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Indian Pharmaceutical Industry: A study of the post-liberalization period

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Abstract
The pharmaceutical industry is a vital sector of an economy in the sense that it has direct effect on the health of the people of the nation. This is a sector where continuous innovation is required to invent new drug for new diseases and new forms of old diseases. For innovation continuous investment in R&D is required. Investment in R&D is risky and the inventions require legal protection in the form of Intellectual Property Rights (IPR). Patent is the most relevant form of Intellectual Property Right which a pharmaceutical company acquires whenever it discovers a new drug or new process of manufacturing a drug. Continuous research and development (R&D) and low cost of production have helped the industry to expand in the domestic market as well as in the export world. In the context of liberalization of the Indian economy it is important to study the pharmaceutical companies of India. Liberalisation measures and the subsequent enactment of TRIPS (Trade related aspects of Intellectual Property Rights) compliant patent law have far reaching impact on the pharmaceutical industry. Now more than a decade has passed since liberalization and the enactment of the new patent law. So it might be considered as very important to examine the performance of the pharmaceutical companies in India. The objective of this paper is to evaluate the performance of the pharmaceutical industry in India in the post-liberalisation and post-TRIPS period. This study shows that the pharmaceutical companies have shown considerable resilience and have performed well in the post-liberalization and post-TRIPS period. Our study also examines the opportunities and threats extended by the process of liberalization and subsequent change in the national patent law.

Keywords: Liberalisation, Patents, Pharmaceutical Industry, R&D, TRIPS, JEL Classifications: L 65, O 14, O 31, O 34.

1. Introduction
India's pharmaceutical industry is one of the technologically most vibrant sector of the Indian economy. The level of growth and technological development achieved by the sector is a result of the different policy interventions undertaken by the government from time to time. The specific objectives of the government were achieving self-sufficiency in drugs production, self-reliance in drugs technology and accessibility of quality drugs at reasonable prices.

The annual turnover of the Indian pharmaceutical industry for the financial year 2016-17 is estimated to be Rs. 219755 crores. The share of export of Bulk Drugs, Drug Intermediates and Drug Formulations, Biologicals is Rs. 107618 crores for the financial year 2016-17. The pharmaceutical industry has achieved tremendous progress in terms of technology, infrastructure and range of products. The Indian pharma industry has carved a niche for itself by being a cost effective generic drugs manufacturer for lifesaving drugs. USA is now sourcing anti-Retroviral drugs from Indian companies which are approved by USFDA. Indian pharma companies now maintain high standards in purity, stability, safety, health and environmental protection. Outside USA, India has the highest number of USFDA approved plants. A major share of Indian pharma exports is sourced to developed countries especially USA. This speaks not only about the good quality of Indian pharmaceuticals but also about the competitive price that the industry offers. Low cost of production, skilled labour and continuous R&D have helped the Industry to flourish and become highly competitive. A close study of this sector is very essential particularly in the context of liberalisation and the

subsequent changes in the national patent law as per TRIPS which has come into force in 2005. Government policies regarding drugs and medicines, the grant of 100 percent Foreign Direct Investment (FDI) permissions and amendments of Patent Act have immense effect on this sector. These changes have opened new challenges for the pharmaceutical industry in India. The aim of the present paper is to examine the performance of the Indian pharmaceutical industry in the post-liberalisation and post-TRIPS period. And to study the opportunities and threats that the industry is facing as a result of the new stringent patent regime.

Liberalisation and the new Patent Law

Liberalisation implies reducing government regulations and restrictions in an economy to achieve greater participation by the private sector. Thus, liberalisation implies "removal of controls" in order to boost economic development. In 1991, during the prime ministership of Narasimha Rao, the process of liberalisation was initiated in the Indian economy. The License Raj was abolished and private sector was given more freedom. The policy makers wanted to make the economy more market and service-oriented, expand the role of the private sector and enhance foreign investment. The liberalisation measures have far reaching impact on the different sectors of the Indian economy including the pharmaceutical sector.

Since independence the Government has changed the patent laws from time to time and used them as policy instruments for industrial development of the country. After independence the prevalent patent law was the Patents and Designs Act, 1911. During this time the Multinational Corporations (MNCs) dominated the industry. After independence two committees under the chairmanship of Dr. Bakshi Tek Chand and Justice N. Rajagopala Ayyangar were appointed with a view to ensure that the patent system should be conducive to the national interest and to suggest modifications and alterations to the existing law suitable for making the country self-reliant in technology. As a result of the recommendations of these two committees the Patents Act 1970 came into force on 20th April 1972. This law was suited to changed political situation and economic needs for providing impetus to technological development by promoting inventive activities in the country.

