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Indian Pharmaceutical Industry after TRIPs: an Analysis

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Abstract—*India being a member country of WTO and signatory to TRIPs agreement amended its Patent act to comply with an obligation. With lot of oppositions and debate from almost every corner government amended the law in three phases and finally,Indian patent act become fully TRIPs compliant in the year 2005. It was feared that the TRIPs agreement will have a negative impact on the growth of Indian pharmaceutical industry (IPI),as of now we have travelled ten years since its implementation. There is a time to analyse the effect of agreement on the growth and performance of IPI. This study is conducted to analyse performance in terms of R&D expenditure, Patent fillingin domestic and through PCT route, Exports of generics and manpower involvement in the industry.The study finds that R&D expenditure as the percentage of sales has improved since 2005, Patent filling in domestic as well as through PCT route is on the rise and employment of technical people has also gone up in the post-TRIPs regime. Further with the findings we can conclude that initial fears were true but India has taken it as a challenge and TRIPs has no such significant effect on blocking the growth rather it has positive impact on Indian pharmaceutical sector.*

Keywords: *Indian Pharmaceutical Industry, TRIPs, patents, R&D*

1. INTRODUCTION

The pre TRIPS era witnessed that the world was divided into two groups of nations: one group allows both product and process patent in all fields of knowledge, and second are those who do not permit product patent and allows only process patent in selected technological area such as food, Agrochemicals, Drug and Pharmaceuticals, chemicals etc. Indian pharmaceutical industry was protected under Indian Patent Act 1970, where only process patent was granted in the area of Drug and Chemical Industry. This clause allows pharmaceutical firms to enjoy the flexibilities in the law that provides them liberty to copy the patented product of R&D based big multinational pharmaceutical firms through reverse engineering. This led to the result that India has become one of the leaders in supplying low cost quality generics to the world.

Formation of world Trade organisation (WTO) on 1 January, 1995, led member countries to make amendments in their present national law governing intellectual property rights (IPR) in an order to make it TRIPs compliant and they were asked to allow product patent in all areas including Drug, pharmaceutical and chemical industry as well.

India being a member of WTO, has to comply with an obligation of TRIPs, Indian patent act 1970 was amended thrice. First amendment was done in the year 1999 followed by second amendment of 2002 and final amendment of 2005 made Indian patent law fully TRIPs compliant. With the substantial amendment in the Indian patent law in March 2005 in compliance with the TRIPs agreement applicable w.e.f. 1 January 2005, much debate has centred on the impact of the product patent on the survival and growth of Indian pharmaceutical sector [11]. It was feared that the new patent regime will have a negative impact on the global competitiveness of Indian pharmaceutical industry in providing low cost quality generics. It is perceived that TRIPs is introduced to benefit developed countries and agreement has nothing in favour of pharmaceutical firms of developing countries. These laws were already in place in developed countries. Intellectual property related changes incorporated in the law had created a new challenge for pharmaceutical firms of developingnations. Introduction of product patent in post TRIPs period woke up Indian pharmaceutical industry to face the challenges of new intellectual property regime [9]. These firms were forced to bring changes in their earlier ways of doing business;[12] they have to modify their present model of doing business by improvising Innovation by investing more in Research and Development activities, technology development and enhancing marketing practices by reconfiguration of their competencies and resources ([2].

The most urgent strategic concern TRIPs raised in front of Indian firms is to maintain their growth and competitiveness in changing IP regime [6]. To survive in the globally competitive environment but yet with abundance in opportunities expenditure on R& D is prime thrust area. This study is conducted to analyse the performance of Indian Pharmaceutical Industry from process patent to product patent regime. Further it highlights how they have maintained their competitiveness by investing in R&D, Patent filing, Export

growth and trends of Technical employment in Pharmaceutical industry.

2. METHODOLOGY

This paper is based on extensive review of the relevant, conceptual and empirical literature. The patenting activity in Indian pharmaceutical industry is being studied from data collected from USPTO and data in the form of report available at Indian patent office site (www.ipindia.nic.in). Exports statistics are collected from Ministry of commerce trade statistics HS code upto 6 decimal places.Data related to Research and Development activities in India are being collected from annual reports of the Controller General of Patents DesignsTrademarks and Geographical Indication and Bulk Drug Manufacturers Association.

