

Drug Patent Expiry in the USA - Rise in opportunity for Indian Pharmaceutical Industry

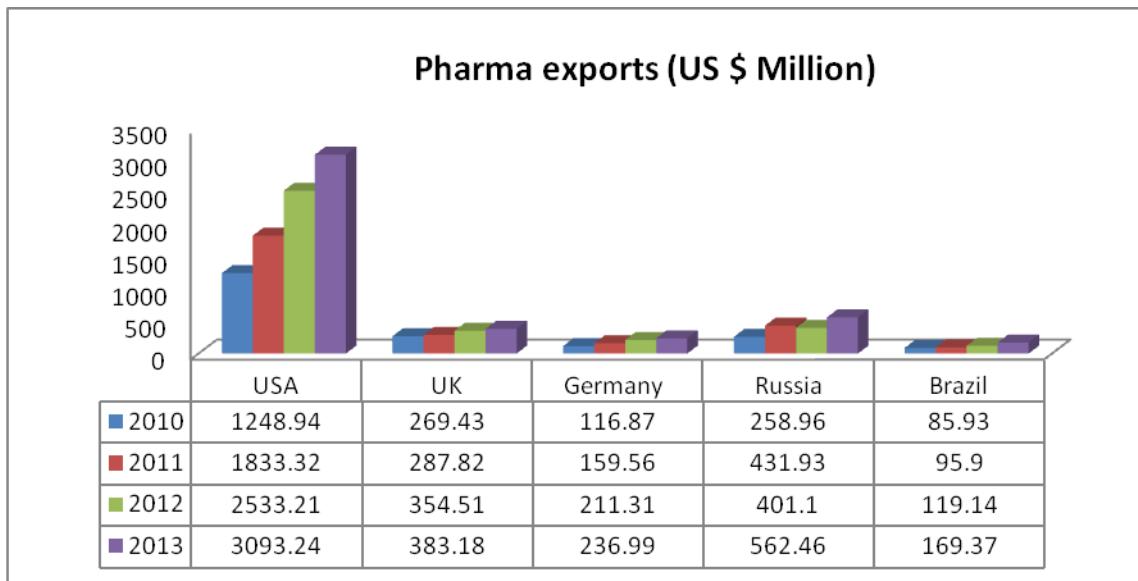
Patent expiration is a great news for not only consumers, with cheaper generics available in the market; but also for the Indian Pharmaceutical industry where generics account for approximately 75% of the total sales. However, extensive scrutiny by USFDA is a major challenge that needs to be addressed.

Indian Pharmaceutical – a burgeoning market:

India's pharmaceutical industry is the world's third-largest market in terms of volume and 13th-largest in terms of value. The lower market share in terms of value can be attributed to the predominance of generic medicines which command lower prices. As per the industry experts; the industry size is expected to increase from US\$ 24.87 billion in 2013 to US\$ 47.88 billion by 2018 at a CAGR of 14%. This growth would be primarily driven by several factors like increasing sales of generic medicines, a greater penetration in rural markets and heightened health awareness. Other factors are increasing affluence, changing lifestyles resulting in higher incidence of lifestyle-related diseases, increasing government expenditure on healthcare such as Central Government Health Scheme (CGHS), National Programme for Healthcare of the Elderly (NPHCE), Rashtiya Arogya Nidhi (RAN) and Janani Suraksha Yojna (JSY). The industry is highly fragmented with more than 20,000 registered manufacturing units, of which approximately 250 large units that constitute about 70% of the total domestic market value.

