Chapter 18
Impact of Product Patent Regime on Pharmaceutical Companies in India

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Abstract During the period between 1970s and the beginning of the new century the Indian pharmaceutical industry and the Indian generic companies, in particular, witnessed high and consistent growth. This was the period when the process patent regime was prevalent in India and the industry was basically governed by severe price competition and governmental price control. During this period, the Indian IP law did not recognize product patents as a result of which Indian companies launched generic versions of proprietary products which were originally researched and developed by multinational companies (MNC's). Indian companies were allowed to reverse engineer the process used by MNCs to manufacture their products and get process patents for the new process. However, in 1994 India became signatory to Trade Related Intellectual Property Rights (TRIPS) agreement under which product patent regime was adopted by India with effect from January 1, 2005. As a result of which, Indian companies could not copy patented molecules that had been researched and launched by MNC's in India. Any molecule with a priority filing date after January 1, 1995 is eligible for product patent in India and cannot be manufactured or marketed as a branded generic in India. The new patent regime posed a grave challenge to Indian pharmaceutical companies to maintain their competitiveness and deliver on profitability targets. Based on secondary data analysis, this chapter outlines the existing patent regime, the Drug Price Control Act in India and its impact on the growth and development of the Indian pharmaceutical industry. This chapter also highlights how Indian pharmaceutical companies have reoriented their strategies to not just meet the new challenges, but also leverage on the opportunities arising with the implementation of this new patent regime.

Keywords Indian pharmaceutical industry · MNCs · Patent regime · TRIPS

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18.1 Introduction

The Indian pharmaceutical industry is one of the fastest growing industries in the country, ranking 4th in terms of volume and 14th in terms of value globally (Dixit 2008; Rai 2008; Kiran and Mishra 2009; Pandey 2010). Before the adoption of TRIPS in 2005 in India, process patent system allowed the Indian companies to copy research molecules of MNC's and launch them under their own brands. These brands had the same molecules that were originally researched by MNCs but were manufactured using a reverse engineered process for which the Indian companies were granted process patents. This coupled with very aggressive marketing strategies which helped Indian companies to compete with MNC's in the Indian market. The consistent growth of Indian pharmaceutical market during this period was attributable to two socialist policies of the Indian government (Sampath 2005; Rai 2008). First, the government set up publically owned pharmaceutical companies to manufacture and produce commonly required drugs to fulfill domestic requirements, e.g. Indian Drugs and Pharmaceuticals Ltd (IDPL). Second, the government formulated the Drug Price Control Order (DPCO) Act to control prices of essential medicines and ensure their affordability. Other policies like restriction of foreign investment in the Indian companies further helped the home grown Indian companies to compete against the MNCs.

The Patent Act of 1970 ended the product patent laws prevailing till then and started recognizing process patents (Chandran et al. 2005). The enactment of the Patent Act of 1970 was with the intent to promote and develop indigenous pharmaceutical industry so as to produce low cost medicines for Indian population. The provisions of this Act allowed Indian companies to reverse engineer the manufacturing process owned by MNCs and manufacture generic versions of these drugs under their own brand names. As a result of this, the Indian companies were able to copy many blockbuster molecules available globally and sell them in Indian market at considerably lower prices (Rai 2008).

The Drugs Price Control Order of 1979 was another policy decision that helped Indian pharmaceutical companies to compete with MNC's since it controlled prices of essential medicines, which ensured that MNC's launch products at reduced prices, considerably reducing their profitability. Due to the dual impact of patent laws and lower profitability due to price controls, MNCs stopped launching new products in Indian market and this gave room for Indian companies to consolidate and strengthen their position. As a result of these policies, the market share of Indian companies in the market started to increase. MNC's share in the Indian pharmaceutical market reduced to 60 % in 2000 from about 85 % in 1970 (Kunnapallil 2012). In 2008, before the acquisition of Ranbaxy by Japanese Daiichi Sankyo, out of the top 10 pharma companies in India, 8 were Indian companies.

