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The Impact of TRIPS Compliant Patent Laws on R & D Activities of Indian Pharmaceutical Industry

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Abstract

Patent protection in India existed since the British rule. Patent Act was first enacted in India as Act VI of 1856. The first provision for the patent of drug molecule appeared in The Patents and Designs Act 1911. This patent protection led to very high medicine prices and dominance of multinational pharmaceutical companies in India. To encourage the domestic pharmaceutical industry and to ensure availability of cheap medicines to Indian citizens the Patent Act 1970 was enacted. The act made provision for process patents for pharmaceuticals and agro-chemical products. This Act paved way for exponential growth of Indian pharmaceutical which became world leader in the manufacture of generics. India signed the TRIPS Agreement in April 1994. At that point in time, India's existing enactment of the Patent Act of 1970 directly contravened Article 27 of the TRIPS Agreement. To comply with this article product patent was reintroduced in India. This changed the level playing field for Indian pharmaceutical companies which were earlier spending a dismal percentage of total sales on R&D activities are now spending significant amount on R&D activities. Pattern of 'R&D' by Indian pharmaceutical companies has also changed. Earlier the Indian pharmaceutical companies were taking process patents but now are taking product patents.

The present paper is an attempt to assess the R&D activities of Indian pharmaceutical companies in changed legal scenario. Data from various secondary sources has been taken and suitably analyzed to achieve a detailed account of R&D activities of Indian pharmaceutical companies in pre and post TRIPS period. The paper provides an insight to Indian pharmaceutical industry.

Key Words: Generics, Process Patent, Product Patent, TRIPS.

I. Introduction

The success of pharmaceutical industry depends upon Research & Development. R & D is the value creator for the industry. Pharmaceutical companies do R&D in specific areas. Specific therapeutic areas are chosen depending on their strengths in the market, and the trade prospective. In the drug development process a typical product takes 7-10 years, and $350-500 million internationally.

Under the protective umbrella of the Indian Patent Act 1970, the Indian pharmaceutical companies are doing research in the area of process patent. That is the new methods of manufacturing an already patented molecule. This helped Indian pharmaceutical companies to become the largest manufacturer, of generic drugs and biggest exporter of anti-retroviral drugs. The Indian Pharmaceutical Industry flourished and exported life-saving drugs to developing countries and also supplied quality drugs to the rich nations at affordable prices.

The process of economic liberalization in 90's initiated by the former Prime Minister P.V. Narasimha Rao and the then Finance Minister, Dr. Manmohan Singh helped the Indian

Pharmaceutical industry to become Global leader in many sectors.

Protective umbrella for Indian pharmaceutical companies was removed when India signed the TRIPS Agreement. At that point in time, India's existing enactment of the Patent Act of 1970 directly contravened Article 27 of the TRIPS Agreement1. To comply with this article product patent was reintroduced in India. The legal transition has worked in favour of the Indian pharmaceutical industry which is investing in R&D activities related with clinical research and new medicine development. Due to sturdy R&D process and low production cost, exports also increased throughout this period.

Post-TRIPS period saw the strongest performance of the Indian pharmaceutical industry on several fronts.
In the recent years, Indian pharmaceutical industry has increased the R&D expenditure notably. With an increase in R&D spending, Indian companies have filed large number of Drug Master Files and Abbreviated New Drug Application (ANDA) with USFDA. Indian Pharmaceutical companies are increasing the number of regulatory filings such as DMF and ANDA as these enable them to manufacture and market drugs in the regulated market such as the US and Europe. Indian pharmaceutical industry has become the global hub for R&D activities, in the area of new drug discovery. In 2014 the ranking of the Indian pharmaceutical industry was 3rd in the world in terms of volume and 14th in terms of value2.

II. Nature of R&D and in Indian Pharmaceutical Industry

Developing a pharmaceutically active compound takes 7-10 years, and $350-500 million are spent, the statistic varies greatly with the disease type. Due to different patent laws in force the structure of pharmaceutical industry R&D has changed over the years. In the 1950's MNC spent on the R&D.

Patent act of 1970 recognized only process patent in pharmaceutical sector and it allowed Indian companies to reverse engineer the original version of the drug. R&D activity during this period focused on the development of generics. During the regime of this act, Indian companies spent on R&D activities related with the development of generics, development of novel drug delivery system, development of new processes and a little amount on the development of new chemical entities (new drugs). The Indian companies did R&D primarily for generic drugs because new drug development is a costly, time consuming and risky business.

Pharmaceutical R & D can be broadly classified into pre-clinical and clinical stages. The aim of the pre-clinical phase is to develop a promising molecule which is found safe in animal testing. At the clinical stage, the molecule is tested on humans. One of the important indicators of R&D efforts is the increasing patent filings by Indian companies in Indian as well at US patent office. Product patent in pharmaceuticals was fully introduced in India on January 1, 2005. It acted as a catalyst for making India a promising centre of pharmaceutical research and development. Companies like Dr. Reddy's Labs, Wockhardt, Advinus, Lupin, Zydus, Cadilla, Cipla, and many have invested in pre-clinical development of small molecules with novel targets and with novel mechanism of action. Although the Indian Companies are investing in R&D activities but still India lacks the amount of domestic private investments and the "academia-collaborations" that match the level of pharmaceutical industry of Europe and the U.S3. These are necessary for R&D pharmaceutical sector. Additionally, the biggest obstruction lies in regulatory price controls, which hinders innovation. Although price control in India has the

objective of providing drugs to the poor, but it has reduced the R&D investments4.

