as well as allowing for the purchase and importation of generic antiretrovirals, according to the coalition. In addition, the coalition said it is necessary to rescind a law that requires a manufacturing or pharmaceutical license to import and register medicines in Mexico. The law "limits our access to many options for importing generic medicines," the coalition said.

According to the National AIDS Prevention and Control Center, between 8,000 and 8,500 new cases of HIV/AIDS are diagnosed annually in Mexico, and about 50,000 of the country's more than 108 million residents are currently receiving treatment for HIV/AIDS. The country in August will host the XVII International AIDS Conference in Mexico City, which will provide a "unique opportunity to show the world and the international community the advances made by Mexico in reducing the prices of medications," the letter said. The letter's signatories include the Mexican Sex Workers Network, the National Human Rights Commission, the health secretariat in the state of Jalisco, the AIDS Healthcare Foundation and writer Carlos Monsivais (EFE News Service, 6/17).

Kaisernetwork.org is the official webcaster of the XVII International AIDS Conference in Mexico City. Click here to sign up for your Daily Update email during the conference.

Link to this story.

Index Ranks Drug Makers Worldwide on Efforts To Make Medicines Available in Developing Countries

[Jun 18, 2008]

European pharmaceutical companies surpass their U.S. counterparts in making their medicines available and affordable to developing countries, according to an index released on Monday that ranks drug makers based on their corporate responsibility, the Financial Times reports (Jack, Financial Times, 6/15). The list, called the Access to Medicine Index, was created for "social responsibility" funds and investors who want to know how drug makers are helping people with HIV/AIDS, malaria, tuberculosis and other diseases prevalent in the developing world, according to the New York Times (McNeil, New York Times, 6/17).

Produced by the Netherlands-based Access to Medicine Foundation, the ranking is based on eight main criteria, including companies' policies on increasing drug access, **patents,** research into neglected diseases and pricing systems. The United Kingdom's GlaxoSmithKline topped the list, followed by Denmark's Novo Nordisk in second place and the U.S.' Merck in third. Pfizer, the world's largest drug maker, ranked 17th, and there were no Japanese drug companies on the list. India-based generic companies **Ranbaxy** Laboratories and Cipla also were on the list.

Wim Leereveld, head of the Access to Medicine Foundation, said the index will provide investors with the resources to assess companies' social responsibility and "prompt laggards into actions." In terms of the gap between European and U.S. companies, Leereveld said it is largely cultural. "Europe is closer to Africa and has deeper relations with Africa," he said, adding, "But it is also clear from issues like carbon emissions and climate change that there is something of a transatlantic divide on corporate social responsibility issues" (Hirschler, Reuters, 6/16). However, Leereveld said he hopes the index will make some companies "shining examples to others" and be useful to governments, medical charities and journalists (New York Times, 6/17).

Some long-term investors are concerned that the index could have a negative impact on drug makers' reputations and operations if they fail to focus on providing access to medicines in developing countries, Reuters reports (Reuters, 6/16). However, a group of fund managers who endorsed the index in a statement said there is a need for tools that help investors and analysts assess the long-term investment value of companies, including how they respond to the issue of access to medicine (Financial Times, 6/15).

Link to this story.

Science & Medicine

Rwandan First Lady Kagame Hosts HIV/AIDS Vaccine Roundtable

[Jun 18, 2008]

Rwandan first lady Jeannette Kagame last week at the United Nations in New York hosted a roundtable discussion about HIV/AIDS vaccine research and development, Rwanda's New Times reports. Kagame, who also serves as the high representative for the African AIDS Vaccine Programme, said that the "recent setbacks in HIV vaccine trials should not discourage our efforts." She added that a "preventive vaccine is the only long-term sustainable solution to combating HIV." Participants in the roundtable discussion included Seth Berkley, president and CEO of the International AIDS Vaccine Initiative; Alan Bernstein, executive director of the Global HIV Vaccine Enterprise; Margaret Chan, director-general of the World Health Organization; and Peter Piot, executive director of UNAIDS.

HIV/AIDS is "more than 25 years old, and we may spend another 25 years searching for its vaccine," Kagame said, adding, "[B]ut we have to keep the faith -- the same faith that scientists kept for 47 years as they searched and found a vaccine against polio." Berkley and Mark Dybul, U.S. Global AIDS coordinator who administers the President's Emergency Plan for AIDS Relief, chaired a session on research and development aimed at developing a vaccine for Africa, according to the Times. Issues discussed during the session included how to encourage countries to increase spending on vaccine development, as well as how to persuade African leaders to integrate vaccine efforts in their national HIV/AIDS control plans.

In addition, Chan called on African governments to commit more of their budgets to HIV/AIDS vaccine research and development. She also called on development partners to support programs that might be outside mainstream efforts, the Times reports (New Times, 6/17).

Link to this story.

Across The Nation

New York City STI Clinics Stop Use of Oral Fluid with HIV Tests Because of Rate of False Positives

[Jun 18, 2008]

New York City sexually transmitted infection clinics have stopped have stopped using oral fluid with OraSure Technologies' OraQuick Advance Rapid HIV 1/2 Antibody Test because of an increased rate of false positives, Bloomberg reports. According to city health officials, the rate of false positives from the test rose as high as 1.1% -- or about five times higher than the kit's label claims -- over the past eight months (Lauerman, Bloomberg, 6/16). In a statement, the New York City Department of Health and Mental Hygiene said its STI clinics have switched to OraSure's OraQuick ADVANCE Rapid HIV Test that screens blood (Health department release, 6/18).

The OraQuick oral test requires users to swab their gums and then place the swab in a holder. After 20 minutes, one line appears on the strip if the test result is negative and the person is HIV-negative, and two appear if the result is positive and the person is HIV-positive. Positive results require a follow-up test with a medical professional for confirmation. The test initially was provided in the city in response to the number of new AIDS diagnoses among people ages 13 to 26, which increased by 6% in 2006. In addition, about one-third of people tested for HIV at public health clinics with other tests do not return for the results, according to CDC (Kaiser Daily HIV/AIDS Report, 4/1).

Susan Blank, city commissioner for STI prevention and control, said that although the test meets U.S. standards and is still on the market, the city's 10 STI clinics stopped using it to screen oral fluid for HIV on May 27. Health officials started noticing problems in October 2007, and they continued through April, Blank said. She added that although test results returned to normal in May, the city's clinics stopped using the tests. "So far, false positives have not been linked to handling, storage conditions, lot numbers, clinic sites and test operators," Blank said.

According to OraSure spokesperson Ron Ticho, the oral test kit has performed better in other cities. He added that in more than 250,000 tests over the past 17 months at 400 sites in the U.S., the test had a 0.2% false positive rate. "What's happening in New York City appears to be a slight aberration," Ticho said Monday, adding, "Performance results may fall slightly outside the expected range for a short period of time. That's expected." Ticho noted that Orasure is following standard company procedure for investigating product performance and is cooperating with CDC and New York officials to understand the issue.

Bernard Branson, associate director for laboratory diagnostics at CDC's Division of HIV/AIDS Prevention, said the agency is investigating whether health officials in other cities are experiencing similar problems with the oral tests. New York -- as well as health departments in San Francisco, Minnesota and Utah -- recorded similar elevated rates of false positives with the test in 2004 and 2005, according to Bloomberg.

Branson added that Blank has filed a report with CDC and that the agency is considering publishing a notice in its Morbidity and Mortality Weekly Report. "When oral testing showed low numbers of false positives, that reassured everyone," Branson said, adding, "When that changes, people need to find out what the problem is and get to the bottom of it" (Bloomberg, 6/16).

Link to this story.

Public Health & Education

HIV Screening Among People Ages 55, Older Worthwhile, Study Finds

[Jun 18, 2008]

Screening for HIV/AIDS among people ages 55 and older is worthwhile in terms of the potential savings in health care costs and the years of life gained from early detection, according to a study published Tuesday in the Annals of Internal Medicine, Reuters Health reports. CDC guidelines recommend routine HIV screening for people between ages 13 and 64.

For the study, Gillian Sanders of Duke University and colleagues calculated the cost of HIV screening and counseling among people age 65 to determine the costs and benefits of screening among people ages 55 to 75. According to the study, the costs and benefits of HIV screening depend on the total expense of testing and counseling, prevalence of the disease in the community, likelihood of transmission and the potential benefits when the disease is caught early. The study found that the cost of screening a person age 65 would be less than $60,000 for every "quality-adjusted life-year saved," even in areas where one in 1,000 people is HIV-positive, Reuters Health reports.

According to the researchers, the cost-benefit ratio compares favorably with other interventions that are considered worthwhile. "Advanced age alone should not preclude screening for HIV," the researchers said, concluding, "Rather, for many people in this age group, the cost-effectiveness of screening is within the range of that of other accepted interventions" (Reuters Health, 6/16).

The study is available online.

Link to this story.

Media & Society

NPR Program Examines Comic Book That Aims To Increase HIV/AIDS Awareness, Education

[Jun 18, 2008]

NPR's "News & Notes" on Monday included a discussion with comic book illustrator Robert Walker, who has written a comic book, titled "O+ Men," that aims to increase HIV/AIDS awareness. HIV-positive characters in the book take an experimental antidote that unexpectedly gives them superpowers, according to NPR.

Walker said he chose to focus on HIV/AIDS because he believes there "should be more of a push" for awareness about the disease following the increasing number of new cases, especially among young people. He added that he "felt it very important to use [his] talents to try to advocate AIDS awareness." The book details how people contract HIV and incorporates "real-life situations" faced by people living with HIV/AIDS, Walker said. The book also addresses HIV prevention.

Walker collaborated with HIV/AIDS specialist Howard Grossens to ensure the information in the book is accurate. In addition, the book includes two pages of HIV/AIDS resources, including telephone hotlines and facilities that provide HIV tests or support groups. Walker said the book is suited for teenagers and could be incorporated into sex education classes and other HIV/AIDS education programs (Chideya, "News & Notes," NPR, 6/16).

Link to this story.

**LOAD-DATE:** June 18, 2008

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**PUBLICATION-TYPE:** Newsletter

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[Return to List](#cite_id_117)

117 of 200 DOCUMENTS

The Nikkei Weekly (Japan)

**June** 16, 2008 Monday

**Daiichi Sankyo targets generics**

**LENGTH:** 724 words

Daiichi Sankyo targets generics

Daiichi Sankyo Co. announced on June 11 that it will purchase **Ranbaxy** Laboratories Ltd., India's leading maker of generic drugs, through a tender offer. For up to 500 billion yen ($4.7 billion), the Japanese drugmaker seeks to acquire a majority stake in the Indian firm.

Daiichi Sankyo agreed to purchase some 129 million shares - about 30% of all shares outstanding - from **Ranbaxy's** controlling family, the Singhs. In addition to launching the tender offer, the firm will buy new shares to be issued by **Ranbaxy**, aiming for a stake of more than 50.1% by next spring.

The acquisition is expected to boost Daiichi Sankyo's group sales over the 1 trillion yen mark and propel the firm to the No. 2 spot in the domestic market, behind Takeda Pharmaceutical Co.

Daiichi Sankyo aims to break into the more than 7 trillion yen global market for generic drugs, using **Ranbaxy's** facilities to produce low-cost offerings.

Behind the action, which appears to run against the pharmaceutical industry trend of taking over leading-edge drug developers, is a carefully conceived strategy.

Shortly after Sankyo Co. and Daiichi Pharmaceutical Co. merged to become Daiichi Sankyo in April 2007, President Takashi Shoda told his executives, "India will be the trump card allowing a Japanese pharmaceutical firm to go global." He appears to have already had **Ranbaxy** in mind at the time. The Indian generic leader ranks eighth in the world, grossing 180 billion yen annually and selling in 49 countries. It has production bases in 11 countries.

Opinion within Daiichi Sankyo was split over the **Ranbaxy** takeover scenario because it would mean entering the generic drug market. Pharmaceutical orthodoxy is to work to develop revolutionary new drugs that can each bring in hundreds of billions of yen per year. Generic drugmakers, on the other hand, make their money by gaining market share with mass-produced, low-cost drugs using ingredients that are no longer under **patent**. The two types of drugmakers are often opponents in lawsuits.

But Shoda was sure of his decision because, first, the prescription drug market has been slowing amid a worldwide trend toward lower health-care costs. While the market's annual growth for 2008 has been 4-5% in the West, according to IMS Health of the U.S., and 1-2% in Japan due to a recent cut in official drug prices, the generic market is growing by 14-15%.

Under new legislation enacted in April, the Japanese government plans to raise the volume share of generics in the drug market from the 17% now to 30% by 2012. The Japan Pharmaceutical Manufacturers Association, of which Shoda became chairman in May, is lobbying for reform in the pricing regime to maintain drug prices during their **patent** periods and only allow major price cuts afterward. If implemented, it will lead to substantial sales decreases for firms like Daiichi Sankyo, which depends on drugs with expired **patents** for 40% of its sales, against 20% for Eisai Co. and Astellas Pharma Inc.

Conversely, the reform would offer greater opportunity for generic makers, adding sense to the **Ranbaxy** takeover.

A second motivator for the takeover is market expansion from 21 countries currently to 56. India is particularly attractive because the drug market there is growing by 15% per year, far faster than in the developed world. Also making the country an exciting target is the fact that it introduced a **patent**-protection system in 2005, and lifestyle-related ailments, where Daiichi Sankyo is strong, are increasing with the booming economy. Daiichi Sankyo can also use **Ranbaxy** to conduct takeovers in the developing world.

**Ranbaxy's** low-cost production further justifies the takeover, as Daiichi Sankyo must cut its high consolidated cost-to-sales ratio of 26.7% in fiscal 2007, against 20.3% for Takeda Pharmaceutical and Eisai's 16.2%, while costs for raw materials have risen 20-30% over the past year. It will be a significant help to supply ingredients for leading products worldwide from **Ranbaxy** plants, where labor costs are reportedly half those in Japan.

Investors will be watching to see how Daiichi Sankyo copes with the three major challenges of a large foreign takeover, the Indian market and generic operations.

Nikkei staff writer Eiichiro Shimoda contributed to this article.

(The Nikkei Weekly 06/16/2008 Edition)

**LOAD-DATE:** June 17, 2008

**LANGUAGE:** ENGLISH

**PUBLICATION-TYPE:** Newspaper

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[Return to List](#cite_id_118)

118 of 200 DOCUMENTS

The Irish Times

**June** 14, 2008 Saturday

**Pfizer 'may counter' EUR3bn Ranbaxy deal**

**SECTION:** FINANCE; Other Stories; Pg. 21

**LENGTH:** 331 words

PFIZER MAY make a bid for **Ranbaxy** Laboratories to counter a $4.6 billion (EUR 2.99 billion) package from Japan's Daiichi Sankyo Co Ltd for the Indian generic drug maker, India's *Business Standard*newspaper reported yesterday.

Pfizer, the world's largest drug maker, may bid for the approximately 65 per cent of **Ranbaxy** held by institutions and public shareholders, the newspaper said.

**Ranbaxy** has an generic drug manufacturing facility in Cashel, Co Tipperary, which employs about 80 people. The company set up in the Republic in 1996 with the acquisition of another pharmaceutical group, Rema, but had announced plans to sell its Irish facility in 2006.

**Ranbaxy** had decided to consolidate its European drug production at a site in Romania, but later took the Cashel facility off the market and it is still operational.

Daiichi Sankyo's deal to take control of India-based **Ranbaxy** will mean the two firms seeking to become a pharmaceuticals powerhouse, selling brands and gen-erics. Japan's third-biggest drugmaker agreed to acquire 34.8 per cent of the firm from **Ranbaxy's** founding Singh family, and make an open offer for up to 20 per cent, in line with Indian regulations.

The newspaper said Pfizer had held talks with the **Ranbaxy** founders for a possible acquisition a year earlier, and may now offer to buy out the stake held by lenders and other investors.

"That is speculation," a **Ranbaxy** spokesman said. "We have a binding contract with Daiichi. It is a final contract."

On Thursday, when asked in Tokyo what he would do if another bidder appeared at a higher price, **Ranbaxy** chief executive Malvinder Singh said: "This is a firm and binding agreement between the two sides."

Daiichi Sankyo declined to comment on the report and Pfizer could not be immediately reached for comment.

**Ranbaxy** has been battling Pfizer over **patent** rights for the US firm's blockbuster cholesterol lowering drug, Lipitor, in several countries, and has been successful in certain cases. It failed in the Republic. -

**LOAD-DATE:** June 14, 2008

**LANGUAGE:** ENGLISH

**PUBLICATION-TYPE:** Newspaper

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[Return to List](#cite_id_119)

119 of 200 DOCUMENTS

The International Herald Tribune

**June** 13, 2008 Friday

**Generic-drug makers appear to be attractive targets;**

**DEALTALK**

**BYLINE:** Lewis Krauskopf - Reuters

**SECTION:** FINANCE; Pg. 17

**LENGTH:** 648 words

**DATELINE:** NEW YORK

Daiichi Sankyo's bid for control of **Ranbaxy** Laboratories shows that pharmaceutical companies have a major appetite for generic-drug makers despite concerns about differences in their business models.

Large pharmaceutical companies have encountered a wave of product setbacks and political uncertainty that have sent many of their stocks to multiyear lows.

Acquiring companies that specialize in manufacturing low-cost, off-**patent** generic drugs would allow large makers to diversify, and seize on international efforts by governments to promote generics to cut health-care expenses.

Novartis, which is based in Switzerland, is the only large brand-name drug manufacturer that has fully embraced generics through its unit Sandoz, which is among the world's largest generic makers.

But the move by Daiichi for **Ranbaxy**, a large Indian generic manufacturer, leads some analysts to believe that other brand companies may not be far behind.

''I think it's something that Big Pharma is going to take a hard look at, and you'll see more deals like this in the future,'' said David Webster, president of Webster Consulting Group. ''Historically, there's been huge cultural aversion to it, but that's evaporating.''

Large drug makers will see revenue from some of the world's most lucrative medicines plummet from 2010 through 2012 when **patents** expire and generic copies eat up market share.

Brand-name companies that stand to lose out because of impending **patent** expirations could be the most likely to acquire a generic manufacturer, Webster said.

Brand companies in the past have had active generic units, and a few have continued to operate units that tend to sell only versions of their own medicines that lose **patent** protection.

''Big Pharma companies, after a decade of exiting the generic business, may be exploring potential reentry into this space as they face pressure in their core branded portfolios,'' Tim Anderson, an analyst with Sanford Bernstein, said in a research note.

The argument for pursuing generics, he added, ''is that generics would enhance branded drug companies' growth prospects across multiple geographies and would allow them to have a complete offering to payers of both branded and generic products.''

Beyond Daiichi, other Japanese drug makers might also follow suit to capitalize on recent efforts in Japan to make generics more widely available.

As brand companies seek to draw more sales from emerging markets, they also may need to sell more generics to compete effectively against low-cost local producers.

And the looming frontier of generic biotechnology medicines may also draw more large pharmaceutical companies. The main companies in the sector are generic manufacturers, but Pfizer said in March that such ''biogenerics'' were an opportunity for itself.

Interest by large pharmaceutical companies would represent a new wave of consolidation for the generic industry, where companies have gobbled one another up in recent years in an effort to become more global and gain economies of scale.

The most likely outcome, according to the analysts at Cowen, is that the Daiichi-**Ranbaxy** deal puts in play other Indian generic makers that are less expensive and bring lower-cost manufacturing.

But some doubt that large pharmaceutical companies are about to buy many generic makers. Michael Castor, a portfolio manager with the health care fund Sio Capital Management, said the earnings from the generic companies were too small to make a dent in the large companies' bottom lines.

''From a shareholder perspective, the generic companies are worth more as independent companies than as rounding errors in large-cap pharma companies,'' Castor said.

Les Funtleyder, an analyst with Miller Tabak, said the generic companies also had different business models, with lower profit margins and less focus on research, so getting into the business would represent a big strategic shift.

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[Return to List](#cite_id_120)

120 of 200 DOCUMENTS

Business Day (South Africa)

**June** 12, 2008

Business Day Edition

**Japanese take over India's Ranbaxy**

**BYLINE:** Rina Chandran

**SECTION:** ECONOMY, BUSINESS & FINANCE; Pg. 15

**LENGTH:** 537 words

Japanese take over India's **Ranbaxy**

'Strategic reasons' prompt sale of family-owned pharmaceutical giant to Daiichi Sankyo for $4,6bn

Reuters

MUMBAI - At a time when family-run Indian companies are expanding their empires around the globe, **Ranbaxy** Laboratories' Malvinder Singh is taking a different path.

**Ranbaxy**, India's top drug maker by sales, agreed yesterday to a deal worth up to $4,6bn to give majority control to Japan's Daiichi Sankyo, with the founding Singh family selling its 34,8% stake for close to $3.

Underbn the deal Malvinder will stay on as CEO and MD, about two years after he took the reins at the company his grandfather began building up more than half a century ago and which his father had envisioned would become one of the world's top producers of generic drugs.

"For us, it has certainly been a very emotional decision," Malvinder said at a conference in New Delhi.

"**Ranbaxy** is my life, my blood. We explored a series of options, and at the end of it, we believed this was in the best interests of the company, the shareholders and the employees."

The deal, priced at a 31% premium to Tuesday's closing share price, is in sharp contrast to a spate of overseas acquisitions by Indian companies spanning car makers and telecoms service providers.

"This is not a sell-out. This is a strategic deal to position and transform us to the next level. It was time to do something historic, something transformational," he said when asked why the family was selling its holding.

**Ranbaxy** came in to the hands of Bhai Mohan Singh in 1952 for 250000 rupees ($5830) when his cousins defaulted on a loan. They had placed **Ranbaxy**, then a distributor of imported medicines, as collateral.

His son Parvinder later brought in DS Brar as MD and the company grew, but father and son did not agree on several matters, including the need for professional management at **Ranbaxy**.

Parvinder died in 1999, and at the time Malvinder was considered too young to run the company he had joined as a management trainee in 1994.

He took over after a tough 2005, when **Ranbaxy's** profit fell by almost two-thirds and its share price nearly halved as stiff competition, high legal and research costs and **patent** battle setbacks weighed on it.

Since then, **Ranbaxy** has made a string of acquisitions, including eight in 2006, which some analysts said had stretched the company as it chased a goal of being among the top five generic companies with revenue of $5bn by 2012.

Its overseas buys included Romania's Terapia for$324,m Bayer's generics business in Germany, the generics business of GlaxoSmithKline in Italy and Spain, as well as SA's Be-Tabs Pharmaceuticals for$70.

Malvinderm and younger brother Shivinder have been looking beyond pharmaceuticals: the group has added hospitals and diagnostics, and has a presence in financial services and travel.

Malvinder, who worked with American Express and Merrill Lynch early on, is chairman of the non-pharmaceutical businesses. He has plans of building a financial giant.

Malvinder Singh, CE of **Ranbaxy**, speaks as Takashi Shoda, CEO of Daiichi Sankyo, watches, at a news conference announcing that the Japanese drug maker had moved to take control of India's biggest drug maker **Ranbaxy**. Picture: REUTERS

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[Return to List](#cite_id_121)

121 of 200 DOCUMENTS

Daily Deal/The Deal

**June** 12, 2008 Thursday

**Daiichi to buy stake in Ranbaxy**

**BYLINE:** by Alex Lash

**SECTION:** M AND A; Deal International

**LENGTH:** 655 words

**HIGHLIGHT:** The deal for the generics company continues to blur the lines between branded and generic drug industries.

**Daiichi Sankyo Co. Ltd.**, Japan's third-largest drug company by sales, said Wednesday, June 11, it would buy a majority stake in **Ranbaxy Laboratories Ltd.**, a generics firm that has built itself into India's largest drugmaker.

The price tag is between $3.4 billion and $4.6 billion, depending on how much Daiichi Sankyo is able to buy on the open market. First, Daiichi will pay **Ranbaxy's** founding Singh family, including CEO Malvinder Singh, 737 rupees ($17.14) per share for their controlling stake, which is nearly 35%. Under Indian law, Daiichi must also tender offers for up to 20% of the company on the open market at the same price to gain an outright majority.

The share price offered by Daiichi is a 31% premium to Tuesday's close and marks **Ranbaxy's** value at $8.5 billion. The transfer of shares will take nearly a year to close, the companies said.

The deal blurs the lines further between the branded and generic drug industries. Swiss giant **Novartis AG**'s Sandoz division used acquisitions to muscle its way into the top spot in the generics business earlier this decade. But Israeli generics firm **Teva Pharmaceutical Industries Ltd.** reacted with a shopping spree of its own that pushed it back ahead and could also expand Teva's reach into branded drugs.

If done correctly, playing both sides of the fence makes sense as drug giants face a future in which they can't rely on a few blockbuster drugs to fill their coffers. "The situation can be complementary," said generics sector analyst Brian Laegeler of **Morningstar Inc.** "Branded drug firms have excess manufacturing capacity, which can hurt gross margins once a major drug goes off-**patent**. Having a generic arm can make for a smoother transition plus cushion the blow to the bottom line."

The branded drug industry faces increased competition from generics as blockbuster products go off-**patent**. In the U.S., generics now comprise 65% of all prescriptions, a figure that creeps up a few percentage points a year, and 20% of all dollars spent on prescriptions, according to research firm **IMS Health Inc.**

The most dramatic example of upcoming **patent** expiration is **Pfizer Inc.**'s cholesterol drug Lipitor, which tallied $12.7 billion in sales in 2007, nearly 30% of Pfizer's total revenue. It goes off-**patent** in March 2010, but generic pressure is already eroding its sales, which fell 7% in the first quarter of 2008. **Ranbaxy** is trying to crack the **patent** before its expiration.

Japanese firms are no exception to the pressure, but Daiichi Sankyo has less upcoming exposure to **patent** loss than many of its rivals. According to a **Lehman Brothers Inc.** study, 25% of its sales by 2012 could disappear due to **patent** loss. Japan's largest firm, **Takeda Pharmaceutical Co. Ltd.**, faces exposure on more than half its sales, according to Lehman Brothers.

Branded firms, or "innovators," that delve into generics also gain a possible leg up when their own drugs go off-**patent**, said Laegeler. "The innovator has the flexibility to launch a couple weeks earlier than the first generic player [and lock] up some of the biggest contracts," Laegeler said. "The first to launch often retains the lion's share of the business."

Daiichi hopes to close the **Ranbaxy** purchase by the end of March 2009 and will finance the deal through new loans and existing cash.

In the first quarter of the year, **Ranbaxy** reported $409 million in sales, up 15% from the same quarter a year earlier, and a profit of $439 million, an increase of 19%. It employs about 12,000 people.

The deal required a phalanx of advisers. For Daiichi Sankyo, **Nomura Securities Co. Ltd.** was exclusive financial adviser and **Mehta Partners LLC** the strategic business adviser. **Jones Day** and **P&A Law Office** provided legal help outside and inside India, respectively, and **Ernst & Young** was Daiichi's accountant.

**Ranbaxy** and the Singh family turned to **Religare Capital Markets Ltd.** for financial advice and **Vaish Associates** for legal assistance.

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[Return to List](#cite_id_122)

122 of 200 DOCUMENTS



The Independent (London)

**June** 12, 2008 Thursday

First Edition

**Japanese pharma group takes control of Indian drugs maker;**

**Business News IN BRIEF**

**SECTION:** BUSINESS; Pg. 46

**LENGTH:** 143 words

\*Japan's third biggest pharmaceuticals group, Daiichi Sankyo, has bought a 35 per cent share in India's largest generic drugs maker, **Ranbaxy**. The deal, which will see the Japanese group take a controlling stake in the Gurgaon-based firm, was secured after Daiichi paid $4.6bn (£2.3bn) for the Singh family stake. The deal represents a 31 per cent premium to **Ranbaxy's** closing price on Tuesday. Daiichi has the option to buy further shares and take its holding to 51.1 per cent. The move is Daiichi's first into the generics drug business, in which companies seek to copy treatments as **patents** expire. The worldwide generic drugs business is worth $120bn, with UK pharmaceutical groups alone expected to lose £2bn in sales to generics groups in the next five years. Daiichi Sankyo was formed three years ago by the merger of two of Japan's best-known drug makers.

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[Return to List](#cite_id_123)

123 of 200 DOCUMENTS

The International Herald Tribune

**June** 12, 2008 Thursday

**Daiichi of Japan to acquire India generics maker**

**SECTION:** FINANCE; Pg. 16

**LENGTH:** 603 words

**DATELINE:** TOKYO

Daiichi Sankyo, a Japanese drug maker, will pay up to $4.6 billion to take control of **Ranbaxy** Laboratories of India, a leading producer of generic drugs, the latest in a string of international deals by pharmaceutical companies looking to bulk up and diversify to fend off aggressive rivals.

The deal represents a major foray by Daiichi Sankyo into the high-growth area of generic drugs, following large overseas acquisitions by other Japanese drug makers.

Generic drug sales are booming as countries look to curb spiraling health care costs, but competition in the sector is intense. Drug makers worldwide are searching for new and emerging markets to drive profit growth as sales of branded drugs in the United States, Europe and Japan start to slow.

The deal values **Ranbaxy**, the largest drug maker by revenue in India, at $8.5 billion, with the offer price representing a 31.4 percent premium to its closing price Tuesday.

''I like this deal very much,'' Kenji Masuzoe, a senior pharmaceuticals analyst at Deutsche Securities, said. ''The pure pharma business model has limitations, and the industry has to think about hybrid models like pharma and agribusiness or pharma and generics.''

The deal would give Daiichi Sankyo operations in 60 countries, up from 21 now, and make it one of the largest pharmaceutical companies in the world, Takashi Shoda, the chief executive, said at a news conference in New Delhi.

IMS Health, a health care information group, estimates that drug sales in emerging markets will hit $400 billion a year by 2020, equivalent to the revenue today from the top five markets in the United States and Europe combined, and contribute more than 50 percent to global market growth.

Generics are expected to play a pivotal role in accessing these large but relatively low-price markets, playing into the hands of Indian companies like **Ranbaxy**, which have unrivaled expertise in developing inexpensive versions of medicines that are no longer covered by **patents.**

**Ranbaxy** has said it expects earnings to rise 25 percent this year, and revenue to grow 20 percent.

In the quarter to March, its profit rose 7 percent to 1.53 billion rupees, or $36 million, on sales of 16.2 billion rupees.

Daiichi Sankyo will buy the 34.8 percent controlling stake held by the **Ranbaxy** founders, the Singh family, at 737 rupees a share.

It will then make an open offer for up to a further 20 percent of **Ranbaxy** shares, as required by Indian market regulations.

Daiichi Sankyo will also get preferential allotments of shares and share warrants, with a goal of acquiring a minimum 50.1 percent stake.

The final holding would depend on the response to the open offer, and the companies said the transaction was expected to be worth anywhere from $3.4 billion to $4.6 billion.

Shares in Daiichi Sankyo, best known for the high blood pressure medication Benicar, ended nearly 5 percent higher at •2,975, or $27.72, on Wednesday following reports of the deal.

**Ranbaxy** shares rose more than 5 percent at one point, adding to gains of more than 10 percent in the previous two sessions. But the stock ended little changed as investors realized that about two-thirds of the shares that are held by the public would not be part of the offer.

Malvinder Singh, the chief executive of **Ranbaxy**, said at the news conference in New Delhi that his family had to sell their stake to clinch the deal.

''This is not a sellout,'' he said. ''This is a strategic deal to position the company and transform us to the next level.''

''This is my passion,'' he added. ''I love this business.''

Singh will remain chief executive, and **Ranbaxy** will remain listed in India.

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[Return to List](#cite_id_124)

124 of 200 DOCUMENTS

Pharma Marketletter

**June** 12, 2008 Thursday

**Generic firms file for IP protection in India**

**LENGTH:** 56 words

India's **Patent** Office has revealed that generic drugmakers are increasingly registering their products, according to a report by The Economic Times. Israel-based Teva has filed 380 drug **patent** requests, with local generic specialist firm **Ranbaxy** making 225 applications. This compares with 86 from research-based US drugmaker Eli Lilly.

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[Return to List](#cite_id_125)

125 of 200 DOCUMENTS



The Times (London)

**June** 12, 2008 Thursday

**Japanese take over drugmaker Ranbaxy**

**BYLINE:**  Leo Lewis, Rhys Blakely

**SECTION:** BUSINESS; Pg.51

**LENGTH:** 536 words

\* Daiichi Sankyo in $4.6bn deal for Indian group

A Japanese pharmaceuticals group has astonished the Tokyo market by taking over **Ranbaxy** Laboratories, India's largest maker of generic drugs, in a deal worth up to $4.6billion (£ 2.3billion).

Daiichi Sankyo's move on **Ranbaxy** was described by Tokyo investors as being bold and out of character and it may mark the start of a strategic shift towards emerging markets by Japan's pharmaceutical industry.

The agreed offer for 50.1 per cent of **Ranbaxy's** shares is a response to a worsening profit crisis in Japan's drugs industry. The remedy may lie in emerging markets, analysts said.