3. INDIAN PHARMACEUTICAL INDUSTRY: AN OVERVIEW

Indian pharmaceutical industry is about 125 year old industry. Production of modern medicines by indigenous unit was started with setting up of Bengal chemical and pharmaceutical works in Kolkata (1892) which was followed by establishment of Alembic chemical works in Vadodara (1907) and Bengal Immunity in 1919.

Today Indian pharmaceutical industry is highly fragmented. Presently we are having around 25000 registered companies [15] with top 250 companies controlling 70% of the domestic market. Industry has grown from mere 0.3 billion USD in 1980 to 12 billion in 2012 and it is expected to be 45 billion in revenue by 2020. Indian generic will account for USD 26.1 billion in 2016. Indian generic drug accounts for 20% of global export in terms of volume, which makes India the largest provider of generic medicines to the world in terms of volume. India is the sixth largest market globally in terms of size because of its population,socio economic changes in life style and growth in urbanized cities. India is expected to rank amongst the top three pharmaceutical markets in term of incremental growth by 2020. Pharmaceutical industry revenues are expected to expand at a CAGR of 12.1% during 2012-2020 and reach USD 45 Billion. Currently healthcare sector in India is around 65 Billion US Dollar which is expected to grow to USD 250 Billion by 2020. India is one of the suppliers of low cost quality generics to the world. It is expected to be third largest global market for active pharmaceutical ingredient (API) by 2016 with a 7.2% increase in market share. Amongst the total Drug Master Filling (DMF) in the US for the year 2012 India registered 49% share. Besides this, India has largest number of USFDA approved manufacturing plants outside USA. In formulation industry India is the largest exporter of formulations with 14% market share and ranks 12th in the world in terms of export value and it is expected to grow over a period of time.

Indian pharmaceutical industry has shown this tremendous growth since introduction of Indian Patent Act 1970, which restricts product patent and permits process patent as far as pharmaceutical, drug and chemical industry is concerned.

Introduction of Product Patent in year 2005 bought some challenges in the way firms do business. This study is focused on analysing the measures IPI has adopted to maintain its growth trajectory. Out of several we focused on R&D expenditure, Patent filled (Domestic and through PCT route), Export sales and Technical manpower employed after 2005.

4. R & D EXPENDITURE

Learning hierarchy model suggests that developing countries progress from learning to produce, learning to produce efficiently, learning to improve production, learning to improve product and finally culminates in learning to develop new product (Klae 2009). It is considered that R&D is the key to the future of pharmaceutical industry. In the Pre TRIPs scenario, R&D in the pharmaceutical companies was primarily for the development of new process.Post-WTO era has witnessed a steep rise in R&D spending as a percentage of sales in pharmaceuticals, data collected from 339 R&D Units with NIC code 21(Table 1) and certain firms have matched international standards [3]. In the new patent regime firms has started spending on product patent as well to realign their competencies.

Firms like Ranbaxy, Dr. Reddy's laboratory, Dabur, Sun, Wockhardt, and Torrent are seriously pursuing new drug discovery programmes [13]. These are the firms that have invested more in the R content of R&D and have gradually moved away from reverse engineering. Other firms like Cipla, Lupin and Cadila have invested more in the D content and have strengthened their infrastructure and financial position through process efficiencies, economies of scale and large product baskets rather than research. [2]

Although a large portion of R&D budget of these pharmaceutical firms are still invested in Generic formulation development and active pharmaceutical ingredient process research, but a positive trend towards the development of new drug discovery is also noted by few pharma majors. Dr Reddy's laboratory is one that had the vision of starting a discovery research lab in new chemical entities (NCE) at the start of 1990s. DRL as a result now carved out a niche for itself in the new drug discovery arena [5]

Table 1: Research and Development expenditure as percentage of sales

Year	R&D Expenditure in Crores	R&D Expenditure as % of Sales
2004-05	1527	4.98
2005-06	2843	5.35
2006-07	3521	5.01
2007-08	4280	4.78
2008-09	4918	4.89
2009-10	5269	4.50
2010-11	5829	4.45