The process of R&D for new chemical entities was started after the implementation of the some provisions of the TRIPS in the mid 1990s5. R&D investments were initiated by Dr Reddy's Laboratories followed by Ranbaxy Laboratories. Since then nine other companies – Wockhardt, Sun, Cadila Healthcare, Torrent, Lupin, Nicholas Piramal, Dabur Pharma, Orchid and Glenmark have also started Investing in R&D6.

Starting early 2000s, there has been a remarkable enhancement in R&D activities by the Indian Pharmaceutical Companies. In 2013-14, Hetero Drugs, which is a mid-sized Indian pharmaceutical company alone, spent Rs 362.4 million which is more than what the 8 MNCs together spent in the same year (Rs 359.3 million). There are 32 other Indian companies each of which spent more than the 8 MNCs put together in that year.

The large Indian pharmaceutical companies spend more on R&D. Lupin, for example spent Rs 9929.2 million Dr Reddys Rs 10706 million Cipla Rs 5175.1 million Cadila Healthcare Rs 4451 million in 2013-14.

The model that the Indian companies have preferred is to evolve new molecules up to a certain stage and then license out to partners from developed countries, primarily to MNCs. This has been a beneficial proposition for both the partners. Further the development of biotechnology companies has encouraged specialization according to stages of the drug development process.

It is seen that at the pre-clinical stage, Indian companies do not carry out all the R&D. Indian companies are not doing the basic research for target identification for new drugs. They rely on the basic research of others and adopt an approach called 'analogue research.' This involves work on definite pre-recognized targets for specific diseases in order to develop molecules that alter the target's mechanism in the diseased person.

Indian pharmaceutical companies have also started investing in the new promising area of Novel Drug Delivery System. It is a combination of advance technique and new dosage forms, which are far better than conventional dosage forms. Indian pharmaceutical companies have also started to use this technique for herbal drugs. The traditional Ayurvedic formulations have advantage because phyto-pharmaceuticals create less or no side effects, In addition, since they are lone and purified compounds, they can be effortlessly standardized making it easier to incorporate them in modern drug delivery systems compared to herbs8.

Res-Q the world's first poly-herbal mouth dissolving tablet, of Asoka Life science, is a fast mouth dissolving drug. This drug has a novel delivery system that imparts increased efficacy. Res-Q dissolves in mouth by mixing with the saliva and gets absorbed in very little time. This drug is similar to the efficiency of Sorbitrate, a revolutionary mouth dissolving drug used in cardiac distress 9.

III. Research Objectives

1. Study the R&D structure of Indian Pharmaceutical Industry under the Indian Patent Act 1970.
2. Study the R&D structure of Indian Pharmaceutical Industry under the TRIPS compliant patent laws.
3. Study the R&D spending of Indian Pharmaceutical Industry under the Indian Patent Act 1970.
4. Study the R&D spending of Indian Pharmaceutical Industry under the TRIPS compliant patent laws.

IV. Data Analysis

Year	Table 1: Research and Development Expenditure of Indian Pharmaceutical Industry from 1995 to 2010.			
	Growth in R&D Expenditure Rs Cr.		R&D Expenditure As % of Sales	
	Domestic Companies	Foreign Companies	Domestic Companies	Foreign Companies
Mar 1995	80.61	64.13	1.34	0.77
Mar 1996	142.50	83.37	1.71	0.91
Mar 1997	148.12	89.41	1.55	0.95
Mar 1998	154.15	90.65	1.43	0.88
Mar 1999	218.66	79.78	1.56	0.70
Mar 2000	256.80	90.17	1.56	0.66
Mar 2001	435.07	109.81	2.30	0.72
Mar 2002	597.91	110.04	2.64	0.65
Mar 2003	686.74	232.73	2.93	0.71
Mar 2004	1084.26	346.69	3.81	1.10
Mar 2005	1527.24	510.50	4.98	1.63
Mar 2006	1850.97	816.02	5.35	2.39
Mar 2007	2371.79	695.62	5.01	2.67
Mar 2008	2772.63	700.18	4.78	2.86
Mar 2009	3316.14	846.05	4.89	3.84
Mar 2010	3342.32	934.40	4.50	4.01

Source: Government of India Ministry of Chemicals & Fertilizers Department of Pharmaceuticals (2012) Annual Report 2011[10].

