

## Research and Development, Exports and Patenting in the Indian Pharmaceutical Industry: a Post TRIPS Analysis

Ravi KIRAN<sup>\*</sup>, Sunita MISHRA<sup>\*\*</sup>

### **Abstract**

*The Pharmaceutical Industry witnessed a change after the formation of World Trade Organization (WTO) in 1995 when India, being a signatory member of WTO, adopted Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. Indian pharmaceutical industry, being a highly fragmented one and dominated mostly by a large number of smaller enterprises, was also apprehensive when TRIPS was included in WTO. In the above backdrop, this paper examines the Impact of TRIPS on Research and Development, Exports and Patenting activity of The Pharmaceutical Industry of India. The results of the study highlight an increase in R & D Expenses, and R& D Intensity of leading Pharmaceutical companies in the Post-TRIPs period. Moreover, the Indian companies have been at the forefront, both in terms of Drug Master Filings (DMF) and abbreviated New Drug Applications (ANDA) filings in post TRIPS period.*

**Keywords:** Pharmaceutical Industry, India, Research and Development, Patents.

**JEL Classification Codes:** O30

---

<sup>\*</sup> Professor Thapar University, Patiala. e-mail: [kiranravee@gmail.com](mailto:kiranravee@gmail.com)

<sup>\*\*</sup> Professor, MM University, Mullana. email: : [sunita\\_mmu@yahoo.com](mailto:sunita_mmu@yahoo.com)

## 1. Introduction

Indian pharmaceutical industry is about 120 years old. Production of modern medicine by indigenous units started with the setting up of Bengal Chemical and Pharmaceutical works in Calcutta (1892), which was followed by the establishment of Alembic Chemical works in Baroda (1907) and Bengal Immunity in 1919. At that point of time, the Patents Act of 1911 was in practice, which facilitated patenting all the known and possible processes of manufacturing a drug besides patenting the drug itself. Foreign multinational corporations (MNCs) were quick to take advantage of this provision. They consistently imported bulk drugs from their home countries and produced/mixed formulations in India, contending that locally available bulk drugs were not of desired quality. They also patented heavily in the country (Kamath, 2002). The indigenous firms were legally prevented from manufacturing most of the new drugs introduced by the transnational corporations (TNCs) during the life of the patent secured by the latter, i.e., for 16 years, which could be extended to a maximum of another 10 years if the working of the patent had not been sufficiently remunerative to the patentee. The domestic firms were also forbidden from processing a patented drug into formulations or importing it.

As a result, at the time of independence, the industry was dominated by multinational corporations and the prevailing drug prices were among the highest in the world. (Henderson, 1997) Between 1947-57, ninety-nine percent of the 1704 drugs and pharmaceutical patents in India were held by foreign multinational enterprises (MNEs) which controlled 80 percent of the market (Dubey 1999). To study patents and provide suggestions on the type of patent system that India should implement, two expert committees were established in independent India. The Patent Enquiry Committee (1948-50) reported that, "the Indian patent system has failed in its main purpose, namely to stimulate inventions among Indians and to encourage the development and exploitation of new inventions for industrial purposes in the country so as to secure the benefits thereof to the largest section of the public." (Ramanna, 2003). The second committee, known as the Ayyangar Committee (1957-59), noted that foreign patentees were acquiring patents not "in the interests of the economy of the country granting the patent or with a view to manufacture there, but with the object of protecting an export market from competition from rival manufacturers particularly those in other parts of the world". Thus India "is deprived of getting, in many cases, goods at cheaper prices from alternative sources because of the patent protection granted in India". (Ramanna, 2003). These reports concluded that foreigners held 80-90 per cent of the patents in India and were exploiting the system to achieve monopolistic control of the market. The committees therefore suggested that a patent system, which focused on access to resources at lower prices, would be beneficial to India. The Patent Act of 1970 was based on the recommendations of these committees. The act found support among domestic firms and various political parties in India. Under this act, only one process that was used in the actual manufacturing could

be patented. The period 1970-95, generally known as pre-TRIPS period, was a flourishing phase of Indian pharmaceutical industry.