Domestic consumption accounted for about 47% and export market about 53% of the total production in India in FY13 (refers to the period April 01 to March 31). The domestic market has grown at a CAGR of about 11% in the past five years ended FY13 on the back of increase in lifestyle-related diseases, rising penetration of medical insurance, healthcare infrastructure development, increase in per capita income, etc. On the other hand, export market has grown at a higher CAGR of about 19% in the past five years ending FY13 due to increasing demand for generics on the back of patent expiries of several high-value drugs such as Lipitor (from Pfizer), Boniva (from Roche), Combivir (from GlaxoSmithKline), etc. India exports pharmaceutical products to more than 200 nations and the USA is the largest export market among all countries; being the world's largest generic drug market. Exports to the USA are primarily driven by increased Abbreviated New Drug Applications (ANDAs) approvals by United States Food & Drugs Administration (USFDA) and Indian Pharma companies' ability to produce high-quality medicines at competitive prices.

According to the Commerce Ministry data, the country's pharma exports aggregated US\$ 10.1 billion during FY13 as against US\$ 8.48 billion during FY12. Exports to US accounted for approximately 31% of the total pharmaceutical product export by India during FY13. During 9MFY14, the country's pharma exports aggregated to US\$ 8.04 billion, out of which USA accounted for 31%.



Source: Department of commerce, May 2014

PATENT CLIFF

'Patent Cliff' is a term used to describe the phenomenon of drugs approaching their patent expiration date, resulting in steep decline in sales of the branded drug as generics enter the market place and undercut the price, thereby capturing the market share earlier served by the branded drugs. So there is a twin effect of steep fall in patented drugs prices as also flooding of market by generics.

The following table shows the comparison of prices of a branded drug and its generic version:

Branded Drug	Walmart Price for 30 tablets(US\$)	Generic Version	Walmart Price for 30 tablets(US\$)
Avapro (75 mg)	107.00	Irbesartan	14.14
Caduet (10 mg)	305.00	Amlodipine	129.00
Combivir (150 mg)	481.04	Lamivudine	275.14
Geodon (60 mg)	418.30	Ziprasidone	71.14
Levaquin (500 mg)	792.96	Levofloxacin	14.74
Lipitor (20 mg)	235.34	Atorvastatin	15.8

Source: GoodRX, May 2014

Impact of patent expiration on Indian Pharmaceutical industry

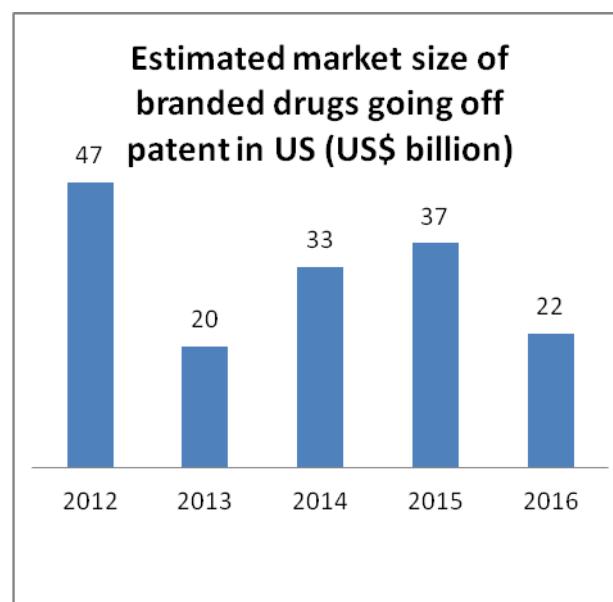
Indian pharmaceutical companies have the opportunity to capitalize on the patent cliff and gain a greater share of the growing generics market. Currently, India accounts for nearly 40% of generic drugs and over-the-counter products and 10% of finished dosages used in the USA.

During 2014-2016; about US\$ 92 billion worth patented drugs are expected to go off patent in the USA as compared with US\$ 65 billion during 2010-12. Indian companies' share in the US generics market has grown rapidly on the back of aggressive ANDA filings and successful pursuit of Para-IV, capitalizing on the patent expiries of blockbuster drugs.

Under the US laws, ANDA filed with a Para-IV certification states that; the generic company which is the first-to-file a para IV, gets 'exclusive rights' to sell the generic version of a branded drug for 180 days, with only the patent holder as the other player in the market. Ranbaxy, Dr Reddy's and Lupin have been the most prolific filers for Para-IVs. Indian players with robust product portfolio, filings and necessary manufacturing infrastructure are well placed to capitalize on this upcoming opportunity.