After India became a signatory to TRIPS in 1994, product patent regime was implemented in India from January 1, 2005. Countries that are signatory to the TRIPS agreement are obliged to enforce and implement product patent in all fields of technology, and pharma being one of the most technology oriented and

research driven industry was impacted the most. India also adopted the product patent regime in January 2005 and since then all eligible products can be granted a product patent in India as well. This has enabled MNCs to get their intellectual property around new researched products protected in India and launch their global products in India while enjoying exclusivity for the duration for which product patent is valid. For example, Merck's (MSD) anti-diabetes drug Januvia is patented till 2017, Novartis' anti-diabetes drug Galvus is patented till 2019 and their respiratory drug Onbrez is patented till 2020 (competitive intelligence). Similarly drugs like Onglyza (AstraZeneca/BMS) and Brillinta (AstraZeneca) enjoy exclusivity vide a product patent in India.

While in the short term, implementation of TRIPS has restricted the Indian companies from launching branded generic versions of products originally researched by MNCS, but in the long term it has also provided an opportunity for the Indian companies to focus and strengthen their research facilities. So implementation of the product patent regime has had both positive and negative implications for the Indian pharmaceutical companies. While on one hand it has restricted Indian companies from launching reverse engineered, branded generic versions of the innovator molecules, on the other hand it has propelled Indian companies to consider investing in research and development activities for new molecules and other avenues of novel drug delivery systems for existing molecules (Janodia et al. 2009). Many Indian companies like Glenmark, Lupin and Intas have significantly enhanced their R&D expenditure over the last few years while trying to maintain their profitability by launching novel and differentiated formulations of molecules that are not protected by product patent. Another strategy that Indian companies have adopted in the post patent era is to partner with MNCs to market their patented molecules in India.

18.2 Methodology

This chapter is based on review of existing literature and published research related to implementation of product patent regime in India and the strategies adopted by Indian Pharmaceutical Industry to meet the challenges therein. Renowned journals like European Journal of Economics, Finance and Administrative Services, Journal of Intellectual Property Rights, International Review of Business Research Chapters, and International Journal of Business Research were referred to while searching for relevant articles and research chapters. From around 40 relevant articles, 9 articles focusing on implications of product patent regime on Indian Pharmaceutical Companies were considered for evaluation and detailed analysis. During the analysis and review of published literature the authors attempted to identify the perception of Indian pharma companies towards product patent regime. Whether they consider it to be a hindrance to the growth of the industry or do they foresee it providing impetus to the R&D capabilities of the Indian pharma industry? The chapter also attempts to analyze the measures taken by these companies to survive and grow in the Post-TRIPS period.

18.3 Results and Discussion

The pharmaceutical sector in general and the Indian pharmaceutical companies, in particular, has witnessed tremendous change and transformation over the past few decades, especially due to changes in patent laws. In order to address such volatile situations, the organizations usually balance change by leveraging it with existing continuities, and adopt flexible strategies (Sushil 2005; Nasim and Sushil 2011; Nasim 2015).

The implementation of product patent regime in India with effect from January 2005 compelled Indian Pharmaceutical companies to reconsider their marketing strategies so as to survive and compete with MNCs and global pharma majors who were better prepared for the situation. The MNCs were way ahead of their Indian counterparts in terms of New Chemical Entity (NCE) research and other allied areas of Pharma research. Many MNCs had products and molecules that were already granted product patent in India whereas any Indian company was yet to come up with an indigenously researched molecule nearing commercialization. Hence, they had to consider strategies that could help them sustain and compete in the market. After detailed analysis based on their view of the literature, following strategies and options have emerged as the most preferred by Indian companies to face this new market dynamic.

18.3.1 Emerging R&D Business Models

With the advent of product patent regime, for the Indian companies to withstand competition from global Pharma majors and survive, they need to invest more in their R&D efforts for development of new chemical entities (NCE's) and novel drug delivery systems (NDDS) of existing molecules. Before patent regime, with the help of reverse engineering and process patent companies were able to copy molecules researched by MNC's and introduce them under their own brands. However, this is not possible anymore. Indian companies can no longer launch a product as branded generic that has been granted a product patent. As a result of this, the model of R&D investment by Indian firms is shifting from core process research to new drug development and new drug delivery system (Fig. 18.1) (Rai 2008). The major R&D expenditure on new drug discovery and development is conducted by limited number of companies like Dr. Reddy's, Lupin, etc.