However, the scenario again changed when the world trade organization (WTO), was established in 1995 as a successor to the general agreement on tariffs and trade 1947 (GATT- 1947). India was a founder member of the GATT-1947 and the WTO-1995. Being a signatory member of WTO, India had signed onto TRIPS. Under TRIPS, all countries have to provide for protection of product patents from January 1, 1995. However, developing countries like India, which did not have a regime of product patents, could avail a transition period of ten years - until January 1, 2005

Domestically and internationally India resisted conforming to TRIPS and refused to comply with its provisions earlier. The simple reason was that to conform to TRIPS, India would have to revise one of the main aspects of its patent policy that only process and not product patents would be granted to pharmaceuticals and agrochemicals

However, perspectives about IPRs in India changed over time and caused a marked shift in India's policy around 1998-99. Industry bodies and various groups changed their stand and now took a pro-patent view (Ramanna,2003; Rangnekar, 2005).The CII (Confederation of Indian industry), ASSOCHAM (Associated chambers of commerce and industry of India), and even FICCI, the most influential representative of Indian industry, now started favouring intellectual property rights. (Ramanna 2002; Ramanna 2003; Rangnekar, 2005).

Even some domestic firms like Dr. Reddy's laboratories and Ranbaxy who had been prospered under the existing patent structure, now started visualizing significant avenues for profit from the new patent regime. As a result, a marked shift in India's policy occurred around 1998-99 (Ramanna, 2002; Ramanna, 2003; Rangnekar,2005). Accordingly 'The Patent Act 1970' was amended. Three amendments viz. The Patents (Amendment) Act, 1999, The Patents (Amendment) Act, 2002 and The Patents (Amendment) Act, 2005, were made to the patent Act 1970 with a view to fulfilling India's obligation of the TRIPS requirements.

### **1.1. Pharmaceutical industry in post-TRIPS period (1995-2008):**

The period 1995-2008 (i.e. the post-TRIPS period) saw the strongest performance of the Indian pharmaceutical industry on several fronts. TRIPS compliance of the intellectual property right regime has not reduced the innovation capacity of the domestic pharmaceutical industry which has visualized an increase in both, research budget and patenting. The recent surge in patent applications in India in the post-1995 period, has now received attention in policy analysis. It provides important data for evaluating the potential for domestic actors to adjust to the new patent regime. The number of patent applications filed in the Indian Patent

Office has risen approximately 420 per cent in 2006 from 1995. (WIPO,2009). In terms of the number of PCT international applications (IAs) filed in 2008, India stood at 18th position. (PCT yearly review, 2008). R&D expenditure as a percentage of sales, which stood at around 2 percent in 1993-94, increased to around 5 percent in 2005-06.(Occasional paper by Export-Import bank of India, 2007). Presently, Indian pharma companies are increasing the number of regulatory filings such as DMFs and ANDAs as these enable them to manufacture and market drugs in the regulated markets such as the United States and Europe. In the above backdrop, the present study examines the impact of TRIPS on pharmaceutical industry of India in post-TRIPS period in terms of patents, R&D and exports.

The broad objectives of the study are to analyse the R&D, Exports and Patents in pharmaceutical industry in post-TRIPS period. The hypotheses related to achieve the above objective are:

**H1:** R&D activity of Pharmaceutical companies / industry has improved in the Post-TRIPS period.

**H2:** Exports of Pharmaceutical companies has improved in the Post-TRIPS period.

**H3:** Patenting activity of Pharmaceutical companies has increased in the post-TRIPS period

## **2. Review of Literature:**

A few empirical studies showing performance of pharmaceutical industry in post TRIPS period are mentioned here. In the past three and a half decades most of the large private Indian pharmaceutical firms focused on reverse engineering R&D, and activity was limited to applying known knowledge, or to making small adjustments in the contents (Wendt, 2000). This resulted in introducing new drugs early in the markets. (Lanjouw, 1996) opines that production technologies were well mastered and the lag period between the launch of a new product in its first market and India was thus reduced, in some cases as low as two years. The earlier literature points out that the firms in developing countries compete on the basis of production capabilities, largely acquired from elsewhere and reinforced by basic to intermediate technological capabilities related to a simple knowledge base (Lall, 1987; Bell and Pavitt, 1995). With the signing of WTO, specifically TRIPS in 1994, the Indian industry and market structure is poised to change.