Key Patent Expirations in US-2014			
Drug	Manufacturer	Market size 2012 (billion \$)	Therapeutic Use
Micardis	Boehringer Ingelheim	2.2	Arrhythmias
Nasonex	Merck & Co	1.3	Rhinitis
Sandostatin LAR	Novartis	1.5	Cytoprotective and supportive care agents
Evista	Lilly	1	Bone Disorder
Nexium	AstraZeneca	3.9	Hyperacidity and Ulcers
Copaxone	Teva	4.3	Multiple sclerosis
Exforge	Novartis	1.3	Hypertension

Source: IHS, January 2014



Source: CARE Research

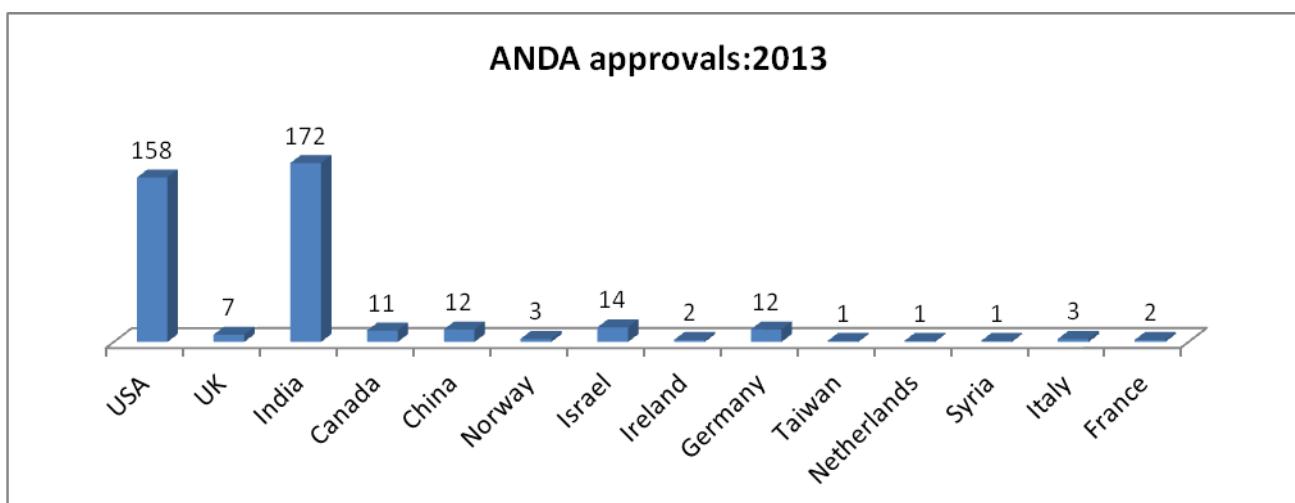
Factors conducive to take on the opportunity

a) Indian companies hold strong Product Filing Pipeline

Indian companies have built a strong pipeline of products to be sold in the US. During 2013, Indian companies secured 39% of total 400 ANDA approvals from USFDA as against 37% of total 476 ANDA approvals during 2012.

Indian companies with strong generic portfolios have been successful in gaining a good foothold in the US pharmaceutical market. The large number of patent expiration in US presents interesting opportunities for Indian generic products manufacturers like Sun Pharmaceuticals, Lupin, Dr. Reddy's, Cipla and others. Thus, generic manufacturers are leveraging this opportunity by increasing their ANDA filings.