Many big Indian companies have already started investing significantly into R&D. Table 18.1 mentions the absolute amount invested by some of the top Indian pharma companies between 2001 and 2010.

Besides investing in core research, Indian companies are also adopting a combination of the following alternative R&D strategies to navigate competition and leverage opportunities.

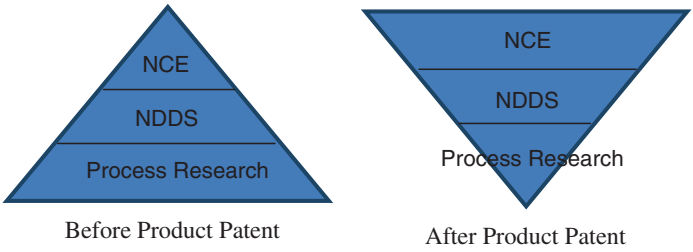

Fig. 18.1 Model of R&D investment by Indian pharmaceutical companies

Table 18.1 R&D investment by top Indian pharma companies (figures in INR Cr)

Year	Ranbaxy	DRL	Sun	Wokhardt	Cadila	Glenmark	Torrent	Cipla
2001	77	51	25	30	42	12	22	22
2002	192	74	34	34	38	31	31	52
2003	276	141	97	60	88	37	40	57
2004	331	199	127	69.3	103	48.7	67.3	98.4
2005	486	254	143	81.1	119	46.7	87.4	155
2006	386	215	202	138	124	45	74	176
2007	460	246	279	152	134	43	91	232
2008	471	253	287	165	133	51	113	244
2009	506	271	301	176	145	57	144	262
2010	514	286	312	182	183	63	163	275
CAGR	23 %	21 %	32 %	22 %	18 %	20 %	25 %	32 %

Source Company reports, websites

18.3.1.1 Out-Licensing of Innovations

Since a start-to-finish development of an NCE is an expensive affair, with some estimates going as high as $2 billion for researching a new molecule, Indian companies are out-licensing molecules to MNCs after reaching a certain phase in early stage clinical development. Such out-licensing arrangements are typically done for milestone payments and rights for certain markets after conducting early stages of clinical development (Preclinical or Phase I) (Table 18.2).

18.3.1.2 Services Models

With India emerging as the preferred destination for outsourcing research activities, global pharma majors have started off-shoring their back end activities like clinical trial monitoring, regulatory affairs and data management (Rai 2008). Many contract research organizations like Wipro, TCS, Cognizant, etc., which focus on contract research are following this model. Depending upon nature of

Table 18.2 Out-licensing deals by Indian pharma companies

Indian company	MNC partner	Product
Dr. Reddy's	Novo Nordisk	DRF 2593, DRF 2725
Ranbaxy	Bayer	Cipro XR, RBX 2258
Torrent	Novartis	Diabetes
Glenmark	Forest, Teijin	GRC 3886

Source Competitive Intelligence, Company Reports

service provided, margins are typically in the range of 20–30 %. Table 18.3 enlists certain service level agreements recently entered into by Indian companies.

18.3.1.3 Collaborative R&D Arrangements

Collaborative research agreement is another avenue which is found favorable with both Indian and global pharma companies. Such agreements typically involve joint ventures/collaborations between two pharma companies wherein both share risks involved with clinical development (Rai 2008). Table 18.4 enlists a few such agreements entered into in the recent past by Indian companies.

18.3.2 Emerging Commercial Strategies

Besides the change in Research oriented strategies adopted by Indian companies to meet the challenges posed by the product patent regime and leverage on the opportunities offered by the change in market dynamics, there has been a significant shift in the strategies adopted for commercialization of products by Indian pharmaceutical companies. Apart from focusing on development of novel formulations of existing drugs, companies have looked at partnering and alliances for late stage and commercialized products to augment their portfolio and sustain in the market.