The transaction marries two classes of company that traditionally have been foes. Makers of generic drugs produce ultra-cheap copies of drugs invented by developers such as Daiichi. **Ranbaxy** has been especially aggressive in challenging **patents** that protect blockbuster medicines worth billions of pounds in annual revenues.

The merged group, which will have a market value of about $30,billion will combine Daiichi's research expertise with **Ranbaxy's** low-cost factories and global distribution network, the companies said. The takeover is thought to be the largest of an Indian listed group by a foreign buyer.

Takashi Shoda, chief executive of Daiichi Sankyo, said that the deal would "complement our strong presence in innovation with a new, strong presence in the fast-growing business of non-proprietary pharmaceuticals".

Countries with ageing populations, such as Japan, where generic drugs at present comprise only 5 per cent of the market, are expected to encourage use of generic drugs to cut healthcare costs.

Daiichi has agreed to buy the 34.8per cent stake in **Ranbaxy** held by the founding Singh family at 737 rupees a share, a 31percent premium to Tuesday's closing price. Under Indian takeover rules Daiichi must make a tender offer for a further 20 per cent.

Malvinder Mohan Singh, **Ranbaxy's** chief executive, said that the sale would create "a new powerhouse ... spanning the entire pharmaceutical spectrum". Making only generics, which typically sell at a 97 per cent discount to their patented templates, was not a sustainable business model, Mr Singh said. Cost cutting and new drug pipelines do not appear to have played a role in Daiichi's decision, and although investors queried what appeared to be a deal with no synergies, the move by Daiichi will give the group access to generic drugs markets in 50 countries.

To try to cut costs, the Japanese Health Ministry has sought to persuade doctors and patients that generic drugs are as good as their branded equivalents, but it has met with failure. Even changing prescription forms to make generic drugs the default recommendation of doctors has been unsuccessful. Part of the problem, state officials say, is that generic drug companies in Japan are small and doctors do not trust them. By effectively rebranding **Ranbaxy** generics under the well-known name of Daiichi Sankyo, this may change.

Mr Singh, who has made a series of acquisitions in recent years, said that he would stay **Ranbaxy's** chief executive.

\* $30bn Market value of merged group

\* Source: Daiichi Sankyo/**Ranbaxy**

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**LANGUAGE:** ENGLISH

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**JOURNAL-CODE:** tt

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[Return to List](#cite_id_126)

126 of 200 DOCUMENTS



The Times (London)

**June** 12, 2008 Thursday

**Sugaring the generics pill**

**BYLINE:**  Rhys Blakely

**SECTION:** BUSINESS; Pg.51

**LENGTH:** 238 words

At first sight, generic drugs appear to be just the tonic for a traditional pharmaceutical company (the type that plunges billions into inventing new medicines) looking to diversify.

Increases in life expectancy come at a cost and the generics market is set to reap a demographic dividend. Japan's annual medical bill is set to rise 70 per cent to 56 trillion yen (£ 267billion) by 2025. To mitigate the burden, Tokyo wants nearly a third of drugs consumed to be cheap copies by that date, compared with as little as 5 per cent at present.

Moreover, a steady stream of key drugs are coming off-**patent.** Motilal Oswal, the broker, expects **patents** on medicines worth $50billion to expire in the next two years. Generics may command only 3 per cent of the price of their branded forebears, but that equates to $1.5billion in new sales.

There is, of course, a catch: the cost factors that make generics popular with patients mean that it is tough to make money out of them.

India's big three generics groups - Dr Reddy's, **Ranbaxy** and Sun Pharma - may post flat or falling sales this year, analysts say. That is partly because the world's biggest generics companies - Teva, of Israel, valued at $33billion (compared with $8.5billion for **Ranbaxy)** and Sandoz, which is owned by Novartis, the Swiss giant - have already ploughed ahead with big acquisitions, building scale and cutting costs to levels that will be hard to match.

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[Return to List](#cite_id_127)

127 of 200 DOCUMENTS

Pharma Marketletter

**June** 9, 2008 Monday

**Dr Reddy's calls bluff on AZ's Nexium patent**

**LENGTH:** 179 words

Indian generic drugmaker Dr Reddy's Laboratories has filed for a declaratory judgement with a US court for its **patent** clash with Anglo-Swedish drug major AstraZeneca over the UK firm's gastrointestinal treatment Nexium (esomeprazole).

The litigation, common in **patent** suits, forces AstraZeneca to either bring a law suit against Dr Reddy's for **patent** infringement or else declare its **patent** invalid. The firm says it hopes to trigger exclusivity for the drug before the current trigger date of 2014.

AstraZeneca recently settled a **patent** dispute with another Indian firm, **Ranbaxy,** offering it exclusivity in marketing a generic version of Nexium (Marketletter April 21). Dr Reddy's move is an attempt to invalidate this agreement and gain the rights to market its own generic version of the blockbuster drug.

Nexium achieved sales of $5.18 billion during 2007, with $3.53 billion coming from the USA. As well as other litigation with Dr Reddy's, Israel's Teva is also suing for generic rights to the blockbuster, although the latter company's suits are unnaffected by the judgement.

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[Return to List](#cite_id_128)

128 of 200 DOCUMENTS

The International Herald Tribune

**June** 7, 2008 Saturday

**Health care faces new horizons and hurdles;**

**Traditional business plans aren't working as pressure to cut costs rises throughout the industry**

**BYLINE:** Barbara Wall - The New York Times Media Group

**SECTION:** FINANCE; Pg. 19

**LENGTH:** 1417 words

Analysts are telling drug companies to shape up or ship out as new winners emerge in the global health care industry.

The sector has traditionally been viewed as a defensive investment on the ground that consumers are usually reluctant to cut spending on health care. But analysts like Holger Geissler of DWS in Frankfurt are not so sure any more.

''The group's problems are so firmly entrenched that it is difficult to imagine a scenario where stock prices can stage a convincing recovery,'' he said. ''We anticipate cash flow to be under significant pressure over the next few years as **patents** on blockbuster drugs expire and generic competitors increase their market share.''

According to IMS Health, a business information and consulting group based in the United States, global pharmaceutical sales rose from $1.9 billion in 1957 to over $700 billion in 2007. But growth is set to slow significantly as headwinds begin to slow the industry. IMS Health predicts that sales of products at risk from generic competition will rise to $32 billion in 2010 from $26 billion in 2007.

''Increasing regulatory pressure and the need for further research and development expenditure to top up leaky pipelines may also keep stocks back,'' Geissler warned. ''Put bluntly, everything is pitted against big pharma.''

Alice Evans, a portfolio manager with Henderson's Global Investors in London, could not agree more. She has lost patience with the pharmaceutical giants and is looking for investment opportunities elsewhere.

''Business models are no longer sustainable,'' she said. ''Even assuming the drugs companies manage to cut costs and reinvent themselves, investors would still have to wait a long time to see a return on their investment.''

Too grim a prognosis? Anne Marden, a health care analyst at JPMorgan Asset Management in London, thinks so. She acknowledges the problems facing the drug giants but is reluctant to advise investors to steer clear altogether.

''Some companies are doing just fine,'' she said. ''If there was a protracted recession, well-diversified companies such as Novartis, Sanofi-Aventis and Bayer would probably hold up better than the broader market.''

Bayer is a favorite with many mainstream fund managers because of its businesses in crop protection and materials science. Novartis and Sanofi-Aventis are highly rated for their decent pipelines of new drugs and limited exposure to **patent** expirations.

Debbie Wang, a health care analyst with Morningstar in New York, agreed with Marden and suggested that valuations in the sector were compelling.

''Clearly some companies are not worth the risk; Elan Pharmaceutical fits into this category because of side-effect issues with its blockbuster drug Tysabri,'' a multiple sclerosis treatment, she said. ''But there are many other companies that would make nice investments in a downturn.''

Wang cited Schering-Plough and Novartis as good defensive calls.

But recession or no recession, Evans, of Henderson's Global Investors, said she believed ''big pharma'' was on a downward trajectory.

''In today's cost-conscious health care market, those companies whose products and services are demonstrably reducing costs while helping to improve the outcomes for patients are likely to be the long-term winners,'' she said. ''The most effective way to limit cost is by better prevention and earlier detection, which is why we have backed Qiagen in Germany.'' That company is involved in the relatively new field of molecular diagnostics to detect cervical cancer and other expensive diseases, she said.

Evans is betting that vaccination will also have an increased role in the future. She likes Intercell of Austria, which is developing a vaccine for multidrug-resistant Staphylococcus aureus, or MRSA. The vaccine would be administered to high-risk surgical patients ahead of admission to a hospital, where such staph infections have led to increasing numbers of fatalities.

''The cost of treating the growing incidence of hospital-acquired infections is an increasing burden to the health system,'' she said.

Where hospital admission cannot be avoided, technological innovations, including minimally invasive surgery, can help reduce the length of stay and the costs. Evans backed Intuitive Surgical, a pioneer of robotic surgery, months before it became a hot name in the broker community. It was an astute move, as shares in the company tripled in value last year.

Another of Evans's stock picks is Gyrus of Britain, a leader in surgical tools for minimally invasive operations that is now the subject of a bid by Olympus of Japan, illustrating the attraction of this part of the market.

Information technology companies are also helping to deliver savings to the health care system through identifying and eliminating inefficiencies and waste. Evans singled out HMS Holdings as a company with potential.

''HMS Holdings, which provides cost containment and payment accuracy services in the U.S., has designed software that can identify health insurance claims which are paid in error,'' she said. ''Various reports suggest that around 5 percent of Medicare claims are erroneous.'' That would amount to more than $37 billion in erroneous payments from the U.S. government's health care program for poor Americans.

Like Evans, Gemma Game, a health care analyst with AXA Framlington in London, is eager to back small to midsized health care companies. She has focused on out-of-favor stocks in the medical devices areas.

Game favors Hologic, a company in the United States that develops and manufactures medical imaging technology for mammograms.

Wang, at Morningstar, is also drawn to equipment providers. Her picks include Medtronic and Boston Scientific, which together comprise around 50 percent of the pacemaker market in the United States.

Geissler suggested that makers of generic drugs could deliver decent investment returns over the next year or two, especially those with business interests in countries with developing economies. Teva Pharmaceutical, for example, is expanding its activities in Eastern Europe, and Hikma Pharmaceutical Group, which is based in Jordan and has interests throughout the Middle East, have interesting business models, he said.

Nora Frey, managing partner of Adamant Biomedical Investments in Switzerland, is focusing on investment opportunities in the Asia-Pacific region. ''The rise in wealth in the region and the expansion of the middle class has created the demand and the ability to pay for improved provision of health care therapies and services,'' she said. ''We are seeing an increased interest in health insurers such as Apollo Group and Fortis Healthcare in India.''

Large investors are putting their money on Asian hospital groups, Frey said. ''Singapore's Temasek and the Qatar Investment Authority have acquired stakes in Raffles, while Newbridge Capital has purchased a stake in Singapore's Parkway Group, which is growing in Malaysia through its acquisition of a significant stake in Pantai Holdings ,'' she said.

Medical tourism is another fast-growing area in the Asian health services market. ''Some sources speak about a 50 percent yearly increase in medical tourism in India and Thailand,'' Frey noted. ''That equates to around one to two million medical tourists per year in each of these countries.''

Another phenomenon is the opening of the Asian pharmaceuticals market. ''Companies have become much more aggressive in their expansion plans,'' Frey said. ''For example, the Japanese pharma company Astellas is actively looking for U.S. and European collaborations. It has signed research and development deals with German and U.S. companies and has in-licensed a number of compounds from U.S. companies.''

Takeda, also of Japan, announced its intention last month to buy Millennium, one of the 10 largest U.S. biotech companies, for $8 billion, and it is not only Japanese companies that are acquisitive.

''Many Indian companies started their expansion course some years ago,'' Frey said. ''A much-discussed takeover was Dr. Reddy's acquisition of Germany's Betapharm. **Ranbaxy** has also ramped up their sales and marketing efforts in Europe and the U.S., while Glenmark has bought a range of dermatology products to start their business in the U.S.''

Other Asian companies that are casting their nets farther afield include two from India, Sun Pharmaceutical Industries, which is expanding in Europe and the United States, and Strides Arcolab, which recently bought a stake in Genepharm in Australia.

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[Return to List](#cite_id_129)

129 of 200 DOCUMENTS

Pharma Marketletter

**May** 29, 2008 Thursday

**Big patent decisions on Lovenox and Lipitor**

**LENGTH:** 131 words

Decisions have been reached in two **patent** appeals for Sanofi-Aventis' Lovenox (enoxaparin) and Pfizer's Lipitor (atorvastatin), respectively. The US Federal Court of Appeals upheld the decision by the District Court that French drug major Sanofi-Aventis' **patent** on Lovenox was unenforceable. This leaves generic competitors USA's Amphastar and Israel's Teva free to market their versions of the drug. Conversely, in Australia, the Full Federal Court upheld the exclusivity of global drug giant Pfizer's Australian **patent** on atorvastatin, the active ingredient in Lipitor, through 2012. The court found that a generic variant of the drug produced by **Ranbaxy** would infringe Pfizer's **patent**. However, a claim on the calcium salt in atorvastatin was deemed invalid during the same litigation.

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[Return to List](#cite_id_130)

130 of 200 DOCUMENTS

The Nikkei Weekly (Japan)

**May** 26, 2008 Monday

**Foreign makers of generic drugs going on offensive**

**LENGTH:** 325 words

Foreign makers of generic drugs going on offensive

Overseas manufacturers of generic drugs are expanding operations in Japan, where demand for low-cost alternatives to brand-name medicines is expected to grow under a government initiative to reduce health-care spending.

Global leader Teva Pharmaceutical Industries Ltd. of Israel plans to broaden its lineup of raw ingredients it supplies to other drugmakers, increasing its offerings by 40% to 100 items by 2010. Many are used in treatments for osteoporosis and lifestyle diseases.

The firm, which used to take several months to fulfill orders, has improved inventory management, making next-day deliveries possible. It aims to boost Japanese sales of ingredients by 150% to about 7 billion yen by 2012.

Indian firm **Ranbaxy** Laboratories Ltd. will team up with I'rom Holdings Co. to introduce a generic version of the amlodipine blood pressure reducer in July. Amlodipine, sold by U.S. giant Pfizer Inc. and others, is the top-selling drug in Japan, with sales exceeding 200 billion yen a year. But its **patent** expired in March.

Since entering the Japanese market in 2002 via a tie-up with Nippon Chemiphar Co., **Ranbaxy** has struggled. But it now plans to leverage the generic version of the blockbuster drug to boost its share.

Germany-based Sandoz, which ranks No. 2 worldwide, sells 79 generic drugs in Japan. It seeks to increase this to 100 products over the next two years.

Indian midtier firm Zydus Cadila plans to increase its offerings from seven today to 50 by March 2009, with plans to boost sales to 10 billion yen in 2015 from the current 150 million yen. After acquiring Nippon Universal Pharmaceutical Co. last year, the company will consider another buyout.

Global sales were almost 1 trillion yen at Teva and nearly 850 billion yen at Sandoz in 2007, far above the 37.6 billion yen earned by Sawai Pharmaceutical Co. in the year ended March 31.

(The Nikkei Weekly 05/26/2008 Edition)

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[Return to List](#cite_id_131)

131 of 200 DOCUMENTS

Pharma Marketletter

**May** 1, 2008 Thursday

**USPTO confirms patentability of basic Lipitor patent**

**LENGTH:** 121 words

Global drug giant Pfizer says that the US **Patent** and Trademark Office has issued a communication notifying the company that it will confirm the patentability of the claims of its '893 basic **patent** for Lipitor (atorvastatin).

The **Patent** Office had conducted a re-examination of the '893 **patent** in response to a request by a law firm that represented the India-headquartered generic company **Ranbaxy** Laboratories. The **patent,** which expires in March 2010 (including pediatric exclusivity), was previously the subject of litigation against **Ranbaxy,** in which Pfizer prevailed in both the trial and appeal courts.

Pfizer noted that it is pleased with the decision, which affirms the company's position that the **patent** was properly granted.

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[Return to List](#cite_id_132)

132 of 200 DOCUMENTS



The Independent (London)

**April** 25, 2008 Friday

First Edition

**AstraZeneca blames customer cutbacks for disappointing results**

**BYLINE:** Alistair Dawber

**SECTION:** BUSINESS; Pg. 60

**LENGTH:** 410 words

The Anglo-Swedish pharmaceutical group AstraZeneca posted what analysts considered to be disappointing first-quarter sales figures yesterday, but said that its full-year earnings growth was on track to meet expectations.

The company blamed customers cutting back on stocks of drugs in the first quarter as the main reason for the numbers, which showed 10 per cent sales growth, below forecasts. The group manufacturers Nexium, the blockbuster ulcer treatment, which had faced a **patent** challenge from the Indian generics company **Ranbaxy** that was resolved in AstraZeneca's favour last week.

Analysts expected that Nexium sales growth would be slower, but were mystified why other drugs had also been de-stocked. Simon Louth, AstraZeneca's chief financial officer, said there was "no particular reason".

First-quarter, pre-tax profits were up 12 per cent to $2.65bn (£1.34bn), although this figure did not include restructuring costs associated with the buyout of the biotechnology group MedImmune. Shares in the company fell by 5 per cent on the announcement, with analysts blaming a misunderstanding of the figures. The group has said that due to beneficial movements in the dollar, earnings per share growth had increased by 5 cents.

Peter Cartwright, an analyst at Evolution, said that most investors had assumed that the growth increase had been worked out by taking a set dollar price for the whole year, when in fact it is worked out by the company on a quarterly basis. Shares had recovered to 2,120p by the close of trading, down 0.6 per cent, with investors assuming that the 5 cent figure will improve during the year.

Despite the group maintaining that it will hit annual sales targets, Simon Mather, a pharmaceutical industry watcher at WestLB, said the company would come under pressure in the next year, particularly from generics groups.

The **patents** of Seroquel, the company's psychiatric treatment, and Crestor, an anti-cholesterol drug, face challenges in the next 18 months. Mr Louth said he would vigorously defend its intellectual property rights.

Seroquel recorded sales of $1.05bn in the first quarter, up from$923m last year, while Crestor made$772m against$628m in 2006.

Mr Louth also refused to rule out a move away from the UK. Last week, one of AstraZeneca's rivals, Shire, said it was to re-domicile in the Republic of Ireland to take advantage of the country's 12.5 per cent corporate tax rate. UK corporate tax is charged at 28 per cent.

**LOAD-DATE:** April 25, 2008

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[Return to List](#cite_id_133)

133 of 200 DOCUMENTS

Investors Chronicle - magazine and web content

**April** 25, 2008

**AstraZeneca shares tumble on disappointing Nexium sales**

**SECTION:** 0261-3115

**LENGTH:** 447 words

AstraZeneca's first-quarter results weren't just about declining Nexium sales, but that's what the market initially focused on

AstraZeneca's first-quarter results removed some of the gloss from the euphoric sentiment that drove the shares up 11 per cent the previous week following a settlement with Indian generics company **Ranbaxy** Laboratories concerning its $5bn-a-year ulcer treatment, Nexium.

Astra's share price fell 7 per cent immediately after the announcement of the first-quarter results, partly due to a larger-than-expected decline in sales of Nexium. The shares have now declined 24 per cent over the past 12 months on fears of profit erosion due to competition from low-cost generic drugs providers as its major blockbuster drugs go off **patent.** Sales of Nexium were $1.24bn (GBP620m) during the three months to end-March, a 5.4 per cent decline from a year earlier. Revenues of other big selling drugs, Seroquel (psychotic disorders) and Crestor (cholesterol), were also below many analysts' expectations.

Overall sales for the quarter rose by 4 per cent in constant currencies to $7.7bn from a year earlier, boosted by the inclusion of MedImmune - the group's $15.2bn acquisition last year - and there is increasing pressure on the US biotechnology company to fill the sales gap. Astra raised its expectations for its 2008 core EPS number from $4.45 to $4.75 (237p), reflecting currency-related gains.

EVOLUTION SECURITIES

Add. There is a lot of noise in the first-quarter results due to factors like destocking, but the guidance is unchanged in constant currency terms. True, Astra should experience continuing modest short-term earnings growth, but the market's rating on the stock is unduly conservative. MedImmune has a drug on the market and there is another drug for which it has just filed for approval. It was an expensive acquisition, but that is already reflected in the share price. Expect core EPS of $4.63 in 2008, rising to $5.00 in 2009.

CHARLES STANLEY

Reduce. The results missed our expectations due to lower-than-expected sales of Nexium. It's disappointing because only two weeks ago Astra achieved a settlement with Rambaxy. The investment story is the same as ever. MedImmune has brought in a swathe of early stage products, but there is nothing in late stage to make good the shortfall on the top line from drugs going off-**patent**. Astra has nudged up its own EPS forecasts but that is reflecting currency movements. We are reviewing our forecasts.

Astra Zeneca shares are lowly rated on a forward PE of 9, but this looks justified given concerns over its late stage pipeline and the hit to revenues as drugs go off-**patent**. Fairly priced at 2,107p.

FairlyPriced

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[Return to List](#cite_id_134)

134 of 200 DOCUMENTS

Pharma Marketletter

**April** 25, 2008 Friday

**AstraZeneca set to meet 2008 targets, despite 1st-qtr profit decline**

**LENGTH:** 626 words

Anglo-Swedish drug major AstraZeneca's first-quarter 2008 financial results were slightly below expectations, with pretax profit down 5% (-15% at constant exchange rates) at $2.14 billion, and were impacted by restructuring and amortization charges, as well as reduced sales of Nexium (esomeprazole), as lower-priced generic gastrointestinal drugs joined the market.

Notwithstanding, chief executive David Brennan stated: "the first quarter performance puts us on track to achieve our full-year financial targets. We have also announced the motavizumab [Biological License Application] submission in January - the first of three regulatory filings planned for 2008 - and the agreement to settle the Nexium **patent** infringement litigation against **Ranbaxy** [Marketletter April 21], which has provided increased clarity and stability to allow us to continue the substantial investment in our growing pipeline of new medicines."

The filing for saxagliptin is on track for mid-year, with Phase III clinical data to be presented at the upcoming American Diabetes Association meeting. The regulatory submission for Zactima (vandetanib) for lung cancer is planned for the fourth quarter.

Sales for the quarter reached $7.68 billion, a rise of 10% (+4% at CER), with operating profit up 4% (-5% at CER) to $2.26 billion and earnings per share rising 1% (-9% at CER) to $1.03.

By geographic regions, turnover in the USA was up 5% to $3.4 billion, with the inclusion of MedImmune, acquired last year (Marketletter April 30, 2007), more than offsetting the decline in Toprol-XL (metoprolol) revenues in the US market. Sales in the Rest of World were up 4%. Sales in established markets (western Europe, Japan, Australia and New Zealand) were up 1% at $2.97 billion, despite a 1% decline in western Europe. Turnover in emerging markets were up 11% to $981.0 million, driven by strong growth in China and other Asian markets, the company noted.

Product performance varied

For the reporting quarter (all at CER), sales of Nexium fell 9% to $1.24 billion, and for the forerunner, off-**patent** Losec/Prilosec (omeprazole) they were 16% lower at $252.0 million. AstraZeneca said it expects a mid-single-digit sales decline for worldwide sales of Nexium over the full year.

In its cardiovascular therapy areas, the firm's cholesterol-lowerer Crestor (rosuvastatin) saw turnover advance 16% to $772.0 million. In the USA, the drug's sales rose 3% to $353.0 million and achieved an 8.75% share of the country's statin market. Revenues from Toprol-XL/ Seloken slumped 60% globally to $190.0 million, with US turnover plummeting 81% to $64.0 million, including authorized generics to Par. Atacand (candesartan cilexetil), an angiotensin receptor blocker, saw global revenues advance 6% to $346.0 million.

In other therapy sectors, sales of AstraZeneca's asthma drug Symbicort (budesonide and formoterol) increased 21% to $471.0 million, while its breast cancer drug Arimidex (anastrozole) edged up 2% to $430.0 million, but grew 13% to $183.0 million in the USA and fell 6% in Europe. Casodex (bicalutamide), for the treatment of prostate cancer, dropped 5% to $316.0 million. The group's second best-selling drug, the antipsychotic Seroquel (quetiapine fumarate), saw turnover advance 10% to $1.05 billion for the quarter.

AstraZeneca's first-quarter sales were light of consensus expectations, but the company is not changing any of its turnover guidance for the year, noted analysts at Evolution Securities. They pointed out that EPS guidance is raised, reflecting currency movements as they impact on the first three months alone. However, they said, given the current level of the US dollar, "there are clearly further currency-related uplifts to come for the remaining three quarters."

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[Return to List](#cite_id_135)

135 of 200 DOCUMENTS

Pharma Marketletter

**April** 24, 2008 Thursday

**Stock Commentary - Europe - week to April 21, 2008**

**LENGTH:** 275 words

EUROPEAN: bourses were all higher week-on-week in the reporting period to April 21, although markets ran out of steam on the last day, with financial issues leading the downturn. Analysts at Lehman Brothers note that, despite the desire for "defensive" exposure, pharmaceutical stocks have failed to provide it and have underperformed the European market by 16% since the second week of January. In ZURICH, there was a good showing from Novartis, which rose 6.8% after the firm reported first-quarter figures which beat expectations, despite generic competition for its pharmaceutical division in the USA (see page 11). Fellow Swiss drug major Roche, however, suffered a small 0.9% dip, posting figures below expectations, as well as negative clinical results for majority-owned Genentech's Avastin (bevacizumab; see pages 11 and 21). In FRANKFURT Evotec jumped 10.8%, on news of its licensing deal with Japan's Ono Pharmaceuticals regarding a fragment-based drug targeting a protease of the latter's choosing. German pharmaceutical majors Bayer and Merck KGaA were up 3.7% and 3.4%, respectively, ahead of results.

LONDON: drug share prices were mixed, with the biggest riser being Ireland-based Elan Holdings, which jumped 15.7% on positive news for Tysabri (natalizumab), co-developed with Biogen Idec, presented at the American Academy of Neurology (see pages 19-20), as well as an upgrade from analysts at Goldman Sachs. Vernalis was down 5.9%. Drug major AstraZeneca advanced 6.0%, buoyed by the news of a **patent** infringement settlement with India's **Ranbaxy** over Nexium (esomeprazole; see Marketletter April 21), while GlaxoSmithKline rose 2.9%.

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[Return to List](#cite_id_136)

136 of 200 DOCUMENTS



The Independent (London)

**April** 21, 2008 Monday

First Edition

**RBS's huge rights issue 'would end bear story';**

**THE WEEK AHEAD**

**BYLINE:** Nikhil Kumar

**SECTION:** BUSINESS; Pg. 40

**LENGTH:** 870 words

All eyes will be on Royal Bank of Scotland, which is expected to unveil a record rights issue this week. The bank, which is due to hold its annual general meeting on Wednesday, will be raising capital to shore up its finances in the face of credit crunch writedowns, which so far this year are set to hit £5bn. If, as expected, the rights issue exceeds £10bn, it will be the biggest ever, surpassing last year's £9.6bn share issue by the Belgian bank Fortis.

"We believe RBS will have little trouble raising capital and that £10bn or so would materially remove the capital risk bear story at RBS," said Collins Stewart analyst Alex Potter. "Therefore, whilst the rights issue will be dilutive, it is likely to mark the floor for the stock.

"We would, however, wait to purchase at a discount with the issue," added Mr Potter, who currently maintains a "hold" rating for the stock.

Monday: Results/updates: Sport Media, China Biodiesel International, Clearstream Technologies, Peter Hambro Mining, Bluebay Asset Management.

Tuesday: Associated British Foods is due to publish interim results and Citigroup is expecting "no material surprises".

"Notwithstanding uncertainty surrounding the high street, we expect that ABF will reiterate its qualitative guidance that, while [the EU sugar industry reforms] will have a materially negative [year-on-year] profit impact, the rest of the group will show good progress," the broker said, predicting first-half earnings before interest, tax and amortisation of £292m and pre-tax profits of £282m.

JP Morgan adds that the current valuation leaves limited upside potential for the stock. "ABF shares have rallied 15 per cent since [15 January], outperforming the wider food and ingredients sector," the broker said, adding: "We continue to see plenty of business turnaround and underlying profitable growth opportunities at ABF - not to mention external growth opportunities. However, it appears clear that 2008 will be challenging and that ABF does not have a lot of room for manoeuvre to surprise on the upside."

Results/updates: Rugby Estates, Tanfield, Associated British Foods.

Wednesday: GlaxoSmithKline will kick off the pharmaceuticals reporting round with first-quarter results. From its key products, analysts expect £910m from sales of Advair; £203m from Avandia; £294m from Lamictal; £245m from Valtrex; and £440m from sales of its vaccines. Consumer health is expected to bring in £867m in sales. Elsewhere, Citigroup notes that while 2008 is a "transition year of numerous **patent** expiries for GSK", the company is "no stranger to this and has managed multiple **patent** expirations since 2002 whilst maintaining compound EPS growth of 7 per cent from 2003-2007".

Results/updates: Arriva, Gem Diamonds and GlaxoSmithKline. Other: Royal Bank of Scotland AGM.

Thursday: AstraZeneca, the second pharmaceutical group due to update the market this week, will publish first-quarter results. Last week brought news of its Nexium **patent** litigation settlement with India's **Ranbaxy** Laboratories, relieving investors and analysts alike, and analysts forecast $2.23bn in pre-tax profits on overall sales of $7.87bn.

For key products, analysts expect $1.28bn from sales of Nexium; $1.08bn from bipolar disorder and schizophrenia medication Seroquel; $780m from cholesterol treatment Crestor; and $450m from Arimidex, its hormonal therapy for the treatment of hormone-sensitive breast cancer in post-menopausal women.

Results/updates: Aquarius Platinum, Punch Taverns, Reckitt Benckiser, Persimmon, AstraZeneca.

Friday: The advertising group WPP is due to publish a first-quarter trading update and UBS expects the company to be "relatively upbeat". "Whilst visibility on [2009] is limited, we believe that even in the event of a severe economic downturn, revenue and margin declines at WPP are unlikely to be as severe as in [2001], given greater exposure to emerging markets, easier [comparatives] and more limited staff cost inflation," the broker said.

UBS forecasts 5 per cent organic growth for the company in 2008, based on the strength of emerging markets, the impact of the Beijing Olympics and the US elections, and the benefit of the AT&T and Dell account wins last year.

"Separately we believe management remain confident on their ability to continue expanding margins by 50 basis points per annum due to the opportunities for cost rationalisation and better execution," the broker added.

Investors in the motor retail sector can look forward to Pendragon's annual general meeting on Friday. The company is expected to issue an update on trading after the meeting, and according to Panmure Gordon, "if the company does not issue a profit warning, the stock could well rally, although the earnings risk for the full year would still exist. If Pendragon comes out of March 'unscathed', we still see earnings risk in its used car business given the excess stock we believe there is in the market," the broker said, adding: "That said, our forecasts already assume a slowdown in the market, and, with £9.2m of closure costs from last year now non-recurring, we have not factored in any real operational improvement/benefits of cost savings."

Results/updates: Colt Telecom, Shire, Pendragon and WPP.

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[Return to List](#cite_id_137)

137 of 200 DOCUMENTS

Pharma Marketletter

**April** 21, 2008 Monday

**Cash-strapped govts and drug patent expiries fuel growth of generics**

**LENGTH:** 1408 words

Driven by the increasing use of cost-containment measures imposed by cash-strapped governments and fed by a constant stream of **patent** expiries going forward, the global generics market continues to grow. In the USA alone, drugs collectively worth more than $62.0 billion in 2006 sales are due to go off **patent** during 2008-12, with the likes of Pfizer's blockbuster cholesterol-lowerer Lipitor (atorvastatin) at the sharp end of generic erosion. The rate of generics sales growth is admittedly slowing in the more mature markets of the USA, Germany and the UK, where the use of copycat drugs is already high.

However, while the less mature markets like France, Spain, Italy and Japan have experienced a slower uptake to date, this is set to change, with legislation promoting generics increasingly being implemented in a bid to moderate health care spending. With the US market increasingly difficult to penetrate, generics manufacturers are looking elsewhere to make an impact. However, a new report by independent market analyst Datamonitor highlights the fact that potential pitfalls exist in each of the seven major markets.

Market expansion in the USA is likely to continue more slowly, with competitive pressure becoming a major obstacle to industry growth, says the report.

The USA is by far the world's largest generics market, says Datamonitor pharmaceutical analyst Pam Narang. "This, combined with the country's free pricing rules and pro-generic environment make it an extremely attractive prospect for foreign investors, despite the intensity of the competition," she notes.

"Of the major international acquisitions involving a US pharma company during 2005-07, two-thirds involve a foreign company acquiring a US one," she says.

Diminishing growth opportunities in USA

However, the level of competition in the USA is increasingly putting a brake on growth, driving consolidation and global expansion. Therefore, for domestic players: "the diminishing growth opportunities in the USA make the relatively less penetrated markets of Europe an attractive prospect," according to Ms Narang.

Moreover, Wal-Mart's foray into the generics market is likely to be cause for concern for the industry, she says. "With US employers footing a large part of the health care bill, it has been suggested that a natural extension of Wal-Mart's current strategy would be for the company to enter directly into specific agreements with corporate health care providers," she notes.