The study by (Kubo, 2004) found that R&D intensity and the patent to R&D ratio has increased after 1995. The study by (Grace, 2004) reveals that the prospects of changing intellectual property on pharmaceutical industry are extremely positive for the future of the Indian industry. The study shows that one third of all FDA applications came from India in 2003 and this number is expected to be one half in 2004. MNCs have been interested in working with Indian firms for some time, attracted by lower cost structure. According to (Chadha, 2005) there is a stricter patent regime has stimulated patenting activity in the Indian pharmaceutical industry. The study by (Sampath, 2005) categorized firms in the Indian Pharma

Industry into 3 main groups based on empirical data collected and identified the main strategies and their triggers in each one of the 3 firm groups. The survey of 103 firms highlighted that Indian firms are adapting a combination of cooperative and competitive strategies, for adapting and capitalizing on the opportunities created by the changing patenting regime. There is a high correlation between export intensity and R&D investments in the Indian Pharma sector. Moreover firms that had greater revenues from exports were able to invest a larger amount on R&D.

The study by (Chadda, 2006) in her paper has tried to show that Indian firms are spending huge resources to secure non-infringing process patents in foreign countries. After tapping the developing countries, they are trying to access developed countries with drug master filings (DMFs) for bulk actives supply and abbreviated new drug applications (ANDAs) for formulations. The study by (Dhar & Gopakumar, 2006) provides analysis to indicate the performance of the firms in the Indian pharmaceutical industry following the changes in the patent regime necessitated by the Agreement on TRIPS. The study shows that the R&D spending of some of the leading firms, in particular, Ranbaxy and Dr Reddy's has shown increase in Post- TRIPS period. As a result, R&D intensities of the firms have improved significantly.

The study by (Sunil, 2006) undertakes a detailed mapping out of the sectoral system of innovation of India's pharmaceutical industry. The study shows that the TRIPS compliance of the intellectual property right regime has not reduced the innovation capacity of the domestic pharmaceutical industry which has visualized an increase in both research budget and patenting. According to (Sheena Reddy, 2006) the growth in R&D for larger pharmaceuticals is greater than the growth for the general pharmaceutical sector. Larger pharmaceuticals have the resources to devote more investment for R&D and can afford to think about the future. Smaller pharmaceuticals do not have these resources and might not be able to survive in the market.

Indian firms are adapting to the changing environments (Chaturvedi and Chataway, 2006). R&D is recognized as the 'survival kit' in the post-TRIPs scenario. The paper observed that Indian firms are investing in R&D not only for new drug discovery but for developing capabilities to assimilate and exploit knowledge available externally. They are also positioning themselves as a partner of choice for technology savvy national and multinational firms. The study by (Pradhan, 2006) examines the impact of a stronger protection regime for intellectual property on the exports of a technologically imitative country, India. The empirical analysis presented in the study suggests that in the case of pharmaceuticals, India stands to benefits from market expansion effects.

In his working paper, (Chaudhuri, 2007) explores that R&D expenditure has dramatically increased for a segment of the Indian pharmaceutical industry after TRIPS came into effect. It is not only that the amount of R&D expenditure has increased, but there has been a drastic shift in the structure of R&D activities of the Indian companies. Earlier they were primarily engaged with the development of new processes for manufacturing drugs, now they are also involved in R&D for new chemical entities (NCE). Indian Pharmaceutical Industry has Exciting Opportunities in Post- TRIPS period. Indian companies are increasing their rate of DMF filings every quarter. Indian generic players are also increasing their participation in the advanced markets, particularly the US. ANDA filings with USFDA are also increasing in Post- TRIPS period (Gupta (2007).

Many Indian pharmaceutical companies have not only shown good performance domestically but have also been able to establish their foothold in overseas markets. Despite challenges posed by the WTO regime, the growth momentum has continued in this sector (EXIM Bank 2007). The study by Nair (2007) points out that future will be bright for the Indian pharma companies focusing on visionary strategies. Drug Discovery, Para IV filings, focus on production of high quantum and moderately priced generics, strengthening API/drug intermediates production, outsourcing to MNC's upgrading manufacturing facilities to USFDA standards and investing in Pharma support services viz. analytical services, diagnostic services, data management services and clinical research operations will prove worthwhile in the long run and help India move up and compete with top global Pharma companies.