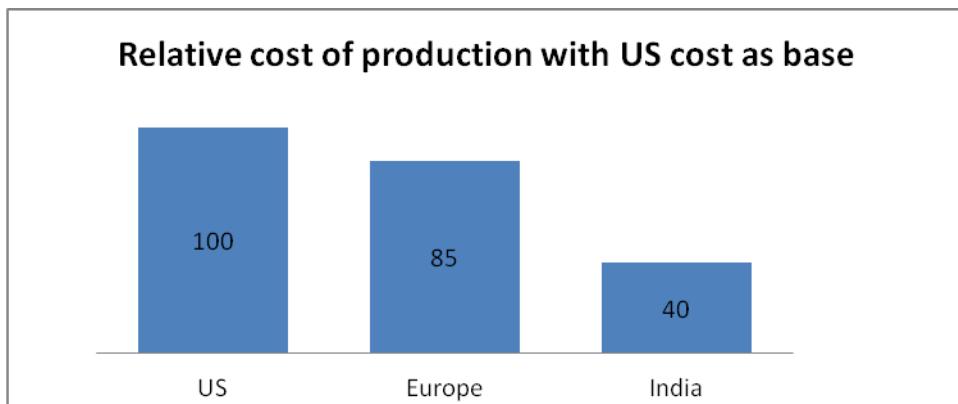
The following figure gives the country-wise distribution of the ANDA approvals in 2013:



Source: CARE Research

b) Low-cost manufacturing base:

Production cost in India is about 50%-60% lower as compared with developed countries like US and Europe because of lower labour cost which is 50%-55% cheaper and capital cost of setting a production plant in India is 40% lower than in western countries. As a result, outside the US, India has the second-highest number of USFDA-approved plants after China. India is home to more than 523 USFDA approved drug manufacturing facilities as on March 31, 2014.



Source: Indian Brand Equity Foundation Report

c) U.S. Healthcare Insurance Reform:

The introduction of The Patient Protection and Affordable Care Act (PPACA) in US signed into law by President Barack Obama in March 2010, which aims at increasing the quality and affordability of health insurance marks a key development in US healthcare insurance reform. This has lead to increase in the proportion of the US population to be covered under medical insurance. As of May 31, 2014, approximately 20 million Americans had gained health insurance coverage under the PPACA and the percentage of uninsured Americans dropped from 18% in 2013 to 13.4% in May 2014. With the market largely catered by Indian companies, this reform is expected to further boost the demand for generic products in the U.S. which will boost the prospects of Indian companies. Already, 86% of prescriptions in 2013 were for generic drugs in US; according to IMS Institute for Healthcare Informatics.

d) Rising M&A activities:

The Indian Pharmaceutical Industry is witnessing increased M&A activities from domestic and international players which will help to boost Research and Development (R&D) expenditure to achieve economies of scale and to strengthen the marketing network. As per the Department of Industrial Policy and Promotion (DIPP), the pharmaceutical sector attracted Foreign Direct Investments of US\$ 11.58 billion during April 2000 to February 2014. Since 2013, there have been 46 M&A deals (including announced and closed deals) in the pharma sector in India. Some of the key M&A deals were:

- Sun Pharma announced to acquire Ranbaxy in April, 2014 for US\$ 4 billion, which will make it the largest pharma company in India and fifth-largest pharma company in the world

- Aurobindo Pharma acquired 100% stake in Andhra-Pradesh based Hyacinths Pharma and 25% stake in Silicon Life Sciences in September 2013
- Competition Commission of India (CCI) has approved Japanese firm Mitsui's proposed takeover of 26.71 % stake in Arch Pharmalabs Ltd in January 2013
- Panacea Biotec Ltd has entered into a strategic alliance with US-based Osmotica Pharmaceutical Corp to develop and market niche generic medicines for several markets including the US in September 2012
- Nicholas Piramal Healthcare sold its domestic formulations business to US-based multi-national drug major Abbott Laboratories for US\$ 3.72 billion in November 2011

However, USFDA scrutiny on generic majors may hamper the generics supply to U.S. from India

The Indian pharmaceutical industry is growing rapidly on the back of increasing exports to all the major drug consumers including the world's largest pharmaceutical market of USA. However, the industry has also been facing some difficulties in the past as Indian drug companies have attracted the highest number of enforcements (refer to the graph below) from the American drug regulator USFDA. A number of drug manufacturing factories across India are now barred from supplying medicines to the US. The restrictions include the import alerts imposed recently on the facilities of Ranbaxy, Sun Pharma, Wockhardt and RPG Life Sciences, Strides Acrolab, etc. Import alert issued against Indian plants in 2013 accounted to 49% of the total 43 such import alerts issued by USFDA worldwide.