New legislation is also likely to impact on industry profits. As part of the Deficit Reduction Act of 2005, pharmaceutical manufacturers are now obliged to include sales of authorized generics in the calculation of average manufacturer price and best price, according to the Datamonitor repeort.

New reforms bring a shift in the way generics companies sell drugs in Germany, with exclusive contracts likely to prove more lucrative than marketing directly to health care providers.

Germany is currently the biggest generics market in Europe, and the second largest globally. Spiralling health care costs have driven the implementation of measures to increase generic use, with the result that uptake levels in Germany are among the highest in Europe.

German market in state of flux

The German health care system has been in a state of flux for several years, with new reforms introduced on an almost annual basis. The most recent changes have significant implications for the country's generics industry, Ms Narang says. "A consequence of the reforms is that the market is more open, having previously been dominated by the larger German players," she notes.

"Now any company that is able to secure a Krankenkasse (sickness fund) contract is automatically placed in a strong position," she says.

A government-led push towards increasing generic substitution for certain drug types in the UK, where generic use is already high, provides further room for growth.

Ms Narang says, in Britain, "generic drug use has been embraced, with the UK showing the highest levels of penetration of the five major European Union markets, at 26% by value and 64% by volume in 2006. The number of generic prescriptions has increased at a rate of 6% year-on-year from 1995 to 2005."

Nonetheless, a recent report by the UK's National Audit Office suggests that savings from generic drugs could be increased if all Primary Care Trusts used them at the same high level. The government is considering the recommendations, however, Datamonitor believes a wholesale shift in prescription behavior is unlikely due to the nature of the drugs in question, such as chronic use statins among them - that makes patients unlikely to accept a change in drugs taken for many years.

Use of generics in France is currently patchy but, once the set of targeted drugs is widened, this situation is likely to change dramatically

Generic substitution for those drugs that the French government has targeted is high, but a combination of physician reluctance and lack of awareness on the part of patients means that, overall, France lags behind Germany and the UK in terms of uptake of copy medicines, Ms Narang says."Brand loyalty is a significant factor in the French pharmaceutical market, and may be responsible for the historically low levels of generic uptake in the country," she points out.

"Although generic penetration is low in France, the eventual increase in uptake that will undoubtedly occur as a result of rising health care costs means that there are substantial growth opportunities, particularly given that France is already the third largest generic, and second largest pharmaceutical market in Europe."

Spain and Italy show low levels of generic use due mainly to general distrust

The proportion of the Italian health care budget that goes on drug spending is the highest in Europe, while the country's generics use is the lowest.

Datamonitor believes that, ultimately, this discordance is likely to disappear in the face of increasing pressures on health care spending, a fact which several international generic companies that have made forays into the Italian market, including India's **Ranbaxy** and Israel's Teva, are counting on.

Distrust of generic drugs among both health care providers and patients is a major obstacle to industry growth in Italy, according to Ms Narang. "The withdrawal of 11 undisclosed generic drugs in September 2006 due to concerns regarding the veracity of their bioequivalence will make a significant dent in efforts to promote generics use," she says.

Distrust of generic drugs is also an issue in Spain. However, Datamonitor believes that price differentials between branded and generic drugs in Spain are almost the lowest in Europe and may have contributed to the relatively poor uptake of copy medicines in the country to date. "As is the case in other countries, the rise in health care expenditure is likely to drive increased generic use," Ms Narang says.

With reforms promoting generics, Japan is poised for rapid growth

Generics' penetration in Japan is also very low due, in part, to the mistrust with which these products have traditionally been viewed. This stems from poor awareness regarding generic drugs, compounded with a lack of incentive for health care providers and patients alike. "However, with the most rapidly aging population in the world and rising health care costs this is set to change," Ms Narang says.

Recent government legislation (Marketletters passim) indicates a clear push towards generic usage. "Generic substitution in Japan has become mandatory, with physicians now required to explicitly state on the prescription if a branded drug is to be dispensed," she explains.

Additionally, generics may now be listed for reimbursement twice annually rather than once, Ms Narang points out. "Japan therefore provides the prospect of immense growth potential for those companies that are correctly positioned - a concept driving the current interest in the country's generic industry. Poor awareness and, crucially, generic supply have been major obstacles hindering generic penetration in Japan, and the industry has taken steps to remedy this. Because Japan is unusual in that a high proportion (43%) of pharmaceutical spending occurs in hospitals, manufacturers are beginning to forge stronger links with wholesalers as a means of increasing generic sales," she concludes.

For more information on this and other Datamonitor reports, visit: www.datamonitor.com.

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[Return to List](#cite_id_138)

138 of 200 DOCUMENTS



The Independent (London)

**April** 18, 2008 Friday

First Edition

**Shire galvanised by renewed bid speculation;**

**MARKET REPORT**

**BYLINE:** Nikhil Kumar

**SECTION:** BUSINESS; Pg. 50

**LENGTH:** 793 words

Renewed bid talk took the pharmaceutical group Shire to an intra-day high of 956p yesterday.

Market speculation suggested AstraZeneca was again mulling a bid for the company. An earlier UBS note, which said "AstraZeneca can pay up to 1,425p [a share] ... and achieve an economically accretive acquisition", sparked talk of a takeover in March, and yesterday's rumours appear to have been borne of the drug giant's recent settlement of its Nexium **patent** dispute with India's **Ranbaxy** Laboratories.

The talk was vague and, unlike past speculation, when rumours suggested an offer price of 1,300 per share, bore no clues about the level of the bid. By the close, Shire had eased back to 925p, down 6p.

Overall, the FTSE 100 came off the rally path, shedding 65.8, or 1.1 per cent, to 5,980.4. The index was depressed by news from Wall Street, where Merrill Lynch unveiled a worse-than-expected earnings report and announced a slew of job cuts. Investor sentiment was also hurt by rumours of larger writedowns at Citigroup, which is due to update the market shortly. The FTSE 250 lost 1.8 points to 10,089.4.

Retailers were depressed after the FTSE 250-listed Findel, the home shopping and educational supplies business, tendered fresh evidence of an economic slowdown. Findel said, in light of the impact of the "deteriorating economic climate" on its Home Shopping debt book, its pre-tax profits for the year to the end of March 2008 will be "below its previous expectations". Findel shed 36.97 per cent, or 164.25p, to 280p.

Next, which has a stake in the home shopping sub-sector via its Next Directory mail order business, was hit by the news - its shares slumped by 45p to 1,103p, claiming fourth place on the FTSE 100 loser board.

Other retailers were also weak, including the B&Q-owner Kingfisher, which lost 4.2p to 123.1p, Marks & Spencer, which was down 11p at 360.25p and Home Retail Group, which lost 4.5p to 250.75p.

Among housebuilders, Taylor Wimpey dampened investor sentiment. "Market conditions in the UK have weakened since we reported our preliminary results, with first-time buyers and investors facing particular difficulties as a result of the increasingly restricted availability of mortgages," the company said, sending its stock down 6.25p to 158.75p and sparking a sell-off in the sector.

The statement confirmed investor fears, cancelled the effect of hopes that the Bank of England may intervene to stimulate the flagging mortgage market, and took Persimmon down by 23p to 659p. Barratt Developments lost 6.25p to 358.5p and Bovis Homes was down 18p at 524p. Redrow lost 6.25p to 280.75p, Bellway was 15.5p weaker at 783.5p, and Berkeley Group Holdings lost 16p to 973p.

The banking sector was a mixed bag. Hopes of a new Bank of England initiative to ease the credit crisis gave a lift to the likes of Alliance & Leicester, which was up 7p at 510p and HBOS, which gained 10.5p to 550p.

Royal Bank of Scotland, however, was depressed following rumours that it was mulling a rights issue. RBS lost 11.25p to 363.75p. Barclays was also down, losing 0.25p to 478.75p

On the FTSE 100, Thomson Reuters made an uninspiring debut, losing 14.57 per cent or 266p to 1,560p.

"There is likely to be some short-term weakness in the share price, due to unwinding of arbitrage positions between Thomson Corp and Reuters Plc," said Amanda Purton, an analyst at Barclays Wealth. She added: "We are long-term sellers due to our concerns around the part of the business based in financial markets, where reduction in headcount and IT budgets following the credit crisis is likely to see forecasts fall."

Relative to the market, Barclays Wealth set a "sell" rating for the new stock. Cazenove set an "in-line" rating, while Collins Stewart set a "sell" rating.

Experian fell by 14.75p to 380.5p after Citigroup downgraded the stock to "sell" from "hold". The broker said the group's trading conditions "look set to worsen during 2009", adding: "Investors can cut through the noise and find the key to Experian's health by focusing on US credit services [which decelerated from -2 per cent to -4 per cent in the fourth quarter of 2008]. Key trends in this division will likely transfer across segments geographies over time."

On the FTSE 250, the oil services group Expro International gained 123p to 1,445p after recommending a much-anticipated £1.6bn takeover offer from a Candover Partners-led consortium. Investors were also excited by the prospect of rival bid after the company confirmed that another party "continues to conduct due diligence on Expro". And while there was no official confirmation of the identity of the rival suitor, market speculation mooted the American private firm KKR and Technip, the French oil services company, as the most likely bidders.

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**PUBLICATION-TYPE:** Newspaper

**JOURNAL-CODE:** IA

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[Return to List](#cite_id_139)

139 of 200 DOCUMENTS

Birmingham Post

**April** 16, 2008, Wednesday

1ST Edition

**SHARE PRICES: Big guns lead FTSE 100 revival after five days;**

**MARKET REPORT**

**SECTION:** NEWS; Pg. 18

**LENGTH:** 483 words

Blue-chip big guns Tesco and Astra-Zeneca led a revival yesterday as the London market broke a five-day losing streak.

The grocery giant's pounds 2.85 billion profits haul and the settling of a **patent** dispute by the drugs company pushed them up the risers board, with gains from heavyweight mining stocks underpinning progress.

This helped the FTSE 100 Index to gains of more than one per cent, closing 75.3 points higher at 5906.9. Wall Street also made early progress amid better than expected manufacturing figures and upbeat results from the likes of consumer giant Johnson & Johnson.

In London, Tesco was the best performer after reporting annual profits up 11.8 per cent and like-for-like sales ahead by more than four per cent in the first five weeks of the new financial year.

Shares were up 28.5p to 419.5p on the back of the update - more than seven per cent. Rivals Sainsbury's and Morrisons followed Tesco higher, adding 7p to 366p and 6.5p to 283.75p respectively.

Drugs firm AstraZeneca was also in demand after it secured an agreement with India's **Ranbaxy** Laboratories to end a lawsuit over **patent** infringements for its Nexium heartburn drug.The verdict on a key product in the Astra portfolio lifted shares seven per cent, or 141p, to 2122p.

Another riser was BG Group after the apparent discovery of a huge oil field off the coast of Brazil. Shares in the firm, which has a 30 per cent interest in the find, were up 66p at 1288p.

As oil prices breached 113 US dollars a barrel to set a new record, exploration firm Tullow Oil also rose 28p to 713p. But others fared less well following the price hikes, with airline British Airways easing 7p to 208.5p and Tui Travel down 6.5p at 255p.

Among the mining stocks on the front foot on higher commodity prices, BHP Billiton was up 64p to 1770p, while Rio Tinto rose 185p to 6007p.

Elsewhere, Friends Provident managed to claw back some losses after yesterday's ultimatum from bidder JC Flowers. Shares were up 2.4p to 118.9p.

Carphone Warehouse was the session's biggest loser, dropping more than 13 per cent, or 35.5p to 231p, after it posted weaker-than-expected broadband additions for the fourth quarter of its financial year.

In the FTSE 250 Index, fashion label Burberry topped the risers' board after announcing that second half like-forlike sales were up six per cent. Shares added 42.5p to 438.5p - a gain of almost 11 per cent.

But early gains for retailer Debenhams were reversed as investors digested pre-taxprofits of pounds 94.1 million - down 12 per cent on a year earlier although better than City forecasts. Shares had been up 1.5p but slipped 1.25p to 55.75p.

The biggest Footsie risers were Tesco up 28.5p at 419.5p, AstraZeneca ahead 141p at 2122p, BG Group up 66p at 1288p and Eurasian Natural Resources ahead 60p at 1260p. The biggest Footsie fallers were Carphone Warehouse down 35p at 231p, Home Retail Group off 9.25p at 240p.

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[Return to List](#cite_id_140)

140 of 200 DOCUMENTS

The Daily Telegraph (LONDON)

**April** 16, 2008 Wednesday

**THE MARKET A&L falls to eight-year low after broker's warning**

**BYLINE:** Ben Bland

**SECTION:** CITY; Markets; Pg. 7

**LENGTH:** 1124 words

MORTGAGE bank Alliance & Leicester hit an eight-year low after one of London's leading brokers warned that its business model was "unlikely to be sustainable'' in the longer term.

JP Morgan said that, along with buy-to-let lender Bradford & Bingley, A&L's reliance on the contracting money markets left it "structurally challenged''.

Although B&B recently dismissed suggestions that it was planning a rights issue, JP Morgan analyst Carla Antunes da Silva said it was "simply a question of time'' before these banks needed to raise additional funds. She added: "The Government should 'encourage' some of these smaller/weaker banks to look for strategic partners in order to avoid getting into this type of situation.''

A spokesman for B&B said it was "fully funded through to 2009''. A&L declined to comment. A&L shares shed 8æ to 471Ωp, while B&B ticked up 1 to 166Ωp.

In the wider market, the FTSE 100's five-day losing streak finally came to an end, with the blue-chip index closing 75.3 firmer at 5906.9. The FTSE 250 rose 58.7 to 9904.2. The Dow Jones Industrial Average finished up 60.4 at 12362.5.

It was a mixed day for the retail sector with supermarket giant Tesco and luxury fashion group Burberry posting positive updates despite the British Retail Consortium unveiling a very weak set of sales figures for March.

Tesco was the top blue-chip performer, rising 28Ω to a year high of 419Ωp after delivering strong full-year results once again and insisting that its US offshoot Fresh & Easy was performing well.

Burberry also surprised investors on the upside, leaping 42Ω to 438Ωp after indicating that demand for its up-market handbags and coats was undented by the global financial crisis.

However, mobile phone retailer and broadband provider Carphone Warehouse was the biggest FTSE 100 faller, sliding 35Ω to a three-year low of 231p after a disappointing fourth-quarter update.

Debenhams, the department store chain, eased 1º to 55æp after reporting a 12pc fall in first-half profits and claiming that the market will "remain challenging'' as consumers keep a tight grip on their purse strings.

Elsewhere, AstraZeneca, Britain's second largest drug-maker, jumped 141p to pounds 21.22 after settling a **patent** infringement lawsuit with India's **Ranbaxy** over Nexium, its best-selling ulcer treatment. Dresdner Kleinwort upgraded AstraZeneca to buy from hold, noting "a settlement with **Ranbaxy** on Nexium significantly de-risks the business''.

Oil and gas producer BG Group moved up 66p to a record high of pounds 12.88 after a leading Brazilian energy official suggested that a deep-water area BG was exploring alongside state-run Petrobras and Spain's Repsol could contain as many as 33bn barrels of oil. The news also boosted Wellstream, which provides Petrobras and other oil companies with the flexible piping that is needed for deep-water drilling. Wellstream shares ended 75p stronger at pounds 13.32.

British Airways slipped 7 to a four-year low of 208Ωp as the departures of two senior executives failed to quell investors' concerns about the damage done by the Terminal 5 shambles.

Zambian nickel miner Albidon Resources rose 4Ω to a record high of 191p on rumours that Xstrata, the acquisitive Anglo-Swiss mining group, was eyeing it up. The shares have been heavily traded in recent sessions, with more than 15 times the normal daily average changing hands yesterday. Market sources said that now that takeover talks with Brazilian suitor Vale were dead in the water, Xstrata was free to look at bolt-on acquisitions in the nickel sector without raising concerns from competition authorities.

The housebuilders were sold off after the latest Royal Institution of Chartered Surveyors survey pointed to an ever-weakening housing market. Persimmon fell 16 to 659p, Berkeley lost 36 to 988p and Bovis Homes dipped 16Ω to 528p.

Independent News & Media, which publishes The Independent newspaper, dipped 3 cents to euro2.035 as chief executive Sir Anthony O'Reilly bought another 2m shares, taking his stake to 27.7pc.

Sir Anthony is locked in a battle with Irish telecoms billionaire Denis O'Brien, who has amassed a 21pc stake in the group.

AIM FOCUS

\* Small-cap stockbroker Blue Oar Securities tumbled 1Ω to 15p after its normally bullish chief executive Andrew Monk warned shareholders at the company's annual general meeting of a difficult outlook.

The flow of new listings on Aim has almost completely dried up, hitting brokers like Blue Oar, which are extremely reliant on the advisory fees they get for carrying out stock market flotations.

Mr Monk told investors yesterday: "Current market conditions are such that our corporate finance revenues, the largest contributor to our overall results last year, are being impacted by significantly lower activity levels.''

He added that there was little clarity as to when the situation would improve, noting: "It remains difficult to predict whether market conditions will improve later in the year.''

\* Despite carrying out a successful rebellion against incumbent management last year, shareholders in Transense Technologies, which is developing tyre pressure sensors, are still facing tough times.

The shares slumped 5º to an all-time low of 11Ωp yesterday after the company revealed that annual pre-tax losses more than doubled to pounds 2.68m because of the costs incurred when the rebel shareholders aborted the old management's planned reverse takeover of an Australian company.

LSE PLUNGE

The London Stock Exchange has been one of the worst blue-chip performers so far this year, losing nearly 40pc of its value because of fears about growing competition and worries about the impact of the credit crunch.

The shares have also been hit as hopes of a takeover by either of the LSE's major Gulf investors (Borse Dubai and the Qatar Investment Authority) faded.

Leading broker Morgan Stanley renewed the focus on the LSE's woes yesterday when it slashed its target price by 29pc to pounds 10.60 and reiterated its underweight recommendation. Analyst Bruce Hamilton believes that the LSE will have to cut its trading fees by around 10pc as it seeks to respond to pressure from new competitors such as Nasdaq OMX, Turquoise and BATS Europe as well as Chi-x, which is already up and running.

"We expect the aggressive pricing by these players to force a response from LSE, placing revenues at risk,'' Mr Hamilton wrote in a note to Morgan Stanley's clients.

He said that the LSE was likely to suffer from the significant drop in new listings caused by the ongoing credit crisis and weaker volumes at Borsa Italiana, with which it merged last year.

"IPO fees are at risk of slowing, with NYSE set to compete more aggressively for international listings,'' he added.

LSE shares ended 4p lower at pounds 11.95.

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[Return to List](#cite_id_141)

141 of 200 DOCUMENTS

The Daily Telegraph (LONDON)

**April** 16, 2008 Wednesday

**PHARMACEUTICAL Patent row settlement boosts UK giant**

**BYLINE:** Jonathan Russell

**SECTION:** CITY; Pg. 4

**LENGTH:** 409 words

SHARES in the UK drug giant AstraZeneca jumped more than 7pc after it settled a long-running **patent** dispute with generic pharmaceutical group **Ranbaxy** over the world's second best-selling drug.

The agreement over a dispute relating to

AstraZeneca's $5.2bn ulcer treatment Nexium will help safeguard sales until May 2014. As part of the agreement, **Ranbaxy** has accepted that six **patents** asserted by AstraZeneca in the **patent** litigation are valid. The settlement will allow **Ranbaxy** to start sales of a generic version of Nexium in May 2014, five years before the final **patent** on Nexium is due to expire.

AstraZeneca has also agreed manufacturing and distribution deals with **Ranbaxy** relating to Nexium and two other US products.

David Brennan, the AstraZeneca chief executive, said: "This agreement is the right business decision and gives increased clarity and stability to allow us to continue investing substantially in our growing pipeline of new medicines.''

Despite the announcements over the **patent** dispute and the manufacturing and distribution deals coming on the same day, Mr Brennan said they were not directly related. Any such deal could fall foul of US anti-trust regulations. Mr Brennan said: "Each agreement has different drivers and has been valued on its own merits.''

AstraZeneca still faces **patent** challenges from two other companies, Teval/IVAX and Reddy's Laboratories, over Nexium. However, the settlement was welcomed by analysts who suggested it would now be very difficult for one of these challenges to succeed. With Nexium having sales of $3.4bn in the US, the drug is a major revenue stream for AstraZeneca.

Analysts at Dresdner Kleinwort said: "A settlement with **Ranbaxy** on Nexium significantly de-risks the business. The concessions from **Ranbaxy** concerning the validity of AZN's **patents** and potential infringement make another challenger unlikely.''

The commercial agreements with **Ranbaxy** relate to the manufacture of a portion of AstraZeneca's US supply of Nexium from May 2010 and the manufacture of the active ingredient in Nexium from May 2009.

The two companies have also agreed a US distribution deal on AstraZeneca's authorised generic versions of Plendil and Prilosec.

Mr Brennan said the company planned to continue outsourcing the manufacture of more of the active ingredients in its products.

The settlement with **Ranbaxy** is expected to be reviewed by the US Federal Trade Commission.

AstraZeneca shares rose 141p to pounds 21.22.

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[Return to List](#cite_id_142)

142 of 200 DOCUMENTS

Daily Mail (London)

**April** 16, 2008 Wednesday

**Gushing oil price fuels rise in FTSE;**

**MARKET REPORT**

**BYLINE:** Caroline Muspratt

**SECTION:** 1ST; Pg. 74

**LENGTH:** 795 words

OIL rose to another high and showed no sign of abating, helping push the FTSE 100 above the 5900 mark.

The price of New York crude oil reached $113.93 a barrel, a record, boosted by the weak US currency and a tightening supply.

Global demand for oil is forecast to grow by 1.2m barrels per day in 2008, the Organisation of Petroleum Exporting Countries said.

Energy stocks helped lift the blue chip index by 75.3 points to 5906.9, ending a five- day losing streak, with Royal Dutch Shell up 27p to 1836p and BP slightly higher at 552 1/2 p, up 3 1/2 p.

Tullow Oil was 28p better at 713p while BG Group, the oil and gas company, jumped 66p to 1288p on the suggestion that an oil find in Brazil could be the world's biggest discovery in 30 years.

Analysts were quick to upgrade BG, which has a 30pc stake in the project. Evolution Securities upped the stock to buy with a target price of 1500p.

Wellstream Holdings, which makes pipelines for the oil and gas industry, also rose 75p to 1332p.

However, the higher oil price was not good news for everyone, with transport stocks taking a knock. British Airways , which said two of its senior managers would leave, slid 7p to 208 1/2 p while budget airline easyJet shed 14 1/4 p to 312p. Bus operator Stagecoach was 8 1/4 p lower at 212 1/4 p.

Tesco was the biggest riser in the FTSE 100, up 28 1/2 p to 419 1/2 p on the back of good full- year results. Rival supermarket operators Wm Morrison also edged up 6 1/2 p to 283 3/4 p and J Sainsbury put on 7p to 366p.

Insurer Friends Provident recovered 2.4p to 118.9p after falling 10pc the previous day when prospective bidder JC Flowers said it would not increase its proposed offer above 150p a share.

Panmure Gordon upgraded the stock to buy from hold, saying if Friends does enter talks, the share price should bounce, but 'if Flowers walks away we do not believe that there is any real downside as Friends Provident will execute the findings of its strategic review'.

Bid rumours helped boost a couple of smaller stocks. Traders speculated that Regal Petroleum , the oil and gas producer, could be a takeover target with a potential bidder interested in its Ukranian assets. Regal rose 15 1/4 p to 156 1/2 p as it announced two appointments - Robert Wilde as finance director and Ronan McElroy as chief technologist.

Volumes were heavier than usual in greeting cards retailer Clinton Cards on speculation that the company could make a tasty acquisition for US rival Hallmark. Clinton Cards ticked up 1 1/4 p to 58 3/4 p.

There was renewed pressure on the housebuilding and mortgage lending sectors after the Royal Institution of Chartered Surveyors said confidence in the UK housing market had sunk to its lowest level in 30 years.

Housebuilder Persimmon lost 16p to 659p, Bovis Homes was off 16 1/2 p at 528p and Barratt Developments slipped 10p to 349 3/4 p.

Taylor Wimpey also eased 3 1/2 p to 158 1/4 p as it said Ian Sutcliffe, head of its UK housing division, had left to join Segro.

Also affected by the RICS news were building materials supplier Wolseley , 8 1/2 p lower at 523p, and Home Retail Group , the owner of DIY retailer Homebase, which shed 9 1/4 p to 240p. Home Retail Group may have to sell one of the stores it bought recently from DIY chain Focus after the Office of Fair Trading raised concerns about overlaps and said it could refer the acquisition to the Competition Commission.

Among the banks and mortgage lenders, Alliance & Leicester was down 8 3/4 p to 471 1/2 p and Royal Bank of Scotland slipped 3p to 348 1/2 p.

The pound fell to a fresh low against the euro, touching 80.64p per euro at one point yesterday, causing further concern that more holidaymakers will choose to stay at home rather than travel abroad. Tui Travel , the owner of First Choice holidays, slipped 6 1/2 p to 255p while rival Thomas Cook was 1p weaker at 293p.

In the US, the Dow Jones was up 17 points at 12319 in mid session, with gains from the energy sector partly offset by fears of more banking losses.

Among UK stocks, drugs giant AstraZeneca was another big riser, leaping 141p to 2122p on the news it had settled a **patent** dispute with generic drug maker **Ranbaxy,** prompting Credit Suisse to raise its target price to 2230p from 2000p.

Cazenove upgraded the stock from underperform to in line, saying the news 'removes a significant downside risk to the shares'.

SSL International, the Scholl- to- Durex group, gained 9 1/4 p to 450 1/2 p as it revealed in a trading update full-year sales are expected to be around £532m, up 7pc on the previous year. Garry Watts, chief executive, said: 'Based on this sales performance, we expect to achieve our double digit operating profit growth target for the year.' Sales of branded goods also rose about 7pc helped by new products like foot creams.

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[Return to List](#cite_id_143)

143 of 200 DOCUMENTS

Daily Mail (London)

**April** 16, 2008 Wednesday

**AstraZeneca in cancer drug deal**

**SECTION:** 1ST; Pg. 76

**LENGTH:** 195 words

SHARES in AstraZeneca shot up 7pc after it agreed a deal with copycat drug maker **Ranbaxy** of India to end **patent** litigation on Nexium, its blockbuster cancer medicine.

Nexium is one of the world's biggest selling drugs, with sales last year of £2.65bn.

**Ranbaxy** was challenging **patents** so it could launch a generic version early, which would have hurt AZ's profits.

To end the pain, AstraZeneca (up 141p at 2122p) agreed **Ranbaxy** can begin selling a version of the drug from May 2014 - the expiry date of the first of a series of **patents.**

A senior industry source said: 'To prevent the share price falling through the floor, AstraZeneca is giving a little bit away in return for certainty of earnings to 2014.'

**Ranbaxy** has also been granted US distribution rights to two other AZ products, rilosec and Plendil, which are already off-**patent.**

It will also begin making the active ingredient for Nexium, esomeprazole, in the US under contract to AstraZeneca.

David Brennan, AstraZeneca's chief executive, said: 'This agreement gives increased clarity and stability to allow us to continue investing substantially in our growing pipeline of new medicines.'

More at thisismoney.co.uk/azn

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[Return to List](#cite_id_144)

144 of 200 DOCUMENTS

Daily Post (North Wales)

**April** 16, 2008, Wednesday

Mersey Edition

**LONDON MARKET;**

**IN ASSOCIATION WITH Rensburg Sheppards Investment Management**

**SECTION:** BUSINESS; Pg. 2

**LENGTH:** 388 words

BLUE-CHIP big guns Tesco and AstraZeneca led a revival yesterday as the London market broke a fiveday losing streak.

The grocery giant's pounds 2.85bn profits haul and the settling of a **patent** dispute by the drugs company pushed them up the risers board, with gains from heavyweight mining stocks underpinning progress.

This helped the FTSE 100 Index to gains of more than 1%, closing 75.3 points higher at 5906.9. Wall Street also made early progress amid better than expected manufacturing figures and upbeat results from the likes of consumer giant Johnson & Johnson.

In London, Tesco was the best performer after reporting annual profits up 11.8% and like-for-like sales ahead by more than 4% in the first five weeks of the new financial year.

Shares were up 28.5p to 419.5p on the back of the update - more than 7%.

Rivals Sainsbury's and Morrisons followed Tesco higher, adding 7p to 366p and 6.5p to 283.75p respectively.

Drugs firm AstraZeneca was also in demand after it secured an agreement with India's **Ranbaxy** Laboratories to end a lawsuit over **patent** infringements for its Nexium heartburn drug. The verdict on a key product in the Astra portfolio lifted shares 7%, or 141p, to 2122p.

Another riser was BG Group after the apparent discovery of a huge oil field off the coast of Brazil.

Shares in the firm, which has a 30% interest in the find, were up 66p at 1288p.

As oil prices breached EUR113 a barrel to set a new record, exploration firm Tullow Oil also rose 28p to 713p. But others fared less well following the price hikes, with airline British Airways easing 7p to 208.5p and Tui Travel down 6.5p at 255p.

Among the mining stocks on the front foot on higher commodity prices, BHP Billiton was up 64p to 1770p, while Rio Tinto rose 185p to 6007p.

Elsewhere, Friends Provident managed to claw back some losses after yesterday's ultimatum from bidder JC Flowers. Shares were up 2.4p to 118.9p.

Carphone Warehouse was the session's biggest loser, dropping more than 13%, or 35.5p to 231p.

The biggest Footsie risers were Tesco up 28.5p at 419.5p, AstraZeneca ahead 141p at 2122p, BG Group up 66p at 1288p and Eurasian Natural Resources ahead 60p at 1260p.

The biggest Footsie fallers were Carphone Warehouse, down 35p at 231p, Home Retail Group, off 9.25p at 240p, Tui Travel, off 6.5p at 255p, and Persimmon down 16p at 659p.

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**PUBLICATION-TYPE:** Newspaper

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[Return to List](#cite_id_145)

145 of 200 DOCUMENTS

Daily Post (North Wales)

**April** 16, 2008, Wednesday

Mersey Edition

**In brief: Drug patents dispute settled;**

**IN ASSOCIATION WITH Rensburg Sheppards Investment Management**

**SECTION:** BUSINESS; Pg. 12

**LENGTH:** 60 words

PHARMACEUTICAL giant AstraZeneca has settled a **patent** row over its Nexium heart-burn treatment with Indian company **Ranbaxy,** which had submitted an application for a generic version of the drug.

**Ranbaxy** has conceded the validity of six **patents** subject to dispute.

AstraZeneca chief executive David Brennan said: "We will vigorously defend our intellectual property."

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**PUBLICATION-TYPE:** Newspaper

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[Return to List](#cite_id_146)

146 of 200 DOCUMENTS

Daily Star

**April** 16, 2008 Wednesday

U.K. 1st Edition

**ASTRA SETTLES;**

**IT'S THE BUSINESS**

**SECTION:** BUSINESS; 47

**LENGTH:** 66 words

ASTRAZENECA yesterday settled a long-running lawsuit against an Indian company planning copycat versions of its ulcer medicine Nexium.

The drugmaker's shares leapt 141p to 2122p, on news of the settlement.

Nexium generates worldwide sales of GBP 2.6billion.

Under the deal **Ranbaxy** has accepted that the **patents** are valid.

And it will be given a licence to produce its own version of Nexium from 2014.

**LOAD-DATE:** April 17, 2008

**LANGUAGE:** ENGLISH

**PUBLICATION-TYPE:** Newspaper

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[Return to List](#cite_id_147)

147 of 200 DOCUMENTS

The Globe and Mail (Canada)

**April** 16, 2008 Wednesday

**Ranbaxy to keep top generic off U.S. market**

**BYLINE:** JEANNE WHALEN

**SECTION:** REPORT ON BUSINESS: THE WALL STREET JOURNAL; PHARMACEUTICALS; Pg. B14

**LENGTH:** 151 words

**AstraZeneca PLC** said it has settled a lawsuit against India's **Ranbaxy Laboratories Ltd.** in a pact that will keep **Ranbaxy's** generic copies of the blockbuster heartburn drug Nexium off the U.S. market until 2014.

AstraZeneca also said it was awarding **Ranbaxy** some valuable contracts, saying that they were separate from the settlement. Some analysts said the contracts could trigger questions from the U.S. Federal Trade Commission. The commission has objected to some deals where it believed a **patent** holder was giving a generic company something of value in exchange for staying off the market, arguing this stymied competition and hurt consumers.

AstraZeneca chief executive officer David Brennan declined to predict how the FTC would react but called the agreements with **Ranbaxy** "perfectly lawful." .

The settlement lifted a cloud hanging over AstraZeneca and sparked a rally in the company's shares.

