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and Cadila Healthcare Limited

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

TAKEDA PHARMACEUTICALS COMPANY LIMITED, TAKEDA PHARMACEUTICALS USA, INC., and TAKEDA PHARMACEUTICALS AMERICA, INC., Plaintiffs, v. ZYDUS PHARMACEUTICALS (USA) INC., and CADILA HEALTHCARE LIMITED, Defendants.	Civil Action No. 18-01994 (FLW) (TJB) (Jury Trial Requested)

DEFENDANTS ZYDUS PHARMACEUTICALS (USA) INC. AND CADILA HEALTHCARE LIMITED'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS

Defendants Zydus Pharmaceuticals (USA) Inc. ("Zydus") and Cadila Healthcare Limited ("Cadila") (collectively, "Defendants") hereby answer the Complaint ("the Complaint") filed by Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals U.S.A., Inc., and Takeda Pharmaceuticals America, Inc. (collectively, "Plaintiffs" or "Takeda") by denying each and every allegation contained therein, except those that are specifically admitted or modified in this answer. Zydus responds to the Complaint's specific allegations as follows:

THE PARTIES

1. Plaintiff Takeda Japan is a Japanese corporation, having a principal place of business at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka, Japan. As part of its business, Takeda Japan is involved in the research, development, and marketing of pharmaceutical products. Takeda Japan manufactures lansoprazole orally disintegrating tablets.

ANSWER: Admit, upon information and belief, that Takeda Japan is a Japanese corporation, having a principal place of business at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka, Japan. Except as so admitted, Defendants lack information and knowledge sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 1 of the Complaint.

2. Plaintiff Takeda Japan is the owner of record and assignee of U.S. Patent No. 6,328,994 ("'994 Patent"), U.S. Patent No. 7,431,942 ("'942 Patent"), U.S. Patent No. 7,875,292 ("'292 Patent"), and U.S. Patent No. 7,399,485 ("'485 Patent") (collectively, "the patents-in-suit").

ANSWER: It is admitted that the United States Patent and Trademark Office lists the last assignments of U.S. Patent No. 6,328,994 ("'994 Patent"), U.S. Patent No. 7,431,942 ("'942 Patent"), and U.S. Patent No. 7,399,485 ("'485 Patent") to assignee Takeda Pharmaceutical Company, Limited, however it notes that no assignment is recorded for U.S. Patent No. 7,875,292 ("'292 Patent"). As assignments may not be recorded with the USTPO, lacking information and belief, Defendants deny the remainder of any allegations.

3. Plaintiff Takeda U.S.A. is a Delaware corporation, having a principal place of business at One Takeda Parkway, Deerfield, Illinois 60015. As part of its business, Takeda U.S.A. is involved in the research, development, and marketing of pharmaceutical products. Takeda U.S.A. is the registered holder of approved New Drug Application ("NDA") No. 21-428. In addition, Takeda U.S.A. has the exclusive right to import lansoprazole orally disintegrating tablets into the United States. Takeda U.S.A. purchases from Takeda Japan and imports into the United States, lansoprazole orally disintegrating tablets manufactured by Takeda Japan.

ANSWER: Admit, on information and belief, that Takeda U.S.A. is a Delaware corporation, having a principal place of business at One Takeda Parkway, Deerfield, Illinois 60015. Except as so admitted, Defendants lack information and knowledge sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 3 of the Complaint.

4. Plaintiff Takeda America is a Delaware corporation, having a principal place of business at One Takeda Parkway, Deerfield, Illinois 60015. As part of its business, Takeda America is involved in the purchase, sale, and marketing of pharmaceutical products. Takeda America has the exclusive right to purchase lansoprazole orally disintegrating tablets from Takeda U.S.A. and sell those tablets to the public in the United States. Takeda America sells lansoprazole orally disintegrating tablets manufactured by Takeda Japan that it purchases from Takeda U.S.A. to the public in the United States.

ANSWER: Admit, on information and belief, that Takeda America is a Delaware corporation, having a principal place of business at One Takeda Parkway, Deerfield, Illinois 60015. Except as so admitted, Defendants lack information and knowledge sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 4 of the Complaint.

5. On information and belief, Zydus is a corporation organized and existing under the laws of the State of New Jersey, with a principal place of business at 73 Route 31 North, Pennington, New Jersey 08534, and is in the business of, among other things, manufacturing, selling, and marketing generic copies of branded pharmaceutical products throughout the United States, including in this District.

ANSWER: Admit that Zydus is a New Jersey corporation, having a principal place of business at 73 Route 31 North, Pennington, New Jersey 08534 and is engaged in the sale of pharmaceutical products. Except as expressly admitted, Defendants deny the remaining allegations contained in paragraph 5 of the Complaint.

6. On information and belief, Cadila is a corporation organized and existing under the laws of the Republic of India, with a principal place of business at Zydus Tower, Satellite Cross Roads, Ahmedabad-380015, Gujarat, India, and is in the business of, among other things, manufacturing, selling, and marketing generic copies of branded pharmaceutical products throughout the United States, including in this District.

ANSWER: Admit that Cadila Healthcare Limited is an Indian corporation, having a principle place of business located at Zydus Tower, Satellite Cross Roads, Ahmedabad – 380015 Gujarat, India, and that Cadila manufactures pharmaceutical products. For the purposes of this case only, Cadila does not contest personal jurisdiction of venue in this District. Defendants deny the remaining allegations of Paragraph 6.

7. On information and belief, Zydus is a wholly owned subsidiary of Cadila.

ANSWER: Admit.

8. On information and belief, Zydus is controlled and/or dominated by Cadila.

ANSWER: Deny the allegations contained in paragraph 8 of the Complaint.

9. On information and belief, Cadila conducts its North American operations, at least in part, through Zydus.

ANSWER: Admit only that Defendants conduct business in the United States of America. Except as expressly admitted above, Defendants deny the remaining allegations contained in paragraph 9 of the Complaint.

10. On information and belief, Zydus and Cadila operate and act in concert as an integrated, unitary business for purposes of manufacturing, marketing, selling, and distributing generic pharmaceutical products.

ANSWER: Paragraph 10 sets forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations.

JURISDICTION AND VENUE

11. This action arises under the patent laws of the United States of America, Title 35, United States Code. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

ANSWER: Admit.

12. Zydus is subject to personal jurisdiction in this District by virtue of, inter alia, its incorporation in New Jersey, its regular and established place of business in this District, its conduct of business in this District, its purposeful availment of the rights and benefits of New Jersey law, and its substantial and continuing contacts within the State.

ANSWER: Paragraph 12 sets forth legal conclusions to which no response is required. For the purpose of this case, Defendants do not contest personal jurisdiction in the District of New Jersey. To the extent that there are any remaining allegations of paragraph 12, Defendants deny them.

13. On information and belief, Cadila regularly transacts business within this District and derives substantial revenue from services or things used or consumed in this jurisdiction, including but not limited to directing the operations and management of Zydus, as well as shipping pharmaceuticals to Zydus from locations outside the United States for distribution by Zydus within the United States generally, and within this District specifically.

ANSWER: For purposes of this action, Defendants do not contest personal jurisdiction in this District, but deny any remaining allegations contained in paragraph 13 of the Complaint.

14. On information and belief, Zydus acts as an agent of Cadila with respect to the acts complained of herein.

ANSWER: Paragraph 14 sets forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the same.

15. On information and belief, the acts of Zydus complained of herein were done at the direction of, with the authorization of, with the cooperation, participation, and assistance of Cadila, and, in part, for the benefit of Cadila.

ANSWER: Paragraph 15 sets forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the same.

16. On information and belief, Cadila directed Zydus to perform the acts complained of herein, in whole or in part, to shield itself from liability for patent infringement based upon those acts.

ANSWER: Paragraph 16 sets forth legal conclusions to which no response is required. To the extent a response is required, Defendants deny the same.

17. On information and belief, Cadila and Zydus know and intend that, following any approval of Abbreviated New Drug Application ("ANDA") No. 200816, including any amendments thereto, Defendants' ANDA Product will be distributed and sold in New Jersey.

ANSWER: Defendants do not contest venue in New Jersey. Defendants admit that its ANDA Product is intended to be distributed and sold in New Jersey upon FDA approval.

18. Zydus' acts and contacts with this District, as an agent of Cadila, are attributable to Cadila for jurisdictional purposes.

ANSWER: Paragraph 18 sets forth legal conclusions to which no response is required. To the extent a response is required, Defendants do not contest subject matter jurisdiction, personal jurisdiction or venue in this District.

19. Cadila is subject to personal jurisdiction in this District by virtue of, inter alia, its incorporation of Zydus in New Jersey, its conduct of business in this District, its purposeful availment of the rights and benefits of New Jersey law, and its substantial and continuing contacts within the State.

ANSWER: Paragraph 19 sets forth legal conclusions to which no response is required. To the extent a response is required, Defendants do not contest personal jurisdiction in this District.

20. Cadila and Zydus are also subject to personal jurisdiction in this District because, on information and belief, Cadila and Zydus acted collaboratively in the preparation and submission of ANDA No. 200816, including any amendments thereto, to the United States Food and Drug Administration ("FDA") for the purpose of obtaining approval to distribute and sell Defendants' Proposed ANDA Product throughout the United States, including in New Jersey.

ANSWER: Paragraph 20 sets forth legal conclusions to which no response is required. To the extent a response is required, Defendants do not contest personal jurisdiction in this District.

21. Cadila and Zydus are also subject to personal jurisdiction in this District because they purposefully availed themselves of the benefits and protections of this Court by previously initiating litigation in this District. *See, e.g., Zydus Pharms. (USA) Inc. and Cadila Healthcare Ltd. v. Gilead Scis., Inc.*, No. 14-7080 (FLW)(LHG) (D.N.J.). Cadila and Zydus have also been sued on certain of the patents-in-suit in this District by Takeda without objection that this Court lacks personal jurisdiction over them. *See Takeda Pharmaceutical Co. Ltd. et al. v. Zydus Pharmaceuticals (USA) Inc. et al.*, No. 10-01723-JAP-TJB (D.N.J.); *see also, Otsuka Pharm. Co., Ltd. v. Zydus Pharmaceuticals USA Inc. et al.*, No. 17-02754-JBS- KMW (D.N.J.); *Celgene Corp. v. Zydus Pharmaceuticals (USA) Inc. et al.*, No. 17-02528- SDW-LDW (D.N.J.); *Helsinn Healthcare S.A. v. Zydus Pharms. (USA) Inc. and Cadila Healthcare Ltd. (d/b/a Zydus Cadila)*, No. 16-4239 (MLC)(DEA) (D.N.J.); *AstraZeneca AB, et al. v. Zydus Pharms. (USA) Inc. and Cadila Healthcare Ltd. (d/b/a Zydus Cadila)*, No. 15-7415 (MLC)(TJB) (D.N.J.); *Supernus Pharms., Inc. v. Zydus Pharms. (USA) Inc. and Cadila Healthcare Ltd.*, No. 14-7272 (SDW)(LDW) (D.N.J.).

ANSWER: Paragraph 21 contains conclusions of law for which no response is required. To the extent a response is required, Defendants state that they do not oppose personal jurisdiction in this District.

22. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

ANSWER: Paragraph 22 contains conclusions of law for which no response is required. To the extent a response is required, Defendants state that they do not oppose venue in this District.

FACTS PERTINENT TO ALL CLAIMS FOR RELIEF

23. On December 11, 2001, the United States Patent and Trademark Office ("PTO") issued the '994 Patent, entitled "Orally Disintegrable Tablets," to Takeda Chemical Industries, Ltd. (now Takeda Pharmaceutical Company Ltd.), the assignee of the named inventors Toshihiro Shimizu, Shuji Morimoto, and Tetsuro Tabata. Plaintiff Takeda Japan is the record owner of the '994 Patent. A copy of the '994 Patent is attached hereto as Exhibit A.

ANSWER: Admit that, according to the face of U.S. Patent No. 6,328,994 (the '994 patent), entitled "Orally Disintegrable Tablets," that the patent was issued on December 11, 2001, and that a copy of the document purporting to be the patent was annexed to Plaintiffs' Complaint as Exhibit A. Except as expressly admitted above, Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 23 of the Complaint, and therefore deny them.

24. On October 7, 2008, the PTO issued the '942 Patent, entitled "Orally Disintegrable Tablets," to Takeda Pharmaceutical Company Limited, the assignee of the named inventors Toshihiro Shimizu, Shuji Morimoto, and Tetsuro Tabata. Plaintiff Takeda Japan is the record owner of the '942 Patent. A copy of the '942 Patent is attached hereto as Exhibit B.

ANSWER: Admit that, according to the face of U.S. Patent No. 7,431,942 (the '942 patent), entitled "Orally Disintegrable Tablets," that the patent was issued on October 7, 2008, and that a copy of the document purporting to be the patent was annexed to Plaintiffs' Complaint as Exhibit B. Except as expressly admitted above, Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 24 of the Complaint, and therefore deny them.

25. On January 25, 2011, the PTO issued the ’292 Patent, entitled “Orally Disintegrable Tablets,” to Takeda Pharmaceutical Company Limited, the assignee of the named inventors Toshihiro Shimizu, Shuji Morimoto, and Tetsuro Tabata. Plaintiff Takeda Japan is the record owner of the ’292 Patent. A copy of the ’292 Patent is attached hereto as Exhibit C.

ANSWER: Admit that, according to the face of U.S. Patent No. 7,875,292 (the '292 patent), entitled “Orally Disintegrable Tablets,” that the patent was issued on January 25, 2011, and that a copy of the document purporting to be the patent was annexed to Plaintiffs’ Complaint as Exhibit C. Except as expressly admitted above, Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 25 of the Complaint, and therefore deny them.

26. On July 15, 2008, the PTO issued the ’485 Patent, entitled “Rapidly Disintegrable Solid Preparation,” to Takeda Pharmaceutical Company Limited, the assignee of the named inventors Toshihiro Shimizu, Masae Sugaya, and Yoshinori Nakano. Plaintiff Takeda Japan is the record owner of the ’485 Patent. A copy of the ’485 Patent is attached hereto as Exhibit D.

ANSWER: Admit that, according to the face of U.S. Patent No. 7,399,485 (the '485 patent), entitled “Rapidly Disintegrable Solid Preparation,” that the patent was issued on July 15, 2008, and that a copy of the document purporting to be the patent was annexed to Plaintiffs’ Complaint as Exhibit D. Except as expressly admitted above, Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 26 of the Complaint, and therefore deny them.

27. On August 30, 2002, the United States Food and Drug Administration (“FDA”) approved NDA No. 21-428 for lansoprazole delayed release orally disintegrating tablets, 15 and 30 mg. Plaintiff Takeda U.S.A. is the holder of NDA No. 21-428 for lansoprazole delayed release orally disintegrating tablets, which Plaintiff Takeda America sells under the name Prevacid® SoluTab™.

ANSWER: Admit that, on information and belief, the United States Food and Drug Administration ("FDA") approved NDA No. 21-428 for lansoprazole delayed release orally disintegrating tablets, 15 and 30 mg, and that Takeda sells its lansoprazole delayed release orally disintegrating tablets, both 15 mg and 30 mg, under the name Prevacid® SoluTab™. Defendants lack information sufficient to admit or deny the remaining allegations in paragraph 27, and therefore deny them.

28. The patents-in-suit are listed in a FDA publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations (known as the "Orange Book") for Prevacid® SoluTab™, lansoprazole delayed release orally disintegrating tablets, 15 and 30 mg.

ANSWER: Admit.

29. On information and belief, through the coordinated efforts of its staff worldwide, including in India and the United States, Cadila seeks to constantly expand the range of generic products itsells.

ANSWER: Admit only that Cadila offers a broad range of generic pharmaceutical products. Except as expressly admitted above, Defendants deny the remaining allegations contained in paragraph 29 of the Complaint.

30. On information and belief, Cadila and Zydus collaborate in the manufacture, marketing and sale of many pharmaceutical products (including generic drug products manufactured and sold pursuant to an approved abbreviated new drug application) within the United States generally and the State of New Jersey specifically.

ANSWER: Deny the allegations contained in paragraph 30 of the Complaint.

31. On information and belief, Cadila actively reviews pharmaceutical patents and seeks opportunities to challenge those patents.

ANSWER: Deny the allegations contained in paragraph 31 of the Complaint.

32. On information and belief, Cadila reviewed the patents-in-suit and certain commercial and economic information relating to Prevacid® SoluTab™, including estimates of the revenues generated by the sale of Prevacid® SoluTab™, and decided to file an Abbreviated New Drug Application ("ANDA"), seeking approval to market lansoprazole delayed release orally disintegrating tablets.

ANSWER: Deny the allegations contained in paragraph 32 of the Complaint.

33. On information and belief, Cadila and Zydus collaborated in the research, development, preparation, and filing of ANDA No. 200816 for lansoprazole delayed release orally disintegrating tablets.

ANSWER: Defendants deny the allegations contained in paragraph 33 of the Complaint.

34. On information and belief, Zydus submitted to FDA ANDA No. 200816 seeking approval to engage in the commercial manufacture, use and sale of lansoprazole delayed release orally disintegrating tablets, 15 and 30 mg, prior to the expiration of the patents-in-suit.

ANSWER: Admit that Zydus submitted to the FDA ANDA No. 200816 prior to the expiration of the patents-in-suit for the purpose recited therein. Except as expressly admitted above, Defendants deny the allegations contained in paragraph 34 of the Complaint.

35. Plaintiffs received a letter from Zydus, dated February 19, 2010, notifying Plaintiffs of ANDA No. 200816 and that ANDA No. 200816 included a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification") that, in Zydus' opinion, no valid, enforceable claim of the '994 Patent, '942 Patent, '485 Patent, and U.S. Patent No. 5,463,632 ("'632 Patent") would be infringed by the commercial manufacture, use, or sale of the lansoprazole delayed release orally disintegrating tablet products described in ANDA No. 200816.

ANSWER: Admit that Zydus sent a letter dated February 19, 2010, which referenced letter speaks for itself. Except as expressly admitted, Defendants deny the allegations contained in paragraph 35 of the Complaint.

36. On April 5, 2010, Plaintiffs filed suit in this District against Defendants for infringement of the '994 Patent, '942 Patent, and '632 Patent, based, inter alia, upon Zydus' written notification of its filing of ANDA No. 200816 and accompanying Paragraph IV certification. See Takeda Pharmaceutical Co. Ltd. et al. v. Zydus Pharmaceuticals (USA) Inc. et al., No. 10-01723-JAP-TJB (D.N.J.). That suit was resolved on October 16, 2014. Id. (D.I. 389).

ANSWER: Admit that a suit was filed in this District against Defendants for infringement of the '994 Patent, '942 Patent, and '632 Patent, and that suit was finally resolved by a District Court opinion dated October 16, 2014 based on an earlier Federal Circuit Opinion on appropriate claim construction.

37. On information and belief, Defendants subsequently submitted to FDA an amendment to ANDA No. 200816 ("Amended ANDA No. 200816") in order to modify the formulation of their ANDA Product. On information and belief, Amended ANDA No. 200816 specifically seeks FDA approval to market Defendants' ANDA Product prior to the expiration of thepatents-in-suit.

ANSWER: Defendants admit that an amendment was made to ANDA No. 200816 and that Defendants seek to market the product of this ANDA prior to the expiration of the patents- in-suit. Except as expressly admitted above, Defendants deny the allegations contained in paragraph 37 of the Complaint.

38. On or about January 4, 2018, Plaintiffs received a letter from Zydus, dated January 3, 2018, notifying Plaintiffs of Amended ANDA No. 200816 and that Amended ANDA No. 200816 included a Paragraph IV certification that, in Zydus's opinion, no valid, enforceable claim of the '994 Patent, '942 Patent, '292 Patent, or '485 Patent will be infringed by the commercial manufacture, use, or sale of the lansoprazole delayed release orally disintegrating tablet products described in Amended ANDA No. 200816.

ANSWER: Admit that such a letter was transmitted to all plaintiffs and otherwise notes that the referenced letter speaks for itself. Except as expressly admitted, Defendants deny the allegations contained in paragraph 38 of the Complaint.

39. On information and belief, Cadila made the ultimate decision to file Amended ANDA No. 200816 with FDA, and encouraged and directed Zydus to file Amended ANDA No. 200816 and the Paragraph IV certification, and Zydus did so at Cadila's direction.

ANSWER: Deny the allegations contained in paragraph 39 of the Complaint.

40. On information and belief, Cadila was necessarily aware of the patents-in-suit when it directed Zydus to file Amended ANDA No. 200816 with a Paragraph IV certification.

ANSWER: Deny the allegations contained in paragraph 40 of the Complaint.

41. Plaintiffs commenced this action within days of the date they received Zydus' notice of Amended ANDA No. 200816 containing the Paragraph IV certification.

ANSWER: Admit.

42. On information and belief, Zydus and Cadila continue to collaborate in seeking approval of Amended ANDA No. 200816 from FDA and intend to collaborate in the commercial manufacture, marketing, and sale of lansoprazole delayed release orally disintegrating tablets (including commercial marketing and sale of such products in the State of New Jersey) in the event that FDA approves Amended ANDA No. 200816.

ANSWER: Admit only that Zydus continues to seek approval of ANDA 200816 from the FDA. Except as expressly admitted, Defendants deny the allegations contained in paragraph 42 of the Complaint.

FIRST CLAIM FOR RELIEF
(Direct Infringement of the '994 Patent by Zydus and Cadila)

43. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 42 hereof, as if fully set forth herein.

ANSWER: Defendants repeat, reiterate and re-allege their responses to paragraphs 1 through and including 42 of the Complaint with the same force and effect as if hereinafter set forth at length.

44. Through the conduct alleged above, Defendants have directly infringed, and continue to directly infringe, one or more claims of the '994 Patent.

ANSWER: Deny the allegations contained in paragraph 44 of the Complaint.