Table 18.3 Contract research agreements by Indian companies

Indian company	MNC partner	Nature of services
Syngene	AstraZeneca	Drug Discovery
Strides	AstraZeneca	Drug Discovery
Advinus Therapeutics	Merck & Co	Drug Discovery in Metabolics
Biocon	BMS, Pfizer, AstraZeneca	Contract research for bulk drugs
Jubilant	Eli Lilly	NCE Research
Shasun Chemicals	Sanofi-Aventis, Eli Lilly, GSK	Contract Research

Source Competitive Intelligence, Company Reports

Table 18.4 Collaborative research agreements by Indian companies

Indian company	MNC partner	Nature of services
Ranbaxy	GSK	Drug development arrangement across various therapy areas
Ranbaxy	Eli Lilly	Drug Discovery
Torrent	AstraZeneca	Drug Discovery in CV
Biocon	Bristol Myers Squibb, Bayer	Biologics Drug Discovery JV
Jubilant	Amgen	Drug Discovery
Suven Lifesciences	Eli Lilly	CNS R&D Collaboration

Source Competitive Intelligence, Company Reports

18.3.2.1 In-Licensing Agreements

Since Indian companies cannot launch generic versions of patented products anymore and do not have many new formulations of old drugs coming from their NDDS research efforts, they have started to forge in-licensing arrangements with MNCs to launch their products in India. Under an in-licensing arrangement, the Indian company could get exclusive or semi-exclusive rights to market the MNCs product in India. These arrangement could vary from being a pure marketing and selling relationship to a more elaborate technology licensing agreement where the Indian company manufactures goods at their own facility and shares profits with the MNC partner (Rai 2008). These arrangements work particularly well with small to midsized MNCs who otherwise face a lot of hurdles in launching their products in India. Such alliances give quick profits and MNCs also leverage on their Indian partners equity to get quick success which may not be guaranteed had they themselves launched the product. In-licensing arrangements are cheaper and less risky way of augmenting portfolio rather than acquiring companies or investing in research and development activities. Table 18.5 enlists some of the in-licensing deals done by Indian companies in the recent past.

18.3.2.2 Out-Licensing Agreements

These are exactly opposite to in-licensing agreements. Here, the Indian company sits on other side of the table by being the seller. Taking cue from their MNC counterparts and also taking advantage of the new found focus of MNCs in super generics, Indian companies have entered into out-licensing deals for their branded generic products and novel formulations with MNCs, wherein they supply finished goods to MNCs who then market the products. Recent examples of such arrangements include the multicountry/multiproduct deal between Pfizer and Aurobindo, injectables deal between Claris and Pfizer, Biocon's deal with Pfizer for Insulin, Torrent's deal with Astrazeneca for 15 branded generic products in India.

Table 18.5 In-licensing agreements by Indian companies

Indian company	Partner	Product
Ranbaxy	Nihon Nohyaku, Japan	Lulliconazole
Ranbaxy	Sirtex, Australia	SIR Spheres
Ranbaxy	QLT Inc, USA	Eligard
Piramal Healthcare	Gilead, USA	Ambisome
Biocon	Abraxis, USA	Abraxane
Elder	Gnosis, Italy	SAMe
Glenmark	NAPO Pharma	Crofelemer
Wokhardt	Syrio Pharma, Italy	Derma products
Lupin	Novartis, India	Onbrez

Source Competitive Intelligence, Company Reports

18.3.2.3 Co-marketing Alliances

This is another of the most favored partnering strategy adopted by Indian companies wherein they market the MNC brands under a different brand name. Under a co-marketing arrangement, two firms market the same product under two different brand names (Rai 2008). These arrangements are a lot like in-licensing arrangement with the minor difference in co-marketing being that the MNC may also market the product in a different brand name. While it ensures quick sales for the Indian companies, it comes with the risk of establishing a brand which is not owned by them. Table 18.6 enlists a few co-marketing agreements executed by Indian pharma companies.

18.3.2.4 Marketing Alliances

Many Indian pharma companies in their quest to globalize have chosen to enter into marketing tie-ups rather than setting up subsidiaries and production facilities in markets of interest. For example. DRL's alliance with PLIVA for development and marketing of oncology products in Europe, Glenmark's supply and marketing agreement with Lehigh Valley Technologies to make and market liquid generic products in the US.