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**PUBLICATION-TYPE:** Newspaper

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[Return to List](#cite_id_148)

148 of 200 DOCUMENTS



The Guardian (London) - Final Edition

**April** 16, 2008 Wednesday

**Financial: AstraZeneca settles lawsuit with Ranbaxy**

**BYLINE:** Graeme Wearden

**SECTION:** GUARDIAN FINANCIAL PAGES; Pg. 28

**LENGTH:** 261 words

AstraZeneca vowed yesterday it would keep battling generic competitors after settling a legal fight over Nexium, its best-selling stomach ulcer medicine.

After a two-and-a-half-year legal battle, the UK pharmaceutical firm has reached an agreement with India's **Ranbaxy**, a maker of generic drugs.

**Ranbaxy** had hoped to overturn AstraZeneca's **patents** on Nexium and launch its own, cheaper heartburn treatment in the US market. Under the deal it won't start selling a generic version of Nexium until 2014, licenced under AstraZeneca.

The deal sent AstraZeneca's shares soaring to £21.23, up 7%. **Ranbaxy**'s shares rose 8.6% on the Bombay stock exchange.

AstraZeneca declined to release full details of the settlement, citing commercial sensitivity. It said it had signed a manufacturing and distribution deal with **Ranbaxy**, under which it would start manufacturing the active ingredient of Nexium from 2009. This prompted suggestions AstraZeneca had paid off **Ranbaxy** to keep its Nexium **patents** secure until 2014, when they begin to expire.

Two makers of generic drugs, Teva/IVAX and Dr Reddy's Laboratories, are still embroiled in litigation over Nexium.

AstraZeneca's chief executive, David Brennan, said the **Ranbaxy** deal showed its commitment to vigorously defend its intellectual property.

Under the agreement, **Ranbaxy** has conceded that all six of AstraZeneca's **patents** are valid and enforceable.

But Jeremy Batstone-Carr, analyst at Seymour Pierce, suggested the deal was "a partial giveaway" by AstraZeneca and recommended that investors reduce their shareholding in the company.

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[Return to List](#cite_id_149)

149 of 200 DOCUMENTS



The Independent (London)

**April** 16, 2008 Wednesday

First Edition

**LogicaCMG fails to catch market updraught;**

**MARKET REPORT**

**BYLINE:** Nikhil Kumar

**SECTION:** BUSINESS; Pg. 42

**LENGTH:** 781 words

The IT services specialist LogicaCMG missed out on a market rally after attracting some bearish broker sentiment yesterday.

Citing the company's "weak strategic market positioning", Morgan Stanley cut its target price for the stock from 130p to 110p.

"The company is neither a global player nor a niche specialist and its cyclical business mix offers limited recurring revenues," the broker said, adding: "We also fear that if market conditions were to get tougher, the weak balance sheet could become a problem."

The broker also struck a note of caution about the company's ongoing strategic review: "Although we recognise the strategic review could address some of the issues, we believe the margin's upside potential is limited ...The stock looks fairly valued at current levels. We would recommend that investors sell the stock if it gets above 120p and would-be buyers at levels below 90p."

The negative assessment kept the company's shares weak and they closed at 105.50p, down 1.25p.

Overall, the FTSE 100 mounted a comeback yesterday, climbing by 75.30 points to 5906.90. The London benchmark was lifted by some positive company news: supermarket group Tesco published strong preliminary results, allaying investor fears about trading and gaining 7.29 per cent or 28.50p to 419.50p; drug marker AstraZeneca announced the settlement of its Nexium **patent** infringement litigation against India's **Ranbaxy** Laboratories, securing future sales of the medication and helping its stock climb by 7.12 per cent or 141p to 2,122p; and energy giant BG Group rose by almost 5.40 per cent or 66p after Brazil's National Petroleum agency said an oil find in which the company has a stake may be the world's biggest discovery in 30 years.

A mixed start on Wall Street took the index off earlier highs, but failed to drag it into the red. US investors were cheered by an unexpected rebound in manufacturing activity in New York in April and by above-forecast profits at healthcare products giant Johnson & Johnson, but worried by rising inflation.

Elsewhere, the FTSE 250 was up, gaining 58.70 points to 9,904.20. The mining sector stood out for its strength yesterday. Metals prices continued to rise, taking the Eurasian Natural Resources Corporation to fourth place on the FTSE 100 leader board, up 60p at 1,260p.

Rio Tinto gained 185p to 6,007p as rumours suggested that BHP Billiton, which rose by 64p to 1,770p, may supplement its all-share bid with a cash sweetener.

Other miners, including Xstrata, which climbed 18p to 3749p, Vedanta Resources, which added 24p to 2374p, and Anglo American, which gained 43p to 3264p, also remained firm.

Housebuilders, on the other hand, fell by the wayside after figures from the Royal Institute of Chartered Surveyors tendered fresh evidence of a downturn in the domestic property market. Seventy-eight and-a-half per cent more chartered surveyors reported a fall instead of a rise in house prices in March, the lowest figure since1968.

The news bore on Persimmon, which slumped by 16p to 659p. Berkeley Group Holdings lost 36p to 988p while Bellway was weaker by 23.50p at 760.50p.

Others in the sector, including Barratt Developments, which lost 10p to 349.75p, Bovis Homes, which was down 16.50p at 528p, and Taylor Wimpey, which lost 3.50p to 158.25p, were also off-colour yesterday.

On the FTSE 100, Friends Provident was up 2.40p at 118.90p after Panmure Gordon upgraded the stock to "buy" from "hold".

"We have only ever had a Hold or Sell recommendation on [Friends Provident] since we initiated coverage a year ago," the broker said, "However, we believe that [Monday's] 11 per cent share price fall [in response] to news that JC Flowers will not increase its initial offer above 150p is an over reaction."

Panmure added: "If discussions open the share price will bounce, [but] if Flowers walks away we do not believe that there is any real downside."

On the FTSE 250, M&A speculation was evident around JKX Oil & Gas, which gained 15.50p to 492.75. Market talk suggested that JKX may merge with, or bid for, Regal Petroleum, the smaller oil & gas exploration and production company. "The rumour is based on the fact that both have interests in Ukraine," said one trader.

Regal, which announced the appointment a new fin-ance director yesterday, rose by 15.25p to 156.50p. On AIM, Tanfield swung to the top of the AIM UK 50 index after launching a new zero-emission electric vehicle in collaboration with Ford.

The company's trading division, Smith Electric Vehicles, launched the Ampere van, which utilises the Ford Transit Connect chassis, at the Commercial Vehicle Show in Birmingham yesterday.

Tanfield's shares closed at 116.75p, up 12.26 per cent, or 12.75p.

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[Return to List](#cite_id_150)

150 of 200 DOCUMENTS



The Independent (London)

**April** 16, 2008 Wednesday

First Edition

**AstraZeneca rises 7% after Ranbaxy agrees Nexium deal**

**BYLINE:** Alistair Dawber

**SECTION:** BUSINESS; Pg. 34

**LENGTH:** 366 words

Shares in AstraZeneca soared by more than 7 per cent yesterday after the group settled a long-running dispute with the Indian drug maker **Ranbaxy** over the production of its biggest-selling drug, Nexium.

The row blew up in November 2005 when AstraZeneca sued **Ranbaxy** over its intention to produce a generic version of the ulcer treatment, which makes the Anglo-Swedish group $5.22bn (£2.66bn) a year. Under the terms of the deal, **Ranbaxy** will be able to produce the drug from May 2014, which is when the first **patents** held by AstraZeneca expire. A spokesman for AstraZeneca confirmed that no damages had been paid by **Ranbaxy**, but that the Indian firm did accept AstraZeneca's **patents**.

The agreement also allows **Ranbaxy** to make Nexium for the US market under licence from May 2010 and has given the Indian firm distribution rights over two of AstraZeneca's other treatments, Plendil and Prilosec.

Market sources hailed the settlement as a victory for AstraZeneca and for other drug companies trying to assert their **patents**. "The decision represents a complete climb down for **Ranbaxy**," Peter Cartwright, an analyst at Evolution, said. "**Ranbaxy** have been forced to recognise the value of the **patents**."

AstraZeneca's shares were up 141p yesterday to 2122p a share yesterday, with other sector watchers pointing out that the group's stock has been depressed by the overhanging possibility of expensive litigation.

"AstraZeneca's shares have underperformed in the last 12 months," said WestLB's Simon Mather. "When the stock was down at £18 a share [they traded at £17.48 on 17 March] it was because the market was discounting US sales of Nexium."

According to analysts the agreement will cost AstraZeneca about $1bn of sales, but that the group would save by avoiding costly court cases. The winner of such litigation can normally expect to recover costs.

AstraZeneca is not completely free of legal wrangles concerning Nexium. It has two writs outstanding against another Indian group, Dr Reddy's, and Israeli company Teva.

Both companies have lodged proposals to manufacture their own generic version of the drug. Even though **Ranbaxy** opted to recognise AstraZeneca's **patents**, they remain to be tested by a court.

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[Return to List](#cite_id_151)

151 of 200 DOCUMENTS

The International Herald Tribune

**April** 16, 2008 Wednesday

**AstraZeneca settle lawsuit;**

**HOT STOCKS**

**SECTION:** FINANCE; Pg. 16

**LENGTH:** 100 words

AstraZeneca said that it had settled a U.S. **patent** dispute with **Ranbaxy** Laboratories of India over its top-selling drug, the ulcer pill Nexium, securing future sales. Its shares rose 10 percent.

Under the deal, **Ranbaxy** will be allowed to start selling a cheaper generic version of Nexium on May 27, 2014, which is the expiration of the earliest **patents** on the medicine, the two companies said. **Ranbaxy** will have 180 days of exclusivity as the only distributor for generic Nexium.

The deal is a relief for AstraZeneca investors, who had feared revenue from Nexium could plunge in the face of generic drugs.

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**PUBLICATION-TYPE:** Newspaper

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[Return to List](#cite_id_152)

152 of 200 DOCUMENTS

The Irish Times

**April** 16, 2008 Wednesday

**In Short**

**SECTION:** FINANCE; Other Stories; Pg. 22

**LENGTH:** 629 words

A round-up of today's other stories in brief...

**IL&P chief executive Casey earned EUR 1.36m last year**

Irish Life & Permanent (IL&P) chief executive Denis Casey earned EUR 1.362 million last year, according to the group's 2007 annual report.

Mr Casey, who succeeded David Went as chief executive of the financial services group last May, earned a salary of EUR 694,000, a bonus of EUR 617,000, benefits of EUR 30,000 and other remuneration, including profit-share payments, of EUR 21,000. He received pay of EUR 602,000 in 2006.

Finance director Peter Fitzpatrick received EUR 945,000 in 2007, up from EUR 788,000 the previous year, while Kevin Murphy, chief executive of Irish Life, received EUR 923,000, an increase from EUR 582,000 the previous year.

Mr Went, who is chairman of The Irish Times Ltd, retired from IL&P last May. He received EUR 343,000 last year, down from EUR 1.335 million in 2006.

IL&P chairwoman Gillian Bowler received fees of EUR 320,000, up from EUR 300,000. Eight non-executive directors shared fees of EUR 909,000 last year, an increase of EUR 86,000.

**AstraZeneca in patent deal**

AstraZeneca has settled US **patent** litigation against India's **Ranbaxy** Laboratories Ltd over its top-selling ulcer drug Nexium, securing future sales and sending its shares soaring.

Under the deal, **Ranbaxy** will be allowed to start selling a cheap, copycat version of Nexium in 2014, when the earliest **patents** on the medicine expire, the two companies said.

**Ranbaxy**, however, will benefit before that date via an agreement that means it can formulate a portion of AstraZeneca's US supply of Nexium from May 2010, with the active ingredient in the drug, esomeprazole magnesium, being made from May 2009.

The deal is a relief for AstraZeneca investors, who had feared revenues from Nexium could collapse in the face of generics. - (Reuters)

**Debenhams profits down**

Pretax profits at British department store Debenhams, which acquired Roches Stores two years ago, fell by 12.4 per cent to £94.1 million in the six months to March 1st. Although ahead of analysts' forecasts, Debenhams chief executive Rob Templeman said market conditions were "tough".

The company did not give details for its Irish operations. However, it said it was very pleased with the performance of its Irish stores.

"Conversion of the nine stores acquired from Roches in September 2006 was completed by December 2007 and all are now trading well as Debenhams," it said.

Like-for-like sales fell by 0.7 per cent during the half, reflecting the challenging trading conditions across the retail sector, it said.

**Salaries up at Tullow Oil**

Tullow Oil chief executive, Aidan Heavey, was paid of EUR 1.28 million in salary, bonuses, pension and other benefits last year, compared with just over EUR 1 million in 2006, according to the company's annual report.

The figures show that financial officer Tom Hickey received EUR 781,245 in 2007, compared with EUR 660,330 the previous year. Tullow paid chairman Patrick Plunkett EUR 150,000 in fees last year, compared with EUR 125,000 in 2006.

Company secretary Graham Martin received EUR 710,841 and Angus McCross, Tullow's exploration director, was paid EUR 674,025.

**J&J outstrips forecasts**

Johnson & Johnson (J&J) posted better-than-expected quarterly earnings yesterday as the weak dollar and cost-cutting offset plunging sales of anaemia drugs hit by safety concerns and medicines facing generic competition.

Demand for the company's consumer products boosted results. Its two other major businesses, pharmaceuticals and medical devices, would have fared poorly if they had not been propped up by the beaten-down dollar.

The healthcare company earned $3.6 billion, or $1.26 a share, up from $2.57 billion a year earlier, when it took several merger-related charges. - (Reuters)

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[Return to List](#cite_id_153)

153 of 200 DOCUMENTS

The Scotsman

**April** 16, 2008, Wednesday

1 Edition

**Need To Know: Drug market grows 6.4 per cent to dollars 712bn**

**SECTION:** Pg. 40

**LENGTH:** 226 words

THE global prescription drug market grew by 6.4 per cent last year to an estimated dollars 712 billion (GBP 363bn), according to data compiled by IMS Health.

While the US remained the largest market at dollars 286.5bn in sales, it contributed only a quarter of the growth to the global market last year - its lowest ever contribution.

In a report last month, IMS said 2007 US prescription drug sales grew at the slowest rate since 1961 at 3.8 per cent.

The five major European markets - the UK, France, Germany, Italy and Spain - saw sales grow by 4.8 per cent to dollars 140bn, while Russia and Turkey saw the largest growth rate in other European markets.

Lookers good Car dealership heavyweight Lookers is planning to buy east-of-England Volkswagen dealer Bramall & Jones VW for around GBP 2 million. Lookers said the proposed deal would increase its Volkswagen representation from nine to 11 outlets and offer an entry into the contract hire market with Bramall's fleet of around 1,500 vehicles.

Row settled Drugs group AstraZeneca has settled a **patent** row over its Nexium heartburn treatment with Indian company **Ranbaxy**, which had submitted an application for a generic version of the drug. **Ranbaxy** has conceded the validity of six **patents** subject to dispute. Astra chief executive David Brennan said: "We will vigorously defend our intellectual property."

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[Return to List](#cite_id_154)

154 of 200 DOCUMENTS

The Scotsman

**April** 16, 2008, Wednesday

1 Edition

**Tesco and oil price rise lift Footsie out of losing streak**

**BYLINE:** Scott Reid

**SECTION:** Pg. 43

**LENGTH:** 618 words

LONDON FTSE 100 CLOSE 5,906.9 +75.3

BRITAIN'S leading share index ended higher yesterday as crude prices and an oil find lifted energy stocks, while retail behemoth Tesco was boosted by a strong start to its new financial year.

The FTSE 100 moved up 75.3 points, or 1.3 per cent, to 5,906.9 to snap a five-session losing streak.

The positive sentiment was boosted in the latter stages of the session when data showed US wholesale inflation met expectations in March, while a gauge of regional manufacturing activity beat forecasts.

Among the best UK blue-chip gainers, Tesco, the world's third-biggest food retailer, reported a record annual profit and said it had made a strong start to its new financial year.

Analysts said that despite yesterday's rise, which was driven by company news, the overall picture for stock markets was blurred by uncertainties over the economy and bank losses from a credit crunch.

Commenting on the Footsie's performance, Howard Wheeldon, a senior strategist at BGC Partners, said: "The market seems to be just going through a yo-yo phase, with volumes next to nothing, and uncertainty remains the order of the day."

Jimmy Yates, a dealer at CMC Markets, added: "It's certainly too early to start thinking that [yesterday's] gains are anything more than a quick rally in what is still a bear market."

Tesco shares were up 28.5p to 419.5p - a rise of more than 7 per cent - after the retail giant reported annual profits up 11.8 per cent and like-for-like sales ahead by more than 4 per cent in the first five weeks of the new financial year.

Rivals Sainsbury's and Morrisons followed Tesco higher, adding 7p to 366p and 6.5p to 283.75p respectively.

Drugs firm AstraZeneca was also in demand after it secured an agreement with India's **Ranbaxy** Laboratories to end a lawsuit over **patent** infringements for its Nexium heartburn drug. The verdict on a key product in the Astra portfolio lifted shares 7 per cent, or 141p, to 2,122p.

Another riser was BG Group after the apparent discovery of a huge oil field off the coast of Brazil. Shares in the firm, which has a 30 per cent interest in the find, were up 66p at 1,288p.

As oil prices breached dollars 113 a barrel to set a new record, exploration firm Tullow Oil also rose 28p to 713p. But others fared less well following the price hikes, with airline British Airways easing 7p to 208.5p and Tui Travel down 6.5p at 255p.

Among the mining stocks on the front foot on higher commodity prices, BHP Billiton was up 64p to 1,770p, while Rio Tinto rose 185p to 6,007p.

Elsewhere, Friends Provident managed to claw back some losses after Monday's ultimatum from bidder JC Flowers. Shares were up 2.4p to 118.9p.

Carphone Warehouse was the day's biggest loser, dropping more than 13 per cent, or 35.5p to 231p, after weaker-than-expected broadband additions for Q4 of its financial year.

DOW JONES 12,362.47 +60.41

WALL Street ended an erratic session moderately higher last night after investors sorted through a mixed batch of data including a rebound in New York manufacturing, signs of rising inflation and uneven first-quarter earnings.

After a recent spate of disappointing readings on the economy, investors were pleased the New York Federal Reserve reported that regional manufacturing expanded modestly in April, after shrinking at a record clip in March.

Economists, on average, had been expecting another contraction.

But the market remains anxious about inflation.

The Dow Jones industrial average rose 60.41 points, or 0.49 per cent, to end at 12,362.47. The Standard & Poor's 500 index advanced 6.11 points, or 0.46 per cent, to finish at 1,334.43 while the Nasdaq Composite Index gained 10.22 points, or 0.45 per cent, to close at 2,286.04.

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[Return to List](#cite_id_155)

155 of 200 DOCUMENTS



The Sun (England)

**April** 16, 2008 Wednesday

**AZ deal A1**

**BYLINE:** Ian King

**SECTION:** SUN CITY

**LENGTH:** 77 words

SHARES of ASTRAZENECA, Britain's No2 pharmaceuticals company, surged 141p to 2122 yesterday after it reached an agreement over its best-selling drug.

AZ agreed that Indian firm **RANBAXY** can start selling a cheap version of its ulcer treatment Nexium from May 2014, when the earliest **patents** expire.

The tie-up ends a long legal fight with **Ranbaxy** and will also delay the launch of copycats. AZ chief executive David Brennan said: "It is the right business decision."

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[Return to List](#cite_id_156)

156 of 200 DOCUMENTS



The Times (London)

**April** 16, 2008, Wednesday

**AstraZeneca settles Ranbaxy dispute**

**BYLINE:** Rhys Blakely in Bombay

**SECTION:** BUSINESS; Pg. 43

**LENGTH:** 338 words

AstraZeneca has settled a legal battle with India's largest generic drugs maker over the rights to produce one of the world's most valuable medicines. Under the terms of the out-of-court deal, **Ranbaxy** Laboratories will scrap plans to market a cheap, unauthorised copy of Nexium, the ulcer pill developed by AstraZeneca, in the United States.

Instead, **Ranbaxy** will start to produce a generic version of the drug - with AstraZeneca's blessing - in six years' time, when **patents** on Nexium start to expire. The settlement pushed shares in Astra up 8 per cent to £ 21.41.

Nexium, the second-most lucrative prescription drug in the world, accounted for sales of $5.2billion (£ 2.6billion) last year, trailing only Lipitor, Pfizer's cholesterol treatment, which achieved revenues of about £ 6billion, the **patents** for which have also been contested by **Ranbaxy**.

AstraZeneca will also outsource the production of part of its US supplies of Nexium to **Ranbaxy** from May 2010. The Indian group will manufacture supplies of the active ingredient in the drug - esomeprazole magnesium - from May 2009. AstraZeneca said that the deal would give it greater control over the transition of its original drugs into the generics markets and was in line with its strategy to outsource the manufacture of active pharmaceutical ingredients entirely by 2018.

Investors in both companies welcomed the deal, which analysts said sharply reduced the uncertainty surrounding a large proportion of AstraZeneca's revenues.

In America, a **patent** confers protection for 20 years, a significant portion of which may be spent in clinical trials. When the **patent** expires, revenues tumble because generic drugs often sell at a 97 per cent discount to their patented templates.

AstraZeneca said that the settlement would not affect other litigation in which it is involved. The most important involves Seroquel, the schizophrenia drug that produced sales of $4billion last year. The US **patent** for the medicine has been challenged by the generics group Teva/IVAX.

Tempus, page 49

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[Return to List](#cite_id_157)

157 of 200 DOCUMENTS



The Times (London)

**April** 16, 2008, Wednesday

**Pharmaceuticals produce some safe-haven medicine**

**BYLINE:** James Rossiter

**SECTION:** BUSINESS; Pg. 49

**LENGTH:** 459 words

After a dismal first three months of 2008, the stock performance of Britain's big three pharmaceutical companies suddenly found favour four weeks ago, as a sharp sell-off in financial and property-related stocks prompted a scrabble for safe havens. AstraZeneca, Britain's second-largest drugs company, was the greatest beneficiary of the sector's re-rating as its shares gained about 15 per cent from the ten-year low of £ 17.48 touched in March.

Investors woke up to the yield differential that existed for less than a week between GlaxoSmithKline, Britain's largest drug company, and Astra, with the former yielding about 5 per cent and Astra nearly 6 per cent, despite the near-term outlook for revenue growth from each company looking broadly similar.

Glaxo shares have also rallied over the past month, up about 7 per cent to £ 10.71, benefiting from the rush to safe-haven stocks, bringing the yield for Astra and Glaxo back in line to just under 5 per cent.

The question for investors who may have missed this mini-rally is whether there is still fundamental growth to be had from buying into big UK pharma. The big risk factors hanging over Glaxo, Astra and Shire, Britain's third largest drugs company, are the threat of generic competition and the depth and reliability of each company's pipeline of new drugs. Yesterday one of those big risk factors was removed for Nexium, Astra's blockbuster heartburn drug, as it settled a **patent** infringement lawsuit with **Ranbaxy**, the Indian company, that was to be free to start selling its generic version of the drug this month. **Ranbaxy** must now hold back selling its version until 2014.

Astra shares gained another 141p yesterday to close at £ 21.22, but they are still off from January's high of £ 23. Astra has still to quash in the courts efforts by Teva Pharmaceutical Industries to market a generic to Seroquel, its schizophrenia drug. This explains why Astra is still trading at a 15 per cent discount to the sector.

Astra shares peaked at £ 35 in the summer of 2006, but quickly suffered from the failure of three late-stage trial drugs, earmarked as blockbusters. Astra has replenished its drugs pipeline by buying drug development companies. Investors will be relieved by the removal of competition for Nexium, but they have a long wait for the next generation of blockbusters. Hold.

Investors in Glaxo are also in need of a quick-fix cure for the company's flagging drugs pipeline. Safety issues surrounding Avandia, its diabetes treatment, have kept the shares hovering near four-year lows. The answer to Glaxo's growth plans a decade ago was to merge with SmithKline. Ten years on with Glaxo shares showing little improvement, that path for growth - either buying Astra or Shire - may be revived. Buy.

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[Return to List](#cite_id_158)

158 of 200 DOCUMENTS



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**SECTION:** BUSINESS; Pg. 43

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Tempus, page 49

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[Return to List](#cite_id_159)

159 of 200 DOCUMENTS



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[Return to List](#cite_id_160)

160 of 200 DOCUMENTS

WALL STREET JOURNAL ABSTRACTS

**April** 16, 2008 Wednesday

**astrazeneca settles patent suit against ranbaxy**

**BYLINE:** Jeanne Whalen

**SECTION:** Section B; Column 1; Pg. 3

**LENGTH:** 30 words

AstraZeneca PLC says it has settled lawsuit against **Ranbaxy** Laboratories Ltd in pact that will keep **Ranbaxy's** generic copies of heartburn drug Nexium off US market until 2014; chart (M)

**LOAD-DATE:** April 22, 2008

**LANGUAGE:** ENGLISH

**GRAPHIC:** Graph

**PUBLICATION-TYPE:** Abstract

**JOURNAL-CODE:** WSJ

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Information Bank Abstracts

[Return to List](#cite_id_161)

161 of 200 DOCUMENTS

Western Daily Press

**April** 16, 2008 Wednesday

**Astra looks healthier after no-cost deal over generics**

**SECTION:** Pg. 26

**LENGTH:** 204 words

Astrazeneca, the drugs giant with a major site near Avonmouth, has done a deal with the company that was threatening to release a rival version of a top heartburn drug.

The Anglo-Swedish medicine maker has been involved in a three-year legal action against Indian firm **Ranbaxy**, one of the industry's "generics-makers" which challenge drug **patents** so that they can profit by releasing copycat versions.

The pill at the centre of the long- running wrangle - Nexium, which treats stomach ulcers and heartburn - is one of the world's top-sellers with annual sales of £2.6 billion.

Under the settlement **Ranbaxy** will delay its release of Nexium in return for a licence to sell a generic version from 2014 and distribute other Astra- Zeneca products from next year. No financial details were unveiled but Astra chief executive David Brennan said no money had changed hands.

It is being viewed by commentators as a win-win arrangement for the two companies. The question now is whether a similar deal can be reached with Teva, the Israeli firm that is the biggest generics player.

Paul Diggle, analyst at Nomura Code, said: "The next point is whether Astra decides to do a deal with Teva." Astra shares rose 7.1 per cent to £21.22, up £1.41.

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[Return to List](#cite_id_162)

162 of 200 DOCUMENTS

The Western Mail

**April** 16, 2008, Wednesday

First Edition

**Tesco profits lead Footsie back into positive territory;**

**city bulletin**

**SECTION:** BUSINESS; Pg. 20

**LENGTH:** 439 words

BLUE-CHIP big guns Tesco and AstraZeneca led a revival yesterday as the London market broke a five-day losing streak.

The grocery giant's pounds 2.85bn profits haul and the settling of a **patent** dispute by the drugs company pushed them up the risers board, with gains from heavyweight mining stocks underpinning progress.

This helped the FTSE 100 Index to gains of more than 1%, closing 75.3 points higher at 5906.9. Wall Street also made early progress amid better than expected manufacturing figures and upbeat results from the likes of consumer giant Johnson & Johnson.

In London, Tesco was the best performer after reporting annual profits up 11.8% and like-for-like sales ahead by more than 4% in the first five weeks of the new financial year.

Shares were up 28.5p to 419.5p on the back of the update - more than 7%. Rivals Sainsbury's and Morrisons followed Tesco higher, adding 7p to 366p and 6.5p to 283.75p respectively.

Drugs firm AstraZeneca was also in demand after it secured an agreement with India's **Ranbaxy** Laboratories to end a lawsuit over **patent** infringements for its Nexium heartburn drug. The verdict on a key product in the Astra portfolio lifted shares 7%, or 141p, to 2122p.

Another riser was BG Group after the apparent discovery of a huge oil field off the coast of Brazil. Shares in the firm, which has a 30% interest in the find, were up 66p at 1288p.

As oil prices breached EUR113 a barrel to set a new record, exploration firm Tullow Oil also rose 28p to 713p. But others fared less well following the price hikes, with airline British Airways easing 7p to 208.5p and Tui Travel down 6.5p at 255p.

Carphone Warehouse was the session's biggest loser, dropping more than 13%, or 35.5p to 23 1p, after it posted weaker-than-expected broadband additions for the fourth quarter of its financial year.

But early gains for retailer Debenhams were reversed as investors digested pre-tax profits of pounds 94. 1m - down 12% on a year earlier although better than City forecasts. Shares had been up 1.5p but slipped 1.25p to 55.75p.

The biggest Footsie risers were Tesco up 28.5p at 419.5p, AstraZeneca ahead 141p at 2122p, BG Group up 66p at 1288p and Eurasian Natural Resources ahead 60p at 1260p.

The biggest Footsie fallers were Carphone Warehouse down 35p at 23 1p, Home Retail Group off 9.25p at 240p, Tui Travel off 6.5p at 255p and Persimmon down 2122p. 16p at 659p.

Companies reporting results this week include:

TODAY

Finals: JJB Sports, Manganese Bronze

Trading updates: Experian, Legal & General, WS Atkins

THURSDAY

Finals: Corin

Interims: WH Smith

Trading update: Prudential

AGMs: Drax, Taylor Wimpey, BP

FRIDAY

Finals: UK Coal

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[Return to List](#cite_id_163)

163 of 200 DOCUMENTS



The Evening Standard (London)

**April** 15, 2008 Tuesday

**BG gushes as Brazil looks a blockbuster**

**BYLINE:** MICKEY CLARK

**SECTION:** B; Pg. 35

**LENGTH:** 605 words

SHARES of BG surged to record highs today, rising 71p to 1293p amid signs that the oil and gas explorer may have struck it rich in Brazil for the second time in six months.

Overnight, the head of Brazil's National Petroleum Agency said the Sugar Loaf structure in the Santos Basin could contain a whopping 33 billion barrels of oil equivalent five times the size of Tupi, BG's other venture in the region which would make it the biggest discovery in 30 years.

BG has exposure to Sugar Loaf through its BM-S-9 block and newsflow on the structure is likely to continue over coming months, with Exxon expected to start drilling later this year, followed by BG. It was estimated last October that the Tupi Field could contain anything from eight billion to 30 billion barrels of oil and gas. BG has a 25% stake in the project.

Centrica , which was demerged from British Gas a few years ago, also rose 1 1 . 4 p to 304 1 . 2 p. There was big turnover in the shares towards the close of business yesterday, including one block trade which may have contained 40 million shares.

BP firmed 1 1 . 2 p to 550 1 . 2 p with the management seemingly unperturbed by the news that Chinese sovereign wealth fund SAFE Investment had splashed out £1 billion on mopping up a 1% stake in the oil giant. BP said it was aware of the purchase but had no reason to be concerned about it.

SAFE manages China's $1.7 trillion currency reserves.

The latest boost to the oil price, which has now topped $112 a barrel in the US, attracted buyers for the exploration companies. Cairn Energy put on 72p to 3035p, Dana to 1329p, and Royal Shell 23p to 1857p.

Shares generally rebounded, investors to claw back of yesterday's losses. The 100 index rallied 48.4 points 5880.0, despite fresh falls on Street overnight and a mixed in the Far East today.

A 12% jump in pre- tax profits year enabled Tesco to put on 4 p at 413 3 . 4 p. The City also gave thumbs- up to the latest trading from Burberry , up 35 1 . 4 p at 4 p. This is one retailer that has progress despite tough trading conditions on the High Street. luxury goods group reported 18% increase in underlying during the second half, by strong growth in its and wholesale operations. It full- year figures at the end next month.

But another retailer failed to live to expectations amid signs that is slowing. Carphone fell 26 3 . 4 p to 239 3 . 4 p, the blue-chip performer.

AstraZeneca has signed a settlement deal in its Nexium **patent** litigation against **Ranbaxy** Laboratories. This will allow to start sales of a generic of Nexium under licence AstraZeneca on 27 May 2014..

YOU CAN BUY AND SELL SHARES ONLINE FOR £ 1e AT www. thisismoney. co. uk The Sharedealing Service is provided by The Share Centre in association with This is Money AstraZeneca and **Ranbaxy** have entered into agreements under which **Ranbaxy** will formulate a portion of Astra's US supply of Nexium from May 2010, including provisions for the manufacture of the active pharmaceutical ingredient in Nexium, from May 2009. Dresdner Kleinwort has raised its rating on the drugs giant from hold to buy and its target from 1970p to 2350p.

Astra shares shot up 157p to 2138p, making it the best performer among the top 100 companies.

Mears Group rose 6 1 . 2 p to 282 1 . 4 p after its specialist housing division landed a clutch of new contracts worth £57 million with Watford Community Housing Trust, Castle Morpeth Housing and Catalyst.

Arbuthnot Securities says the wins underpin its profit forecasts and the shares deserve a higher rating..

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[Return to List](#cite_id_164)

164 of 200 DOCUMENTS



The Evening Standard (London)

**April** 15, 2008 Tuesday

**BG gushes as Brazil looks a blockbuster;**

**MARKET ROUND-UP**

**BYLINE:** MICKEY CLARK

**SECTION:** A; Pg. 35

**LENGTH:** 607 words

SHARES of BG surged to record highs today, rising 66p to 1288p amid signs that the oil and gas explorer may have struck it rich in Brazil for the second time in six months.