45. By filing Amended ANDA No. 200816 with a Paragraph IV certification seeking FDA approval to engage in the commercial manufacture, use and sale of lansoprazole delayed release orally disintegrating tablets described therein, prior to the expiration of the '994 Patent with pediatric exclusivity, Defendants have infringed the '994 Patent under 35 U.S.C. § 271(e)(2).

ANSWER: Deny the allegations contained in paragraph 45 of the Complaint.

46. Defendants were aware of the existence of the '994 Patent prior to filing Amended ANDA No. 200816 but took such action knowing that it would constitute infringement of the '994 Patent.

ANSWER: Admit only that Zydus was aware of existence of the '994 Patent prior to submitting ANDA No. 200816. Except as expressly admitted, Defendants deny the allegations contained in paragraph 46 of the Complaint.

47. On information and belief, Defendants acted without a reasonable basis for a good faith belief that they would not be liable for infringing the '994 Patent.

ANSWER: Deny the allegations contained in paragraph 47 of the Complaint.

48. Defendants' conduct renders this case "exceptional" within the meaning of 35 U.S.C. § 285.

ANSWER: Deny the allegations contained in paragraph 48 of the Complaint.

49. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '994 Patent.

ANSWER: Deny the allegations contained in paragraph 49 of the Complaint.

SECOND CLAIM FOR RELIEF
(Inducement of Infringement of the '994 Patent by Cadila)

50. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 49 hereof, as if fully set forth herein.

ANSWER: Defendants repeat, reiterate, and re-allege their responses to paragraphs 1 through and including 49 of the Complaint with the same force and effect as if hereinafter set forth at length.

51. Through the conduct alleged above, Cadila has knowingly and actively induced Zydus to infringe, and continue to infringe, one or more claims of the '994 Patent.

ANSWER: Deny the allegations contained in paragraph 51 of the Complaint.

52. By reason of Cadila's inducement of Zydus' direct infringement of the '994 Patent, Cadila has caused and continues to cause irreparable harm to Plaintiffs.

ANSWER: Deny the allegations contained in paragraph 52 of the Complaint.

53. On information and belief, Cadila's inducement of Zydus' direct infringement of the '994 Patent will continue unless enjoined by this Court.

ANSWER: Deny the allegations contained in paragraph 53 of the Complaint.

54. Plaintiffs have no adequate remedy at law for Cadila's inducement of Zydus' direct infringement of the '994 Patent.

ANSWER: Deny the allegations contained in paragraph 54 of the Complaint.

55. Defendants' conduct renders this case "exceptional" within the meaning of 35 U.S.C. § 285.

ANSWER: Deny the allegations contained in paragraph 55 of the Complaint.

THIRD CLAIM FOR RELIEF
(Direct Infringement of the '942 Patent by Zydus and Cadila)

56. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 55 hereof, as if fully set forth herein.

ANSWER: Defendants repeat, reiterate and re-allege their responses to paragraphs 1 through and including 55 of the Complaint with the same force and effect as if hereinafter set forth at length.

57. Through the conduct alleged above, Defendants have directly infringed, and continue to directly infringe, one or more claims of the '942 Patent.

ANSWER: Deny the allegations contained in paragraph 57 of the Complaint.

58. By filing Amended ANDA No. 200816 with a Paragraph IV certification seeking FDA approval to engage in the commercial manufacture, use and sale of lansoprazole delayed release orally disintegrating tablets described therein, prior to the expiration of the '942 Patent with pediatric exclusivity, Defendants have infringed the '942 Patent under 35 U.S.C. § 271(e)(2).

ANSWER: Deny the allegations contained in paragraph 58 of the Complaint.

59. Defendants were aware of the existence of the '942 Patent prior to filing Amended ANDA No. 200816 but took such action knowing that it would constitute infringement of the '942 Patent.

ANSWER: Admit only that Zydus was aware of the existence of the '942 patent prior to filing ANDA 200816. Except as expressly admitted, Defendants deny the allegations contained in paragraph 59 of the Complaint.

60. On information and belief, Defendants acted without a reasonable basis for a good faith belief that they would not be liable for infringing the '942 Patent.

ANSWER: Deny the allegations contained in paragraph 60 of the Complaint.

61. Defendants' conduct renders this case "exceptional" within the meaning of 35 U.S.C. § 285.

ANSWER: Deny the allegations contained in paragraph 61of the Complaint.

62. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '942 Patent.

ANSWER: Deny the allegations contained in paragraph 62 of the Complaint.

FOURTH CLAIM FOR RELIEF
(Inducement of Infringement of the '942 Patent by Cadila)

63. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 62 hereof, as if fully set forth herein.

ANSWER: Defendants repeat, reiterate and re-allege their responses to paragraphs 1 through and including 62 of the Complaint with the same force and effect as if hereinafter set forth at length.

64. Through the conduct alleged above, Cadila has knowingly and actively induced Zydus to infringe, and continue to infringe, one or more claims of the '942 Patent.

ANSWER: Deny the allegations contained in paragraph 64 of the Complaint.

65. By reason of Cadila's inducement of Zydus' direct infringement of the '942 Patent, Cadila has caused and continues to cause irreparable harm to Plaintiffs.

ANSWER: Deny the allegations contained in paragraph 65 of the Complaint.

66. On information and belief, Cadila's inducement of Zydus' direct infringement of the '942 Patent will continue unless enjoined by this Court.

ANSWER: Deny the allegations contained in paragraph 66 of the Complaint.

67. Plaintiffs have no adequate remedy at law for Cadila's inducement of Zydus' direct infringement of the '942 Patent.

ANSWER: Deny the allegations contained in paragraph 67 of the Complaint.

68. Defendants' conduct renders this case "exceptional" within the meaning of 35 U.S.C. § 285.

ANSWER: Deny the allegations contained in paragraph 68 of the Complaint.

FIFTH CLAIM FOR RELIEF
(Direct Infringement of the '292 Patent by Zydus and Cadila)

69. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 68 hereof, as if fully set forth herein.

ANSWER: Defendants repeat, reiterate and re-allege their responses to paragraphs 1 through and including 68 of the Complaint with the same force and effect as if hereinafter set forth at length.

70. Through the conduct alleged above, Defendants have directly infringed, and continue to directly infringe, one or more claims of the '292 Patent.

ANSWER: Deny the allegations contained in paragraph 70 of the Complaint.

71. By filing Amended ANDA No. 200816 with a Paragraph IV certification seeking FDA approval to engage in the commercial manufacture, use and sale of lansoprazole delayed release orally disintegrating tablets described therein, prior to the expiration of the '292 Patent with pediatric exclusivity, Defendants have infringed the '292 Patent under 35 U.S.C. § 271(e)(2).

ANSWER: Deny the allegations contained in paragraph 71 of the Complaint.

72. Defendants were aware of the existence of the '292 Patent prior to filing Amended ANDA No. 200816 but took such action knowing that it would constitute infringement of the '292 Patent.

ANSWER: Admit only that Zydus was aware of the existence of the '292 patent prior to filing ANDA 200816. Except as expressly admitted, Defendants deny the allegations contained in paragraph 72 of the Complaint.

73. On information and belief, Defendants acted without a reasonable basis for a good faith belief that they would not be liable for infringing the '292 Patent.

ANSWER: Deny the allegations contained in paragraph 73 of the Complaint.

74. Defendants' conduct renders this case "exceptional" within the meaning of 35 U.S.C. § 285.

ANSWER: Deny the allegations contained in paragraph 74 of the Complaint.

75. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '292 Patent.

ANSWER: Deny the allegations contained in paragraph 75 of the Complaint.

SIXTH CLAIM FOR RELIEF
(Inducement of Infringement of the '292 Patent by Cadila)

76. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 75 hereof, as if fully set forth herein.

ANSWER: Defendants repeat, reiterate and re-allege their responses to paragraphs 1 through and including 75 of the Complaint with the same force and effect as if hereinafter set forth at length.

77. Through the conduct alleged above, Cadila has knowingly and actively induced Zydus to infringe, and continue to infringe, one or more claims of the '292 Patent.

ANSWER: Deny the allegations contained in paragraph 77 of the Complaint.

78. By reason of Cadila's inducement of Zydus' direct infringement of the '292 Patent, Cadila has caused and continues to cause irreparable harm to Plaintiffs.

ANSWER: Deny the allegations contained in paragraph 78 of the Complaint.

79. On information and belief, Cadila's inducement of Zydus' direct infringement of the '292 Patent will continue unless enjoined by this Court.

ANSWER: Deny the allegations contained in paragraph 79 of the Complaint.

80. Plaintiffs have no adequate remedy at law for Cadila's inducement of Zydus' direct infringement of the '292 Patent.

ANSWER: Deny the allegations contained in paragraph 80 of the Complaint.

81. Defendants' conduct renders this case "exceptional" within the meaning of 35 U.S.C. § 285.

ANSWER: Deny the allegations contained in paragraph 81 of the Complaint.

SEVENTH CLAIM FOR RELIEF
(Direct Infringement of the '485 Patent by Zydus and Cadila)

82. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 81 hereof, as if fully set forth herein.

ANSWER: Defendants repeat, reiterate and re-allege their responses to paragraphs 1 through and including 81 of the Complaint with the same force and effect as if hereinafter set forth at length.

83. Through the conduct alleged above, Defendants have directly infringed, and continue to directly infringe, one or more claims of the '485 Patent.

ANSWER: Deny the allegations contained in paragraph 83 of the Complaint.

84. By filing Amended ANDA No. 200816 with a Paragraph IV certification seeking FDA approval to engage in the commercial manufacture, use and sale of lansoprazole delayed release orally disintegrating tablets described therein, prior to the expiration of the '485 Patent with pediatric exclusivity, Defendants have infringed the '485 Patent under 35 U.S.C. § 271(e)(2).

ANSWER: Deny the allegations contained in paragraph 84 of the Complaint.

85. Defendants were aware of the existence of the '485 Patent prior to filing Amended ANDA No. 200816 but took such action knowing that it would constitute infringement of the '485 Patent.

ANSWER: Admit only that Zydus was aware of the existence of the '485 patent prior to filing ANDA 200816. Except as expressly admitted, Defendants deny the allegations contained in paragraph 85 of the Complaint.

86. On information and belief, Defendants acted without a reasonable basis for a good faith belief that they would not be liable for infringing the '485 Patent.

ANSWER: Deny the allegations contained in paragraph 86 of the Complaint.

87. Defendants' conduct renders this case "exceptional" within the meaning of 35 U.S.C. § 285.

ANSWER: Deny the allegations contained in paragraph 87 of the Complaint.

88. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '485 Patent.

ANSWER: Deny the allegations contained in paragraph 88 of the Complaint.

EIGHTH CLAIM FOR RELIEF
(Inducement of Infringement of the '485 Patent by Cadila)

89. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 88 hereof, as if fully set forth herein.

ANSWER: Defendants repeat, reiterate and re-allege their responses to paragraphs 1 through and including 88 of the Complaint with the same force and effect as if hereinafter set forth at length.

90. Through the conduct alleged above, Cadila has knowingly and actively induced Zydus to infringe, and continue to infringe, one or more claims of the '485 Patent.

ANSWER: Deny the allegations contained in paragraph 90 of the Complaint.