Table 18.6 Co-marketing agreements by Indian companies

Indian company	Partner	Brand
Ranbaxy	Ferring, Switzerland	Adiuretin
Ranbaxy	Eurodrugs, Belgium	Synasma
USV	Novartis	Jalra
Piramal Healthcare	Novartis	Zomelis
Sun	MSD	Istavel

Source Competitive Intelligence, Company Reports

18.3.3 Overall Corporate Growth Strategies

While the trend seems to be reversing in the recent past, there was a period immediately after advent of product patent regime in India when few of the top Indian pharmaceutical companies were very active in acquiring companies overseas and expanding their global presence. The prime motive behind these acquisitions was to penetrate into overseas markets, strengthen geographic reach, diversify, and enhance their product and IP portfolio and gain access to highly regulated markets like US and Europe (Rai 2008). During 2005 and 2006, Indian companies spent close to $ 1.6 bn to acquire companies in Europe, North America, and LATAM. Most famous of these acquisitions were Ranbaxy's acquisition of Terapia in Romania and DRL's acquisition of Betapharm in Germany. However, looking at the integration hurdles, it cannot be said whether all of these transactions made commercial sense, but they definitely helped Indian companies to set shop in global markets (Table 18.7).

The new patent regime also forced small Indian pharma companies to go on the radar and were picked up by bigger Indian companies that had global presence, significant R&D infrastructure and above all deep pockets to buy them. Few examples of such transactions include Wokhardt's acquisition of Merind, Ranbaxy's acquisition of Crosland, etc.

However, off-late the trend has reversed significantly and now MNCs are actively seeking acquisition of Indian companies. Recent transactions wherein Daiichi Sankyo from Japan acquired Ranbaxy, Abbott's acquisition of Piramal Healthcare and Mylan's acquisition of Matrix have turned the focus on acquisition of Indian companies by MNCs. These transactions also appear to be well thought out strategies by family driven business houses to leverage the brand equity earned by these home grown companies and encash on the increasing urge by MNCs to widen their presence in this high growth emerging market. The money that these conglomerates earn is being plowed into allied healthcare businesses.

Table 18.7 Acquisitions by Indian companies

Acquirer	Target (country)	Year	Value ($ Mn)
Ranbaxy	Terapia (Romania)	2006	324
Dr. Reddy's	Betapharm (Germany)	2006	574
Ranbaxy	Ethimed NV (Spain)	2006	–
Ranbaxy	Allen Spa (Italy)	2006	–
Sun Pharma	Able Laboratories (US)	2005	24
Glenmark	Uni-Ciclo	2005	4.6
Dr. Reddy's	Roche's API business (Mexico)	2005	59

Source Company reports/web pages, Industry Reports, Economic Times

18.4 Conclusion

Till 2005, Indian pharmaceutical companies were enjoying the process patent regime prevalent in India and by reverse engineering the manufacturing process of MNC molecules were able to launch blockbuster products in India as branded generics. But after the implementation of Patent Act 2005, only off patent molecules can be introduced by Indian companies. Under the new regime all products that have been granted a product patent or are eligible for same are out of bounds for the Indian pharmaceutical companies till the time the patentee holds exclusive marketing rights for the product. Hence, all those companies who wish to increase their market share and survive in the long run have embarked upon a two pronged strategy of augmenting their research capabilities and also to forge commercial alliances with global companies to augment their portfolio. Companies that are financially sound have invested significantly in core research activities.

However, those efforts will reap results only in the long term due to the long drawn process involved with pharma research. As they work towards enhancing their research abilities, Indian companies should put their efforts in development of NCE's in neglected therapeutic segments like TB, Malaria, etc. As the top Indian companies go about strengthening their research capabilities, many home grown contract research firms are focusing on the highly lucrative CRAMS industry wherein they are emerging partner of choice for global pharma in carrying out back end activities like clinical trial management, regulatory filings and data management. On the other hand, marketing oriented companies are focusing on forming commercial alliances with pharma MNCs in order to seek marketing rights for their patented products and launching them in India. Agreement types like co-marketing, in-licensing, co-promotion, etc., are favorable to Indian companies and are proving to be a win-win strategy for both Indian companies and the MNCs in India.

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