Overnight, the head of Brazil's National Petroleum Agency said the Sugar Loaf structure in the Santos Basin could contain a whopping 33 billion barrels of oil equivalent five times the size of Tupi, BG's other venture in the region which would make it the biggest discovery in 30 years.

BG has exposure to Sugar Loaf through its BM-S-9 block and newsflow on the structure is likely to continue over coming months, with Exxon expected to start drilling later this year, followed by BG. It was estimated in October, last year that the Tupi Field contains up to 30 billion barrels of oil and gas and BG has a 25% stake.

Centrica , which was demerged from British Gas a few years ago, also rose 1 1 4 p to 304 1 2 p. There was big turnover in the shares towards the close of business, including one block trade which may have contained 40 million shares.

Shares generally rebounded, helping investors to claw back most of yesterday's losses. The

FTSE 100 index rallied 56.12-points to 5887.8, despite fresh falls on Wall Street overnight and mixed performance in the Far East today.

A 12% jump in pre- tax profits last year, enabled Tesco to put on 11 3 4 p at 408 3 4 p. The City also gave the thumbs- up to the latest trading update from Burberry , up 20 1 2 p at 416 1 2 p. This is one retailer that has made progress despite tough trading conditions on the High Street.

The luxury goods group reported an 18% increase in underlying sales during the second half, driven by strong growth in both its retail and wholesale operations.

The company reports full-year figures at the end of next month.

But another retailer failed to live up to expectations amid signs that growth is slowing. Carphone Warehouse fell 26p to 240 1 2 p the worst blue-chip performer.

AstraZeneca has signed a settlement deal in its Nexium **patent** infringement litigation against **Ranbaxy** Laboratories.

This will allow **Ranbaxy** to start sales of a generic version of Nexium under licence from Astra- Zeneca on 27 May 2014.

AstraZeneca and **Ranbaxy** have separately entered into agreements under which **Ranbaxy** will formulate a portion of Astra's US supply of Nexium from May 2010, including provisions for the manufacture of the active pharmaceutical ingredient in Nexium, from May 2009. Astra shares responded with a rise of 164p to 2145p, making it the best performer among the top 100 companies.

In New York overnight, a surprise first-quarter loss and cut in dividend by Wachovia, America's fourth-biggest bank, added to the agony of stock market investors

YOU CAN BUY AND SELL SHARES ONLINE FOR £ 1 . AT www. thisismoney. co. uk The Sharedealing Service is provided by The Share Centre in association with This is Money and share prices extended recent losses.

Wachovia's losses and write-offs totalling $2.8 billion came on the heels of last Friday's profit warning from General Electric and lacklustre numbers from Alcoa. The first-quarter earnings season has got off to a dismal start and several big US investment banks are expected to announce further heavy write-offs this week. The Dow finished down 23.36 at 12,302.06.

In Tokyo today, share prices rallied, with resource-related shares such as trading house Mitsui boosted by oil's record closing high.The Nikkei 225 closed up 73.07 at 12,990.58.

Hong Kong stocks reversed opening gains, and the Hang Seng index ended down 95.33 at 23,906.53..

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[Return to List](#cite_id_165)

165 of 200 DOCUMENTS

Evening Gazette

**April** 15, 2008, Tuesday

BUS Edition

**Market report**

**SECTION:** NEWS; Pg. 6

**LENGTH:** 190 words

BIG gains for Tesco and pharmaceuticals firm AstraZeneca ensured the London market snapped out of its five-day losing streak today.

With Wall Street also resilient after a difficult session on Friday, the FTSE 100 Index stood higher after an hour of trading.

Much of the focus was on Tesco after the supermarket posted a reassuring update with annual profits up 11.8% and like-for-like sales ahead by more than 4% in the first five weeks of its new financial year.

Investors welcomed the figures as shares rallied 15.75p to 406.75p, or 4%.

The biggest rise came from AstraZeneca after ecured an agreement with India's **Ranbaxy** Laboratories to end a lawsuit over **patent** infringements for its Nexium heartburn drug.

The verdict on a key product in the Astra portfolio lifted shares 166p to 2147p, a rise of 8%.

Carphone Warehouse disappointed investors, dropping 8% or 20.5p to 246p, after it posted weaker than expected broadband additions for the fourth quarter of its financial year.

In the FTSE 250 Index, Debenhams rose 5% or 3p to 60p as the market cheered pre-tax profits of pounds 94.1m, down 12% on a year earlier but better than City forecasts.

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[Return to List](#cite_id_166)

166 of 200 DOCUMENTS

Investors Chronicle - magazine and web content

**April** 15, 2008

**Astra threat removed... for now**

**SECTION:** 0261-3115

**LENGTH:** 209 words

AstraZeneca's shares climbed 11 per cent after some much needed good news regarding a generic challenger

AstraZeneca's shares rose as much as 11 per cent as investors breathed a sigh of relief after it said it had reached a settlement over a **patent** infringement lawsuit with Indian generics company

Nexium's sales fell 9 per cent in the final quarter of 2007 and the company said it expected lower future sales due to pressure from generic competition. In the new agreement **Ranbaxy** can begin selling a generic copy of Nexium in 2014 and it gets 180 days marketing exclusivity. **Patents** on Nexium expire between 2014 and 2019.

This means that AstraZeneca faces one less competitor to its biggest selling drug and that generic challenges from

Although Charles Stanley analyst Jeremy Batstone-Carr believes it is a positive, he is less sanguine than other analysts because of the paucity of AstraZeneca's late-stage pipeline: "AstraZeneca still faces a significant generic threat and doesn't have enough in its late-stage pipeline to replace drugs like Nexium, Seroquel and Crestor."

At 2,145p AstraZeneca continues to look fairly priced, trading on a forward price-earnings ratio of less than 10 times and a current dividend yield of over 4 per cent.

FairlyPriced

**LOAD-DATE:** April 23, 2008

**LANGUAGE:** ENGLISH

**PUBLICATION-TYPE:** Magazine

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[Return to List](#cite_id_167)

167 of 200 DOCUMENTS

Pharma Marketletter

**April** 15, 2008 Tuesday

**AstraZeneca's shares rocket on settling with Ranbaxy over ulcer drug Nexium**

**LENGTH:** 334 words

Anglo-Swedish drug major AstraZeneca has settled the **patent** infringement litigation over its blockbuster gastrointestinal drug Nexium (esomeprazole) with India's **Ranbaxy** Laboratories. News of the deal, announced on April 15, saw the London-headquartered firm's share price leap 11%.

Under the agreement, **Ranbaxy** has conceded that all six **patents** asserted by AstraZeneca in the litigation are valid and enforceable. **Ranbaxy** also accepted that four of the **patents** would be infringed by the unlicensed sale of its proposed generic product. The deal will allow the Indian drug company to commence sales of a generic version of Nexium in the USA under a licence from AstraZeneca on May 27, 2014.

Nexium generated 2007 sales of $5.18 billion for AstraZeneca, with $3.53 billion coming from the USA, thus investors were nervous this revenue stream could be interrupted after **Ranbaxy** filed with the US Food and Drug Administration for approval to market a generic version of the proton-pump inhibitor. This triggered the start of litigation by the UK firm. However, law suits against Israeli generics giant Teva Pharmaceuticals and India's Dr Reddy's Laboratories are ongoing, with no court date yet set. Under the deal, **Ranbaxy** may have forfeited its 180-day exclusivity rights in the USA, and Lehman Brothers' analysts note that Teva has a more aggressive track record on "at risk" generic launches.

AstraZeneca and **Ranbaxy** have separately entered into agreements under which the latter will formulate a portion of the drug major's US supply of Nexium from May 2010, including provisions for the manufacture of esomeprazole magnesium, the active pharmaceutical ingredient in the drug, from May 2009. The two companies have also made two separate deals designating **Ranbaxy** as the US distributor for authorized generic versions of Plendil (felodipine) and 40mg Prilosec (omeprazole), the precursor to Nexium. **Ranbaxy** will be compensated for its distribution services on standard commercial terms, says the UK company.

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[Return to List](#cite_id_168)

168 of 200 DOCUMENTS



telegraph.co.uk

**April** 15, 2008 Tuesday 4:05 PM GMT

**Market continues on its dreary path**

**BYLINE:** By Ben Bland

**SECTION:** BLOG

**LENGTH:** 123 words

Welcome back fellow market watchers. Apologies for the lack of posts but I've been away on holiday and luckily for me as a journalist, holiday means holiday (no Blackberry here).

The stock market is still looking rather dreary with slim volumes and no real confidence in London's dealing rooms. The slight recovery of two week's ago was quickly retraced and the FTSE 100 just seems to be bouncing around at the moment.

For what it's worth, the FTSE 100 is currently up 56.4 at 5888 but this move comes after five straight losing sessions. The market has been boosted by positive corporate news from the likes of Tesco (good results), AstraZeneca (**patent** agreement with Indian generic drug manufacturer **Ranbaxy)** and Debenhams (good figures).

**LOAD-DATE:** October 26, 2012

**LANGUAGE:** ENGLISH

**PUBLICATION-TYPE:** Web Publication

**JOURNAL-CODE:** WEBDTB

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[Return to List](#cite_id_169)

169 of 200 DOCUMENTS



Business & Finance Magazine

**March** 28, 2008

**Big Pharma Falls Off Patent**

**LENGTH:** 2305 words

Patrick Freyne looks at how major drug producers inIreland are facing dry pipelines as their existingproducts are devoured by generic rivals.

When the **patent** is up on something like Lipitor [Pfizer'sblockbuster cholesterol drug] there is some risk ofhaving to scale back in Ireland," says David Gallagher,country manager with Pfizer.

"But, at the moment, we're determined to see what else wecan bring into Ireland, both as a manufacturing facilitybut also in terms of development and we're also lookingto see how we can compete when Lipitor goes."

The **patent** on Lipitor ends in 2011, and these sentimentsare being rehearsed in several pharmaceutical companiesaround the country.

"Effexor, which is made by Wyeth, Zoloft from Pfizer,Fosomax, made by Merck, Seroxat, which is GSK, and Zocorwhich is from Merck, all of these are major blockbustersat least partly produced in Ireland, and all approachingthe end of their 20-year **patents**," says Mart Moran,director of Pharmachemical Ireland (a division withinIbec).

"When they go off **patent**, competition from genericscompanies enters the equation and the price drops.Ireland is a low-tax, high-value manufacturing locationand, obviously, if the price drops, it makes lower-costlocations a more viable option in which to manufacturethe product."

So it's a challenging time for the pharmaceuticalindustry (indeed the Wall Street journal maintains thatgeneric competition could wipe $67bn from USpharmaceutical sales between 2007 and 2012) and Irelandis not unaffected.

In February, GlaxoSmithKline announced that it was to cutits workforce by 100 employees and medical devicemanufacturing plants owned by Abbott and Allergan werealso recently culled.

Currently, the Irish pharmaceutical sector exports aboutEur 33bn worth of produce, directly employs 19,500 peopleand is Ireland's largest contributor of corporation tax.

Furthermore, nine out of the 10 globalpharmaceutical companies have a presence in Ireland(Merck, Wyeth, Genzyme, GlaxoSmithKline, Pfizer,Johnson&Johnson, Novartis, ScheringPlough and Bristol-Myers-Squibb), and seven of the top 10 blockbuster drugsare produced here.

So Ireland has served pharma and pharma has servedIreland pretty well over the years. But, as the songgoes, "there may be trouble ahead" - as the olderblockbuster drugs go off **patent** and face competition andthe pipelines for new blockbuster drugs run dry.

"Worldwide, the pharmaceutical industry is under a lot ofpressure," admits Frank Gannon, director general ofScience Foundation Ireland, an organisation that bridgesthe gap between research and industry. "If you look atwhat's happening, there's only the same number oftherapeutics in the pipeline as there were in 1983.That's not good."

Part of the reason for this is that the industry hasbecome more risk-averse in the face of a more litigiousconsumer and a more stringent regulatory sector.

"It's certainly not from lack of research because there's10 times as much being done now as therewas in 1983," says Gannon.

"But one thing that has changed dramatically is thelitigious nature of the world. If there is a side effectthat shows up when a product is being used on millions ofpeople then the company will be hit hard [for example,Merck had to pull its pain-relieving drug Vioxx due tocomplaints]. And this goes beyond loss of sales - sharevalue will also go down. So companies often stop drugsgoing through the system at an earlier stage, becausethere is a concern about the consequences of going aheadwith something that mightn't work.

We're getting to a stage where we're getting paralysed byperfection because we want to find the ideal silverbullet to kill the disease with zero side effects in anypopulation group that we've considered."

So, over the next few years, there will be strategicchanges in how the industry operates. Instead ofsearching for one big sweeping cure for illnesses likecholesterol, depression or erectile dysfunction,companies such as Roche are leading the search for moretargeted medicines (often with the aid of biotechnology),or what the experts call "nichebusters".

Barry O'Dowd, head of life sciences with the IDAexplains: "The development model is becoming more focusedon customised personalised medicine, as biologics comemore into the market and assert themselves more.

Personalised medicines by their nature bring down volumebecause you're finding a medicine for a particular genomerather than Paddywhack's genome down the street. Soyou're into much smaller runs but with much more targetedeffects. What it means is that over time you're going tosee more of these "nichebusters" and fewer blockbusters."Moran contends that such changes perfectly suit a speedy,flexible economy like Ireland's.

"Developing a drug and taking it to the market is atorturous process, it's quite risky and very expensive,"he says. "So what companies are increasingly trying to dois to introduce an element of certainty into the process.

It's obviously preferable if the drug doesn't crash inphase three of the clinic as opposed to manufacturingwhen they've invested a whole amount of money in it. Yousee companies now trying to screen out their entities atan earlier stage. So you're also seeing companies tryingto bring their products through more quickly from thepipeline into manufacturing.

That activity is becoming increasingly important for theindustry and some people call it D&M (development plusmanufacturing) or codevelopment/comanufacturing."

Moran estimates that around 25% of the companies herehave a D&M component and points towards Merck's new plantin Ballydine and Wyeth's Eur 24m investment in Newbridgeas examples of this.

"Wyeth is basically prioritising the Newbridge site asone where it brings products through from the developmentstage into manufacturing and it makes it a much morepivotal site and strategically more important," he says.

In the past, the pharmaceutical sector in Ireland wasfocused on the "simple" manufacturing of activepharmaceutical ingredients (APIs). But in the light ofhow the industry is changing, O'Dowd says the IDA isfocusing on attracting, retaining and developing moreresearch dependent investment.

And Gannon has noticed this change. "The amount ofinvestment into R&D by the companies has tripled in thelast three or four years," he says. "There's a much moreintense engagement in Ireland by the industry. There islittle doubt that there is an increase of engagement bythe pharma companies into the research agenda in Ireland.

All the big names have now made an initial and growingconnection with the Irish scientific research community."

And Gannon asserts that this deeper engagement keeps thecompanies' rooted much more firmly in Irish soil.

"Generally speaking with D&M the connection becomes muchmore robust," he says. "The production of activepharmaceutical ingredients on the other hand isn't rocketscience, so neither is it rocket science to go andproduce them somewhere else at a lower cost. But ifyou're doing something more research-based, that needsconstant input, and then you need to have skilled peopleand you are much more dependent on the expertise of thosepeople. So it's a bit harder to move."

However, John Kelly, a partner with PricewaterhouseCooperwho specialises in the pharmaceutical industry, doesn'tfeel its emerging fast enough. "There's more 'D' beingdone in Ireland than there was in the past, but it's notenough," he says. "It's impossible to manufacture bulkactive in Ireland without doing process enhancement.There's a lot of the 'D' in process enhancement, butthere needs to be more 'pure' development done here. Thetax situation doesn't help. If you look at R&D taxcredit, it benefits a small number of companies who havethe right tax pattern. It hasn't benefited the bulk ofthe industry."

Kelly has also seen how the dearth of new blockbustershas already affected this country. "I have clients whosedrugs have gone off **patent** over the past few years andit's astonishing to watch," he says. "In one particularinstance last year, the revenue stream disappeared withinthree months. You have generic manufacturers waiting inthe wings and the owner of the **patent** has no alternativebut to follow them downward in the price.

"JP Garnier from GSK said that, with the blockbustermodel, every 10 or 12 years your business disappears andyou have to reinvent it."

Lipitor is an interesting example. To offset thepotential loss to income that would occur when Lipitor'scycle ends, Pfizer pumped money into developing acompound called Torcetrapib (which was to be mixed withLipitor). The failure of this had a direct effect ontheir Irish business. "We had built the plant in Cork tomake Torcetrapib and we had geared up appropriately,"explains Tara Delaney, director of external affairs withPfizer.

"People were very buoyant about its potential success,but it failed in third stage clinical trials. Thosetrials were abandoned and that obviously had an impact onour future plans here. Torcetrapib represented about 40%of our future capacity and we had to restructure on thebasis of that. There were a number of other issues,particularly the threat of lower-cost locations and newtechnologies, but the failure of the medicine was the bigdriver. We had a gap in capacity and nothing to fill itwith and that meant we had to cease production in two ofour plants."

At the moment Pfizer are attempting to sell these plantsas going concerns. "Hopefully we'll be successful indoing that," says Delaney. "But the people won't beworking for Pfizer."

One way or another, the end of **patent** protection casts ashadow over the Irish pharmaceutical industry.

"When the **patent** for Lipitor is up in 2011 it will bevery challenging," says Gallagher frankly. "It would bevery difficult for any company to lose 25% of its salesin one year. But we're very determined to replace thosesales with new medicines and also look at other oldermedicines we have and use them more creatively and manageour costs more tightly. So I think we'll weather it."

Moran is hopeful. "At the moment the pharmaceuticalindustry is clearly going through a competitiveshakeout," he says. "But we're seeing most of thecompanies maintaining their employment and investmenthere, and the layoffs have been relatively minor comparedto what's been happening globally. We've also seen ashift in value in terms of the investments coming in -they tend to be much more high-end.

Even the cuts in GlaxoSmithKline reflect this. They mayhave announced 100 job cuts, but last year they announced150 new jobs and a brand new facility, so in many waysit's just a move from the old to the new.

It's strategically very important that Ireland isconsidered the obvious launch site for new products.

Once products drop in value they will be off-shored andmove elsewhere. But as long as you have a stream of newproducts coming behind then you're secure for thefuture."

According to Kelly, however, the future is uncertain."We're in an uncomfortable period now," he says. "Theindustry built up huge momentum through the late 1980sand 1990s but that momentum is running down. There's aneed for reinvention. But the industry is very much in atransition phase and it's not totally clear how it'sgoing to come out of it."

Opportunity with generics While it's a challenging timefor the major innovative pharmaceutical companies, it's agood time for the generic companies. Once a product goesoff **patent**, there are swarms of generic companies waitingto manufacture their own low-cost version of the drug.

Companies such as **Ranbaxy,** Teva and Dr Reddy'sLaboratories are also becoming more assertive when itcomes to challenging **patents** and criticising thetactics of the bigger companies.

Israeli generics company Teva recently announced 165 newjobs for a plant in Waterford. Marcel Daniels, TevdsEuropean vicepresident of government relations, has aproblem with big pharmds practice of "ever-greening"their products at the end of their **patents**.

"They often look at ways they can extend the life cycleof their molecules by **patent** evergreening," he says. "Bythis I mean the adding and combining of molecules tocreate a new product which mightn't be a completelybreakthrough invention but something which continues thepatent protection. We feel this practice creates adistortion in the market, often making it impossible forgeneric competition."

Of course the big companies don't let their monopolies godown without a fight. They often launch their own genericversions of products to keep the generic companies atbay. Currently regulators are also investigating thebehind-the-scenes agreements that have been made betweenbig pharma and the generics.

"Something is rotten in the state," said Neelie Kroes,the European Commission's competition commissioner inJanuary when she instigated raids on many of the majorcompanies. It is suspected that some were engaging insecret settlements with generics companies to keepproducts of the market. Teva themselves are reportedlyunder investigation in this regard.

In many ways, however, this is all just about movingdeckchairs on the Titanic. Ultimately big pharma and thegenerics are drinking from the same well. Without aninnovative sector, there would be no generics industry.

"The number of blockbusters that have gone off **patent** hashave made the generics big players all of a sudden," saysGannon' "But the generics can only thrive and bring downprices in the long term if the primaries are there in thefirst instance. So it's in all of our interest toencourage more primaries coming through."

Daniels agrees. "Yes that's a concern for allpharmaceutical companies," he says. "New products arecrucial for all our futures. But I think the pipelinewould be better served by pumping resources into newmedicine rather than expending so much energy protectingmonopolies and making minor adjustments to productsalready on the market."

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[Return to List](#cite_id_170)

170 of 200 DOCUMENTS

The Australian (Australia)

**March** 26, 2008 Wednesday

1 - All-round Country Edition

**CRITERION**

**BYLINE:** Tim Boreham

**SECTION:** FINANCE; Pg. 23

**LENGTH:** 1158 words

Sigma Pharmaceuticals (SIP) $1.27

ON a positive note for Sigma, the drug manufacturer and wholesaler has stabilised its earnings after last year's preoccupation with the efforts to acquire rival Symbion Health's pharmacy distribution business.

History shows that Sigma's $1.085 billion bid was trumped by a mere $1 by private equity outfits aligned with Healthscope, which in turn missed out to crafty Ed Bateman's Primary Health. Since then, Sigma's Elmo de Alwis has turned to refocusing on a business that suffered not just from the Symbion distraction but potent external forces that led to two earnings downgrades.

Aided by some good old cost cutting, Sigma yesterday unveiled an underlying profit of $90 million for the year to January 31, in line with the reduced guidance but well off the previous year's $105 million.

The happiest aspect was the stronger second-half showing, which, de Alwis insists, will flow through to the current year. But one wonders how Sigma will achieve growth in a business constrained by government-imposed price reductions and red-hot competition.

Sigma's business remains fundamentally unbalanced in that 75 per cent of its revenues are derived from the drug wholesaling business, which delivers only 26 per cent of EBITDA. The rest is gleaned from the pharmaceutical arm, an amalgam of drug manufacturing (of generic and over-the-counter drugs) and the Amcal and Guardian chemist banners.

While over-the-counter brands such as Herron are faring OK, Sigma's future is inextricable in generic drugs. Sigma saw to that by acquiring Arrow, the biggest generics maker, from the Duchen family in 2005.

While generics accounted for 14 per cent of Sigma's sales and 32 per cent of EBITDA, there has been some cheeky competition from Indian newcomer **Ranbaxy.** Mylan, which took over nearest rival Alphapharm, has also stepped up its marketing activity. In extreme cases, the drugs are being virtually given away at an 85 per cent discount.

At the same time, the federal Government is mandating price cuts in an effort to reduce the rising costs of the Pharmaceutical Benefits Scheme (a 25 per cent price cut is due in August).

According to de Alwis, the undercutting has not affected Sigma's existing market share, but it has been harder to make further inroads. Sigma has scheduled the release of 20 new generic drugs in the current year, with a current PBS value of $459 million.

On the drug distribution side, Sigma competes as a universal provider with Symbion and Australian Pharmaceutical Industries. A new entrant, DHL, has dropped out of the game after losing key contracts, but de Alwis sees the need for more rationalisation. ``We're operating in a market structure with excess capacity with three wholesalers doing the work two can do.''

De Alwis tips current year EBITDA growth of 16-19 per cent and a net result of $83-88 million, an improvement of at least 7.8 per cent. We should hope so, too, given last year's net result was weighed down by a $10 million restructuring charge.

Management has also warned of an expected interest bill of $81-85 million, a sharp rise on last year's $49 million. De Alwis says the extra impost is ``readily explainable'' by last year's $150 million share buyback and the $130 million acquisition of medical products house Orphan Australia.

Sigma's net debt stands at $421 million, 65 per cent higher than the previous $255 million a year ago. Including a further $357 million of debt housed in Sigma's chemists' rewards scheme, Sigma is working on a debt to equity ratio of 39 per cent.

Given the market's aversion to debt, it is serendipitous that Sigma missed out on the Symbion deal. In any event, Sigma remains in the mix to buy Symbion assets -- most likely its vitamins business and perhaps the whole distribution arm. But alternative buyers are reportedly queuing up as well.

Criterion has backed Sigma as both a turnaround prospect and a participant in the long-awaited industry shake-out, last ascribing a speculative buy at $1.43 in September last year.

Sigma remains the biggest contract drug manufacturer and generics maker, while its wholesale business still boasts the healthiest profits in what is a low-margin game. Sigma also enjoys a receptive customer base through the nation's two biggest chemist groups. Yet we must now question whether Sigma can exploit its advantages and rate the stock an avoid.

Ipernica (IPR) 9.7c

THE **patent** enforcement mob is stoical about a US judgment that will deliver the company a net $6 million, markedly short of the $100 million figure management bandied around earlier.

But balancing the scales of justice, Ipernica last week revealed it would pocket $30 million from a local ruling against telco giant Ericsson.

Ipernica yesterday announced the $US12 million ($13 million) settlement of the US case in which it was suing Nortel for wilful violation of telco technology **patents**. The move followed a long-awaited ruling from a Texas judge, awarding $US11.82 million of damages and an additional punitive loading of 1.7 times that amount, taking the total to $US20 million.

But with Nortel almost certain to settle, management deemed a $US12 million settlement, of which Ipernica pockets $US5.5 million after contingent legal fees, as being in the best interest of shareholders.

The odd aspect is that a jury initially awarded $US28 million, with the judge then expected to revise the figure upward to take account of Nortel's wilful breach. However, the beak took a year to ponder the decision and during that thinking time other **patent** cases suggested the royalty amount underpinning the judgment was too high.

Ipernica chief Graham Griffith yesterday assumed his best courtroom poker face. ``Any litigation has its own profile and risks and rewards,'' he said.

In the local case, Ipernica and litigation funder IMF sued Ericsson for **patent** breaches. A confidential settlement was announced on March 4, with IMF putting up its hands for $4 million. Ipernica last week joined the dots by revealing it would receive $35 million, less $5 million owed to other parties.

The payout leaves Ipernica with cash backing of 13c a share and a pipeline of other cases, including German proceedings against Siemens and Deutsche Telecom. Ipernica recorded a net $4.4 million on revenue of $21 million in 2006-07 and expects current-year earnings ``significantly north'' of that.

We rated Ipernica a speculative buy at 18c in October. Griffith says Ipernica has graduated from a ``speculative high-risk company to a stable company with a good business model''. Criterion wouldn't be so generous, given the tendency of the judiciary to produce unanticipated outcomes. But we agree the stock looks cheap and rest our case by maintaining a speculative buy.

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The Australian accepts no responsibility for stock recommendations. Readers should contact a licensed financial adviser. The author does not hold shares in the companies mentioned.

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[Return to List](#cite_id_171)

171 of 200 DOCUMENTS

Daily Mail (London)

**March** 20, 2008 Thursday

**Oil rival staking out Faroe stock;**

**MARKET REPORT**

**BYLINE:** Karl West

**SECTION:** 1ST; Pg. 96

**LENGTH:** 832 words

THE high price of oil continues to grab its share of the headlines, falling $4 to $105.40 a barrel yesterday on signs of falling demand and concerns about the US economy.

However, drilling down from the macro-economic picture, there is some interesting jockeying to secure prime position ahead of any consolidation among the second line players in the oil and gas sector.

One that caught the attention yesterday was FTSE 250 producer Dana Petroleum moving its tanks even further up the lawn of smaller rival Faroe Petroleum, raising its stake from 24pc to 27.53pc.

The move is even more interesting when a smaller 2.17pc stake in Faroe, owned by Aimlisted oil consultancy Parkmead Group, is taken into account.

What links Dana with Parkmead is their respective boards. Colin Goodall and Tom Cross are chairman and chief executive respectively of Dana. Meanwhile, the chairman of Parkmead is - you guessed it - Goodall, while Cross is also on the board.

Now, if Dana and Parkmead were acting together, their combined stake in Faroe would be 29.7pc, taking it very close to the 29.9pc ceiling that usually triggers a full bid for a company.

Both companies claim to be acting independently though, despite being guided by the same people. Watchdogs at the FSA are sure to be keeping a watchful eye.

The high cost of oil is forcing easyJet to pay a high price with its reputation after the budget airline warned profits would miss previous guidance as it misjudged the soaring cost of fuel.

The carrier helped drag the FTSE 250 down 50.3 points to 9551.2, as its own shares lost altitude, closing the session down 35 3/4 p at 339 1/4 p.

The warning sent shockwaves through top flight constituent British Airways , which endured a turbulent session as its shares closed down 7 1/4 p at 223p. BA recently warned its own profits are likely to be hit this year because of the severe headwinds from record oil prices.

The FTSE 100 survived an early shock when shares in mortgage bank HBOS fell almost 20pc as fear over the lender's ability to fund its business swept through the market.

However, traders steadied their nerves after the bank formally denied there was any cash crisis. Shares in HBOS made up some of its earlier losses, but it was still the biggest loser on the bluechip index, closing down 34p at 446 1/4 p.

The sell off at HBOS appeared to benefit rivals Barclays , up 10p at 422 3/4 p, and Lloyds TSB , 10 3/4 p firmer at 427 1/4 p, as investors switched into them..

Given the fear that is permeating the market, the Footsie did well to lose just 60.2 points to close at 5545.6. On the other side of the pond, the Dow was trading 74 points easier by mid-session at 12314.4. By the end of the day it was 293 points down at 12099.

Top-flight property and housebuilding stocks continued their miserable run of form on the back of fears over the credit crunch and the fragility of the UK housing market.

Persimmon eased 24p at 680p, Taylor Wimpey was 3.4p lighter at 152p, and British Land fell 33 1/2 p at 874p. Among the second string, Barratt Developments was off 15 1/2 p at 367 1/2 p.

Shares in building supplies distributor Wolseley are down 61pc in the last year as the stock has been hammered because of the group's exposure to the US housing market. It lost another 2 3/4 p yesterday to close at 483 1/4 p.

Drugs giant AstraZeneca received a welcome boost as HSBC ratcheted up its rating on the stock to 'overweight' from 'neutral' with a 12-month target price of 2,100p. The upgrade revived the flagging share price, pushing it up 53p at 1841p to challenge at the top of the Footsie leaderboard..

In a research note, analysts at HSBC said that Astra is acting vigorously to close the window of opportunity for US rival Teva Pharmaceuticals to exploit a potential launch of a generic version of Astra's schizophrenia drug Seroquel by bringing forward a judgment on the **patent.**

The brokerage said that an agreement with India's **Ranbaxy** on Astra's heartburn drug Nexium is also possible for the group. HSBC concluded that while it expects AZ to remain volatile, the upside is worth the risk.

Future dividend payments from US mobile operator Verizon Wireless to 45pc owner Vodafone were being questioned by analysts after the auction of the American airwaves, known as the spectrum, ended.

Verizon is thought to have bid up to £2.37bn for one block of the spectrum. Analysts at Investec said: 'If Verizon wins this block, then it is likely that dividend payments to Vodafone are delayed and associate earnings are dampened by the increased amortisation expense.' Voda's shares tracked back 4.4p to 148.6p.

SPECULATORS in the oil and gas sector might want to take a look at Enegi Oil, which is today being admitted to Aim. Led by chief executive Alan Minty, it has raised about £15m and will have a market value at the 181p listing price of around £55m. Enegi is an independent explorer focused on the proven petroleum region of Western Newfoundland. Minty has worked on contracts for most of the oil majors.

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[Return to List](#cite_id_172)

172 of 200 DOCUMENTS

Pharma Marketletter

**February** 15, 2008 Friday

**FDA sues Cephalon for generic blocking**

**LENGTH:** 449 words

The US Federal Trade Commission has filed a complaint in federal district court against drugmaker Cephalon alleging anticompetitive conduct that is preventing competition to its branded drug Provigil (modafinil). This is approved for the treatment of excessive spleepiness in people with sleep apnea, narcolepsy and shift-work sleep disorder and generated sales of some $800.0 million for the company in 2007, according to the agency.

The conduct includes paying four firms to refrain from selling generic versions of Provigil until 2012. Cephalon's anticompetitive scheme, the FTC states, denies patients access to lower-cost, generic versions of the drug and forces consumers and other purchasers to pay hundreds of millions of dollars a year more for it, said the FTC.

According to the Commission's complaint, filed in the US District Court for the District of Columbia, Cephalon entered into agreements with four generic drug manufacturers that each planned to sell a generic version of Provigil. Each of these had challenged the only remaining **patent** covering the drug, one relating to the size of particles used in the product. The complaint charges that Cephalon was able to induce each of the generic companies to abandon its **patent** challenge and agree to refrain from selling a generic version until 2012 by agreeing to pay the firms a total amount in excess of $200.0 million. In so doing, Cephalon achieved a result that assertion of its **patent** rights alone could not.

The "suit against Cephalon seeks to undo a course of anticompetitive conduct that is harming American consumers by depriving them of access to lower-cost generic alternatives to an important branded drug," said FTC Bureau of Competition Director Jeffrey Schmidt.