India is now emerging as a preferred supplier of Active Pharmaceutical Ingredients (APIs) to many global companies for considerations beyond costs (Sharma, 2008) . It is today the third largest API player after China and Italy. India is way ahead of its competitors in Drug Master File (DMF) filings. The proportion of DMF filings by Indian players has gone up more than three times in the last few years. India has the largest (being outside the US) US FDA approved facilities. Indian firms are able to tackle complex synthesis in relatively short periods of time with cost efficiency.

### **3. Data Sources and Research Design**

The present study is based on secondary data. Secondary data has been collected from Indiastat database which shows statistics from Indian Government agencies relating to all aspects of Indian life: population, health, economy, education, annual reports and websites of pharma companies and other pharma websites. The R&D and Exports of pharmaceutical industry has been taken for the period 1981-82 to 2006-07. Growth rates have been calculated for pre-TRIPS and post-TRIPS separately. Patents of pharmaceutical industry have been taken after 1995. R&D, Exports and Patents of leading pharmaceutical companies has been analysed for the period 1998-2008. This paper attempts to analyze R&D, Exports and Patents of pharmaceutical industry of India as well as of some leading pharmaceutical firms in

post TRIPS period. For this, nine leading pharmaceutical companies have been selected on the basis of their sales performance and profitability ratios. (Profitability ratio has been calculated as percentage of net profits to sales). These firms are i) Ranbaxy ii) Dr. Reddy's laboratory (DRL) iii) Sun pharmaceutical industries limited iv) Wockhardt limited. v) Cadilla healthcare limited vi) Glenmark pharmaceuticals limited vii) Torrent pharmaceuticals limited viii) Cipla and ix) Aurobindo pharma.

## 4. Results and Discussion

### 4.1. R&D and R&D Intensity

The first objective of this paper is to analyse R&D activity of Pharmaceutical industry in the Post-TRIPS period. Accordingly, the R&D expenditure of pharmaceutical industry has been analysed.

**Table 1: R&D Expenditure of Pharmaceutical Industry (Rs Million)**

S No	Year	R&D expenditure	S No	Year	R&D expenditure
1	1981-82	293	14	1994-95	1405
2	1982-83	322	15	1995-96	1607
3	1983-84	400	16	1996-97	1859
4	1984-85	426	17	1997-98	2203
5	1985-86	480	18	1998-99	2604
6	1986-87	508	19	1999-00	3209
7	1987-88	514	20	2000-01	3703
8	1988-89	540	21	2001-02	4351
9	1989-90	561	22	2002-03	6721
10	1990-91	606	23	2003-04	10543
11	1991-92	805	24	2004-05	11243
12	1992-93	952	25	2005-06	12352
13	1993-94	1250	26	2006-07	14305
<b>Growth Rates (%)*</b>					
<b>Period I Pre-TRIPS</b>		<b>4.89</b>	<b>Period II Post-TRIPS</b>		<b>6.56</b>
<b>Entire Period</b>		<b>6.05</b>			

Source: Indiastat database \*self calculated

The results as depicted by Growth rates (Table 1) highlight that growth of R&D of the industry as a whole is more in the latter period i.e., post-TRIPS period (4.89) as compared to pre-TRIPS period (6.56). In addition to this, R&D intensity of nine leading pharmaceutical firms has also been analyzed.

Table 2 shows that most of the sample pharmaceutical companies showed the most impressive increase in their R&D intensities. The implication, which comes out from this analysis, is that these firms have realized the need of R&D in post TRIPS period and as such, they are increasing the percentage of R&D expenditure. The

above results show that R&D activity of Pharmaceutical industry as well as of firms has improved in the Post-TRIPS period.