The important features of the Act of 1970 in the context of R&D in pharmaceutical industry are as follows: The life of the drug patent was reduced from at least 16 years in the previous act to 5 years from the date of sealing or 7 years from the date of filing of complete specifications, whichever is shorter. The 1970 Act categorically states that drugs can now be patented only for a new method or process of manufacture not for the products as such. The Patents Act 1970 is a land mark in the industrial development of India. The complete elimination of product patent brought about significant changes in the sphere of R&D of the pharmaceutical industry in India. The Indian pharmaceutical companies began to invest in R&D to develop process for manufacturing the latest drugs introduced in the domestic as well as the international market.

This act enabled India to dislodge the MNCs from a position of dominance and helped the local pharmaceutical industry to achieve remarkable growth. This act was expected to provide a reasonable balance between adequate and effective protection of patents on the one hand and the technology development, public interest and specific needs of the country on the other hand.

A major landmark in international economic relations was the successful conclusion in 1994 of the controversial negotiations on the Agreement on Trade Related aspects of Intellectual Property Rights (TRIPS) as a part of the Uruguay round of multilateral trade negotiations. TRIPS now form part of the legal obligations of the newly founded successor organization to the General Agreement on Tariffs and Trade (GATT), the World Trade Organization (WTO). TRIPS, when fully implemented, will unambiguously strengthen protection of IPRs almost worldwide. Thus, TRIPS has necessitated changes in the IPR laws of all WTO member countries without exception. The increasing pace of globalization accelerated by faster and cheaper methods of transportation and communication, combined with the growing ease of imitation, produced a strong and continuing demand for improving the international legal framework for the protection and enforcement of IPRs. As a member of the WTO, India is committed to the different agreements arrived at as a part of these negotiations. Under the Agreement on Trade Related aspects of Intellectual Property Rights (TRIPS), India is obliged to change her patent laws considerably.

Under the new patent law India now have to recognize and grant product patents in pharmaceuticals. And the patent holder will have not only the sole right to produce but also to import. Thus, when a foreign firm introduces a new drug and gets a patent for it, indigenous firms will be prevented from manufacturing (for domestic market or for exports) or importing it for at least 20 years (i.e. during the life of the patent as specified in TRIPS) even if they can develop their own processes of manufacturing it. Finally, a pharmaceutical company can acquire four types of patents – patent on dosage, formulation, process and product. Hence, we notice that there is a gradual shift in government policy from the regime of control and process patents to a regime of decontrol and product patents. It is thus expected that such changes in policy will have a far-reaching effect on the industry.

Literature Review

Earlier studies on the impact of liberalisation and stringent patent protection on the pharmaceutical sector of different countries show mixed results. While some studies find a modest impact of liberalisation and strong patent protection on this sector, others suggest that these reforms have a positive effect on the pharma sector.

The TRIPS have initiated considerable debate in academic and inter-governmental fora on the economic implications of strengthened intellectual property protection in developing countries. The commentators of the TRIPS say that the amendment of the patent law of the different countries would stimulate R&D activities in the research-intensive industries in general & pharmaceutical industry in particular. It will lead to knowledge transfer and technology acquisition (Dutta, 2004). The supporters of TRIPS further claim that stronger IPRs would have a positive effect on both FDI and licensing especially in countries with strong imitative capabilities. They suggest that there is a close connection between the development of strong IPRs and the emergence of markets for technology transfer. For example, strong IPRs can induce licensing activity since patent protection reduces the monitoring and

litigation costs, and other enforcement measures (Chaudhuri, 2005). A study on the impact of a restructured patent regime on the R&D expenditure and the patenting activity of Indian pharmaceutical companies suggest that there is an increase in both R&D investment and measured inventive output in the form of patents (Bedi, Bedi, and Sooch, 2013). According to Kiran and Mishra (2009), the period 1995-2008 saw the strongest performance of the Indian pharmaceutical industry on several fronts. The industry improved its production performance by a significant margin. The pharmaceutical industry turned into a net foreign exchange earner during this period. Haley and Haley (2012) observed that Indian pharmaceutical industry became competitive with the new patent laws. Chaudhuri (2014) finds that multinational corporations (MNCs) were more interested to import patented drugs and market those in the developing countries rather than to manufacture those in the host countries and Indian patent laws in fact encouraged indigenous manufacturing units. Bagchi and Bhattacharya (1995) showed how patents reflected competitive instruments in the economy. Dhar and Rao (2008) noted the relations between economic development and patents. Joseph (2009) examined the trade scenario of India in the context of Drugs and pharmaceuticals. Basak and Bhattacharya (2014) analysed the innovation scenario of india with reference to the period 1970 to 2010.