91. By reason of Cadila's inducement of Zydus' direct infringement of the '485 Patent, Cadila has caused and continues to cause irreparable harm to Plaintiffs.

ANSWER: Deny the allegations contained in paragraph 91 of the Complaint.

92. On information and belief, Cadila's inducement of Zydus' direct infringement of the '485 Patent will continue unless enjoined by this Court.

ANSWER: Deny the allegations contained in paragraph 92 of the Complaint.

93. Plaintiffs have no adequate remedy at law for Cadila's inducement of Zydus' direct infringement of the '485 Patent.

ANSWER: Deny the allegations contained in paragraph 93 of the Complaint.

94. Defendants' conduct renders this case "exceptional" within the meaning of 35 U.S.C. § 285.

ANSWER: Deny the allegations contained in paragraph 94 of the Complaint.

PLAINTIFFS' PRAYER FOR RELIEF

Defendants deny that Plaintiffs are entitled to any of the relief requested in their Prayer for Relief.

ZYDUS' AFFIRMATIVE DEFENSES

First Affirmative Defense

Defendants do not infringe, and have not infringed, either literally or under the doctrine of equivalents, any valid and enforceable claim of U.S. Patent No. 6,328,994 ("'994 Patent"), U.S. Patent No. 7,431,942 ("'942 Patent"), U.S. Patent No. 7,875,292 ("'292 Patent"), and U.S. Patent No. 7,399,485 ("'485 Patent") (collectively, "the patents-in-suit") and will neither induce nor contribute to the infringement of any valid and/or enforceable claim of the patents-in-suit.

Second Affirmative Defense

Each and every claim of the patents-in-suit are invalid because they fail to satisfy one or more conditions for patentability stated in Title 35 of the United States Code, including, *inter alia*, §§101, 102, 103 and 112.

Third Affirmative Defense

Plaintiffs' claims for relief are barred in their entirety under at least the judicial doctrines of res judicata and collateral estoppel.

Fourth Affirmative Defense

Plaintiffs' claims for relief are barred by one or more of the equitable doctrines of waiver, estoppel and/or unclean hands.

Fifth Affirmative Defense

Plaintiffs' claim for injunctive relief are barred because Plaintiffs have brought this case in bad faith, have not been irreparably harmed, the balance of hardships is not in their favor, and the public interest is not served by granting injunctive relief.

Sixth Affirmative Defense

Plaintiffs' claims for damages are limited and/or barred under 35 U.S.C. §§ 286 and 287.

Seventh Affirmative Defense

Plaintiffs are not entitled to enhanced or increased damages for willful infringement, because Defendants have not engaged in any conduct that meets the applicable standard for willful infringement.

Eighth Affirmative Defense

Defendants reserve the right to assert additional defenses that may become known to them through discovery, including, but not limited to, inequitable conduct.

COUNTERCLAIMS

Zydus Pharmaceuticals (USA) Inc. ("Zydus") and Cadila Healthcare Limited ("Cadila") (collectively, "Counter-Plaintiffs" or "Zydus") assert the following Counterclaims against Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals U.S.A., Inc., and Takeda Pharmaceuticals America, Inc. (collectively, "Counterclaim Defendants" or "Takeda").

I. NATURE OF THE CASE

1. These Counterclaims seek injunctive relief, treble damages, and other relief under federal and state antitrust laws to remedy plainly anticompetitive conduct by Takeda. Takeda's conduct complained of herein has had, and continues to have, the intended effect of foreclosing competition in the sale of an important prescription medicine, lansoprazole delayed release orally disintegrating tablets, 15 and 30 mg ("Prescription Lansoprazole ODT"), thereby preserving Takeda's monopoly position for that medicine and inflicting substantial harm to consumers by denying the marketplace lower-priced competition from Zydus' therapeutically equivalent generic version.

2. Facing the prospect of imminent generic competition, Takeda filed this sham patent infringement action against Counter-Plaintiffs in a brazen attempt to exploit a feature of the Hatch-

Waxman Act through which the manufacturer of a branded drug product can block otherwise imminent Food & Drug Administration ("FDA") approval of a rival generic product for thirty (30) months by filing a patent-infringement suit. Takeda has unlawfully perverted this regulatory provision—designed to allow patent holders an opportunity to pursue legitimate, well-grounded patent infringement claims—by filing an objectively baseless patent infringement suit with the sole purpose of delaying FDA approval for Zydus' product and prolonging the monopoly enjoyed by Takeda's product, Prevacid® SoluTab™. The antitrust laws, however, condemn such tactics.

3. Takeda's patent-infringement suit against Zydus is objectively baseless for at least two reasons. *First*, Takeda has re-asserted infringement allegations that the parties previously litigated and that were fully resolved in Zydus' favor against Takeda involving the same patents-in-suit.

4. In 2010, after Zydus submitted an Abbreviated New Drug Application ("ANDA No. 200816") to the FDA for its generic version of Takeda's Prevacid® SoluTab™, Takeda filed a lawsuit in this Court (the "2010 Lawsuit") alleging that Zydus' product infringed three of the four patents-in-suit here ('994, '942, '292). Zydus counter-claimed for a declaratory judgment of non-infringement on the fourth patent ('485), as well as the other three. By filing the 2010 Lawsuit, Takeda then benefitted from the Hatch-Waxman Act's automatic thirty month stay of FDA approval of Zydus' product. Prior to trial in the 2010 Lawsuit, however, Takeda dismissed its claims *with prejudice* with respect to Patents '942 and '292 and entered into a binding covenant not to sue on Patent '485. Following a trial with respect to Patent '994, and an appeal to the Federal Circuit, Zydus' product was found to literally not infringe '994. In particular, the Federal Circuit held that Zydus' product did not infringe '994 because the fine granules in the product did not have an average particle diameter of 400 μm or less, which, according to the Federal Circuit, is how the term in Patent '994 must be construed—400 μm is thus a hard cut-off above which Zydus' product would not infringe. On remand, the district court dismissed the action, declaring "[t]here is no dispute that under the claim

construction directed by the Federal Circuit, Defendant's ANDA product does not literally infringe the claim at issue." *Takeda Pharm. Co., Ltd. v. Zydus Pharm. USA Inc.*, No. CV 10-1723 (JAP), 2014 WL 12629965, at *2 (D.N.J. Oct. 16, 2014).

5. The '942 and '292 Patents claim fine granules having an average particle diameter of 300 to 400 μm and the '485 Patent claims a preparation using such fine granules. All of the patents-in-suit are bound by the same hard cut-off of 400 μm. Thus, the parties' dispute with respect to whether Zydus' product infringed the same patents-in-suit at issue here was litigated and fully resolved in Zydus' favor by October 2014.

6. In October 2014, to address the FDA's questions about certain attributes of Zydus' product that had nothing to do with the claims in Takeda's patents-in-suit, Zydus filed an amended ANDA No. 200816, which reflected changes to the formulation of its product relating solely to inactive excipients. These changes did not have any material effect on Zydus' product, nor did they affect the prior non-infringement findings in any way. On January 3, 2018, after the FDA indicated to Zydus that it was prepared for approval of Zydus' amended ANDA No. 200816, Zydus sent a letter to Takeda notifying it of amended ANDA No. 200816, which described in detail the bases for non-infringement of Takeda's patents.[1] In the same letter, Zydus offered Takeda access to the amended ANDA so that Takeda could review it to verify that Zydus' product would in no way infringe Takeda's patents. Takeda had no objectively reasonable basis to conclude the Zydus product infringes any Takeda patents, especially given the outcome of the 2010 Lawsuit and, as described below, Takeda's purposeful failure, despite Zydus' repeated invitations, to inspect Zydus' amended ANDA prior to filing its current patent-infringement suit.

[1] FDA's general practice is to require re-notification of non-infringement to the New Drug Application holder and patent owner(s) any time an ANDA applicant amends its application to reformulate the drug product, even if the reformulation is immaterial.

7. *Second*, Takeda's suit is objectively baseless because Takeda purposefully failed to investigate before filing whether Zydus' product actually infringed any of the patents-in-suit; instead, it specifically rebuffed repeated invitations from Zydus for Takeda to confirm as much by reviewing the amended ANDA. These refusals to conduct even the most basic pre-litigation investigation readily available to Takeda lay bare that the true purpose and intended effect of Takeda's lawsuit is not to prevent any patent infringement, but purely to delay FDA approval of Zydus' product in order to protect Takeda's monopoly, gouge consumers, and injure Zydus.

8. Under the Hatch-Waxman Act, upon receipt of Zydus' January 3, 2018 letter regarding amended ANDA No. 200816, Takeda had 45 days to file a lawsuit for patent infringement, during which period the FDA could not approve Zydus' ANDA absent Takeda's indication that it would not file suit.

9. Takeda waited nearly to the very last day of this 45-day period to file this lawsuit, and *not* because they were investigating whether the infringement claims had any merit. To the contrary, on at least *eight* occasions between January 3, 2018 and February 12, 2018, the date Takeda filed their current lawsuit, Zydus offered Takeda access to the amended ANDA No. 200816 so that Takeda could verify for itself that Zydus' product did not infringe the patents-in-suit. Zydus also detailed to Takeda that the only changes to the product were immaterial and had nothing to do with the claims in Takeda's patents. Zydus further specified that, consistent with the Federal Circuit's 2014 ruling and previous resolution of Takeda's infringement claims, the only changes to Zydus' ANDA were the addition of excipients, and that the ANDA still requires common pellets for Lansoprazole delayed-release, orally-disintegrating tablets, 15 mg and 30 mg, to possess an average particle diameter of *not less than 440 μm*—in other words, that the basis for the finding of non-infringement in the 2010 Lawsuit applied with equal force to Zydus' product found in the amended ANDA.

10. Egregiously, Takeda never responded to *any* of Zydus' communications between January 3 and February 4, 2018, let alone accept Zydus' repeated invitations to review the amended ANDA to confirm the non-infringing nature of Zydus' product. Had Takeda done so, it would have quickly determined that Zydus' product does not infringe any of the patents-in-suit, the same conclusion that ensued from the 2010 Lawsuit and the only objectively reasonable assessment under the facts. On February 5, 2018, Takeda finally responded to Zydus' eight emails for the first time, but not substantively, and it did not address, let alone accept, Zydus' repeated offers for it to review the amended ANDA.

11. Instead, on February 12, 2018, knowing that it faced the imminent prospect of generic competition from Zydus and loss of its monopoly power, Takeda filed a sham lawsuit against Zydus for alleged infringement of the exact same four patents that were either determined or conceded as non-infringed in the 2010 Lawsuit.

12. Even after filing its current lawsuit, Takeda steadfastly has refused to evaluate whether Zydus' product infringes any of the patents-in-suit, or even to substantively respond to Zydus' repeated offers to inspect the Zydus ANDA. To date, Zydus has made this offer at least *eleven* times. Thus, even if Takeda might have believed it had a reasonable basis to initiate the lawsuit—which they did not and could not, as highlighted by the facts in this Counterclaim—its ongoing prosecution of this suit is itself objectively baseless and constitutes further unlawful anticompetitive conduct.