According to the Commission, four companies - Teva Pharmaceuticals USA, **Ranbaxy** Pharmaceuticals, Mylan Pharmaceuticals and Barr Laboratories - submitted applications with the Food and Drug Administration to market generic versions of Provigil. Cephalon filed **patent** litigation against each of the generic companies. By late 2005, however, the **patent** litigation was still pending and Cephalon, the generic firms, and Wall Street analysts all expected generic Provigil entry in the near term. Facing the prospect of billions of dollars in lost revenue, Cephalon entered into agreements through which it compensated generics firms to settle the **patent** litigation and agree to forgo generic entry until April 2012, the FTC alleges.

Cephalon to defend itself

In response to the charges, Cephalon said it is prepared to "vigorously" defends itself, arguing that it stand by the "strength and validity" of its **patents** and the legal basis for the settlements it reached.

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[Return to List](#cite_id_173)

173 of 200 DOCUMENTS

The Philadelphia Inquirer

**February** 14, 2008 Thursday

CITY-D Edition

**FTC accuses Cephalon over Provigil in patent case**

**BYLINE:** By Linda Loyd; Inquirer Staff Writer

**SECTION:** BUSINESS; P-com Biz; Pg. C03

**LENGTH:** 433 words

The Federal Trade Commission filed a lawsuit yesterday against Cephalon Inc. over deals it struck with four makers of generic drugs that had challenged the **patent** on Cephalon's biggest drug, Provigil.

The agreements, which the FTC said were worth more than $200 million, would prevent four companies - Teva Pharmaceutical Industries Ltd., Mylan Pharmaceuticals Inc., Barr Laboratories Inc. and **Ranbaxy** Laboratories Ltd. - from selling a generic version of the sleep-disorder drug until 2012.

Cephalon's "anticompetitive conduct," the FTC said, denies patients access to lower-cost generic versions of Provigil and forces consumers and other purchasers to pay "hundreds of millions of dollars a year more." Provigil had sales of $852 million last year.

"Cephalon prevented competition to Provigil by agreeing to share its future monopoly profits with generic drugmakers poised to enter the market, in exchange for delayed generic entry," said FTC Bureau of Competition director Jeffrey Schmidt. "Such conduct is at the core of what the antitrust laws proscribe."

Cephalon said, in a statement, that it stood by the "strength and validity" of its Provigil **patents** and the "legal basis for these settlements." The company said the agreements complied "with both the spirit and letter of the antitrust laws" and would "vigorously defend itself" and "expects to prevail."

The FTC has fought similar **patent** settlements. "We've had numerous other cases of the same type of behavior," said FTC assistant director Markus Meier, in an interview.

The FTC settled similar cases of **patent** disputes involving Abbott Laboratories, Hoescht AG and Bristol-Myers Squibb Co., Meier said. The FTC litigated and lost a case against Schering-Plough Corp. and American Home Products, now Wyeth.

Provigil, which treats excessive sleepiness in patients with sleep apnea, narcolepsy, and shift-work sleep disorder, accounts for more than 40 percent of Cephalon's total sales, the FTC said. The prospect of generic competition was "a major financial threat" to the company, the lawsuit said.

The accords with generic companies would keep intact Provigil sales until 2012. The company had faced potential loss of those sales to low-cost competitors as early as mid-2006.

Analyst Corey Davis at Natixis Bleichroeder Inc. suggested in a note to clients that Cephalon will survive the regulatory challenge from the commission.

"The FTC has yet to win any of its similar cases and the timeline for such litigation is likely to be very drawn out," Davis wrote.

Contact staff writer Linda Loyd at 215-854-2831 or lloyd@phillynews.com.

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[Return to List](#cite_id_174)

174 of 200 DOCUMENTS

Daily Mail (London)

**February** 8, 2008 Friday

**Pharma giants hit by £5bn hangover**

**BYLINE:** Ian Lyall

**SECTION:** 1ST; Pg. 92

**LENGTH:** 419 words

IT WAS a bloodbath for the pharmaceuticals industry yesterday.

More than £5bn was wiped from Britain's two leading drugs companies, with both feeling the pain from copycat competition.

GlaxoSmithKline led the way as it warned its earnings will go into reverse this year as a number of its products come under attack from cheap pill pushers The group will also struggle to fill the void left by Avandia, the controversial diabetes treatment dogged by safety concerns.

At one point the shares were down almost 10pc - their sharpest one-day fall ever - but recovered to close down 89p at 1,078p.

Meanwhile, rival AstraZeneca was also in the sick-bay as it emerged that the Indian firm **Ranbaxy** had won permission to produce a cut-price version of its heartburn pill, Nexium, in the US.

The product is AZ's secondbiggest with worldwide sales of more than £2.5bn..

The news sent the share price down 49p to 1,979p marking a three year low for the stock.

The Anglo-Swedish giant's lawyers reckon there are still **patents** protecting Nexium, but **Ranbaxy** may risk running foul of the courts to produce its own version of the pill.

But most of the fireworks were at GSK, where departing boss Jean-Pierre Garnier must be wishing he exited early rather than sticking around until May to take the plaudits at the company's annual meeting.

They are more likely to be brickbats after yesterday's annual results, which leave successor Andrew Witty with a tricky inheritance.

Operating profits were up 8pc at £7.6bn, and the dividend rose 10pc to 53p.

But that's where the good news ends. GSK warned about the after-effects of Avandia's fall from grace and the threat from generic competition, which hits its peak in 2008.

Analysts also detected a worrying weakening in profit margins and an additional US tax claim for £350m.

GSK said its earnings will fall by 'mid-single digits' this year, when some brokers were predicting a rise.

Garnier played up the potential of new drugs such as cervical cancer inoculation Cervarix and Avodart for male prostate problems.

But the market is clearly worried about the demise of staples such Wellbutrin and Seroxat, the depression drugs that could be in demand from investors who have seen the stock fall by a fifth in the past year.

And Avandia, whose sales collapsed 22pc last year amid worries over its side-effects, cast a massive shadow over results.

'We don't know whether we can revive the franchise or not,' said Garnier of the difficult task of rebuilding trust in the company'second-biggest seller. .

**LOAD-DATE:** February 9, 2008

**LANGUAGE:** ENGLISH

**GRAPHIC:** Feeling the pain: GSK boss Jean-Pierre Garnier

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[Return to List](#cite_id_175)

175 of 200 DOCUMENTS

The International Herald Tribune

**February** 8, 2008 Friday

**AstraZeneca stock falls on threat to its best-selling drug**

**BYLINE:** Ben Hirschler and Rina Chandran - Reuters

**SECTION:** FINANCE; Pg. 15

**LENGTH:** 504 words

**DATELINE:** LONDON

**Ranbaxy** Laboratories of India said Thursday it had received tentative U.S. approval to sell a generic form of Nexium, AstraZeneca's blockbuster heartburn and ulcer pill, driving shares of AstraZeneca to a three-year low.

The shares fell as **Ranbaxy's** announcement highlighted the risk that cheap generic copies might soon cannibalize sales of AstraZeneca's best seller in the United States, the world's top market.

Nexium is the second-biggest prescription medicine, with worldwide sales of $5.2 billion in 2007. Pfizer's cholesterol fighter, Lipitor, is No. 1, with sales of $12.7 billion in 2007.

**Ranbaxy** has first-to-file status on the drug, which is also known as esomeprazole magnesium, potentially giving it six months of marketing exclusivity when Nexium loses **patent** protection.

AstraZeneca contends it has valid U.S. **patents** expiring between 2014 and 2019 that protect Nexium from generic competition and the legal strength of those **patents** has yet to be tested in court.

An automatic 30-month legal stay on generic versions of Nexium in the United States expires on April 14.

''AstraZeneca continues to have confidence in its Nexium **patents** and will vigorously defend its intellectual property,'' the company said in a statement.

**Ranbaxy** could take the risk and begin selling a generic version in April, once it gets final clearance from the U.S. Food and Drug Administration.

In practice, many analysts think **Ranbaxy** may be wary and could instead strike a deal with another, larger generic drug maker, like Teva Pharmaceutical Industries, to share the risk. It might also seek to settle the case with AstraZeneca.

**Ranbaxy** officials have declined to comment on their strategy.

Nexium has been a mainstay for AstraZeneca for many years, but sales of the drug are already slowing and prices are coming under pressure as less-expensive versions become available of similar medicines with the same mode of action.

The arrival of a generic form of Wyeth's Protonix, a rival to Nexium, has heightened concerns about AstraZeneca.

Analysts at Credit Suisse said Thursday that they were cutting their target price for shares of AstraZeneca to £20, or $38.89, from £22.10, because of the risk from generics and fears that the erosion of Nexium's U.S. market position was likely to accelerate.

The brokerage firm has reduced its forecast for AstraZeneca's 2008 core earnings per share by 6 percent to $4.53, against guidance from the drug maker for earnings of $4.40 to $4.70.

Dresdner Kleinwort analysts cut their price target for AstraZeneca to £18.40 from £20 and said sooner-than-expected generic competition for Nexium and Seroquel - another AstraZeneca treatment facing **patent** challenges - could lead them to cut their 2008 earnings-per-share forecast by 30 percent.

Shares of AstraZeneca fell 49 pence, or 2.4 percent, to close at £19.79, having sunk as low as £19.64.

Early generic competition for Nexium would also be bad news for Merck because the company, which is based in New Jersey, gets a portion of annual U.S. sales of the drug.

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[Return to List](#cite_id_176)

176 of 200 DOCUMENTS

Pharma Marketletter

**January** 22, 2008 Tuesday

**Generic settlements over Exelon and Imitrex**

**LENGTH:** 94 words

Indian drugmaker Dr Reddy's Laboratories has settled US generic litigation with Novartis that will allow it to market a copycat version of the Swiss drug major's Exelon (rivastigime) patch for Alzheimer's disease before the **patent** expires. The launch date and other terms of the deal were not disclosed. In separate news, **Ranbaxy** Laboratories reached a settlement with GlaxoSmithKline that will allow it to launch a generic version of the UK drug major's $985.0 million-a-year migraine drug Imitrex (sumatriptan) in December, with no other generic rivals for 180 days.

**LOAD-DATE:** January 22, 2008

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[Return to List](#cite_id_177)

177 of 200 DOCUMENTS

The International Herald Tribune

**January** 18, 2008 Friday

**Ranbaxy earnings rise (folo);**

**Stake sale helps push Reliance to profit;**

**But investors punish shares over earnings**

**SECTION:** FINANCE; Pg. 17

**LENGTH:** 124 words

**DATELINE:** NEW DELHI

**Ranbaxy** Laboratories, the top drug maker by sales in India, on Thursday reported a 1 percent rise in quarterly net profit, beating forecasts on strong sales of generic drugs in Western markets, Reuters reported from New Delhi.

**Ranbaxy**, which aims to be among the world's top five generic drug makers with $5 billion in annual sales by 2012, said net profit rose to 1.88 billion rupees, or $48 million, in the December quarter from 1.86 billion rupees a year ago.

**Ranbaxy** has grown internationally by selling generics, cheap copies of branded drugs off-**patent,** or by successfully challenging the **patents** held by Western firms.

In November, the company said it had resolved a U.S. **patent** dispute over tamsulosin capsules, a generic equivalent of Flomax.

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[Return to List](#cite_id_178)

178 of 200 DOCUMENTS

National Post's Financial Post & FP Investing (Canada)

**January** 15, 2008 Tuesday

National Edition

**Pfizer says U.S. rejects Lipitor patent; Decision Not Final**

**BYLINE:** Elizabeth Lopatto, Bloomberg News

**SECTION:** FINANCIAL POST; Pg. FP16

**LENGTH:** 527 words

**DATELINE:** NEW YORK

NEW YORK - Pfizer Inc. said the U.S. **Patent** Office initially rejected the basic **patent** for the cholesterol pill Lipitor, the world's top-selling drug, in a review that could take years before a final decision is made.

An initial rejection isn't unusual in such proceedings, the New York-based company said yesterday in a statement. The "basic **patent** was properly granted and will be upheld," Pfizer said. The **patent** office agreed to take a second look at the **patent** at the behest of a law firm that represented **Ranbaxy** Laboratories Ltd., Pfizer said in a November, 2007, regulatory filing.

The **patent** is keeping **Ranbaxy** from selling a generic version of Lipitor until March, 2010. Lipitor had sales of US$12.9-billion, about 27% of Pfizer's revenue, in 2006. The company may lose half its sales in the next five years as Lipitor and other products lose **patent** protection.

The process "could take as long as a few years," during which the **patent** "remains valid and enforceable," Pfizer said.

Pfizer declined US5¢ to US$23.97 in New York Stock Exchange composite trading, and has fallen 10% over 12 months.

A review by the **patent** office looks only at whether there is an earlier knowledge or publication that would show the **patent** doesn't cover a new invention.

Gurgaon, India-based **Ranbaxy**, India's second-largest drugmaker, lost a court bid to challenge the government's decision to extend the term of the **patent** beyond its original expiration date. The extension was granted to compensate Pfizer for the time it took to get regulatory approval for Lipitor.

A second Lipitor **patent**, which would expire in 2011, was invalidated by an appeals court because of inconsistent wording in the **patent**.

The **patent** office last year issued a non-final rejection of Pfizer's request to reissue the 2011 **patent** with changes to reflect the appeals court ruling. Pfizer's application is still with the agency in Alexandria, Va.

**Ranbaxy** filed a second challenge to the 2010 **patent** as part of its application to sell Caduet, which combines Lipitor with the hypertension drug Norvasc. In November, a federal judge ruled that **Ranbaxy** couldn't renew the challenge to the **patent** because it had already been ruled upon by the appeals court.

In May, 2007, Pfizer lost a Norwegian appeals court ruling that may allow **Ranbaxy** to sell a generic version of Lipitor. The ruling said that four of Pfizer's **patents** covering the world's top-selling drug weren't infringed, or were invalid, Pfizer announced.

In September, Pfizer won protection on Lipitor in Canada until 2016. A German court rejected a **patent** Pfizer owns on Lipitor in October. Pfizer said it would appeal.

Separately, Merck&Co. and Schering-Plough Corp. said yesterday their best-selling combination cholesterol drug Vytorin worked no better than generic Zocor in reducing the buildup of artery-clogging fat in a key study. The pill combines simvastatin, the generic form of Zocor and Zetia. Vytorin, Zocor and Zetia compete with Lipitor.

Pfizer also released a statement saying that patients who took Lipitor were 12% less likely to have cardiovascular events, such as heart attacks, than those taking simvastatin in an observational study.

**LOAD-DATE:** January 15, 2008

**LANGUAGE:** ENGLISH

**GRAPHIC:**

Color Photo: Bloomberg News File Photo; A generic version of Lipitor, made by India's **Ranbaxy** Laboratories Ltd. **Ranbaxy** is fighting for the legal right to sell the cholesterol pill. ; !@AKW=DRUGS

**DOCUMENT-TYPE:** Business

**PUBLICATION-TYPE:** Newspaper

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[Return to List](#cite_id_179)

179 of 200 DOCUMENTS



The Washington Post

**January** 15, 2008 Tuesday

Suburban Edition

**LEGAL**

**SECTION:** FINANCIAL; Pg. D02

**LENGTH:** 813 words

**LEGAL**

**Settlement in Wal-Mart Suit**

The Supreme Court dismissed a lawsuit brought by a Wal-Mart employee who alleged the retailer discriminated against her after an on-the-job accident. The court said the parties had agreed to settle the dispute. At issue was how far employers under the Americans with Disabilities Act must go to accommodate disabled employees.

Pam Huber, who still works at Wal-Mart, was injured in April 2001 while employed as an order filler at a Wal-Mart distribution center in Clarksville, Ark. She applied for a different position at equivalent pay but did not get the job. Wal-Mart said in court papers that it hired a more qualified employee. Huber was later given a job at about half the hourly wage she earned as an order filler.

**Deadline Nears for Vioxx Claims**

The number of claims by Vioxx patients hoping to get a piece of a $4.85 billion settlement makes it appear likely that the deal will proceed, lawyers and drugmaker Merck said. Merck has said it would withdraw from one of the largest settlements in the pharmaceutical industry if 85 percent of certain claimants or their representatives don't sign on.

Thousands of people have sued Merck, claiming they were injured by taking the painkiller before it was pulled from shelves. They and their lawyers have until today to register a claim if they are considering participating in the settlement.

**ENERGY**

**GE Adding to Renewable Energy**

General Electric plans to increase investment in renewable energy by 50 percent, to $6 billion by 2010, as demand rises for alternative power sources. The decision stemmed from rising oil prices, increased focus on environmental protection, and improved technology for boosting interest in wind, solar, biomass, hydro and geothermal power.

**MORGTAGE FINANCE**

**Group Predicts Drop in Lending**

The Mortgage Bankers Association predicts that U.S. mortgage lending will fall 16.2 percent this year, dragged down by a worsening economy and a slumping mortgage market. The trade group forecast that mortgage lending would drop to $1.96 trillion, down from a projected $2.34 trillion last year. The group also said that sales of previously owned homes would drop by 13 percent and that median prices would decline 2 percent.

**INVESTING**

**IBM Makes Big Advance**

IBM shares rose more than they have in five years after preliminary earnings and sales topped analysts' projections. IBM climbed 5.4 percent after saying business in Asia, Europe and developing countries helped bolster results through the weaker U.S. dollar. Fourth-quarter profit climbed to $2.80 a share and sales rose to $28.9 billion, exceeding predictions by more than $1 billion. IBM rose $5.26 to $102.93 at 4 p.m. in New York Stock Exchange composite trading. The gain was the largest since October 2002. The company is scheduled to issue full results on Thursday.

**Fidelity Reopens Magellan Fund**

Fidelity Investments will reopen its $44.8 billion Magellan Fund to new investors effective today. Fidelity closed the fund to new accounts in 1997, after a run of market-beating returns in the 1980s and 1990s. Although Magellan has had recent strong returns, its size has dwindled from its peak of $102 billion in 2000 because of the closure, and Magellan's investors have crept closer to retirement age, when many redeem their investments.

**PHARMACEUTICAL**

**U.S. Rejects Basic Lipitor Patent**

Pfizer said the U.S. **Patent** Office initially rejected the basic **patent** for the cholesterol pill Lipitor, the world's top-selling drug, in a review that could take years before a decision is made. The **patent** remains valid and enforceable during the review. The **patent** office agreed to take a second look at the **patent** at the behest of a law firm representing **Ranbaxy** Laboratories. The **patent** is keeping **Ranbaxy** from selling a generic version of Lipitor until March 2010.

**EARNINGS**

Genentech said its fourth-quarter profit rose 6 percent, to $632 million. Revenue rose 10 percent, to $2.97 billion. Profit for the full year rose 31 percent, to $2.77 billion. Annual revenue rose 26 percent, to $11.72 billion.

Cargill said second-quarter profit rose 44 percent, to $954 million.

**TREASURY BILLS**

T-bill rates fell, with rates on six-month bills dropping to the lowest level in nearly three years. The discount rate on three-month Treasury bills auctioned yesterday fell to 3.08 percent from 3.18 percent last week. Rates on six-month bills fell to 2.95 percent from 3.17 percent. The annualized return to investors is 3.156 percent for three-month bills, with a $10,000 bill selling for $9,922.14, and 3.045 percent for a six-month bill selling for $9,850.86. Separately, the Federal Reserve said the average yield for one-year Treasury bills, a popular index for making changes in adjustable-rate mortgages, fell to 3.04 percent last week from 3.18 percent two weeks ago.

Compiled from reports by the Associated Press and Bloomberg News.

**LOAD-DATE:** January 15, 2008

**LANGUAGE:** ENGLISH

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**GRAPHIC:** IMAGE

**PUBLICATION-TYPE:** Newspaper

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[Return to List](#cite_id_180)

180 of 200 DOCUMENTS

Pharma Marketletter

**January** 10, 2008 Thursday

**US-style FDA for India but R&D tax break "fails"**

**LENGTH:** 432 words

India's government has held talks with the US Department of Health and Human Services with the aim of forming a US-style Food and Drug Administration in the former country.

India's federal Health Minister, Anbumani Ramadoss, announced the formation of two committees to identify key areas for quality control in the country's food and drug industries. A six-month timetable has been set for the review process to be completed, The Hindu reports. One of the two committees formed by the joint India-USA talks will be concerned with technical and scientific issues. It will be chaired by the former director of the Indian Council for Medical Research, NK Ganguly. Among the committee's members will be RA Mashelkar, the former director general of the Council for Scientific and Industrial Research, who was involved in a controversial report last year into India's 2005 **Patent** Law (Marketletters passim).

Dr Ramadoss and US HHS Secretary Michael Leavitt gave details of the new agency's developments at a roundtable organized by the Confederation of Indian Industry, titled: Indo-US Life Sciences, Health Services and Public Health Collaborations.

"Widespread abuse" of R&D tax credit

In other news, lobbying by local drugmakers appears to have failed to persuade the Indian tax authorities to extend an R&D tax credit to stand-alone research facilities owned by pharmaceutical firms. India's Economic Times reports that "allegations of widespread abuse" of existing R&D fiscal incentives for in-house R&D units will reinforce the government's current drive to reduce the number of tax exemptions.

The current tax exemption for in-house R&D is a 150% deduction from declarable income and was extended for five years in 2007. However, some of India's major drug firms have shifted their innovative units into stand-alone corporate entities, which would no longer benefit from the fiscal rebate. The Economic Times reports that, among the affected firms, are Dr Reddy's and Sun Pharma, while **Ranbaxy** and Nicholas Piramal are both in the process of creating a separation between R&D and other elements of their respective groups.

Bad news for the drugmakers is the claim that the Comptroller and Auditor General of India has identified abuses of the existing tax credit and that the government's Kelkar committee on tax reforms has proposed a simplification of the tax code and scrapping exemptions, not adding to them. Politically, an extended tax credit for R&D is difficult for the government to accept, because any drugs developed by these units is exempt from price controls, the Economic Times reports.

**LOAD-DATE:** January 10, 2008

**LANGUAGE:** ENGLISH

**PUBLICATION-TYPE:** Newsletter

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[Return to List](#cite_id_181)

181 of 200 DOCUMENTS

National Post's Financial Post & FP Investing (Canada)

**January** 2, 2008 Wednesday

National Edition

**Apotex will make generic allergy drug**

**BYLINE:** Bloomberg News

**SECTION:** FINANCIAL POST; National Report; Pg. FP2

**LENGTH:** 147 words

Canada's Apotex Inc. is one of a slew of companies planning to produce a generic version of the popular nonprescription allergy medicine Zyrtec. According to documents on the U.S. Food and Drug Administration Web site, at least seven other companies -- including Indian generic-drug makers **Ranbaxy** Laboratories Ltd. and Wockhardt Ltd -- are also planning to produce generic versions of the drug. The branded version of the drug is made by Johnson & Johnson, which won U.S. clearance to sell Zyrtec over the counter in November. J&J gained rights to the nonprescription drug in its US$16.6-billion purchase of Pfizer's consumer unit in December, 2006. Sales of prescription-strength Zyrtec and Zyrtec-D, a formulation with a decongestant, rose 15% to US$1.6-million last year, accounting for about 3% of New York-based Pfizer's revenue. Zyrtec is also known as cetirizine hydrochloride.

**LOAD-DATE:** January 2, 2008

**LANGUAGE:** ENGLISH

**DOCUMENT-TYPE:** Business; Brief

**PUBLICATION-TYPE:** Newspaper

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[Return to List](#cite_id_182)

182 of 200 DOCUMENTS

Australian Financial Review

**December** 17, 2007 Monday

First Edition

**Sigma looks for light at end of 2007 tunnel**

**BYLINE:** Fiona Tyndall

**SECTION:** COMPANIES AND MARKETS; Pg. 15

**LENGTH:** 1049 words

It's been a tough year for the big pharmaceutical, writes Fiona Tyndall.

As bad years go, 2007 topped the charts for Sigma Pharmaceuticals.

There was a profit downgrade in July, a rejected bid for parts of Symbion Health in June, the abrupt exit of major shareholder, the Duchens, in April.

All this came after a failed takeover bid for Australian Pharmaceutical Industries in December last year.

Add to that a regulatory regime Sigma says unfairly forced it to share government reimbursement with rival distributor DHL, aggressive price cutting by new competitor **Ranbaxy** and reforms to the pharmaceutical benefits scheme that cut into margins.

The drugs wholesaler also started and then stumbled over its own sales strategy, Embrace, which aimed to increase revenue by selling more of its products to pharmacists but did just the opposite.

All in the space of 12 months.

Cue a share price fall to $1.36 in September from $3 in December last year and the appointment of Deutsche Bank as a defence adviser just in case a predatory rival made an opportunistic takeover offer.

No one did.

"You could handle any of them alone," Sigma managing director Elmo de Alwis says, in regard to the company's problems. "Every one of those is in itself manageable."

Sigma, which had the additional challenge of integration after merging with Arrow Pharmaceuticals in late 2005, says most of the issues it faced are close to resolution.

At the conclusion of the year, de Alwis is running a steadier business.

He has cut twice-daily deliveries to pharmacies to just one a day, tweaked the Embrace program and is on track to meet downgraded profit guidance of $88 million to $93 million in financial year 2008.

"None of what we have done is rocket science," de Alwis says.

"If I have a regret or a criticism of myself it is that we didn't do it earlier.

"Once a day delivery is a good example.

"We know pharmacists can cope and not reduce their service levels so why didn't we do it last year?

"All we can say is we didn't."

The company's share price has recovered slightly, closing at $1.555 on Friday.

However, analysts still expect Sigma's earnings to miss the new range, their forecast net profit of $85 million to $90 million reflecting a lack of confidence in the company.

"Sigma needs to deliver its revised full-year net profit guidance of $88 million to $93 million," says Merrill Lynch analyst Matthew Prior.

"Until we see evidence of a turn-around in Embrace compliance levels and proof of the successful launch of new generics, we are happy to maintain a 'neutral' recommendation on this stock."

But 2008 will have upheavals all of its own.

Price competition between distributors of generic drugs - less expensive but identical versions of branded drugs on which the **patent** has expired - is expected to continue to squeeze margins for drug wholesalers.

This has prompted talk of the need for consolidation between the main players.

Yet with only three wholesalers dominating the market, competition concerns will make any merger an arduous process and probably restrict the benefits the companies hope to reap.

Sigma is keen for straight out rationalisation between itself and either of its rivals - API and Symbion - and says such a proposition might generate synergies of between $30 million and $35 million.

But now API, Sigma and Symbion are the only full-line wholesalers (fourth player, DHL, lost its major contract to API) the Australian Competition and Consumer Commission might view any merger as lessening competition.

Almost five years ago, the ACCC would not allow a Sigma-API merger on that basis.

Back then, the same three companies - API, Sigma and Symbion (then Mayne Group) - dominated the market, each having a roughly equal share.

Approval of the deal would have cut the major players to two.

Since that time, Symbion has increased its market share and DHL has lost its foothold.

The latter could be seen as competition reducing (one less player) or competition enhancing (its presence could be seen as indicating that barriers to entering the sector are relatively low).

De Alwis also argues that fierce regulation of pharmaceutical wholesaling would prevent the abuse of market power if two wholesalers got together.

A government program encourages wholesalers to be able to deliver any drug listed on the pharmaceutical benefits scheme to any pharmacy in the country within 24 hours by offering reimbursement only to wholesalers who can meet the standard.

It deters wholesalers from distributing only the most lucrative drugs in the most lucrative geographic areas. "We buy at a price, we sell at a price and our service levels are regulated," de Alwis says.

"It is a situation where the customer has a lot of power.

"Recently in north Western Australia somebody ordered a $30 product from which we made $2.

"We had to fly it out of Adelaide with refrigerated transport. It cost us $400 to deliver.

"If it was a free market we would have the right to say we will charge the customer $400 or ask them to get it somewhere else.

"But we have an obligation, when somebody orders a product, to deliver it. That is an enormous protection for the customer."

But if the ACCC doesn't see eye to eye with de Alwis on consolidation, he will pursue other options doggedly.

After all, analysts say because wholesalers are hamstrung by low profit margins, consolidation is the next logical driver for profits beyond 2008, increasing pressure on the industry to co-operate.

De Alwis wants API, Symbion and Sigma to work together on warehousing, logistics and delivery to create back-office synergies, such as common distribution.

It would deliver about half the synergies a straight-out merger would, and still require the approval of the ACCC, but so imperative is consolidation that he expects a combined back office will be seriously considered by his peers.

De Alwis hopes all three - API, Symbion and Sigma - can share one back office and use one logistics operator.

Sigma is devising a plan, determining what would be required to operate shared services and what savings could be made by honing the operators' duplicated logistics.

"We have got to find a way to consolidate," he says.

"There is pressure on all three and the driver [for consolidation in 2008 will] be pressure on the profitability and performance of each of the companies."

**LOAD-DATE:** April 6, 2012

**LANGUAGE:** ENGLISH

**GRAPHIC:** PHOTO: Sigma managing director Elmo de Alwis favours rationalisation. Photo: EAMON GALLAGHER GRAPH: AILING. Sigma, Share price, daily. Source: Bloomberg.

**PUBLICATION-TYPE:** Newspaper

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[Return to List](#cite_id_183)

183 of 200 DOCUMENTS

The Business

**December** 15, 2007

**Big pharma catches cold as new drug pipeline dries up**

**BYLINE:** Catherine Boyle

**LENGTH:** 915 words

BIG PHARMA S sniffle has turned into full-blown flu in the past year. The industry has to change the way it does business and fast. It has been clear for some time that difficulties in bringing new drugs through the research and development (R&D) pipeline will leave many of the 10 biggest pharmaceutical companies facing a steep drop in revenues between 2010 and 2012 and this trend will become obvious for all investors to see next year.

The malaise can in part be blamed on the US Food and Drug Administration (FDA). After a number of high-profile safety issues with drugs such as Merck s painkiller Vioxx, the FDA is treading more carefully with new drugs. New drug approvals by the FDA plunged in 2007, with just 51 new medicines approved by end-October, down 29% from 68 in 2006 and 13% below the 10-year average of 59.

Recent research by Citi analysts showed that even if all the drugs currently being researched and tested by big pharma companies make it to market, there will still be a significant drop in revenues between 2010 and 2012.

Not all of this can be blamed on FDA intransigence. Pfizer, for one, has thrown money at potential blockbusters rather than building on established drugs with smaller markets. The result has been disasters such as Exubera, forecast to bring in $2bn (£986m; E1.34bn) in annual sales, which was pulled in October after selling a paltry $7m. Pfizer announced a $2.8bn write-down on Exubera.

Even Pfizer s iconic Viagra brings in respectable but hardly sensational sales of $1.7bn annually. Pfizer seemed to forget this in throwing money at Exubera and at torcetrapib, a cholesterol drug that cost $1bn for first stage clinical trials yet never made it to market. Its development was halted in 2006 amid concerns over a high death rate during tests.

Drugmakers need to resign themselves to the fact that it is not easy to spot a blockbuster, and realise that it may be better to back several drugs in relatively small disease areas, rather than throw all their weight behind a few potential big hitters.

Drugs companies are highly vulnerable to negative sentiment. In May, GlaxoSmithKline (GSK) saw $18bn wiped off its market value in a week after an article in the New England Journal of Medicine suggested that Avandia, its diabetes drug, caused heart disease. Third-quarter sales of Avandia fell 38% to £225m.

In October, Jean-Pierre Garnier, GSK s departing chief executive, unveiled an operational excellence "programme intended to deliver annual pre-tax cost savings of up to £700m by 2010. Initial savings of £350m in 2008 would partly mitigate the impact of lower sales of Avandia and competition from generic drugs.

Some 40% of GSK s cuts will come from manufacturing, another 40% from sales and administration and the remaining 20% from research and development infrastructure. GSK s pipeline is better placed for the long term than most, but Andrew Witty, chief executive-elect, will have a lot on his to-do "list when he takes over from Garnier in June 2008.

The doom and gloom across the industry makes job cuts inevitable. Seven of the world s 10 biggest pharma companies have announced large-scale retrenchments in the past year, with 34,210 jobs to go across the world. Sales and marketing forces will be culled. Big pharma companies have realised that they need to spend more on research rather than on touting their drugs. Manufacturing jobs in Britain, Europe and America will be lost as production shifts to lower-cost manufacturing centres in Asia.

The industry has been reluctant to outsource to China and India, in part because of the increased risk of counterfeiting. AstraZeneca s move to start buying Lactam, a key chemical ingredient used in Seroquel, its $3.4bn schizophrenia drug, from contract manufacturers in China, will be the first of many similar cost-cutting measures as companies focus on drug development.

AstraZeneca has suffered more than most pharma companies from generic challenges to its bestselling drugs. Intellectual property is jealously guarded by big pharma, but aggressive generics firms, such as Teva in Israel and **Ranbaxy** and Dr Reddy s in India, are increasingly challenging **patents** at an early stage. AstraZeneca has recently lost appeals on its bestselling drug Nexium, and Symbicort, its asthma medicine.

One way out of the problem is for Big Pharma to snap up biotech firms. AstraZeneca paid $15.6bn for US biotech MedImmune earlier in 2007, but it has yet to prove to the market that this acquisition will cure difficulties in its pipeline.