It has been observed that long-term benefits of IPRs could conflict with other short-term public policy objectives. It is also argued that the possible impact of the new patent could turn to be a regime with higher consumer prices, delayed introduction of new drugs, larger foreign exchange outflow from larger imports and lesser exports. It could also lead to a smaller employment generation due to lower domestic production (Abrol, 2004). Again Abrol (2014) showed how globalization has discouraged technological innovations in indigenous pharmaceutical industry. Academicians and policy makers were apprehensive about the new patent regime because they thought that this new regime will adversely affect the access to medicine. This debate was of particular relevance for India where a strong generic industry had taken roots since the 1970s, which was able to provide medicines at prices that were among the lowest in the world. Dhar and Gopakumar (2006) analyzed the likely impact that the change in the country's patent regime could have on the Indian generic pharmaceutical industry. They have found that the leading firms of the industry have shown considerable dynamism during the past decade. The consolidation of the Indian firms, which began in the first half of the 1990s, improved considerably since the beginning of the past decade. Particularly noteworthy was the increase in the R&D spending of some of the leading firms. Stiglitz (2006) noted how the TRIPs reflected the triumph of corporate interest and advanced industrial countries.

Indian Pharmaceutical Industry: Trends and patterns

Strategic government policies adopted after independence were the main factors that transformed the Indian pharmaceutical industry from a mere importer and supplier of drugs and pharmaceuticals to an innovation-driven cost-effective producer of quality drugs. When a number of liberalisation measures were adopted in the 90's with subsequent change in the national patent law (as already mentioned in the above section), economists were apprehensive about the future of this industry. With the onset of liberalisation measures and global patent regime, the issue of competitiveness becomes important for understanding the strength of any industry. The competitive strength of an industry can be judged in several ways. One simple way is to look at the growth performance. Table 1 shows the index number for this sector for five years from 2012-2013. From this table it is evident that production has increased considerably in this sector for the period mentioned. The rapid growth in production is also evident from the revenue of this sector (Table 2) during the same period. The revenue earned by this sector shows a constant growth during the period mentioned. Growth in production is one of the key determinants of competitiveness of any sector.

Table 1

Index Number (Base: 2011-12 = 100)						
	Weight	2012-13	2013-14	2014-15	2015-16	2016-17
Manufacture of pharmaceuticals, medicinal chemical and botanical products	0.5	108.1	114.3	116.9	132.1	172.3

Source: Reserve Bank of India

Table 2

	FY11	FY12	FY13	FY14	FY15	FY16	FY17E
Revenue of Indian pharmaceutical sector (US $ billion)	20.95	22.46	24.52	28.53	29.77	27.57	29.61

Source: www.ibef.org

From Table 3, it is observed that a pharmaceutical export of India has increased since 2006, i.e. in the post-liberalisation and post-TRIPS period. This increase in exports has enabled India to achieve favourable trade balance in pharmaceuticals during the period mentioned. This favourable trade balance indicates the fact that, the pharmaceutical sector has been able to sustain itself in a globally competitive environment.

Table 3

	FY06	FY07	FY08	FY09	FY10	FY11	FY12	FY13	FY14
Exports of Indian pharmaceutical products (in billion $)	2	3	4	5	5	7	9	10	8

Source: www.asa.in

In Table 4 we focus on the sales of some selected top pharmaceutical companies in India. The figures are given for 2001-02, 2005-06 and 2010-11. In 2001-02 only the first phase of TRIPS compliant patent law was enacted. The other two financial years given in the table i.e. 2005-06 and 2010-11 captures the post-TRIPS scenario. Thus, the data captures the period when the liberalisation measures as well as the TRIPS compliant new patent regime has initiated. From the table it is evident that sales have increased for almost all the companies included in the list. And in many cases the increase is quite significant. Thus it is evident that the Indian pharmaceutical companies have not only survived after liberalisatio and post TRIPS but have performed well and have been able to adapt itself to the drastic institutional change against many apprehensions from the industry and academia.