13. The reason for Takeda's sham litigation is obvious: its instant lawsuit has forestalled and continues to forestall generic competition by Zydus by attempting to trigger an automatic 30-month stay on the FDA's authority to approve Zydus' product. But for this anticompetitive conduct, Zydus would have launched a therapeutically equivalent generic product—at a price substantially lower than Takeda's pricing—as soon as the FDA approved its ANDA, which would have occurred, at the very latest, promptly after the 45-day notice period had concluded.

14. Through its unlawful and exclusionary conduct, Takeda has foreclosed competition and unlawfully maintained its monopoly, denying consumers the benefit of lower-cost, therapeutically equivalent, AB-rated generic alternatives, and causing Zydus millions of dollars in competitive injury, before mandatory trebling under the antitrust laws.

II. JURISDICTION AND VENUE

15. This Court has subject matter jurisdiction based upon: 28 U.S.C. §§ l331, l338(a), 1367(a), 2201, and 2202, as well as 15 U.S.C. § 1 *et seq*.

16. This Court has personal jurisdiction over Counterclaim Defendants for the reason that they have consented to personal jurisdiction by commencing an action for patent infringement in this judicial district, as set forth in the Complaint.

17. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b)-(c) and 1400(b), and 15 U.S.C. §§ 15 and 22.

III. THE PARTIES

18. Counter-Defendant Takeda Japan is a Japanese corporation, having a principal place of business at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka, Japan. As part of its business, Takeda Japan is involved in the research, development, and marketing of pharmaceutical products. Takeda Japan manufactures lansoprazole orally disintegrating tablets.

19. Counter-Defendant Takeda Japan is the owner of record of U.S. Patent No. 6,328,994 ("'994 Patent"), U.S. Patent No. 7,431,942 ("'942 Patent"), U.S. Patent No. 7,875,292 ("'292 Patent"), and U.S. Patent No. 7,399,485 ("'485 Patent") (collectively, "the patents-in-suit").

20. Counter-Defendant Takeda U.S.A. is a Delaware corporation, having a principal place of business at One Takeda Parkway, Deerfield, Illinois 60015. As part of its business, Takeda U.S.A. is involved in the research, development, and marketing of pharmaceutical products. Takeda U.S.A. is the registered holder of approved New Drug Application ("NDA") No. 21-428. Takeda

U.S.A. purchases from Takeda Japan, and imports into the United States, lansoprazole orally disintegrating tablets manufactured by Takeda Japan.

21. Counter-Defendant Takeda America is a Delaware corporation, having a principal place of business at One Takeda Parkway, Deerfield, Illinois 60015. Takeda America sells lansoprazole orally disintegrating tablets manufactured by Takeda Japan that it purchases from Takeda U.S.A. to the public in the United States.

22. Counter-Plaintiff Zydus is a corporation organized and existing under the laws of the State of New Jersey, with a principal place of business at 73 Route 31 North, Pennington, New Jersey 08534, and is in the business of, among other things, manufacturing, selling, and marketing generic copies of branded pharmaceutical products throughout the United States, including in this District.

23. Counter-Plaintiff Cadila is a corporation organized and existing under the laws of the Republic of India, with a principal place of business at Zydus Tower, Satellite Cross Roads, Ahmedabad-380015, Gujarat, India, and is in the business of, among other things, manufacturing, selling, and marketing generic copies of branded pharmaceutical products throughout the United States, including in this District.

IV. REGULATORY BACKGROUND

24. The Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 21 U.S.C. §§ 335(b)(2) and 355(j), and 35 U.S.C. § 271(e), establish procedures designed to facilitate and speed competition in prescription drug markets from lower-priced generic drugs, while maintaining incentives for pharmaceutical companies to invest in developing new drugs.

25. A company seeking to market a new pharmaceutical product in the United States must file a New Drug Application ("NDA") with the FDA demonstrating the safety and efficacy of the

product. Products approved following submission of an NDA are referred to as "brand-name drugs" or "branded drugs."

26. To facilitate generic competition, the Hatch-Waxman Act provides that a company seeking to market a generic drug may file an Abbreviated New Drug Application ("ANDA") with the FDA. The ANDA applicant is not required to conduct full clinical trials to demonstrate the safety and efficacy of the proposed generic drug. Instead, it may rely on the approved branded drug's profile for safety and efficacy.

27. The Hatch-Waxman Act also provides a framework for the holders of pharmaceutical patents to enforce their patents against generic competitors. When filing an ANDA, a generic manufacturer must certify whether its generic drug will infringe any patents listed in the FDA-published "Orange Book" as being associated with the branded drug. 21 U.S.C. § 355(j)(2)(A)(vii). For each listed patent, the ANDA applicant must make one of four possible certifications (respectively, the Paragraph I, II, III, and IV Certifications): (I) that no patent information on the branded drug has been submitted to the FDA; (II) that the patent has expired; (III) that the patent will expire on a stated date; or (IV) that the patent is invalid or will not be infringed by the generic drug. 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV).

28. Along with a Paragraph IV Certification, the applicant must provide notice to the patent holder of its invalidity or noninfringement position. 21 U.S.C. § 355(j)(2)(B)(i). The patent holder has forty-five days after receiving that notice to file a patent infringement suit. 21 U.S.C. § 355(j)(5)(B)(iii). Significantly, if an infringement suit is filed, FDA approval of the ANDA is stayed until either thirty months have passed or a court rules that the patent is invalid or not infringed. *Id.*

29. Pharmacies often substitute the branded-drug with a generic equivalent. Many states have "automatic substitution" laws that require pharmacists to substitute "AB-rated" generic versions for prescriptions written for the reference listed drug ("RLD") unless the prescribing physician

specifically requests otherwise. Conversely, generic drugs that are not AB-rated to the reference listed branded drug cannot be automatically substituted for the RLD at the pharmacy level.

V. FACTUAL AND PROCEDURAL BACKGROUND

A. Prevacid® SoluTab™

30. On August 30, 2002, the FDA approved NDA No. 21-428 for lansoprazole delayed release orally disintegrating tablets, 15 and 30 mg. Takeda sells its lansoprazole delayed release orally disintegrating tablets, both 15 mg and 30 mg, under the name Prevacid® SoluTab™.

31. Prescription Lansoprazole ODT is used to treat gastroesophageal reflux disease ("GERD") in a specific subset of patients for whom other treatments are not a practical option. Prescription Lansoprazole ODT treats GERD by decreasing the amount of acid produced by the stomach. The ODT formulation allows the tablet to disintegrate in a patient's mouth leaving behind thousands of coated granules, which are then swallowed and released into the bloodstream. This feature distinguishes Prescription Lansoprazole ODT from other GERD treatments, including other products containing the active ingredient lansoprazole, and is especially important for patients who cannot easily swallow pills in tablet form.

32. Prevacid® SoluTab™ is approved for use in adults and pediatric patients 1 year of age and older. Prevacid® SoluTab™ is only available by prescription. Takeda knew when it filed this lawsuit that Prevacid® SoluTab™ was the only Prescription Lansaprazole ODT Product approved for both adults and pediatric patients, and there was no AB-rated therapeutically equivalent generic alternative. In 2017, Takeda's sales of Prevacid® SoluTab™ in the United States exceeded $184 million, which accounted for 100% of all sales of Prescription Lansoprazole ODT Products.

B. The '994, '942, '292, and '485 Patents

33. On December 11, 2001, the United States Patent and Trademark Office ("PTO") issued the '994 Patent, entitled "Orally Disintegrable Tablets," to Takeda Chemical Industries, Ltd.

(now Takeda Pharmaceutical Company Ltd.). The '994 Patent claims "[a]n orally disintegrable tablet which comprises (i) ***fine granules*** having an average particle diameter of 400 μm or less, which fine granules comprise a composition coated by an enteric coating layer comprising a first component which is an enteric coating agent and a second component which is a sustained-release agent, said composition having 10 weight % or more of an acid-labile physiologically active substance that is lansoprazole and (ii) an additive wherein said tablet having a hardness strength of about 1 to about 20 kg, is orally disintegrable." United States Patent No. 6,328,994 (emphasis added).

34. On July 15, 2008, the PTO issued the '485 Patent, entitled "Rapidly Disintegrable Solid Preparation," to Takeda. The '485 Patent claims "[a] method for preparing a rapidly disintegrable tablet comprising producing ***fine granules*** containing lansoprazole, said granules having a core and at least one layer coating said core, blending said fine granules with a sugar and a low-substituted hydroxypropylcellulose having 5% to less than 7% by weight of hydroxypropyl groups . . ." United States Patent No. 7,399,485 (emphasis added).

35. On October 7, 2008, the PTO issued the '942 Patent, entitled "Orally Disintegrable Tablets," to Takeda. The '942 Patent is a continuation of the patent application that resulted in the '994 Patent. It claims "[a]n orally disintegrable tablet which comprises (i) ***fine granules*** having an average particle diameter of 300 to 400 μm." United States Patent No. 6,328,994 (emphasis added).

36. On January 25, 2011, the PTO issued the '292 Patent, entitled "Orally Disintegrable Tablets," to Takeda. The '292 Patent is a continuation of the patent applications that resulted in the '994 and the '942 Patents. It claims "[a]n orally disintegrable tablet which comprises (i) fine granules having an average particle diameter of 300 to 400 μm." United States Patent No. 7,875,292 (emphasis added).

C. Takeda's Claims Against Zydus Regarding Patents '994, '942, '292 and '485 Have Been Litigated and Resolved In Zydus' Favor

37. In February 2010, Zydus submitted to the FDA ANDA No. 200816 seeking approval to manufacture a generic version of Takeda's product, lansoprazole delayed release orally disintegrating tablets, 15 and 30 mg.

38. On February 19, 2010, Zydus sent a letter to Takeda notifying it of ANDA No. 200816, including a Paragraph IV Certification that no valid, enforceable claim of the '994 Patent, '942 Patent, or '485 Patent would be infringed by the commercial manufacture, use, or sale of the lansoprazole delayed release orally disintegrating tablet products described in ANDA No. 200816.

39. On April 5, 2010, Takeda filed suit in this District against Counter-Plaintiffs alleging infringement of the '994 Patent, '942 Patent, and another patent that has since expired and is not relevant to the present matter. *See Takeda Pharmaceutical Co. Ltd. et al. v. Zydus Pharmaceuticals (USA) Inc. et al.*, No. 10-01723-JAP-TJB (D.N.J.). Takeda affirmatively chose not to include the '485 Patent in its 2010 Lawsuit and at no time alleged that the '485 Patent would be infringed by the commercial manufacture, use, or sale of the lansoprazole delayed release orally disintegrating tablet products described in ANDA No. 200816. Zydus, however, filed counter-claims seeking a declaratory judgment that its product did not infringe any valid and enforceable claim of the '485 patent, or other Takeda patents listed in the Orange Book, and that such patents in any event are invalid. Thereafter, Zydus invited Takeda to review a copy of ANDA No. 200816 to confirm that Zydus was not infringing the '485 patent. Takeda, already enjoying the 30-month stay of FDA approval of Zydus' product based on its claim of infringement of other Takeda patents, reviewed the ANDA. On or about July 22, 2010, it entered into a binding covenant not to sue Zydus for infringement of the '485 patent based on manufacture, use, or sale of Zydus products that are the subject of and described in the ANDA.