2011-12	6002	4.80
2012-13	6314	4.34

Source: Based upon CMIE Prowess Database, data.gov.in: industrial sector expenditure on R&D

The Research and Development spending of top 25 Indian pharmaceutical firms has increases by 20.6% to 6103 Crores in year 2013-14 as compared to 5060 Crores last year. Although the R&D expenditure of Indian firms in terms of value is negligible as compared to the multinationalpharma giants [8] but in terms of percentage share of sales turnover Indian firms outperformed some big names. [17]

In the last ten years from 2004-05 till end of financial year 2013-14 leading pharmaceutical forms has spent around 32,000 Crores on R&D. Although these companies failed to comeup with single breakthrough innovation, they are focusing on new generics and we have overcome stiff competition by offering affordable off patented products to the world. In the last ten years Dr Reddy's Lab spend 5070 Crores, Rnabaxy (4877 Crores), Lupin (4589 Crores), Cipla (2716 Crores) and cadila (2608 Crores) respectively.

5. PATENT FILING

Patent filing in India increased only slightly from 2000 to 2004, but post TRIPs there has been a significant increase in the rate of filing. In the year 2005 and 2006 there was 38 per cent and 40 percent growth respectively [10]. Filing rate started to decline from 2007 onwards to reach 4.53 per cent in 2009 because of global recession.

It is clearly evident from Table 2 (A) that Post TRIPs patent filing by Indian companies in India has increased after implementation of IP system. Overseas national phase filing through PCT route has also increased substantially in recent times. Table 2 (B)

Table 2: (A) patent filed in India

Year	Drug patent application	Drug patent granted
2005-06	2211	457
2006-07	3239	798
2007-08	4267	905
2008-09	3672	1207
2009-10	3070	530
2010-11	3526	396
2011-12	2762	282
2012-13	2954	344

Source: Annual report CGPTD 2012-13

Since 2005 major blockbuster drugs were going off patent that provides big market for Indian firms to tap on. Modern R&D centres, pool of highly qualified technical staff, ability to handle complex research projects, less expensive clinical trials, growth of biotechnology firms and maximum no of US FDA approved manufacturing plant outside US makes Indian firms highly competitive among rest of the world.

Patent Cooperation Treaty (PCT) assist applicants in seeking patent protection internationally for their inventions, and facilitate the acquisition of patent right in multiple jurisdictions. India in year 2013-14 filled 1,320 PCT applications and it is estimated that it is going to be 1,394 for the year 2014-15 with a growth of 5.6% with a share of 0.6%.

Table 2: (B) PCT National Application Filled by Indians

Year	Individual	Legal entity	Total
2005-06	130	352	482
2006-07	144	390	534
2007-08	169	538	707
2008-09	232	655	887
2009-10	231	521	752
2010-11	243	628	871
2011-12	254	519	873
2012-13	252	790	1042

Source: Annual report CGPTD 2012-13

Pharmaceutical has a substantial contribution among total filing through PCT route. Pharmaceutical has a share of 20.4% and it is on the rise, Companies like Ranbaxy (37)Wockhardt(31) and Hetro Labs (27) are among the top contributors for the year 2014.

Table 2: (C).Patent filed In USA

Year	Filed	Granted
2005-06	1483	N.A
2006-07	1923	N.A
2007-08	2387	N.A
2008-09	2878	678
2009-10	3696	1076
2010-11	4482	1195
2011-12	5515	1599

Source: USPTO

US FDA has approved 400 ANDA filings in pharmaceutical and Indian companies received approval for 154 ANDAs during year 2013 which is around 38.5 % of total grants.

6. EXPORT SALES

With the advent of product patent regime, Indian pharmaceutical companies positioned themselves in a way such that they could portray dominance in the global generic market. India has now emerged as one of the world's top exporter of generic medicines [14]. India is among the top suppliers of low cost quality generics to the world. Amongst the total Drug Master Filling (DMF) in the US for the year 2012 India registered 49% share. Besides this, India has largest number of USFDA approved manufacturing plants outside USA. In formulation industry India is the largest exporter of formulations with 14% market share and ranks 12th in the world in terms of export value and it is expected to grow over a period of time. Generic drugs provide a basic platform to Indian pharmaceutical industry.