Table 4

Sales (in Rs million)			
Company Name	**2001-02**	**2005-06**	**2010-11**
Abbott India Ltd.	3253	4387	
Aurobindo Pharma Ltd.	9993	14555	40827
Cipla Ltd.	13816	30035	61352
Dr. Reddy'S Laboratories Ltd.	16481	22600	51874
Glaxosmithkline Pharmaceuticals Ltd.	10477	14941	
Glenmark Pharmaceuticals Ltd.	2513	6033	11536
Pfizer Ltd.	3091	5392	11696
Sun Pharmaceutical Inds. Ltd.	74122	13510	19331
Torrent Pharmaceuticals Ltd.	4286	6768	17441
Wockhardt Ltd.	6214	10000	17549

Source: Indiastat.com

Table 5, shows the Research and Development expense for some top pharmaceutical companies in India. The date is given for three financial years and captures the post-liberalisation and post-TRIPS period. It is evident from the table that barring a few companies the R&D expenditure of most of the companies has increased during this period. Many industry experts and academicians had predicted that since the indigenous pharmaceutical companies have thrived mainly on reverse engineering, they will perish with the introduction of liberalisation measures and onset of the TRIPS compliant product patent regime. However it is evident that the indigenous companies have understood that they have to change their strategy in the new institutional framework and hence they have started investing in R&D in a large way. The companies which used to imitate earlier have now started investing in R&D to innovate novel drugs. Thus the industry has shown considerable resilience and survived and has not allowed the MNCs to regain its lost position in the country as was predicted by some experts opposing liberalisation of this sector and TRIPS.

Table 5

Research & Development Expenditure (Rs. Million)

Company Name	**05-Mar**	**11-Mar**	**16-Mar**
Abbott India Ltd.	14.4	16.9	7.1
Aurobindo Pharma Ltd.	359.1	1394	4119
Cadila Pharmaceuticals Ltd.		478	114.9
Cipla Ltd.	892	2597.9	7926
Dr. Reddy'S Laboratories Ltd.	2518.2	5457	12738
Glaxosmithkline Pharmaceuticals Ltd.	40	44.3	20
Glenmark Pharmaceuticals Ltd.	325.8	569.2	4349.7
Lupin Ltd.	760.1	4834.2	16037.8
Novartis India Ltd.	6.9	1.7	
Pfizer Ltd.	235.1	103.8	205.4
Sun Pharma Advanced Research Co. Ltd.		649.8	2244.8
Sun Pharmaceutical Inds. Ltd.	742	1572.8	7750.2
Torrent Pharmaceuticals Ltd.	558.6	1385.7	2181.3
Wockhardt Ltd.	507.2	332.7	2638.8

Source: Indiastat.com

Summary and Concluding Observations

Competitive pressure generated by liberalization and subsequent change in the national patent law have worked effectively in pushing Indian pharmaceutical firms into R&D activity, increasing the production, sales, revenue earned and exports of this sector. The Pharmaceutical Industry is one of the prosperous industries in India. In terms of production, sales, employment and exports the Indian pharmaceutical industry should be considered as one of the relatively successful industries operating in India. Low cost of production, R&D and innovations have placed

the industry in a potential successful position. There are arguments for and against the longer new product patent regime as against the shorter duration process patent regime of 1970s. Indian companies need to undertake continuous R&D activity to survive and to compete with the local as well as global players. TRIPS and the consequent changes in the patent law of the country have immense implications for the pharmaceutical sector where R&D activity is necessary for survival.

Our study has revealed that some of the top Indian pharmaceutical companies have increased their R&D expenditure post-TRIPS. They have understood the need of the hour and have reoriented themselves. They have increased their expenditure on inventive activity. The sector has proved to be enough resilient to withstand this stringent patent regime as is evident from the revenue and sales figures in the above section. Many industry experts and academicians had apprehended that liberalisation and the subsequent TRIPS regime will lead to exit of many indigenous players in this sector and only the MNCs will survive. However, this threat could be defended if the Indian companies can utilize the opportunities of low cost production, if they invest more for innovations of medicines for public health and pay attention to the local common and infectious diseases. The need of quality production of new and old drugs are essential.

Liberalisation and the new patent regime have not only imposed restrictions on the pharmaceutical industry but has also thrown open new opportunities and markets for this sector. Within the scope of TRIPs, licensing activity is encouraged and much flexibility have been incorporated for production of medicines for public health necessary for the developing countries. Proper effective use of compulsory licenses, production to support local public needs, exceptions to product patent rights in certain cases might help the industry to prosper further. More investment, more industry – academic linkages and skill development might also help the industry to cope up with the new situation emerged from liberalisation and new product patent regime. The study suggests several policy measures to further indigenous technological efforts of pharmaceutical firms, which include, removing obstacles that inhibit outward orientation of firms, providing special scheme for small size firms in the overall technology policy for the industry, intensifying collaborative research efforts between private sectors and government research institution, and utilizing flexibilities in the TRIMs agreements to persuade foreign firms to relocate their R&D units into the country.

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