40. On July 26, 2011, the day after the PTO issued the '292 Patent, Takeda amended its complaint and added a count alleging infringement of the '292 Patent.

41. On March 25, 2013, Takeda agreed to dismiss all claims with respect to Patents '942 and '292 *with prejudice*. By the time trial commenced on March 26, 2013, only an infringement claim of the '994 Patent remained at issue.

42. On February 20, 2014, on appeal from the district court's decision, the Court of Appeals for the Federal Circuit found that Zydus' product did not literally infringe the '994 Patent. The Federal Circuit concluded that the proper construction of the claim term "**fine granules**" as defined in the '994 Patent was "fine granules having an average particle diameter of ***precisely*** 400 μm or less." *See Takeda Pharm. Co. v. Zydus Pharm. USA, Inc.*, 743 F.3d 1359 (Fed. Cir. 2014) (emphasis added) ("the specification contrasts the 'fine granules' of the claimed invention with larger 'conventional' granules, which it defines as '400 μm or more of average particle diameter' . . . That clear dividing line between the 'fine' granules of 400 μm or less (which avoid a feeling of roughness in the mouth) and 'conventional' granules of 400 μm or more (which do not) disappears if the 'fine granules' are construed as incorporating a 10% deviation."). "Takeda measured Zydus' ANDA product as having an average particle diameter of 412.28 μm—well outside the claimed range." *Id.* The Court of Appeals further concluded "there can be no dispute that Zydus' ANDA product does not literally infringe claim 1 of the '994 patent." *Id.* Notably, the Federal Circuit found "nowhere does the specification suggest that an average particle size of greater than 400 μm could achieve the inventive result." *Id.*

43. Takeda appealed the Federal Circuit's decision to the Supreme Court. On December 1, 2014, the Supreme Court denied certiorari. *See Takeda Pharm. Co. v. Zydus Pharm. USA, Inc.*, 135 S. Ct. 711, 190 L. Ed. 2d 440 (2014).

44. The Federal Circuit remanded the case for further proceedings consistent with its opinion. On remand, this Court found "[t]here is no dispute that under the claim construction directed by the Federal Circuit, [Zydus'] ANDA product does not literally infringe the claim at issue [the '994 Patent]," nor did it find the doctrine of equivalents in play. *Takeda Pharm. Co., Ltd. v. Zydus Pharm. USA Inc.*, No. CV 10-1723 (JAP), 2014 WL 12629965, at *2 (D.N.J. Oct. 16, 2014). Judgment accordingly was entered in favor of Zydus.

D. Takeda Had No Objective Basis to Believe that Zydus' Amended ANDA No. 200816 Contained Any Changes That Would Affect The Federal Circuit and District Court's Disposition of its Infringement Claims

45. Zydus subsequently submitted to the FDA an amendment to ANDA No. 200816. The only difference between ANDA No. 200816 and the amended ANDA No. 200816 is the immaterial addition of inactive substances ("excipients") to the formulation, which Zydus added to address certain issues raised by the FDA regarding administration of the product.

46. On January 3, 2018, after the FDA indicated to Zydus that it was prepared to approve Zydus' ANDA No. 200816, as amended, Zydus sent a letter notifying Takeda of the amended ANDA No. 200816, including another Paragraph IV Certification. Zydus' letter detailed some of the reasons why there could be no infringement of the patents-in-suit, including:

A. The Federal Circuit already determined Zydus' ANDA Product could not infringe the asserted claims of the '994 Patent because it has fine granules having an average particle diameter above the hard cut-off of precisely 400 μm for average particle diameter. The only other independent claim in the '994 Patent also asserts fine granules having an average particle diameter of 400 μm or less and is thus limited by such hard cut-off. Zydus' ANDA No. 200816 requires common pellets for Lansoprazole Delayed-release, orally-disintegrating tablets, 15 mg and 30 mg to possess a d_{50} of not less than 440 μm well above the hard cut-off. In-Process Specification of ANDA No. 200816, p. 8.

B. The '942 and '292 patents are continuation applications of the application that led to the '994 patent, and thus have a common specification, and like the '994 patent have independent claims limited to fine granules having an average particle diameter at or below the hard cut-off.

C. Takeda granted Zydus a covenant-not-to-sue with respect to the '485 patent in respect of ANDA 200816. Zydus' amended ANDA does not alter in any way its formulation to include a low-substituted hydroxypropylcellulose having 5% to less than 7% by weight of hydroxypropyl groups.

47. Because Zydus' product has fine granules having an average particle diameter of *greater than* 400 μm, the basis for the Federal Circuit's determination that Zydus' product does not infringe necessarily applies with equal force to all four patents-in-suit.

48. Following its January 3, 2018 letter and Paragraph IV Certification, Zydus repeatedly attempted to provide the amended ANDA to Takeda. Specifically, between January11 and February 5, 2018, Zydus representatives wrote to Takeda representatives no less than ***eight times*** offering to provide the amended ANDA immediately upon execution of a standard agreement regarding access to confidential information ("OCA"):

A. "Please let[] us know at the earliest whether your client wants any changes to the Offer for Confidential Access Agreement appended to its notice letter regarding Lansoprazole ODT. We are ready to produce the ANDA upon receipt of the same." *See* Email from Steven Moore to Eric Lobenfeld dated January 11, 2018, attached hereto as Exhibit A;

B. "Hope you had a good holiday. Please let us know at the earliest if you would like to have any changes to the OCA. We have the ANDA ready for production." *See* Email from Steven Moore to Eric Lobenfeld dated January 16, 2018, attached hereto as Exhibit A;

C. Just another reminder. We have the ANDA ready to be produced (left a call on your phone)." *See* Email from Steven Moore to Eric Lobenfeld dated January 17, 2018, attached hereto as Exhibit A;

D. "Please see below – we are more than willing to alter the OCA as you may request." *See* Email from Steven Moore to Eric Lobenfeld dated January 18, 2018, attached hereto as Exhibit A;

E. "Sorry for being a pest – Left you another call. Zydus is pushing me to get this ANDA over to you. Please call to discuss the OCA." *See* Email from Steven Moore to Eric Lobenfeld dated January 22, 2018, attached hereto as Exhibit A;

F. "Just another reminder – we have the ANDA for lansoprazole ODT ready to review. It should not take long to make any changes to the OCA you may request." *See* Email from Steven Moore to Eric Lobenfeld dated January 24, 2018, attached hereto as Exhibit A;

G. "We are nearly 30 days into the 45-day period, and Takeda still has not made any efforts to negotiate the OCA under which we will provide our ANDA to Takeda. This ANDA will clearly show that any changes made to Zydus' formulation have no relation to the patents held by Takeda, irrespective of the covenant not to sue and the stipulations not to sue filed in the case against Zydus. In particular the ANDA will confirm that Zydus granules still remain with an average particle diameter which is significantly above that found by the Federal Circuit to be non-infringing." *See* Email from Steven Moore to Eric Lobenfeld dated January 29, 2018, attached hereto as Exhibit A;

H. "Please let me know if Takeda would like to obtain a copy of our ANDA pursuant to the OCA. I understood from your last email that you would be discussing with them the issue last week." *See* Email from Steven Moore to Eric Lobenfeld dated February 5, 2018, attached hereto as Exhibit A.

Several telephone calls were also made in further attempt to cause Takeda to review Zydus' ANDA, but to no avail.

49. In response to these offers, Takeda refused to engage at all, let alone obtain the Zydus ANDA to perform the most basic pre-lawsuit investigation. To the contrary, Takeda went out of its way to stick its head in the sand and avoid obtaining evidence that would have further debunked any lawsuit alleging infringement of the patents-in-suit.

50. On February 12, 2018, Takeda filed the instant patent-infringement lawsuit asserting that Zydus' product infringes the '994 Patent, '942 Patent, '292 Patent, and '485 Patent. The lawsuit is, in every material respect, identical to its 2010 Lawsuit and a blatant, unlawful attempt to manipulate the 30-month stay provision in the Hatch-Waxman Act.

51. After the Complaint was filed, Zydus *again* (for at least the ninth time) offered to provide the ANDA to Takeda. *See* Email from Steven Moore to Eric Lobenfeld dated February 13, 2018, attached hereto as Exhibit B. Takeda, however, again did not respond to Zydus' offer to provide access, merely asking instead whether Zydus' counsel would accept service of its Complaint. *See* Email from Eric Lobenfeld to Steven Moore dated February 14, 2018, attached hereto as Exhibit B.

52. On February 21, 2018, Zydus sent Takeda a draft protective order and once again (for at least the tenth time) offered to provide Takeda the amended ANDA. *See* Email from Steven Moore to Eric Lobenfeld dated February 21, 2018, attached hereto as Exhibit C; *see also* Email from Steven Moore to Eric Lobenfeld dated February 27, 2018, attached hereto as Exhibit D. Again, no response from Takeda.

53. On March 1, 2018, Zydus sent an additional reminder of the ten previous offers and again reminded Takeda that Zydus wanted to provide Takeda the amended ANDA as quickly as possible. *See* Email from Steven Moore to Eric Lobenfeld dated March 1, 2018, attached hereto as Exhibit E. Yet again, no response from Takeda.

54. To date, Takeda has not responded to Zydus' repeated offers to provide access to the ANDA, as amended, and has steadfastly refused to investigate whether its instant lawsuit has a scintilla of merit. The reason is obvious: Takeda's claims have already been fully litigated or otherwise resolved and it knows Zydus' product does not infringe. Instead, Takeda initiated, and continues to prosecute, this meritless patent-infringement lawsuit for the sole purpose of delaying entry of Zydus' competing generic product and preserving its stream of monopoly profits at the expense of U.S. consumers.

E. But For Takeda's Baseless Lawsuit, Zydus Would Have Launched a Lower-Cost, Therapeutically Equivalent Generic Version

55. If Takeda had not filed this baseless lawsuit, Zydus would have been able to launch a therapeutically equivalent, AB-rated generic version of Prescription Lansoprazole ODT as soon as the FDA approved its amended ANDA, which would have occurred promptly after the 45-day notice period expired, if not before.

56. Zydus planned to price its generic version of Prescription Lansoprazole ODT at a substantial discount compared to Prevacid® SoluTab™, providing consumers with a lower-cost, but therapeutically identical, alternative to branded Prevacid® SoluTab™.

57. Generic drugs are typically sold at substantial discounts from the price of the branded reference-listed drug ("RLD"). The first AB-rated generic drug that enters the market is generally priced at a significant discount to the RLD and, as additional AB-rated generic drugs enter the market, generic drug prices continue to fall.

58. Competition from generic drugs generates large savings for consumers. The Generic Pharmaceutical Association reported that use of generic versions of brand-name drugs saved the U.S. healthcare system $217 billion in 2012 alone.

59. Absent Takeda's unlawful anticompetitive conduct, Zydus likely would have captured a significant volume of Prescription Lansoprazole ODT sales within days of FDA approval. As with prior generic products that Zydus has launched in the United States, Zydus expected that pharmacies and other customers would place large orders of Zydus' generic product on the first day it became available, as these customers would have an incentive to build up a sufficient inventory of generic Prescription Lansoprazole ODT to meet demand.