The auction of Biogen, the US biotech which could go for as much as $30bn, will be an interesting process. Carl Icahn, the US investor, was quick to make a $23bn approach; the evaporating credit markets have not killed the deal. Pfizer, GSK and Eli Lilly are among the big drugmakers to have expressed interest in Biogen.

The company would particularly suit Pfizer: Biogen has a good pipeline and several valuable products already on the market, including Avonex for multiple sclerosis and Rituxan for non-Hodgkin s lymphoma and rheumatoid arthritis. With $23bn in cash, Pfizer has the money to do a deal of this size comfortably. The Biogen auction is set to drag on into 2008.

Time is running out for big pharma to find an antidote to its ills. Pfizer, Merck, AstraZeneca and their peers will have to show that they can change the way in which they bring drugs to market. Without such change, 2010-12 will be a bleak period for shareholders and companies alike.

**LOAD-DATE:** December 13, 2007

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[Return to List](#cite_id_184)

184 of 200 DOCUMENTS

Pharma Marketletter

**December** 14, 2007 Friday

**India's drugmakers apply for IP protection**

**LENGTH:** 224 words

Evidence of a shift in the intellectual property rights climate in India can be found in newly-reported figures on **patent** applications at the Indian **Patent** Office. From 1995 to 2004, before the present **patent** legislation was introduced (Marketletters passim), 40% of applications for IP protection with the agency came from domestic firms. **Ranbaxy** Laboratories, Dr Reddy's Laboratories and Cipla, three of the world's major generic drug producers, have filed more than 100 **patent** applications each, according to India's Economic Times newspaper. In 2006 alone, **Ranbaxy** applied for 30 **patents**.

The significance of the numbers reported by the IPO are disputed by Carlos Correa, a former member of the World Health Organization's Commission on Intellectual Property, Innovation and Public Health. Prof Correa described the bulk of the IP applications as "new laboratory techniques" instead of significant advances.

However, India changed its legislation in an effort to become more compliant with World Trade Organization standards in 2005, the extent of which is the subject of an ongoing law suit involving Swiss drug major Novartis' oncology product Glivec/Gleevec (imatinib mesylate; Marketletters passim). The Economic Times reports that this development has triggered a "rush" to claim IP protection by both foreign and locally-based drugmakers.

**LOAD-DATE:** December 14, 2007

**LANGUAGE:** ENGLISH

**PUBLICATION-TYPE:** Newsletter

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[Return to List](#cite_id_185)

185 of 200 DOCUMENTS

Africa News

**December** 10, 2007 Monday

**Africa;**

**Daily HIV/Aids Report**

**BYLINE:** Kaisernetwork.org

**LENGTH:** 2476 words

Election 2008

Huckabee Says He Will Not 'Recant' 1992 Comments on HIV/AIDS

[Dec 10, 2007]

Former Arkansas Gov. Mike Huckabee, who is running for the Republican presidential nomination, on Sunday said that he will not "recant" statements made in 1992 in which he called for people living with HIV/AIDS to be isolated from the general population, the AP/International Herald Tribune reports. Huckabee -- who made the statements in an Associated Press survey while running for Senate that year -- wrote that in order for the federal government to effectively address the spread of HIV, "we need to take steps that would isolate the carries of this plague." He added in the survey, "It is the first time in the history of civilization in which the carriers of a genuine plague have not been isolated from the general population, and in which this deadly disease for which there is no cure is being treated as a civil rights issue instead of the true health crisis it represents" (AP/International Herald Tribune, 12/9).

Huckabee in the 1992 survey also said that HIV/AIDS research was receiving too much federal funding, The Politico reports. "In light of the extraordinary funds already being given for AIDS research, it does not seem that additional federal spending can be justified," Huckabee wrote. "An alternative would be to request that multimillionaire celebrities -- such as Elizabeth Taylor, Madonna and others who are pushing for more AIDS funding -- be encouraged to give out of their own personal treasuries increased amounts for AIDS research," he added (Allen, The Politico, 12/8). In addition, Huckabee in the survey said that homosexuality was an "aberrant, unnatural and sinful lifestyle, and we now know it can pose a dangerous public health risk," the Washington Post reports.

Campaign Response

Huckabee's campaign on Saturday released a statement from him saying that in 1992 there was confusion over how HIV is transmitted. "We now know that the virus that causes AIDS is spread differently, with a lower level of contact than with TB," Huckabee said in the statement, adding, "But looking back almost 20 years, my concern was the uncertain risk to the general population -- if we got it wrong, many people would die needlessly." Huckabee also pledged to make the fight against HIV/AIDS a central part of his presidency if elected (Bacon, Washington Post, 12/9). Huckabee in the statement released Saturday added that his "concern was safety first, political correctness last." Huckabee responded to the 1992 Associated Press survey after it was "well established" that HIV could not be spread through casual contact, the New York Times reports (Luo, New York Times, 12/9). In addition, Huckabee responded to the 1992 survey more than one year after President George H.W. Bush called on Congress to "get on with the job of passing a law" to prohibit discrimination against people living with HIV/AIDS, according to the AP/Herald Tribune. Although Huckabee acknowledged the prevailing scientific view in 1992, and since, that HIV is not transmitted through casual contact, he said he was not certain at the time. Huckabee cited a 1991 report of a dentist who infected a patient with HIV -- an "extraordinary case that highlighted the risk of infection through contact with blood or bodily fluids" -- according to the AP/Herald Tribune.

Huckabee in an interview with Fox News Channel's "Fox News Sunday" said, "I still believe this today" that "we were acting more out of political correctness" in responding to HIV/AIDS. "I don't run from it, I don't recant it," he said of his statements in 1992. He added that his comments were not meant as a call to quarantine HIV-positive people. "I didn't say we should quarantine," Huckabee said, adding that his idea was not to "lock people up" (AP/International Herald Tribune, 12/9). However, Huckabee added that he would state his position "a little differently" today, the Wall Street Journal reports (Meckler, Wall Street Journal, 12/10).

A transcript of the "Fox News Sunday" segment is available online.

Link to this story.

Politics and Policy

Homeland Security Department Provides Inadequate Care, Treatment to HIV-Positive People at Immigration Detention Centers, Report Says

[Dec 10, 2007]

The Department of Homeland Security provides inadequate care and treatment to HIV-positive detainees at immigration detention centers nationwide, according to a report released recently by Human Rights Watch, the Los Angeles Times reports. According to the Times, the report was released in response to the death of an HIV-positive inmate at a San Pedro, Calif., detention center (Griggs, Los Angeles Times, 12/8).

Victor Arellano -- who was transgender and went by the name Victoria -- allegedly was denied vital medical care at the San Pedro center. Attorneys for Arellano's family say that while in custody, Arellano's condition deteriorated to the point that fellow detainees urged staff to provide medical care. Roman Silberfeld, the family's attorney, said that 70 detainees signed a petition urging that Arellano receive medical attention. When Arellano's condition became critical, Arellano was transferred to a San Pedro hospital and died several days later (Kaiser Daily HIV/AIDS Report, 8/29).

For the 71-page report, Megan McLemore of HRW interviewed current and former detainees, as well as Homeland Security and detention facility officials in Alabama, California, New Jersey, Virginia and other states, the Times reports. The report found that the "medical care in three types of facilities, representing nine states, was delayed, interrupted or inconsistent," McLemore said. Other findings included a failure to:

Provide complete antiretroviral regimens consistently, thereby increasing the chance of drug resistance;

Prescribe prophylactic medications to prevent opportunistic infections; and

Ensure continuity of care when detainees were transferred to other facilities (Los Angeles Times, 12/8).

The "U.S. government has no idea how many of these immigrants have HIV or AIDS, how many need treatment and how many are receiving the care that is necessary," McLemore said. She added that DHS "needs to upgrade their policies and more closely monitor and ensure effective treatment for immigrants living with HIV or AIDS. ... Otherwise these individuals will continue to suffer, and even die, in the care of the U.S. government" (AFP/Google.com, 12/8).

Virginia Kice, spokesperson for Immigration and Customs Enforcement, said the agency has not fully reviewed the report but generally disagrees with its findings. She added, "Ensuring the welfare and safety of those in our custody is one of our top priorities" (AP/Google.com, 12/8). According to the Times, government or privately contracted facilities house about 30,000 undocumented immigrants daily (Los Angeles Times, 12/8).

The report is available online.

Link to this story.

Millennium Challenge Corporation Could Receive Budget Cuts Because of 'Slow Pace' in Launching Development Projects, New York Times Reports

[Dec 10, 2007]

The Millennium Challenge Corporation's "slow pace" in launching development projects worldwide has made it "politically vulnerable at budget crunch time," the New York Times reports. MCC -- which aims to encourage economic and political reforms in developing countries -- to date has spent $155 million of the $4.8 billion it has approved for projects in 15 countries in Africa, Central America and other regions, according to the Times. Both the House and Senate have reduced Presidents Bush's fiscal year 2008 budget request for the program, and the Senate is "pushing for a change that African leaders say threatens the essence of the agency's novel approach," the Times reports.

MCC's budget accounts for less than 10% of the U.S. foreign aid budget. Bush requested $3 billion for MCC for FY 2008. The House has approved $1.8 billion in its FY 2008 foreign aid spending bill, and the Senate approved $1.2 billion for the agency. The Senate also has proposed that Congress provide no more than half the financing up-front for future five-year projects, which usually total about $250 million to $700 million. Currently, such projects initially are fully financed. Sen. Patrick Leahy (D-Vt.), chair of the Senate appropriations subcommittee on foreign aid, said that Congress could provide the remaining funds if recipient countries successfully carry out projects. He added that it would be difficult to determine where to make reductions in the foreign aid budget to finance MCC. "Do we cut maternal health?" Leahy asked, adding, "AIDS? Malaria? Do we cut refugees? The only thing that's got a blank check is the war in Iraq."

However, MCC officials and some African leaders have said that such a change would be detrimental. By changing how MCC's projects are financed, the agency "becomes like the World Bank and all the other countries using overseas development aid in stop and go fashion," John Kufuor -- the president of Ghana and head of the African Union -- said. Sheila Herrling of the Washington, D.C.-based Center for Global Development said that MCC management has been more concentrated on creating projects than on launching them. "It shouldn't have taken so long," she said, adding, "The agency needs to figure it out this year. They are part of the problem." However, Herrling said that there are understandable reasons why MCC projects take time, adding that the agency's five-year timeline for each project might be too short. Poor nations, even those with well-run governments, are not used to planning such complex projects and have needed more time than originally thought to launch them, Herrling said.

MCC head John Danilovich recently reorganized the program to concentrate on results with what he called "laser focus." He added, "We need to do better and we will do better." The House and Senate are expected to decide on funding for MCC by this week (Dugger, New York Times, 12/7).

Link to this story.

Drug Access

GlaxoSmithKline Withdraws **Patent** Applications for Antiretrovirals Abacavir, Trizivir in India

[Dec 10, 2007]

GlaxoSmithKline recently withdrew the **patent** applications for its antiretroviral drugs Abacavir and Trizivir in India, the Economic Times reports. According to the Times, GSK formally withdrew its application for Abacavir, and its application for Trizivir was deemed withdrawn after the company requested that India's **Patent** Office not examine the case.

Abacavir is a second-line antiretroviral used to treat people living with HIV/AIDS who have developed resistance to first-line drugs. Trizivir is a triple-combination antiretroviral used for first- and second-line treatments, the Times reports. Both antiretrovirals are on the World Health Organization's recommended list of drugs for HIV treatments, the Times reports. Some Indian generic drug companies -- including Cipla, **Ranbaxy** Laboratories and Hetero Drugs -- already market one or both drugs in the country. GSK declined to comment on the status of the applications. A GSK spokesperson said the company does "not comment on specific **patent** applications. However, as part of our policy, routine reviews of our **patent** applications are undertaken on a regular basis."

An unnamed source said GSK's move is the result of Swiss pharmaceutical company Novartis's failed challenge to a section of the country's **Patents** Act that aims to restrict certain kinds of **patents** (Singh, Economic Times, 12/7).

India's **patent** law, which went into effect in January 2005, allows **patents** for products that are new inventions developed after 1995, when India joined the World Trade Organization, or for an updated drug that exhibits improved efficacy (Kaiser Daily HIV/AIDS Report, 8/6). According to the Times, the company thought it necessary to withdraw the applications rather than be rejected because a rejection could weaken the company's chances of securing **patents** in other developing countries. Medecins Sans Frontieres and I-MAK had challenged the **patent** applications on behalf of the Indian Network of Positive People (Economic Times, 12/7).

Link to this story.

Science & Medicine

First-Line Triple-Combination Antiretroviral Therapy Provides Long-Term Protection Against AIDS-Related Illnesses, Study Says

[Dec 10, 2007]

First-line triple-combination antiretroviral therapy provides long-term protection against AIDS-related illnesses, according to a study published Friday in the Lancet, AFP/Google.com reports. The three first-line classes of antiretrovirals are nucleoside reverse transcriptase inhibitors, non-nucleoside reverse transcriptase inhibitors and protease inhibitors.

For the study, Andrew Phillips of the Royal Free and University College Medical School and colleagues followed 7,916 HIV-positive people living in the United Kingdom who began standard triple-combination therapy. The researchers found that 167 of the participants developed extensive resistance to all three types of drugs and that the resistance was higher among those who began treatment when their CD4+ T cell counts were lower than 200 (AFP/Google.com, 12/7).

The cumulative risk of extensive triple-combination resistance at the end of 10 years was 9.2%, but the risk decreased over time, the study found. The risk of death after five years of developing drug resistance is about 10.6%, according to the study (Phillips et al., Lancet, 12/7). Of the participants who developed drug resistance, 90% were resistant to seven first-line antiretrovirals. Fifty-eight percent of those who were resistant to first-line drugs also were resistant to second-line drugs, the study found (AFP/Google.com, 12/7).

The researchers noted that the study's findings will have implications in developing countries, where "additional drugs outside these classes are unlikely to be available for some time" (Lancet, 12/7). According to the World Health Organization, more than two million people worldwide were receiving standard triple-combination therapy at the end of 2006 -- a 54% increase compared with 2005.

Related Commentary

The finding that 58% of those who developed resistance to first-line drugs also developed resistance to second-line drugs "has implications for the treatment of patients in developing countries," Edward Mills -- of the British Columbia Centre for Excellence in HIV/AIDS -- and Jean Nachega -- of Johns Hopkins University -- write in a commentary that accompanies the study. Mills and Nachega add that in developing countries, "only one or two regimens are normally available, which results in disastrous consequences when these regimes fail."

Mills and Nachega noted that the study participants typically began treatment earlier, when their immune systems had a greater capacity to fight HIV, compared with people living in developing countries (AFP/Google.com, 12/7).

An abstract of the study is available online.

Link to this story.

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[Return to List](#cite_id_186)

186 of 200 DOCUMENTS

Pharma Marketletter

**November** 8, 2007 Thursday

**Astellas/Boeh Ing settle with Ranbaxy over Flomax**

**LENGTH:** 254 words

Japanese-owned Astellas and Germany independent drug major Boehringer Ingelheim have reached an agreement with **Ranbaxy** Laboratories to stipulate a remand of the pending Federal Circuit appeal and subsequent vacatur of the District Court decision in regards to Flomax (tamsulosin) capsules. The case between Indian-headquartered **Ranbaxy** and Astellas/BI has been dismissed without prejudice. The law suit in the USA was related to Astellas' US **patent** 4,703,063, covering tamsulosin and its use in the treatment for functional symptoms of benign prostatic hyperplasia.

Under the accord, **Ranbaxy** will enter the US market on March 2, 2010, eight weeks prior to expiration of the pediatric exclusivity, which is likely to be granted to the innovator company. During this period of pediatric exclusivity, **Ranbaxy** will be the only generic manufacturer to commercialize this product in the US market. **Ranbaxy** believes that its tamsulosin Abbreviated New Drug Application is the first substantially complete one with a Paragraph IV certification to the '063 **patent**. The total annual US sales of Flomax are estimated to be $1.2 billion, according to IMS Health figures.

On June 20, **Ranbaxy** received tentative approval from the Food and Drug Administration for its tamsulosin ANDA. The company says it will continue to pursue a strategy to effectively optimize its pipeline of first-to file and believes that it has a FTF status on around 17 Paragraph IV ANDA filings representing a market size of $26.0 billion valued at innovator prices.

**LOAD-DATE:** November 8, 2007

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**PUBLICATION-TYPE:** Newsletter

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[Return to List](#cite_id_187)

187 of 200 DOCUMENTS

Daily Mail (London)

**November** 2, 2007 Friday

**30 SECOND GUIDE TO ... GENERIC COMPETITION**

**SECTION:** 1ST; Pg. 99

**LENGTH:** 196 words

What is it?

THERE are manufacturers who specialise in challenging **patents** on some the world's biggest prescription medicines. If you are big pharma firm that has spent hundreds of millions of pounds developing your latest blockbuster, the last thing you need is for the product to succumb to cut-price, copycat competition.

But isn't competition good?

Yes. But the big drug companies argue - with some merit - that they need **patent** protection to claw back the huge upfront research and development costs. What irks AstraZeneca and GlaxoSmithkline, is that generic manufacturers never make any of the heavy investment needed to create breakthrough medicines.

Why does it happen?

A successful **patent** challenge can hit paydirt, particularly when the generic drug manufacturer is granted a 180-day period exclusivity, which sometimes happens in the US. That allows firms such as Teva, **Ranbaxy** and Dr Reddy's to undercut the branded competition and capture most of the market for that drug..

Why do we care?

AstraZeneca's cholesterol-buster Crestor has come under generic attack. But the Anglo- Swedish giant is not alone as 17 of the world's top 20 drugs are under siege from the lawyers..

**LOAD-DATE:** November 3, 2007

**LANGUAGE:** ENGLISH

**PUBLICATION-TYPE:** Papers

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[Return to List](#cite_id_188)

188 of 200 DOCUMENTS

Pharma Marketletter

**October** 30, 2007 Tuesday

**Pfizer to appeal Geman Lipitor patent decision**

**LENGTH:** 188 words

Global pharmaceutical giant Pfizer has revealed that the Federal **Patent** Court in Munich, Germany, has revoked the company's **patent** covering atorvastatin calcium, the active ingredient in its blockbuster choleserol-lowerer Lipitor. The **patent** at issue in the law suit (EP 409,281) expires in July 2010.

The decision - which resulted from a **patent** challenge by generic manufacturers **Ranbaxy** Laboratories of India and Basics GmbH of Germany has no immediate commercial impact because neither company has regulatory approval to sell a generic atorvastatin product in Germany, and because Pfizer's basic **patent** covering atorvastatin remains in force, and expires after the enantiomer **patent**. That **patent** expires in November, 2011. Lipitor is sold in Germany under the brand name Sortis.

Pfizer said it will appeal the decision, a process expected to take two to three years. The ruling will have no effect on a pending challenge to the basic atorvastatin **patent** in Germany by the same two companies. Pfizer also noted that the decision will have no impact on **patent** litigation involving Lipitor in other jurisdictions around the world.

**LOAD-DATE:** October 31, 2007

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[Return to List](#cite_id_189)

189 of 200 DOCUMENTS

The Sunday Times (London)

**October** 7, 2007

**Spot the difference**

**BYLINE:** Mark Tighe

**SECTION:** HOME NEWS; Eire News; Pg. 11

**LENGTH:** 1636 words

Karen Millen's High Court case against Dunne's for copying will set a precedent in the EU and may change fashion for ever. By Mark Tighe

In May 2005, a design team from the Karen Millen fashion store visited Hong Kong.

The deadline for new winter designs was approaching and Danielle Benardout, a designer, had been given a sample book of striped fabrics from the Cangioli mill in Italy to work with.

She had been asked to create a shirt that would appeal as workwear to Karen Millen's "youngish" fashion-conscious clientele. Working in her hotel room, Benardout selected three fabrics for her design.

Using her initial drawing, her colleagues worked with the Italian mill to give the fabrics a different colour scheme in order to increase definition of the stripes.

Benardout's design was finally accepted and sent to Lithuania for manufacture. In December 2005 it went on sale in the chain's shops in Ireland and Britain at a cost of E130.

Now that shirt is set to create legal and fashion history.

Last week Michael McDowell, a barrister employed by Karen Millen, entered into evidence in the High Court a Brown Thomas store receipt for the shirt dated March 23, 2006. This was proof it was bought by a member of Dunnes Stores' staff, who sent it to a factory in Turkey where the design was examined and a replica created. In November 2006, Dunnes' copy went on sale as part of the Irish supermarket's Savida range.

This chain of events was revealed by documents Dunnes submitted to the court.

E-mails between supermarket staff and DH International, a clothing manufacturer with factories in Turkey and China, refer to "sampling up" the fabric of the Karen Millen shirt before producing the copy.

Dunnes does not dispute that the company copied the shirt, but is attempting to convince a judge that the Karen Millen designs are too common and too unoriginal to be entitled to the protection of European Union law.

A lot hangs on the outcome. For the first time, a 2001 European directive covering the protection of unregistered designs is being tested by the fashion industry.

Like a new catwalk design in Milan, the result in a Dublin courtroom will be examined and followed by fashionistas around Europe.

DUNNES seems to be revelling in the publicity. Why not, when a copy of a knitted cami-shrug top that costs E130 at Karen Millen for sale in Dunnes at E35 is getting such widespread media attention? Since the trial began last Tuesday, the chain has been taking out half-page colour ads in newspapers for its Savida range, available "exclusively at Dunnes Stores".

In court last week, Dunnes was represented by Richard Nesbitt, a senior counsel and the chairman of Arnotts. Ironically, his arguments could be said to be at odds with his preferences as a high-street retailer. His client's case was to belittle high-street fashion as being unworthy of protection because it is insufficiently different.

The European law on unregistered design affords protection only to new items that create a different "overall impression" on the "informed user". The interpretation of those two terms was at the centre of the four-day trial.

According to David Brophy, a **patent** attorney with FR Kelly, a Dublin legal firm, the case will set a precedent whatever the result. EU law on unregistered designs in the fashion industry has yet to be tested.

Karen Millen's decision to bring the case in Ireland is significant. "The new commercial court allows you to get in and out within six to nine months," said Brophy. "The likes of Karen Millen see it as a good place to come because they could get a judgment here quickly that could then set a precedent for other jurisdictions."

The speed of the case has been impressive. The striped Savida shirt went on sale in November 2006 and Mosaic issued proceedings in the High Court last January.

Usually it would have to wait a couple of years for its day in court.

McDowell, the former justice minister, showed some rustiness upon his return to the Four Courts. In his opening statement last Tuesday he mentioned that a French case involving shoe designs was an example of previous application of the EU directive. Judge Finlay Geoghegan pointed out that this seemed to be an application of French, not EU, law.

Strewn around the witness box were the six items of clothing in dispute: Karen Millen's striped shirt in blue, its counterpart in brown and its knitted top; alongside were each of the Dunnes "copies".

Karen Millen's witnesses said the company's designs were original and not based on existing clothes. McDowell asked Clare Hallam, designer of the cami-shrug top, to point out distinctive design features on the little black number.

While none of the features was original, she said, she'd never seen them all together on one top before, so the "overall impression" it made was different from that made by every other top.

Nesbitt challenged Hallam's contention that the design was not influenced directly by any other item. "I'm fascinated... you just sit down and magiced it out of nowhere?" he said incredulously to the designer.

Interestingly, no Dunnes employees were called to explain where the inspiration for its "copycat" designs originated. Instead, the three witnesses produced by the supermarket chain were "informed users", according to Nesbitt. He said the evidence of the Karen Millen designers was "poisoned" by their training, which made them "concerned about things other people wouldn't notice". He told the judge: "If you rely solely on designer evidence, you are reaching into a poisoned pool."

Dunnes first and most colourful witness was Susan Maher, who runs a fashion website. She said she had found items similar to the Karen Millen top on eBay, but did not bring print-outs to court. She then introduced into evidence a series of "original" designer clothes from her wardrobe. These, she said, would create an "overall impression" on her as something new.

"You would expect the defences in these cases to say 'we didn't copy it' if they can," said Brophy. "But if the only defence available is to say 'this isn't an original design' then you have to show examples of the same design that are common in the trade."

So Dunnes showed the court a series of fashion photos of tops and shirts it said were similar to the Karen Millen items in the case.

The final Dunnes witness was Janine Corletta, a freelance wardrobe consultant based in New York. She was tested as to what range her definition of "overall impression" covered. Asked if a Karen Millen shirt in blue was different to the brown version, she said the "overall impression" was the same. "A child of three could tell the difference," replied McDowell.

The case will close on Tuesday when McDowell and Nesbitt make final submissions.

Given the likely impact of the decision and the fact that Geoghegan has said the case involves "very complex legal issues", a judgment may not be delivered for some weeks.

YOU wait years for an interesting intellectual property case, then they all come together. There was a second legal battle in the High Court last week over rival packages of fig rolls. Jacob's secured an injunction preventing McVitie's, a British chain, from selling its version of fig rolls in similar packages.

"The last time we had a big **patent** case in Ireland was more than 25 years ago," said Brophy. "But within six months we had a pharmaceutical **patent** case decided in the commercial courts for the first time. Such cases are complicated, technical and not very common."

The pharmaceutical case, heard by Justice Frank Clarke, resulted in Pfizer's **patent** of Lipitor, a cholesterol drug, being protected against **Ranbaxy,** a multinational manufacturer of generic drugs.

"There is a **patent** court in the UK in which judges have technical degrees," one legal source said. "Here we have regular High Court judges in the commercial court, but they seem to have a good grasp of intellectual property. So we will see a lot more cases like Dunnes, in which people say others have copied them or infringed their trademarks."

The cost to the losers will be huge. If Mosaic loses its case it will give copiers carte blanche. If it wins, Dunnes may have to change the way it operates. But it might be better for it to find out now where the law lies, before facing any further legal challenges. After all, a stitch in time saves nine.

Better value?

WHILE Dunnes Stores and Mosaic presented their cases to a female judge, many women in Dublin had made up their minds, writes Sarah O'Sullivan.

Linda Nelson, 43, a housewife from Crumlin, recently bought a top for E100 and was appalled to see a similar item in another shop for E18. "It put me off buying expensive clothes," she said.

Una Leavy, 46, a midwife from Rathmines, said: "Everyone knows it happens. As a mother of six, I wouldn't opt for the more expensive item; but my daughter might."

June Demery, from Blackrock, said: "It's always been the way. You can't stop people from copying," she said. "I'd buy the cheaper version myself."

Margaret Flynn, a financial consultant from Laytown, takes a contrary view. She thinks the extra expense of a genuine label is worth it. "I'm familiar with the fit in Karen Millen, so I would always shop there. I don't shop in Dunnes."

Winners and losers

Earlier this year, Levi's filed a lawsuit against Polo Ralph Lauren and other jeans makers whom, it says, had copied pocket stitching. The case continues.

This year Topshop was forced to destroy more than 1,000 yellow dungarees that were too close to a Chloe design. The Chloe version cost E267; the Topshop dungarees E50.

Last year, Marks & Spencer destroyed thousands of E13.50 satin handbags as part of an out-of-court settlement with Jimmy Choo, which said M&S copied its E715 bags.

In 2004, Primark paid E33,229 to settle claims that it had copied a Monsoon top and butterfly dress.

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[Return to List](#cite_id_190)

190 of 200 DOCUMENTS



ICIS Chemical Business

**October** 1, 2007

**Toward a new model ofbulk sourcing?**

**BYLINE:** Enrico Polastro

**SECTION:** FEATURES

**LENGTH:** 2350 words

Building molecules is a cornerstone of the modern pharmaceutical industry, which obtains more than 70% of all active ingredients by organic synthesis. But is it necessarily a core activity? Answers that might have seemed obvious 10 years ago are no longer clear, neither for innovators, nor for companies in the generics market.

Traditionally, innovative pharmaceutical companies engaged in the development of new chemical entities have backward-?integrated their molecule-building ?activities from discovery research up to full-scale bulk production.

It is not uncommon for businesses of this model to have extensive in-house, full-scale synthesis platforms consisting of several plants, manned by several thousand ?workers, with a combined replacement value of more than $1bn (?707m). The rationale behind having such an extensive synthesis base was dictated by considerations such as security of supply, quality, costs and reputation.

With a few notable exceptions, such as Teva, on the other hand, the vast majority of generic marketers have carefully refrained from investing in their own synthesis capacity. Instead, they have relied extensively on third-party vendors for their bulk requirements, the advantage being the flexibility to redirect their product range in response to the rapidly evolving competitive dynamics of the generic space.

From this perspective, backward integration in chemical synthesis has been considered undesirable, yielding only waste and inflexibility.

At least on the face of it, the opposite approaches to bulk sourcing applied by innovators and large pharmaceutical companies and their counterparts in the generics sector can be attributed to the different dynamics characteristic of their respective market spaces (see table, right).

Whereas innovators need to secure access to a handful of active pharmaceutical ingredients (APIs) whose number rarely exceeds multiples of 10, generic marketers have much broader product ranges, often involving more than 100 different APIs.

Similarly, while originators can often count on useful product life cycles of more than 10 years, the planning horizon for generic players is considerably shorter - gross margins as a percentage of sales also being substantially lower.

Furthermore, while new chemical entities (NCEs), being **patent** protected, can be produced legitimately only by the originator or on its exclusive behalf, off-**patent** APIs are most often widely available from several sources, so that the possibility of capturing tax benefits through in-house production are limited.

However, a peculiar transformation is in progress. Innovators and generics marketers are adjusting their bulk-sourcing approaches, but in opposite ways. The implication is that a convergence may not be far off.

Over the past few years, pressures have emerged, particularly from the financial community, pushing large pharmaceutical companies to de-emphasize their full-scale synthesis activities. The thesis is that full-scale synthesis hardly qualifies as a core activity for pharmaceutical innovators.

NEW APPROACHES?

In contrast to research and development (R&D) and marketing and sales, these activities add little, if any, competitive advantage, while detrimentally affecting overall returns on investments.

In sharp contrast, the same financial analysts have been identifying backward integration into bulk as a key success factor for generic marketers.

The questions necessarily arise: should innovators/large pharma phase out their backward integration in molecule building, and should generic marketers follow an opposite approach? A close analysis suggests that the answers to these questions need to be nuanced, and that a more balanced approach must be considered. Most probably, an equilibrium situation will eventually emerge.

Recent developments in terms of approaches to bulk sourcing observed both among innovators and generic marketers are worth noting.

For innovators, the imperative is clearly to reassess their traditional backward integration in full-scale bulk synthesis. This is reflected by the drive among them to divest a number of synthesis units - witness the examples of Merck & Co. or Pfizer, while companies such as Solvay Pharma appear to be moving toward a "virtual" bulk access model. In such a set-up, most - if not all -their bulk production network is either closed or divested, chemical requirements being instead sourced on the merchant market from third-party vendors.

By contrast, a number of generic ?marketers are scrambling to secure access to their own in-house API synthesis ?capacity - almost without exception through acquisitions. Examples include Mylan taking over Matrix or Watson acquiring Seiksharia. Barr, through the acquisition of Pliva, has also secured access to bulk capacity.

But why this change in approaches?

Innovative pharma majors are increasingly of the view that backward integration does not necessarily provide decisive competitive advantages with regard to such considerations as security of supply, quality, cost and reputation. These are also achievable through suitable alternative constructs for the supply chain, including outsourcing from third-party vendors.

The high-profile failures of expected blockbusters have provided additional impetus for a reassessment of the level of backward integration. Pfizer's torcetrapib represents a salient example of such a setback. Bristol-Myers Squibb suffered a similar fate a few years ago with omapatrilat. AstraZeneca and Roche have both been confronted with substantially lower demand than expected for products such as rosuvastatin or orlistat.

Innovators often invest several hundred million dollars in preparing to manufacture such blockbusters, but failure leaves new capacity useless, and there is little chance that an alternative will be found to load it.

Also worth noting are changes in senior leadership at the top of several pharma majors, including AstraZeneca, Merck and Pfizer. Transitions such as these often provide impetus to take a fresh look at how operations are conducted - access to bulk being no exception - and the question whether bulk can be accessed more efficiently and effectively inevitably crops up.

Companies are frequently discovering that having in-house, full-scale synthesis capacity does not necessarily provide a competitive edge, and may even waste precious resources. For example, pharmaceutical companies tend to vastly outspend by a factor of two to four, compared with independent fine chemicals vendors, in terms of investment outlays per unit of capacity (see graph, left).

Further, the paradigm that producing in-house is cheaper than outsourcing is challenged by empirical evidence. In the graph on page 52, it can be seen that companies fully outsourcing their bulk requirements have an impact of bulk costs as a percentage of sales of 2-3% - way below the 6-8% of their backward-integrated counterparts.

Obviously, due care must be taken in comparing these two figures - the bulk costs for integrated pharmaceutical companies often including various overheads, as well as charges reflecting tax optimization strategies, where access to bulk is structured for optimal fiscal efficiency - not ?necessarily going hand in hand with the most cost-efficient set-up.