**Table 2: R & D intensity of the selected leading pharmaceutical companies in the post-TRIPS period**

Year	Ranbaxy	DRL	Sun pharma	Workhardt	Cadila	Glenmark	Torrent	Cipla	Aurobindo
1998	3.22	3.31	4.27	9.27	6.71	3.88	1.21	4.47	3.12
1999	3.53	3.22	5.59	11.05	6.17	5.20	3.33	4.86	2.62
2000	3.28	4.78	4.55	8.96	5.47	7.39	4.84	3.03	1.07
2001	3.75	4.64	4.08	4.62	9.29	6.00	5.50	2.28	0.60
2002	6.81	4.51	4.31	5.01	7.20	10.84	7.85	3.62	1.35
2003	7.81	7.80	10.87	5.87	9.41	9.97	10.36	3.09	1.85
2004	9.16	9.91	12.92	5.16	9.44	12.78	15.65	4.71	3.65
2005	13.74	13.28	12.07	5.20	10.92	7.63	18.52	6.24	4.66
2006	9.51	8.93	12.35	8.02	9.72	5.94	10.93	6.09	5.23
2007	10.99	3.83	13.06	8.79	9.24	3.43	10.32	6.75	4.31
2008	10.56	7.17	8.55	6.23	7.91	2.54	11.66	6.10	4.85

Source: Annual Reports \* R&D as percentage of gross sales

#### 4.2. Exports and Export Intensity

The second objective of the paper is to analyse Exports of Pharmaceutical industry in the Post-TRIPS period. Industry level analysis shows that the growth rate has been 5.29 percent per annum in pre-TRIPS period and 5.68 percent per annum in post-TRIPS period which shows that exports have increased in post-TRIPS period. (Table 3)

**Table 3: Exports of pharmaceutical industry (Rs Million)**

S No	Year	Exports	S No	Year	Exports
1	1981-82	1220	14	1994-95	25123
2	1982-83	1122	15	1995-96	34087
3	1983-84	1552	16	1996-97	43418
4	1984-85	2342	17	1997-98	54193
5	1985-86	1579	18	1998-99	62567
6	1986-87	1613	19	1999-00	66314
7	1987-88	3261	20	2000-01	87574
8	1988-89	4737	21	2001-02	97512
9	1989-90	8496	22	2002-03	128261
10	1990-91	10141	23	2003-04	152132
11	1991-92	15501	24	2004-05	178578
12	1992-93	15330	25	2005-06	225789
13	1993-94	20097	26	2006-07	249429
<b>Growth Rates (%)*</b>					
<b>Period I Pre-TRIPS</b>		<b>5.29</b>	<b>Period II Post-TRIPS</b>		<b>5.67</b>
<b>Entire Period</b>		<b>5.47</b>			

Source: Indiatat database

\*self calculated



Company level analysis show that export intensity of all the nine firms has been increasing in post TRIPS period. Many of these firms have been exporting more than one-half of their sales turnovers. It appears that for these companies, foreign markets are equally important as their domestic market and this gave them the impetus to improve their operating efficiencies. The above results show that Exports of Pharmaceutical firms have improved in the Post-TRIPS period.

**Table 4: Export intensity of the selected leading pharmaceutical companies in the post-TRIPS period**

Year	Ranbaxy	DRL	Sun Pharma	Worhhardt	Cadila	Glenmark	Torrent	Cipla	Aurobindo
1998	44.68	--	--	--	0.00	--	--	14.19	31.86
1999	46.92	--	27.64	--	8.99	8.40	--	19.28	39.27
2000	46.17	--	25.91	--	8.32	8.77	2.66	18.83	49.20
2001	50.07	39.16	19.25	26.35	15.71	9.25	7.25	26.68	54.72
2002	65.60	56.37	17.24	35.55	18.37	7.87	9.37	34.38	47.01
2003	69.84	50.86	29.15	--	12.41	13.42	11.40	30.73	47.31
2004	67.94	48.90	39.27	--	17.23	23.46	12.02	38.85	47.87
2005	66.07	47.78	42.45	--	21.56	21.08	18.18	42.30	47.89
2006	66.96	49.71	42.54	21.05	29.08	18.60	23.63	52.37	55.43
2007	63.11	44.37	45.37	20.99	41.72	24.26	22.90	51.43	51.02
2008	63.01	45.91	56.48	--	52.06	33.75	24.77	53.78	57.54

Source: Annual Reports

### 4.3. Patenting Scenario

The third objective of the paper is to analyze patents of Pharmaceutical industry in the Post-TRIPS period.