VI. TAKEDA'S LAWSUIT IS BASELESS

60. Takeda's exclusionary actions in filing and prosecuting this baseless patent-infringement lawsuit constitute wrongful and unlawful exclusionary conduct. Its conduct has the purpose and effect of blocking competition by delaying the entry of lower-cost, therapeutically equivalent, AB-rated generic substitutes for branded Prevacid® SoluTab™.

61. As explained above, Takeda's lawsuit is objectively baseless on multiple grounds. The '994, '942, and '292 Patents have already been fully litigated and/or resolved in Zydus' favor.

62. Takeda's refusal to investigate the validity of its claims and purposeful avoidance of any such investigation before and after the filing of this lawsuit constitutes bad faith and is itself evidence of Takeda's anticompetitive conduct.

63. Along with Zydus' Paragraph IV Certification, it provided Takeda with a detailed statement explaining why Zydus' amended ANDA and its lansoprazole delayed release orally disintegrating tablets do not infringe the patents-in-suit. Zydus' granules still remain with an average particle diameter that is significantly above that found by the Federal Circuit to be non-infringing. Zydus also offered to provide Takeda with technical material from the lansoprazole delayed release orally disintegrating tablets to further demonstrate lack of infringement.

64. Takeda continues to prosecute its infringement claims without an objectively reasonable basis for doing so and despite contrary evidence made available to it by Zydus.

65. The undisputed facts, readily apparent from the face of Zydus' amended ANDA No. 200816 and the prosecution history, show that Zydus' product does not infringe the '994 Patent, '942 Patent, the '292 Patent, or the '485 Patent.

66. No reasonable litigant, especially one having had access to the information Zydus repeatedly offered to provide Takeda, along with the prosecution history of these patents, could reasonably expect to prevail on the merits of a claim that Zydus' product infringes any of the patents-in-suit. Takeda was fully aware of the prosecution history of the patents-in-suit—and that Zydus' product could not have infringed on those patents—and made the conscious decision to refuse to investigate the validity of their claims. Takeda therefore had no probable cause for initiating the lawsuit. Takeda commenced the lawsuit against Zydus with the subjective and wrongful intent to interfere directly with the business relationships of Zydus. Takeda filed the lawsuit solely to achieve an anticompetitive objective and maintain its monopoly position through improper manipulation of the judicial process.

VII. TAKEDA'S MONOPOLY POWER AND THE RELEVANT MARKET

67. Takeda's monopoly power is demonstrated by direct evidence of its ability to price well above competitive levels in the absence of an AB-rated generic version of its Prescription Lansoprazole ODT Product. For example, on information and belief, Takeda substantially raised prices for Prevacid® SoluTab™ after a therapeutically equivalent, AB-rated generic Lansoprazole ODT Product made by Teva was withdrawn from the market in 2011. It has continued to price at supracompetitive levels ever since. Had Takeda not possessed monopoly power, it would have been unable to significantly raise prices of its product after the exit of Teva's generic version.

68. The relevant product market in which to assess the anticompetitive effect of Takeda's conduct is the market for lansoprazole delayed release orally disintegrating tablets approved by the FDA for prescription-use in adult and pediatric patients, 15 mg and 30 mg ("Prescription Lansoprazole ODT Products"), including Prevacid® SoluTab™ and therapeutically equivalent, AB-rated prescription lansoprazole delayed release orally disintegrating products.

69. The relevant geographic market is the United States. The FDA's elaborate regulatory process for approving drugs for sale in the United States, and the fact that the marketing, sales, and distribution of pharmaceuticals occurs on a nationwide basis, establishes the boundaries of the geographic market.

70. For purposes of this litigation, the market for the sale of Prescription Lansoprazole ODT Products in the United States (the "Relevant Market") constitutes a relevant market.

71. Prescription Lansoprazole ODT Products, including Prevacid® SoluTab™, are not reasonably interchangeable with other products due to, among other factors, price, use, qualities, characteristics, and/or distinct customers or end uses.

72. For example, Prescription Lansoprazole ODT Products, including Prevacid® SoluTab™, have unique features that distinguish them from other medications used to treat GERD,

particularly for certain subsets of patients, such as children, the elderly, and other patients who may have trouble swallowing. Products approved only for use by particular subsets of patients, such as adults, are not reasonably interchangeable for products approved for use by other subsets, such as pediatric patients.

73. Takeda itself represented to the Supreme Court that Prevacid® SoluTab™ is functionally distinct from other GERD treatments, explaining that it is "the only one of its kind available in an orally disintegrating tablet. That means the patient can take the drug by allowing it to disintegrate in her mouth, rather than by swallowing or chewing it. The tablet dissolves in less than a minute, leaving behind thousands of tiny granules; those granules make their way through the stomach to the small intestine, where the lansoprazole is released and absorbed into the bloodstream. For children, the elderly, and other patients who may have trouble swallowing, an orally disintegrating tablet is a significant improvement in treatment for acid reflux." Takeda's Petition for a Writ of Certiorari, *Takeda Pharmaceutical Co. Ltd. et al. v. Zydus Pharmaceuticals (USA) Inc. et al.*, 2014 WL 4199261 (U.S.) (internal citations omitted).

74. The generic Prescription Lansoprazole ODT Products developed by Zydus would be, upon final FDA approval, therapeutically equivalent with and AB-rated to, and thus reasonably interchangeable with, and have a strong cross-elasticity of demand with, their corresponding Prevacid® SoluTab™ formulations. Thus, Zydus' 15 mg generic Prescription Lansoprazole ODT Product would have high cross-elasticity of demand with Prevacid® SoluTab™ of the same dosage strength and Zydus' 30 mg generic Lansoprazole ODT Product would have high cross-elasticity of demand Prevacid® SoluTab™ of the same dosage strength.

75. By contrast, other GERD treatments, including other products containing the active ingredient lansoprazole, are not reasonably interchangeable with, and have a relatively low cross-elasticity of demand with, lansoprazole ODT.

76. Prevacid® SoluTab™ is approved for use in adults and pediatric patients 1 year of age or older. Prevacid® SoluTab™ is available only by prescription.

77. A small, but significant, non-transitory price increase on Prescription Lansoprazole ODT Products above competitive levels would not cause a loss of sales to other therapies sufficient to make the price increase unprofitable.

78. Prevacid® SoluTab™ price levels do not exhibit significant, positive cross-elasticity of demand with respect to prices of any product other than Prescription Lansoprazole ODT Products.

79. There are substantial barriers to entry into the market for Prescription Lansoprazole ODT Products, including FDA's regulatory requirements and the substantial time and expense required to develop an ANDA for a generic product therapeutically equivalent and AB-rated to Prevacid® SoluTab™.

80. Takeda possesses monopoly power in the Relevant Market, as evidenced by, among other factors, its prior pricing actions and its dominant market share.

VIII. ANTICOMPETITIVE EFFECTS OF TAKEDA'S CONDUCT

A. Harm to Competition

81. Takeda's wrongful filing and maintenance of the litigation is exclusionary and unreasonably restrains competition. Takeda is abusing and manipulating the Hatch-Waxman regime through the wrongful filing and maintenance of the litigation for exclusionary and anticompetitive purposes, with the direct and intended effect that FDA's approval of Zydus' ANDA will be improperly delayed, to the detriment of Zydus and consumers alike.

82. But for the wrongful filing and maintenance of the lawsuit, the FDA would have approved Zydus' application promptly following expiration of the 45-day notice period on February 12, 2018, if not before. Zydus has substantial experience submitting applications to FDA and obtaining

approval to sell its pharmaceutical products in the United States. This experience includes ANDA products.

83. The only remaining impediment to approval of Zydus' ANDA is the 30-month stay triggered by Takeda's baseless lawsuit. After approval, Zydus would have sold its product at a substantial discount compared to the prices for branded Prevacid® SoluTab™, resulting in enormous savings to consumers who depend on Prescription Lansoprazole ODT Products.

84. As a direct and proximate result of Takeda's improper and exclusionary conduct, consumers in the United States have paid and will continue to pay higher prices for Prescription Lansoprazole ODT Products. So long as Takeda continues to prosecute the lawsuit, and unless a court renders an earlier decision in Zydus' favor, the mere pendency of the lawsuit will block FDA from approving Zydus' application until the patents-in-suit expire in November 2019.

B. Harm to Zydus

85. As a direct and proximate cause of Takeda's filing and prosecution of the sham litigation, Zydus has suffered and will continue to suffer significant competitive harm. Takeda's wrongful and exclusionary conduct has caused a substantial delay in the approval of Zydus' application, causing a substantial and unjustified delay in the commencement of Zydus' sales of Prescription Lansoprazole ODT Products.

86. Absent Takeda's anticompetitive conduct, Zydus projects that it would have sold tens of millions of dollars in Prescription Lansoprazole ODT Products within 2018 alone after receiving FDA approval to fill initial orders for generic Prescription Lansoprazole ODT Products.

87. Due to Takeda's wrongful conduct, Zydus has suffered the following competitive harms:

A. LOSS of tens of millions of dollars of sales and profits due to being foreclosed from selling in the Relevant Market to date;

B. LOSS of future sales and profits due to being foreclosed from selling in the Relevant Market; and

C. LOSS of valuable customer goodwill and competitive advantage from being foreclosed from selling in the Relevant Market.

88. These injuries with which Zydus is further threatened are directly and proximately caused by Takeda's exclusionary conduct in filing and maintaining the sham lawsuit, erecting artificial and improper barriers to the approval and sale of Zydus and Cadila's lansoprazole delayed release orally disintegrating tablets.

89. These injuries that Zydus has incurred, and continues to be threatened with due to Takeda's wrongful and exclusionary conduct, constitute antitrust injury.

COUNT I

DECLARATORY JUDGMENT OF LITERAL NONINFRINGEMENT OF ALL CLAIMS OF U.S. PATENT NO. 6,328,994 ("'994 PATENT"), U.S. PATENT NO. 7,431,942 ("'942 PATENT"), U.S. PATENT NO. 7,875,292 ("'292 PATENT"), AND U.S. PATENT NO.7,399,485 ("'485 PATENT") (COLLECTIVELY "THE PATENTS-IN-SUIT")

90. Zydus realleges and incorporate each of the preceding paragraphs as if fully stated herein.

91. Zydus' ANDA Products have not infringed, do not infringe, will not infringe, either literally or under the doctrine of equivalents, and will not contribute to or induce the infringement of any of the claims of the patents, for the detailed reasons set forth in its Notice Letter transmitted to each of the Counterclaim-Defendants, and by judicial estoppel of the Federal Circuit decision in *Takeda Pharm. Co. v. Zydus Pharm. USA, Inc.*, 743 F.3d 1359 (Fed. Cir. 2014) ("the CAFC Opinion").