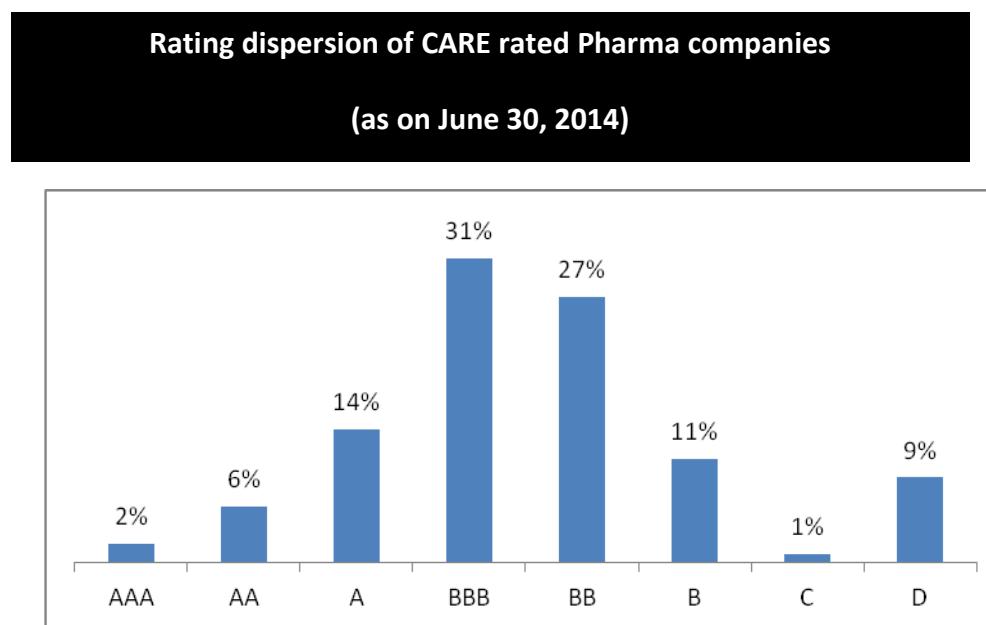
Source: US FDA

Outlook

The outlook for the Indian Pharmaceutical industry remains positive on the back of patent expiries through which the country is expected to gain a larger foothold in the world's generic market. However, as witnessed in the past, there has been an increase in the number of import alerts issued by the USFDA which has hampered the image of Indian Pharma companies and the supplies from such company's units were banned. If this continues in the long term, it may hurt the profitability of Indian generic drug producers. Thus, the need of the hour is that Indian firms should make sure the quality standards are adequately met.

CARE Ratings also believes that in the long term, semi-regulated markets like Latin America, Africa and Asia are likely to offer the next growth avenue for Indian Pharma companies as these markets have high demand for drugs and relatively less stringent regulatory compliance resulting in lower cost of servicing these markets.

Out of the total 103 pharma companies rated by CARE, more than 50% are in investment grade category ('BBB' or above category; refer the graph below) driven by good profitability metrics, comfortable solvency position and moderate liquidity profile. Additionally, some of the pharma companies are in the high investment grade categories ('AAA' and 'AA') on account of their wide geographical presence and well-diversified product portfolio. Furthermore, there has been improvement in the credit profile of companies manufacturing high-value APIs (Active Pharmaceutical Ingredient) in select therapeutic segments like anti-retrovirals catering to the export market. During FY14, the credit profile of CARE rated pharma companies has broadly remained stable.



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