In this respect it is notable that capturing tax benefits does not always require an extensive in-house chemical production base - comparable opportunities can be obtained by suitably structuring contractual agreements with third-party providers. For example, Celgene has been able to reap the tax benefits associated with a production base in Switzerland by entering into a long-term agreement with a local fine chemicals vendor according to which it leases part of the plant - the vendor continuing to operate these assets on its behalf.

Similarly, albeit in a different field - dosage-form production - service providers such as Patheon are emphasizing the opportunity for their customers to capture tax benefits associated with their base in Puerto Rico by co-investing with them - the IRS code taking as criteria to grant such tax benefits elements such as investments, as well as the assumption on the behalf of the customer of some form of risk.

Similarly, tax benefits can be reaped through secondary manufacturing -namely formulation activities - rather than through molecule building - as exemplified by Forest Laboratories having part of its formulation network in Ireland.

THE GENERICS CASE

Parallel to these developments, ?generics marketers are pursuing a completely ?different approach to bulk sourcing, actively securing access to their own ?synthesis capacity.

Such moves are driven by the idea that in the generics space, access to bulk will increasingly emerge as a differentiator in terms of both cost competitiveness and ability to outpace competitors, for ?example, in opening the path to juicy Paragraph 4 exclusivity situations. These views are supported by the success of Indian companies such as Aurobindo, Dr. Reddy or **Ranbaxy** on the international generic scene. There is also Teva, the industry leader, which, having pioneered a model of extensive backward integration, has emerged as one of the largest producers of off-**patent** APIs.

A number of generic marketers have scrambled to secure access to own bulk production capacity, mainly through ?acquisitions. Examples include Mylan, Watson and Barr, with Sandoz also periodically rumored to be considering the ?purchase of a major bulk API producer.

This interest of generic marketers in possessing their own bulk production capacity reflects a paradigm shift. Until recently, most considered owning synthesis capacity anathema. But the view has gained traction that possessing a bulk source is more cost-effective than relying on third-party vendors who need to make a profit on sales. There is also the belief that in-house manufacture increases the chance of securing exclusive positions.

However, this growing emphasis on in-house bulk sourcing among generic marketers can be challenged on the same basis as the backward integration model traditionally pursued by innovators. There is no guarantee that it will effectively provide a competitive edge.

A vision calling for innovators/large pharma to entirely phase out their own full-scale synthesis capabilities and rely, instead, on outsourcing is most probably unrealistic - and so is the idea that generic marketers will engage massively in the synthesis of APIs.

As often in life, extreme approaches should be considered only with great care - access to bulk being no exception.

Rather, an equilibrium situation is likely to emerge, where both sets of players will eventually realize that a nuanced approach to bulk sourcing represents the best formula for success. This formula calls for skillfully combining in-house production with outsourcing from a handful of carefully hand-picked third-party vendors.

Such a setup calls for both innovators/large pharma and generics marketers to maintain or establish in-house, leading-edge chemical process development and pilot-scale synthesis capabilities, as well as suitable limited in-house multipurpose synthesis capacity. These in-house capabilities are to be complemented through a network of relations with carefully selected third-party suppliers.

A MODEL DEVELOPMENT

Such a model will allow both innovators/large pharma and generics marketers to combine the best of the two worlds. They will be able to maintain leading-edge capabilities in process development - a key to securing a grip on robust industrial processes while nurturing the skills required to structure a suitable bulk sourcing setup and the ability to effectively interact with third-party vendors. They will also be able to manage their exposure to possible setbacks in terms of new product developments - avoiding investment in dedicated full-scale synthesis assets that would become desperately inadequate should the product they were designed for fail or projected volumes not be met.

If properly structured and managed, this setup may effectively provide scope for a competitive edge, while allowing for active risk management.

It is worth noting that risk results from the combination of uncertainty - the probability of occurrence of a certain (adverse) event - multiplied by its potential impact on the company's financial performance (see the figure on page 54).

For example, to mitigate risks associated with investing in an in-house synthesis plant dedicated to a single NCE yet to reach the market, the winning approach will be for innovators instead to:

Allocate up-front more resources to process development

Consider from the outset how best to structure the bulk supply chain to provide for optimal flexibility, starting with ?intermediates readily available from ?multiple sources and applying chemistries that can be easily performed in multipurpose equipment

Invest in limited in-house multi?purpose, highly flexible synthesis capacity, being, however, careful not to overspend by ?multiplying the features included in the plant design

Depending on the chemistries, volumes and molecular structures involved - farm out all or part of the full-scale synthesis requirements to third-party suppliers based on technology developed in-house.

Although such steps add to up-front costs and investments, they can be expected to greatly contribute to competitive edge. In-house process development skills are the best guarantee to come with a robust and competitive technology, from the very first phases of the product launch. And limited in-house flexible synthesis capabilities ?provide an element of leverage with regard to third-party vendors. They also enable the in-house process development team to keep aware of the realities of full-scale synthesis!

?? Enrico Polastro is vice president and senior industry specialist at Arthur D. Little (Benelux). A consultant for almost 25 years, he is the author of over 100 publications and a regular speaker at industry events. Before joining ADL, he worked in R&D at Monsanto and Solvay in Europe and the US. Email Polastro.enrico@adlittle.com

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[Return to List](#cite_id_191)

191 of 200 DOCUMENTS

National Post's Financial Post & FP Investing (Canada)

**September** 13, 2007 Thursday

National Edition

**Pfizer wins protection in Canada for main ingredient in Lipitor drug**

**BYLINE:** Bloomberg News

**SECTION:** FINANCIAL POST; National Report; Pg. FP4

**LENGTH:** 212 words

Pfizer Inc., the world's biggest drugmaker, won protection in Canada for a main ingredient in its cholesterol-reducing drug Lipitor, prohibiting a rival drugmaker from making a generic form of the medicine. The Canadian Federal Court in Toronto ruled yesterday that **Ranbaxy** Laboratories Ltd.'s proposed generic drug would infringe Pfizer's **patent** covering a crystalline form of atorvastatin and said **Ranbaxy** can't introduce its drug until 2016, Pfizer said in a statement. The decision may help slow Pfizer's decline in Lipitor sales. Revenue from Lipitor, the world's best-selling drug, sank 13% from a year earlier to $2.7-billion in the second quarter as patients switched to cheaper, generic copies of Merck & Co.'s similarly acting Zocor. Pfizer said in July that Lipitor sales would hold this year at $12.9-billion or drop 5%. A copy of the ruling wasn't immediately available at the Federal Court's Web site. Pfizer's spokeswoman Vanessa Aristide said in an e-mail that the court hasn't yet published the final decision. The Federal Court denied Pfizer's request for a prohibition order in connection with a second **patent** covering a process for making atorvastatin, the active ingredient in Lipitor. **Ranbaxy** can appeal yesterday's ruling to the Federal Court of Appeal.

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**LANGUAGE:** ENGLISH

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[Return to List](#cite_id_192)

192 of 200 DOCUMENTS

Africa News

**August** 15, 2007 Wednesday

**Rwanda;**

**'No Importation of Expensive Aids Drugs'**

**BYLINE:** New Times

**LENGTH:** 374 words

Health Minister Dr Jean Damascene Ntawukuliryayo has said the government cannot import expensive generic HIV/Aids drugs which patients cannot afford. Ntawukuriryayo said this in response to reports that Antiretroviral (ARVs) drugs produced in Canada are allegedly more expensive compared to the ones from India. The importation of Aids drugs from Canada is still in the process, he said. "If we happen to learn that the drugs are expensive we will not import them, given the fact that they serve the same purpose like the ones we are getting from India." Asked why the government has a preference for Canada drugs over those of India, the minister said that it is an opportunity related to low-costs but not quality. "Canadians promised us that their drugs will be bought at a cheap price," Ntawukuliryayo said, but didn't delve into the details of costs per pill from both producers.

However, Prof. Amir Attaran at the University of Ottawa reportedly disclosed in a letter to the Toronto Star news agency that the cost of ARVs from India is about Frw72 per pill. "According to MÈdecins Sans FrontiËres, the same Aids drugs produced by Apotex of Canada are already being sold by **Ranbaxy** of India at about Frw72 a pill," Prof Attaran is quoted by the agency. Attaran, a professor of public health and law, noted that Apotex's president, Jack Kay had previously said that the drug would cost 39 Canadian cents a pill (approx Frw 202). The Canadian health expert anticipated that the higher price reflects the higher cost of producing drugs in Canada relative to India. "If Apotex makes this sale, doesn't it stand to reason that only one-third as many people with Aids will receive treatment for a given budget, and the other two-thirds will likely die?" asked Attaran. Last month, Rwanda became the first developing country to apply for 260,000 packages of generic Aids medication from Canada. This was in line with the 2003 World Trade Organisation (WTO) legislation to allow generic drug makers to produce and export Aids drugs to developing countries, almost regardless of the **patent** holders. Canada was the first country to adopt the legislation, and her generic drug producer Apotex was the first company to apply to use the legislation. Ends

**LOAD-DATE:** August 16, 2007

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**PUBLICATION-TYPE:** Newsletter

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[Return to List](#cite_id_193)

193 of 200 DOCUMENTS

Africa News

**August** 10, 2007 Friday

**Rwanda;**

**Canadian Aids Drugs Cost Three-Times Those From India**

**BYLINE:** Rwanda News Agency/Agence Rwandaise d'Information

**LENGTH:** 412 words

The Wednesday announcement by drug giant GlaxoKleineSmith that it will allow Canadian company - Apotex to produce anti-retrovirals for Rwanda will not save the country money, a Canadian expert has said.

"According to MÈdecins Sans FrontiËres, the same combination of AIDS medicines that Apotex proposes to sell Rwanda is already being sold by **Ranbaxy** of India at about 14 cents (Rwf 72) a pill," Prof. Amir Attaran writes in a letter to the Toronto Star.

The Canadian health expert was responding to the numerous articles lauding the development that Rwanda would be allowed to import generic drugs from his country. The Toronto Star - has also written about the subject.

According to Attaran, a professor of public health and Law at the University of Ottawa, Apotex's president - Jack Kay - has previously testified that the drug would cost of 39 Canadian cents a pill (Rwf 202) - more than triple the cost from the Indian producer.

Mr. Kay appeared before the Industry, Science and Technology Standing Committee of the Canadian Parliament early this year.

The higher price, says Prof. Attaran, reflects the higher cost of producing drugs in Canada relative to India.

"If Apotex makes this sale, doesn't it stand to reason that only one-third as many people with AIDS will receive treatment for a given budget, and the other two-thirds will likely die?", questions Attaran.

In 2003 the World Trade Organization passed legislation to allow generic drug makers to produce AIDS medicine for export to developing countries, almost regardless of the **patent** holders. Canada was the first country to adopt the legislation, with some amendments.

Canadian generic drug producer Apotex was the first company to apply to use the legislation, but excessive red tape has bogged the process to the extent that, to date, not one pill has been exported.

Last month, Rwanda also became the first developing country to apply for medication under the legislation, requesting 260,000 packages of a triple combination AIDS drug.

Boehringer Ingelheim agreed to allow Apotex to use its patented molecule, nevirapine in the AIDS drug.

On Wednesday, GlaxoSmithKline agreed to allow Apotex the use of its two patented molecules-zidovudine and lamiudine-to complete the production of the three-in-one AIDS drug Apo-triAvir for export to Rwanda.

But according to Attaran, "Canada is not the best country to meet Rwanda's medicine needs, and if Apotex made the sale, it would be to Rwanda's profound detriment."

**LOAD-DATE:** August 10, 2007

**LANGUAGE:** ENGLISH

**PUBLICATION-TYPE:** Newsletter

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[Return to List](#cite_id_194)

194 of 200 DOCUMENTS

The International Herald Tribune

**August** 10, 2007 Friday

**Generic pills could end U.S. arrival of diet drug;**

**MARKETPLACE by Bloomberg**

**BYLINE:** Jason Gale and Angela Cullen - Bloomberg News

**SECTION:** FINANCE; Pg. 14

**LENGTH:** 561 words

**DATELINE:** SINGAPORE

Acomplia, a popular weight-loss pill made by Sanofi-Aventis that has been linked to suicide, is becoming popular in generic form in India. That may end the product's chances of ever reaching the United States, where it has been delayed by regulators.

Cipla and **Ranbaxy** Laboratories are among six drug makers exploiting a loophole in Indian **patent** laws, selling copies of the medicine under names like Slimona and Defat. The pills are being sold without prescription for as little as 12 cents each.

Should the generics, used without supervision, lead to an increase in suicides, the U.S. Food and Drug Administration's opposition may stiffen. The company has few medicines to replace lost sales of Acomplia, analysts said. Sanofi had predicted that Acomplia would generate $3 billion a year.

''This is going to be potentially disastrous,'' said Jeffrey Mechanik, an endocrinologist at Mount Sinai Hospital in New York. ''People are going to be overdosing'' if generics flood the market and people take them inappropriately, he said.

Sanofi withdrew its U.S. marketing application for Acomplia on June 29 after the Food and Drug Administration raised safety concerns. In India, drug companies can use a process called reverse engineering to manufacture drugs patented before 1995. The **patent** on Acomplia, which regulates hunger impulses, dates from 1994. Sanofi has not heard from the Indian authorities on some of the company's **patent** applications filed after 2000, a spokesman, Jean-Marc Podvin, said.

Sanofi received approval to sell Acomplia in India in May, the same month as the generic-drug makers. The company has not decided whether to sell its branded version there.

''We're evaluating our options,'' Podvin said. ''Of course, it's a concern.''

The Indian regulator approved Rimonabant, or generic Acomplia, requiring patients have a prescription and medical advice on its risks. Those include depression and anxiety - side effects that were serious enough to prompt an panel of advisers to the Food and Drug Administration to oppose U.S. sales of the drug. A pharmacy in New Delhi's commercial center was selling the pills for the equivalent of 22 cents apiece. At a pharmacy in Mumbai, the tablet can be bought for 5 rupees, or 12 cents. Neither required a doctor's note and there was no printed information with the drug.

European regulators, who approved the medicine last year, tightened prescribing rules last month to say Acomplia should not be used by those taking antidepressants or who have depression. ''There is a risk that if you can just buy it over the counter and really want to lose weight for that wedding, you may end up committing suicide before you get married,'' said Stephen Bloom, a professor of metabolic medicine at Imperial College in London.

''The rest of the world will watch. It's very kind of the Indian nation to be testing drugs for us like this.''

Torrent Pharmaceuticals started selling its version, Rimoslim, two months ago and aims to sell 100 million rupees worth within 12 months. Rimoslim is ''an extremely affordable therapy for the masses,'' the company, based in Ahmedabad, said in May.

Asked via e-mail whether there were concerns about safety, Ruchir Modi, Torrent's vice president of marketing, said, ''We can only wait and see how this unfolds'' with the Food and Drug Administration.

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Angela Cullen reported from Frankfurt.

**LOAD-DATE:** August 10, 2007

**LANGUAGE:** ENGLISH

**PUBLICATION-TYPE:** Newspaper

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[Return to List](#cite_id_195)

195 of 200 DOCUMENTS

Pharma Marketletter

**July** 30, 2007 Monday

**Ranbaxy and GSK settle over Valtrex**

**LENGTH:** 149 words

Indian generic drugs major **Ranbaxy** Laboratories says that it has reached a deal with UK pharmaceutical giant GlaxoSmithKline resulting in the dismissal of their US litigation over the antiviral Valtrex (valacyclovir HCl). The dispute concerned GSK's US **patent** no 4,957,924 covering the drug, which is used for the treatment of herpes virus infection.

Under the agreement, **Ranbaxy** will enter the US market in late 2009 whereby, as the first generic company to file for approval, it will enjoy 180 days of sales exclusivity. **Ranbaxy** has also obtained a license to GSK's US **patent** nos 5,879,706 and 6,107,302, listed in the Orange Book for valacyclovir. The total annual sales of Valtrex were around $1.3 billion in the 12 months to December 2006, according to IMS Health data. In early February, **Ranbaxy** received a final Food and Drug Administration approval to market and manufacture valacyclovir.

**LOAD-DATE:** July 30, 2007

**LANGUAGE:** ENGLISH

**PUBLICATION-TYPE:** Newsletter

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[Return to List](#cite_id_196)

196 of 200 DOCUMENTS

Pharma Marketletter

**July** 26, 2007 Thursday

**Pfizer defends Spanish Lipitor patent in Ranbaxy challenge**

**LENGTH:** 130 words

World drug giant Pfizer says that a Spanish court has upheld its enantiomer **patent** covering the calcium salt of atorvastatin, the active ingredient in its mega-blockbuster cholesterol lowerer Lipitor. The Barcelona court found a second **patent** covering a stabilized formulation that includes atorvastatin is invalid. The **patents** were challenged by Indian generic giant **Ranbaxy,** which can appeal the decision. This case is the fourth in a series of challenges to the calcium salt **patent** by generic companies in Spain. The **patent** was upheld in one of three previous cases and found invalid in two others. All of the earlier decisions are currently on appeal. Pfizer noted that the calcium salt **patent** expires in July 2010 and the stabilized formulation **patent** expires in December 2013.

**LOAD-DATE:** July 26, 2007

**LANGUAGE:** ENGLISH

**PUBLICATION-TYPE:** Newsletter

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[Return to List](#cite_id_197)

197 of 200 DOCUMENTS

Australian Financial Review

**July** 25, 2007 Wednesday

First Edition

**Products improve investors' health**

**BYLINE:** Fiona Tyndall

**SECTION:** PORTFOLIO; Pg. 27

**LENGTH:** 1402 words

An ageing population promises increased profits for the health sector overall, but product producers are likely to outperform service providers, writes Fiona Tyndall.

Eyesight failing (when did they make newsprint so small)? Memory going (where did you leave your glasses)?

It's called getting old, and you're not the only one. By 2024 there will be around 2 million more people aged over 65.

It will be a significant bulge in an age group that suffers more ailments than younger people, and as the age bracket swells it is expected there will be more demand for health products and services - pathology testing, devices such as heart valves, and new and improved treatments - and more money flowing into the health-care sector.

But which health-care companies will prove the best investments?

Analysts say (in theory) every sector - from hospitals, with their reliable income stream, to more speculative biotechnology companies - could benefit from the population's ageing.

"Whether it be Healthscope, with its hospitals and now with [takeover target] Symbion's pathology assets, or Sigma, with pharmacy distribution, they are all exposed to it," Austock analyst Warren Jeffries says.

Within the broader theme, each company must be considered on its own merits, but there are a few rules of thumb.

Tolhurst health-care analyst Colin Mackie favours companies that produce a product, such as a hearing aid, rather than provide a service, such as pathology.

Mackie says blood products group CSL, sleep treatment organisation ResMed and hearing implant business Cochlear, which all have international sales operations, are worth a look.

"Global markets provide expansion opportunities for those products," he says. [Product producers] "offer a faster global market penetration than service providers."

Pathology specialist Sonic Healthcare provides diagnostic services, and while it has announced two acquisitions in recent weeks, its business has generally grown at a slightly slower rate than most analysts had hoped.

Sonic's major growth avenue has been by acquisition, making its penetration into offshore markets slower than companies that produce products, as it takes time to find the right acquisition target and negotiate the right price. And because service providers, such as pathologists, take time to grow their businesses, there is a premium attached to acquisitions.

"The rate of penetration is not going to be quick for service providers," Mackie says.

"If you have a commercial product, like CSL's blood fractionator, once you have FDA [US Food and Drug Administration] approval, global markets pretty much open up for you straight away."

Some analysts also argue that investors will be exposed to the least risk by investing in companies with products in proximity to critical care.

Blood products, for instance, are vital to critical care. Governments are unlikely to cut funding support, or increase regulatory levies, for a product that is essential for saving lives.

In comparison, health insurers and consumers might question paying for more discretionary items, such as sleep-disordered breathing devices.

"There is clearly going to be significant dollars available if you are closer to the critical care end of the spectrum, as opposed to something that is discretionary," Mackie says.

Hospital operators fit into the same space.

Private hospital owners Healthscope and Ramsay Health Care have consistently grown earnings in recent years. Pricing in the sector is stable and underpinned by the private health insurance sector, membership of which is slowly growing.

"The operators are now looking to extract synergies," Austock's Jeffries says. "It will come from the better operators being able to take costs out of existing infrastructure.

"We like both Healthscope and Ramsay."

But the critical-care continuum doesn't always reflect investment worthiness.

Highly discretionary items, such as vitamins, have proved strong lines for pharmaceutical manufacturers and wholesalers. And because of their discretionary (rather than essential) nature, governments have not tried to impose price caps or place limits on profit margins that companies can make from consumer items.

"It is like a retail product - it is discretionary," Jeffries says.

"The consumer health-care sector is gaining traction from the self-medicating trend that's out there. "People are becoming more conscious of taking vitamins, and you're not going to have [government] regulations claw some of it back."

Vitamins and minerals group Blackmores Laboratories, as well as wholesalers Symbion and Sigma Pharmaceuticals, are exposed to the complementary medicines market.

It is an industry growing faster than the economy and is underpinned by the ongoing acceptance of complementary health care, especially in the older population.

But the consumer businesses of wholesalers like Symbion and Sigma need to be balanced with their significant prescription pharmacy businesses.

While the ageing population means more prescriptions will be filled than ever in coming years, the pharmaceutical sector has been highly regulated by the federal government as it has sought to make prescription drugs available to all Australians, regardless of income and geography.

The government insists that wholesalers be able to deliver all drugs listed on the pharmaceutical benefits scheme to any pharmacy in the country within a limited time period and, while it compensates wholesalers for the cost, it is a limited reimbursement that wholesalers say doesn't match the cost of the program.

That was one reason Sigma put forward for downgrading its calendar 2007 earnings guidance by up to 10 per cent earlier this month. It also blamed competition in the prices of generic medicines (less expensive but identical versions of branded drugs whose **patent** has expired).

The entry, into the Australian market, of foreign manufacturers such as Indian group **Ranbaxy,** which manufactures and sells generic drugs cheaply, is expected to cut margins for local wholesalers.

"Generics volumes are only growing at 15 per cent and that is not fast enough to offset the price cut," Mackie says.

There is also concern among investors that the pharmacy sector isn't effectively managed.

In addition to Sigma's shock profit downgrade, wholesaler Australian Pharmaceutical Industries made a loss of $11.3 million for the year to April 30 against a profit of $20.6 million a year earlier.

It also said one-off items had sliced a further $6.2 million from earnings, after late last year revealing a $17.2 million black hole in its accounts, the departure of its chief executive, two profit downgrades and the announcement that it would be hit by one-off losses of $24 million.

The wholesaler is now considered a takeover target, although no firm offers have emerged.

Also at the speculative end of investment in health care is biotechnology companies.

There are a number of Australian biotechs in phase-three clinical trials, the last testing phase before commercialisation can begin.

Clinuvel Pharmaceuticals is conducting trials for a drug that provides protection for human skin against ultraviolet light and sunlight and Progen Industries has just commenced the third testing phase for its liver cancer drug.

Mackie also mentions orthopaedic-implant manufacturer Portland Orthopaedics and cancer-detection equipment company Polartechnics as companies likely to leverage returns from the ageing population.

Many biotechs are trying to deliver new and improved drugs to the over-60s to help keep people young, or make ageing more comfortable.

Others are delving into the nation's significant problems, researching treatments for obesity, cardiology and cancer.

However, investors in biotechs must remember that it is more prone to volatility because it's a risky sector.

In March, shares in one biotech, Metabolic, slumped more than 80 per cent after announcing the failure of phase-IIb clinical trials for its anti-obesity drug.

Analysts say investors should do extensive research on life sciences companies before investing and be aware that many are loss-making research and development groups.

"There [are] some really good stories out there that could well grow very strongly over the next 12 months," Mackie says.

"My concern at the moment is while there is very smart technology in Australia and some of it is very advanced, investors must realise these are long-term investments that require patience."

**LOAD-DATE:** April 6, 2012

**LANGUAGE:** ENGLISH

**GRAPHIC:** ILLUSTRATION: Illustration: KARL HILZINGER GRAPH: MIXED HEALTH Comparative share price performance S&P/ASX 200, CSL, Helathscope

**PUBLICATION-TYPE:** Newspaper

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[Return to List](#cite_id_198)

198 of 200 DOCUMENTS

Daily Mail (London)

**July** 11, 2007 Wednesday

**Pfizer Lipitor victory**

**SECTION:** IRE; Pg. 47

**LENGTH:** 59 words

PFIZER yesterday won a **patent** case involving its Lipitor product, the largest selling drug in the world.

The High Court in Dublin ruled that the basic **patent** covering atorvastatin, the active ingredient in Lipitor, would be infringed by a rival product from Indian generics manufacturer **Ranbaxy.**

Lipitor helps reduce cholesterol in the blood stream of users.

**LOAD-DATE:** July 12, 2007

**LANGUAGE:** ENGLISH

**PUBLICATION-TYPE:** Papers

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[Return to List](#cite_id_199)

199 of 200 DOCUMENTS

The Daily Yomiuri(Tokyo)

**July** 11, 2007 Wednesday

**The brave new world of generic drugs**

**BYLINE:** Tomoki Matsubara and Yasushi Kouchi, Yomiuri Shimbun Staff Writers, Yomiuri

**SECTION:** Pg. 4

**LENGTH:** 929 words

The government, aiming to lessen the budgetary burdens of health care, plans to double the use of generic medicines--drugs that are no longer protected by **patents**--by the end of fiscal 2012.

Encouraging wider use of generics has repercussions for the pharmaceutical industry. The plan, if realized, would reduce the market for newly developed medicines to the tune of nearly 1 trillion yen a year.

Substituting generic drugs also could trigger a far-reaching realignment of pharmaceutical manufacturers.

Apparently reflecting the increasing popularity of generics with physicians and patients, TV commercials touting the products of such generic medicine manufacturers as Sawai Pharmaceutical Co. and Towa Pharmaceutical Co. have been on the rise recently.

In a bid to reverse the perception that their products are inferior to those of name brand pharmaceuticals, the generic drug makers have featured celebrities in the commercials: actor Hideki Takahashi representing Sawai Pharmaceutical and emcee-interviewer Tetsuko Kuroyanagi appearing for Towa Pharmaceutical.

A generic drug is of the same quality as the original medicine whose exclusive **patent** has expired. The active ingredients in generics are essentially the same as in the original drugs and are interchangeable.

Prices can be reduced by half

Developing a new medicine can cost the manufacturer several hundred billion yen and take more than 10 years.

When **patents** expire, allowing the medicine to be copied by other companies, the cost of bringing the generic substitute to market can run into the several tens of millions of yen.

Generic medicine prices immediately after the expiration of the **patents** of their originals are about 30 percent lower than newly developed equivalents.

Generics can often become even cheaper because government-set prices under health insurance plans are often revised downward.

For example, Daiichi Sankyo Co.'s Mevalotin, whose **patent** expired in October 2002, costs 137.8 yen per daily dose of two five-milligram tablets as prescribed by doctors. Generic versions of the drug, which is used to treat excessive levels of lipids in the blood, cost anywhere from 42.8 yen to 94.4 yen for the same dosage.

Currently, about 16.8 percent of all medicines prescribed by medical institutions are generics. The government's Basic Policies for Economic and Fiscal Reform 2007, made public in June, incorporated the goal of expanding this figure to 30 percent or more by the end of fiscal 2012.

The plans call for substituting about 50 percent of newly developed medicines with their generic equivalents in terms of volume. The move is expected to substantially reduce health insurance-covered drug costs.

Market may double

According to estimates by industry sources, in fiscal 2004, generic medicines accounted for about a 5 percent nationwide share, or 300 billion yen to 400 billion yen of an approximately 6.9 trillion yen market.

If the government goal is realized, the market for generic medicines, as gauged based on prices listed under government-run health insurance plans, will double, according to Kaname Mizuno, a senior analyst of Daiwa Institute of Research, a private think tank.

This means the market for newly developed medicines will shrink by at least 700 billion yen to 800 billion yen a year, he said.

One executive of a midsized pharmaceutical company said he felt alarmed at the prospects.

"We're confronted with a bitter choice of three alternatives: redoubling efforts to develop new medicines, specializing in generic products or exiting the pharmaceutical market," he said.

In the pharmaceutical industry, disparities in business results have continued to widen among the Big Four--Takeda Pharmaceutical Co., Daiichi Sankyo, Astellas Pharma Inc. and Eisai Co.--and the rest.

Daiwa's Mizuno added, "Expanding the generic medicine market could accelerate realignment of pharmaceutical companies that have no potent outlets overseas or no strong research and development capabilities to produce new, promising medicines."

Genetic medicine manufacturers, by contrast, have drawn rosy pictures for the future.

Sawai Pharmaceutical has set a goal of raising revenues, which were 34.3 billion yen in the business year that ended March 31, 2007, to as high as 100 billion yen in coming years.

Towa Pharmaceutical also is bullish, and is busy preparing to boost production by increasing capital spending for fiscal 2007 to 2.5 billion yen, double the previous year's level.

M&As loom for Japanese firms

Generic product manufacturers with good business prospects may find themselves the targets of corporate merger and acquisition attempts.

In fact, India's Zydus health care business group took over one of Japan's generic product manufacturers, Nippon Universal Pharmaceutical Co., in April.

Given that major generic medicine manufacturers overseas, including Teva Pharmaceutical Industries of Israel, the world's largest in the field, have grown spectacularly on the strength of mergers and acquisitions, they may soon launch takeover bids against Japan's generic drug makers.

Among Japanese pharmaceutical companies with a primary focus on developing and marketing new medicines, Tanabe-Mitsubishi Pharmaceutical Co.--the entity to be launched in October through the merger of Tanabe Seiyaku Co. and Mitsubishi Pharma Corp.--will establish its generic subsidiary in fiscal 2008.

Another major pharmaceutical firm, Nippon Chemiphar Co., which has affiliated with Indian drug giant **Ranbaxy** Laboratories, plans to have generic medicines account for 70 percent of revenues, up from the present 30 percent.

**LOAD-DATE:** July 10, 2007

**LANGUAGE:** ENGLISH

**PUBLICATION-TYPE:** Newspaper

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[Return to List](#cite_id_200)

200 of 200 DOCUMENTS

The Irish Times

**July** 11, 2007 Wednesday

**In short**

**SECTION:** FINANCE; Other Stories; Pg. 16

**LENGTH:** 521 words

Today's other stories in brief

Jury in Black fraud trial deadlocked

The US jury in the criminal fraud trial against former media mogul Conrad Black and three co-defendants told the judge last night that it is deadlocked in trying to reach a unanimous decision.

Judge Amy St Eve of the US district court asked defence lawyers and prosecutors to meet to decide how they want her to reply to the jury of 12 men and women who were handed the case on June 27th after nearly 15 weeks of testimony. (Reuters)

Dublin airport numbers up 11%

Passenger numbers at Dublin airport exceeded 10.8 million for the first six months of the year, an 11 per cent rise over the same period last year, according to figures released by the Dublin Airport Authority. Almost 1.1 million additional passengers were facilitated during the first six months of the year.

IN&M buys back 1.5m shares

Independent News & Media has returned to market, spending a total of EUR 4.44 million on the purchase of 1.5 million shares. The shares were acquired at a price of EUR 3.625 and EUR 3.63. IN&M shares on the Dublin market closed a half cent weaker last night at EUR 3.63.

The shares repurchased are being held in treasury. The latest buybacks bring to 15.08 million the number of IN&M stock now held in treasury since the group started a buyback programme as "dissident" shareholder Denis O'Brien made moves to increase his stake in the business.

Pfizer wins drug **patent** case

Pfizer has won a **patent** case over its Lipitor drug in the High Court, which ruled a **patent** protecting the blockbuster cholesterol fighter would be infringed by a competing product from India's **Ranbaxy** Laboratories.

The decision by the High Court prevents **Ranbaxy** from launching its drug before the basic Lipitor **patent** expires in November 2011. A **Ranbaxy** spokesman said the company would appeal the ruling.

Lipitor is the world's top-selling drug. It is manufactured at Pfizer's plants in Little Island and Loughbeg in Cork. The group employs 2,000 people in the Republic. (Reuters)

TVC Holdings shares start trading

Shares in TVC Holdings, the holding company for Trinity Venture Capital, begin trading today on the Irish Stock Exchange's IEX market for small and medium-sized companies.

TVC Holdings has raised EUR 50 million in new equity to finance new investments and to develop the group's existing portfolio of investments.

Rise in number of companies formed

Registration rates for new companies picked up in the second quarter, according to figures gathered by Bank of Ireland. The bank found that 10,041 new companies were formed in the Republic in the first six months of the year, slightly ahead of the same point in 2006.

Port of Belfast to reclaim land

The Port of Belfast is planning to reclaim 120 acres from Belfast Lough at a cost of £630 million. The proposed initiative is designed to "accommodate economic growth".

McLoughlin the new CEO of Ipso

The Irish Payment Services Organisation (Ipso) has named Pat McLoughlin as its new chief executive. He was most recently deputy chief executive and director of the National Hospitals Office in the Health Service Executive.

**LOAD-DATE:** July 11, 2007

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**PUBLICATION-TYPE:** Newspaper

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