92. The Federal Circuit in the CAFC Opinion makes clear that its decision on non-infringement was in part based on the patent specification's definition of "fine granules":

"Moreover, the specification confirms that the inventors did not intend to deviate from that

> clear and unambiguous plain meaning. First, **the specification contrasts the 'fine granules' with larger 'conventional' granules, which it defines as '400 µm or more of average particle diameter.'** '994 patent col. 2 ll. 17 – 18. **The specification explains that conventional granules of that size 'produce a feeling of roughness in the mouth'– one of the very problems the claimed invention purports to solve.** *Id.* Col. 2 ll. 16 –17**. That clear dividing line between the 'fine' granules of 400 µm or less (which avoid the feeling of roughness in the mouth) and 'conventional' granules of 400 µm or more (which do not) disappears if the 'fine granules' are construed as incorporating a 10% deviation.** Thus, there can be little doubt that the narrower construction 'most naturally aligns with the patent's description of the invention.' *Renishaw*, 158 F.3d at 1250. **Second, the specification goes on to explain that the maximum particle size is 'practically 425 µm or less,' where 'practically' means that 'the particles may include a small quantity (about 5 weight % or less) of particles whose particle diameter is out of above described range.'** '994 patent col. 5 l. 65 - col. 6 l. 8. Elsewhere, the patent defines 'average particle diameter' to mean the median particle diameter. *See id.* Col. 5 ll. 43-46. **It would be impossible for a tablet to comply with the specification's maximum particle diameter of practically 425 µm (meaning that only 5% of particles have diameters larger than 425 µm) if it had a median particle diameter of 440 µm (meaning that 50% of the particles are larger than 440 µm), as the district court's claim construction would permit."** *Takeda Pharm. Co. v. Zydus Pharm. USA, Inc.*, 743 F.3d 1359 (Fed. Cir. 2014) (emphasis added).

93. The specification of U.S. Patent No. 6,328,994 ("'994 Patent") defines "fine granules" as follows:

> "Conventional granules have large particle diameters, which results in inferior workability when dispensing, and also results in difficulties in consistently adding a regular amount of the granules when they are combined into tablet or capsules. Granules having a large particle diameter (400 µm or more of average particle diameter) also produce a feeling of roughness in the mouth. Accordingly, especially when used in an orally disintegrable tablet, the average particle a diameter of the included granules must be about 400 µm or less, preferably about 350 µm." [col. 2, ll. 11 – 22].
>
> "The "fine granules" have an average particle diameter of about 400 µm or less, preferably 350 µm or less. Preferably; the average particle diameter of the fine granules is 300 to 400 µm. Aside from the average particle diameter of the "fine granules", regarding the maximum particle size, the particle diameter is practically 425 µm or less, and preferably practically 400 µm or less. Preferably, the particle diameter is practically 300 to 400 µm or less." [col. 12; ll. 58 - 65].

94. U.S Patent Nos. 7,431,942 ("'942 Patent") and U.S Patent No. 7,875,292 ("'292 Patent") are continuation applications of U.S. Patent No. 6,328,994 (the "'994 Patent") and therefore contain identical language (albeit at slightly different publication spots) defining the term "fine granules" in their specification, as show below:

U.S. Patent No. 7,431,942

"Conventional granules have large particle diameters, which results in inferior workability when dispensing, and also results in difficulties in consistently adding a regular amount of the granules when they are combined into tablet or capsules. Granules having a large particle diameter (400 μm or more of average particle diameter) also produce a feeling of roughness in the mouth. Accordingly, especially when used in an orally disintegrable tablet, the average particle a diameter of the included granules must be about 400 μm or less, preferably about 350 μm." [col. 2, ll. 15 - 24].

"The "fine granules" have an average particle diameter of about 400 μm or less, preferably 350 μm or less. Preferably; the average particle diameter of the fine granules is 300 to 400 μm. Aside from the average particle diameter of the "fine granules", regarding the maximum particle size, the particle diameter is practically 425 μm or less, and preferably practically 400 μm or less. Preferably, the particle diameter is practically 300 to 400 μm or less." [col. 12; ll. 41 - 48].

U.S Patent No. 7,875,292

"Conventional granules have large particle diameters, which results in inferior workability when dispensing, and also results in difficulties in consistently adding a regular amount of the granules when they are combined into tablet or capsules. Granules having a large particle diameter (400 μm or more of average particle diameter) also produce a feeling of roughness in the mouth. Accordingly, especially when used in an orally disintegrable tablet, the average particle a diameter of the included granules must be about 400 μm or less, preferably about 350 μm." [col. 2, ll. 20 - 29].

"The "fine granules" have an average particle diameter of about 400 μm or less, preferably 350 μm or less. Preferably; the average particle diameter of the fine granules is 300 to 400 μm. Aside from the average particle diameter of the "fine granules", regarding the maximum particle size, the particle diameter is practically 425 μm or less, and preferably practically 400 μm or less. Preferably, the particle diameter is practically 300 to 400 μm or less." [col. 12; ll. 46 - 53].

95. The definition of "fine granules" in the specification of U.S. Patent No. 7,399,485 (which recites a common inventor between all the patents—Toshiro Shimizu) is equivalent:

"In the present invention, 'fine granules' have an average particle diameter of about 400 μm or less, in order that roughness is not felt in the mouth. Preferably, the average particle diameter of the fine granules is 300 to 400 mm.

Aside from the average particle diameter of the above "fine granules", regarding the maximum particle size, the particle diameter is substantially 425 μm or less, and preferably substantially 400 μm or less. Preferably, the particle diameter is substantially 300 to 425 μm, more preferably 300 to 400 μm." [col. 14; ll. 36 - 45]

96. All of the independent claims of U.S. Patent No. 6,328,994 ("'994 Patent"), U.S. Patent No. 7,431,942 ("'942 Patent"), U.S. Patent No. 7,875,292 ("'292 Patent"), and U.S. Patent No. 7,399,485 ("'485 Patent") recite "fine granules" as part of the elements of the claim. Thus, this element is imported into every dependent claim; all claims of the patents-in-suit require fine granules.

97. The Federal Circuit's reasoning as to the '994 patent applies equally to all of the patents-in-suit due to their common definition in the specification of "fine granules." Therefore, none of the patents could reasonably be asserted against Counterclaim-Plaintiffs as would be understood by any party that undertook a reasonable diligence before bringing suit.

98. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq*., Counterclaim Plaintiffs request a declaration from the Court that the manufacture, use, sale, offer for sale, or importation of Counterclaim Plaintiffs' ANDA Product does not infringe any of the claims of the patents-in-suit.

COUNT II
DECLARATORY JUDGMENT OF NONINFRINGEMENT BY THE DOCTRINE OF EQUIVALENTS

99. As noted by the District Count in its October 16, 2014 opinion, "The question during claim construction was whether the particle size limitation in the relevant claim was a hard cutoff (i.e., precisely 400 μm) or whether there was room for error (e.g., 400 μm ± 10%)."

100. The CAFC Opinion determined that 400 μm was a hard cut-off. A hard cut-off does not allow for infringement under the doctrine of equivalents.

101. Moreover, the Federal Circuit Opinion found that: "It would be impossible for a tablet to comply with the specification's maximum particle diameter of practically 425 μm (meaning that only 5% of particles have diameters larger than 425 μm) if it had a median particle diameter of 440 μm (meaning that 50% of the particles are larger than 440 μm)."

102. As relayed to the Counterclaim-Defendants, Counterclaim-Plaintiffs' ANDA's In-Process Specification requires the average particle diameter to be above 440 μm. Therefore, under the specific reasoning of the Federal Circuit in its CAFC Opinion, there is likewise no possibility of infringement under the doctrine of equivalents based on the CAFC Opinion.

COUNT III
SHAM LITIGATION - MONOPOLIZATION
15 U.S.C. §§ 2 AND 26

103. Zydus repeats and incorporates herein by reference its counterclaim paragraphs above.

104. Takeda possesses monopoly power in the Relevant Market.

105. Takeda has engaged in exclusionary and predatory conduct, including without limitation the filing and maintenance of sham litigation.

106. Takeda's wrongful conduct has allowed it to maintain its monopoly power, improperly delaying the entry of Zydus' competitive lansoprazole delayed release orally disintegrating tablet products.

107. Takeda has caused and will continue to cause substantial loss and injury to Zydus due to Takeda's violation of the antitrust laws.

108. Takeda's conduct is the actual and proximate cause of the threatened loss and injury to Zydus.

109. The threatened injury to Zydus results from the anticompetitive nature of Takeda's conduct and constitutes antitrust injury.

110. Takeda's conduct has occurred in interstate commerce, and their threatened future conduct would occur in interstate commerce.

COUNT IV

SHAM LITIGATION - MONOPOLIZATION
N.J. Stat, Ann. §§ 56:9-1

111. Zydus repeats and incorporates herein by reference its counterclaim paragraphs above.

112. In addition to the violations of the Sherman Act, as alleged above, the unlawful acts and conduct of Takeda also violate the New Jersey Antitrust Act.

113. Takeda possesses monopoly power in the Relevant Market.

114. Takeda has engaged in exclusionary and predatory conduct, including without limitation the filing and maintenance of sham litigation.

115. Takeda's wrongful conduct has allowed it to maintain its monopoly power, improperly delaying the entry of Zydus' competitive lansoprazole delayed release orally disintegrating tablet products.

116. Takeda's wrongful conduct has caused and will continue to cause substantial loss and injury to Zydus due to Takeda's violation of the New Jersey Antitrust Act, including lost profits and lost business opportunities in New Jersey.

117. Takeda's conduct is the actual and proximate cause of the threatened loss and injury to Zydus.

118. The threatened injury to Zydus results from the anticompetitive nature of Takeda's conduct and constitutes antitrust injury.

WHEREFORE, Zydus respectfully prays that this Court enter judgment in its favor and against Takeda, and grant the following relief:

A. Declaring that the '994 Patent is not infringed by Zydus' lansoprazole delayed release orally disintegrating tablet products either literally or by doctrine of equivalents;

B. Declaring that the claims of the· '994 Patent are invalid;

C. Declaring that the '942 Patent is not infringed by Zydus' lansoprazole delayed release orally disintegrating tablet products either literally or by doctrine of equivalents;

D. Declaring that the claims of the· '942 Patent are invalid;

E. Declaring that the '292 Patent is not infringed by Zydus' lansoprazole delayed release orally disintegrating tablet products either literally or by doctrine of equivalents;

F. Declaring that the claims of the· '292 Patent are invalid;

G. Declaring that the '485 Patent is not infringed by Zydus' lansoprazole delayed release orally disintegrating tablet products either literally or by doctrine of equivalents;

H. Declaring that the claims of the· '485 Patent are invalid;

I. Declaring this case exceptional and awarding Zydus reasonable attorneys' fees and costs pursuant to 35 U.S.C. § 285 and 28 U.S.C. § 1927;

J. Entering preliminary and permanent injunctive relief enjoining Takeda from continuing with its exclusionary conduct alleged herein, including the continuing maintenance of the lawsuit;

K. Awarding compensatory damages for Zydus' lost sales of generic lansoprazole ODT, trebling those damages pursuant to 15 U.S.C. § 15, and awarding punitive damages and prejudgment interest on the damages, including without limitation the amount trebled;

L. Granting Zydus such other and further relief, including its attorneys' fees and costs, as the Court deems just, proper, and equitable.

Dated: March 29, 2018

Respectfully submitted,

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