Indian pharmaceutical industry is estimated to be worth $4.5 Billion which is growing at an average of 12 to 14 per cent annually (Table 3). ITC HS code up-to 6 decimal place.

Table 3: Exports and domestic sales

Year	Exports (Cr)	Growth %
2004-05	17227	17.38
2005-06	21230	23.23
2006-07	25666	20.89
2007-08	29354	14.37
2008-09	39821	35.66
2009-10	42456	6.62
2010-11	47551	12.00
2011-12	51393	8.07
2012-13	55692	8.34

Source: Annual report DIPP 2011-12, Trade statistics (exports) department of commerce (2012-13)

Indian generics rank very high among third world countries in terms of Technology, Quality and vast range of medicines that are manufactured (CCI 2013). In the list of top ten exporting companies of 2009-10 DR Reddy's Lab tops the chart with 3013.80 Crores followed by Cipla (2900.58 Cr), Ranbaxy (2772.82 Cr), ArbindoPharma (2088.37 Cr), Lupin (2078.72 Cr), Matrix Lab (1537.25 Cr), Orchid chemicals (976.20 Cr), Cadila (960.0 Cr), Sun Pharmaceuticals (838.95 Cr), Divis Lab (835.40 Cr) (Bulk Drug manufacturers association 2011)

7. EMPLOYMENT OF TECHNICAL MANPOWER

Competitiveness of any firm depends upon its ability to innovate, for innovation to continue technically competent employee plays an important role, as Intellectual property is the outcome of the mind of an intellect, it is always advisable on the company part to have sufficient pool of technically equipped and competent employees. Indian pharmaceutical industry is advantageous in this regard as India is rich in such talents. It is evident (Table 4) that as we proceed from pre to post patent regime the number of technical employment in Indian pharmaceutical industry also increases, which shows a healthy sign of growth of IPI. Indian pharmaceutical firms hired scientists experienced in product R&D working overseas in multinational corporation, pharmaceutical R&D firms or Universities to acquire the know how in innovative product R&D. [4]. Few firms have shown a positive trend towards this as Ranbaxy set up new research centre at Gurgaon. It employed 400 scientists (annual report 2007-08). Even recommended by [5] that the companies are required to meet certain specific criteria on R&D activities and they must also have internationally approved production facilities and the company will have to spend five per cent of its turnover, subject to minimum of Rs 50 Crores a year on R&D. the company will also need to have a minimum of 200 scientists in its role.

Table 4: Employment of technical manpower.

Year	No of Employees
2005	265396
2006	290021
2007	336211
2008*	353692

Source: Annual survey of Industries, Ministry of statistics & program implementation.
*****Data available till date

8. CONCLUSION

Above stated facts and discussions clearly depict that introduction of TRIPs in India has a positive impact as far as Indian pharmaceutical industry is concerned. Research and development activity has improved in post TRIPs period, it is observed through the study that companies which were initially reluctant and having fear of losing business in the IP regimes have changed their perspectives of doing business and now they are giving stiff competition to the R&D based companies of developed world. It is observed that Indian companies had encashed the flexibilities of TRIPs agreement which laid down the minimum provisions for companies to follow in the better way, but with the increasing pressure from developed world on the developing countries to make their patent law more stringent. The growth path does not seem easy. In the light of today's increasing pressure on developing countries a lot of joint effort is required from private as well as from government.Few signs of new drug discovery show that we are also coming out of our previous image of drug discovery failure [1] but it still requires lot of efforts.It is suggested that more initiative should be taken at the part of government by public private partnership mode to encourage domestic research and development activities for better growth of Indian pharmaceutical industry. More research labs to be established in government institutions and Universities to facilitate research activities.

Indian companies investing in R&D will play important role when ROI on R&D expenditure of big pharmaceutical majors are diminishing as there is no success in blockbuster drug in past few years. India's investment on developing new products will give stiff competition and fetch lot of revenue in the existing off patented product market.

There are few of issues which remained un addressed in the study like International Mergers and Acquisitions by Indian firms, Compulsory licencing,"Bolar exemption", Market Exclusivity in US, International inspections for US FDA, EMA/EDQM approval which further gives scope for studying the impact of TRIPS on Indian pharmaceutical industry.

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