Table 2: Total count by filing by Indian Pharmaceutical Companies Indicator : Patent Publications by Pharmaceutical Technology

Year	Total count by filing India
1995	37
1996	45
1997	112
1998	55

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1999	107
2000	132
2001	126
2002	169
2003	248
2004	152
2005	101
2006	84
2007	127
2008	116
2009	152
2010	146
2011	141
2012	147
2013	118
2014	114
2015	1464

Source: WIPO database[11]

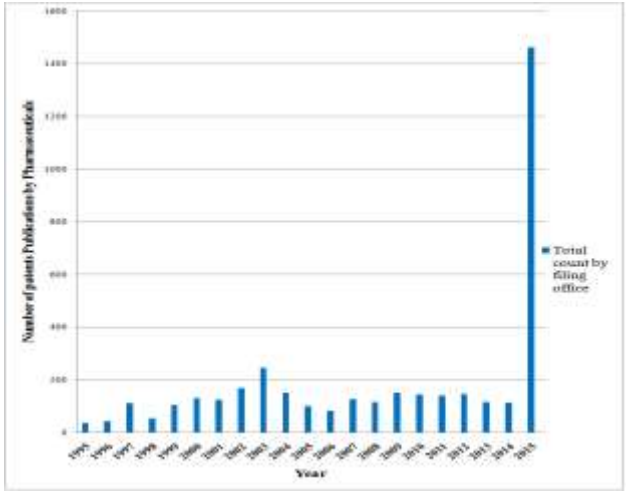

Figure 1 Total count by filing by Indian Pharmaceutical Companies Indicator: Patent Publications by Pharmaceutical Technology
Source: WIPO data base [12]

Table 2: Resident and abroad count by Pharmaceuticals Indicator: Total Patent granted to Indian Pharmaceutical Companies.

Year	Total Patent granted to Indian Pharmaceutical Companies
1995	3
1996	8
1997	13
1998	16
1999	28
2000	27
2001	49
2002	73
2003	134
2004	217
2005	180
2006	390
2007	277
2008	296
2009	269
2010	294
2011	241
2012	340
2013	380
2014	351
2015	357

Source: WIPO data base[13]

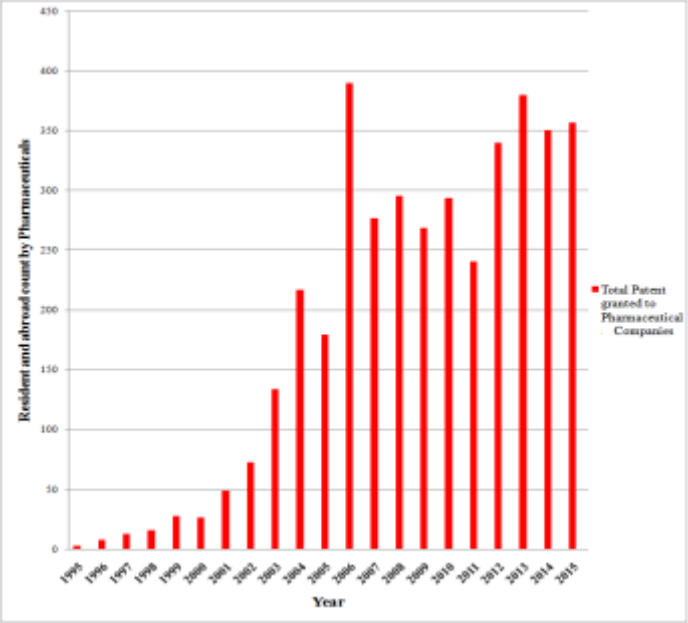

Figure 2 Resident and abroad count by Pharmaceuticals Indicator: Total Patent granted to Indian Pharmaceutical Companies

Source: WIPO data base [14]

V. Discussion

Pharmaceutical industry is highly research dependent industry. Initially the Indian pharmaceutical companies lacked necessary funds to spend on R&D activities and pharmaceutical sector was dominated by the large multinational companies. The Indian Patent Act 1970 paved way for Indian pharmaceutical companies to grow and spend on R&D activities. Throughout this phase the Indian spend for R&D activities were related to the finding of new method of making a molecule because only methods of making a molecule were patentable. Indian pharmaceutical industry gradually became the world leader in the field of generics. The patent protection environment was changed in India after the compliance of TRIPS agreement. The Indian pharmaceutical companies were compelled to change their R&D pattern. Under the changed patent law, pharmaceutical compounds are patentable. This promoted Indian pharmaceutical companies to start investing in the real R&D. Indian pharmaceutical companies made investment in finding new molecules for treating various ailments. This R&D gives exclusive right to the inventor for the use of the invention. The result of the R&D has started to show up as the number of patent application filed by the Indian pharmaceutical companies are continuously increasing and companies are also filling the patent applications in the patent offices of developed and money-spinning counties. Indian pharmaceutical companies have not restricted themselves to the traditional R&D practices but are also investing in some novel areas like Novel Drug Delivery system and the use of this system in herbal formulations which is an area exclusive to the Indian pharmaceutical companies. It has been observed that after the implementation of TRIPS compliant patent laws the Indian pharmaceutical companies are on a winning streak and have a potential to become global leader.

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