The present study analyses the post-TRIPS (1994-95 to 2007-08) patenting scenario of the pharmaceutical industry of India (Table 5). It shows that the patents in drugs and pharmaceutical industry have grown at a higher rate of 6.06 percent per annum as against the 5.57 percent growth of total patents granted.

Table 6 shows that prior to 1995, except Ranbaxy, majority of Indian pharma companies did not have US patents. However in the post-TRIPS period, more firms like DRL, Torrent, Aurobindo, Wockhardt and Sun have also marked their presence in patents granted. Majority of the pharma companies got patents after 2000. This may be attributed to the fact that the process of acquiring patents takes a few years. One of the plausible reasons could be filing of patents immediately after India adhered to the TRIPS agreement.

**Table 5: Patenting scenario in the post-TRIPS period**

Year	Patents granted to drugs and pharmaceuticals ( 1)	Total patents granted (2)	1 as % of 2
1994-95	232	1759	13.19
1995-96	132	1533	8.611
1996-97	71	907	7.828
1997-98	291	1844	15.78
1998-99	150	1800	8.333
1999-00	307	1881	16.32
2000-01	276	1318	20.94
2001-02	320	1591	20.11
2002-03	312	1379	22.63
2003-04	419	2469	16.97
2004-05	453	3021	14.99
2005-06	457	4320	10.58
2006-07	798	7539	10.58
2007-08	1469	15261	9.626
<b>Growth Rates*</b>	<b>6.06</b>	<b>5.57</b>	

Source: Indiatat database \*self calculated

**Table 6: Patents granted to the selected leading pharmaceutical companies by USPTO in post-TRIPS period**

Firms	Ranbaxy	DRL	Torrent	Aurobindo	Workhardt	Sun pharma
Pre 1995	7	-	-	-	-	-
1995	1	-	-	-	-	-
1996	1	-	-	-	-	-
1997	2	-	-	-	-	-
1998	5	-	-	-	-	-
1999	4	-	-	-	-	-
2000	4	-	1	-	-	-
2001	8	-	3	-	-	-
2002	7	-	1	2	-	2
2003	8	7	3	-	3	2
2004	11	3	-	3	2	-
2005	7	5	-	1	2	1
2006	12	7	1	3	4	4
Total	77	22	9	9	11	9

Source: USPTO

**4.3.1. Drug Master Filings**

India is on its way to become a global leader in API production. If the manufacturers want to sell active pharmaceutical ingredients (APIs) in the US, a DMF filing is required. Although Indian pharmaceutical companies started filing DMFs in the US around the 1980s, but until the late 1990s, only a few DMFs were filed. Since then the rate of filing has accelerated. DMFs filed from India as a percentage of total

DMFs filed with the United States Food and Drug Administration (US FDA) has increased steadily especially in the period 2000 to 2007 (IBEF, Market overview, December 2008). Table 7 indicates not only the present level of patenting activity in Indian pharmaceutical industry but commitment (pipeline) for the future as well as has been indicated by a steady rising share of Indian pharmaceutical companies in total DMF filings with USFDA.

**Table 7: India's share in the total DMFs filed with the US FDA**

Year	Total DMF filings with USFDA	DMF filings from India	India's share in global DMF filings (%)
2000	227	33	14.5
2001	280	52	18.6
2002	288	63	21.1
2003	404	124	30.7
2004	517	193	37.9
2005	688	274	39.8
2006	706	306	43.9
2007	226	110	48.7

The current DMF filing scenario of the selected leading pharmaceutical companies has been presented in Table 8.

**Table: 8: Cumulative DMF filings with USFDA by selected leading pharmaceutical companies**

Company	DMF Filings					
	2004	2005	2006	2007	2008	2009
Ranbaxy	16	41	59	80	92	107
DRL	55	64	87	104	127	148
Sun Pharma	22	34	44	59	101#	133#
Wockhardt	--	18	28	41	53	66
Cadilla	12	28	40	51	59	76
Glenmark	--	--	7	18	30	42
Torrent	--	1	3	5	6	15
Cipla	--	59	--	87	--	153
Aurobindo	5	35	86	114**	122	128

Source: Annual Reports, \* as on 31st March \*\*as on 31st July #DMF+CEP applications

Indian firms are also trying to access developed countries with abbreviated new drug applications (ANDAs) for formulations.

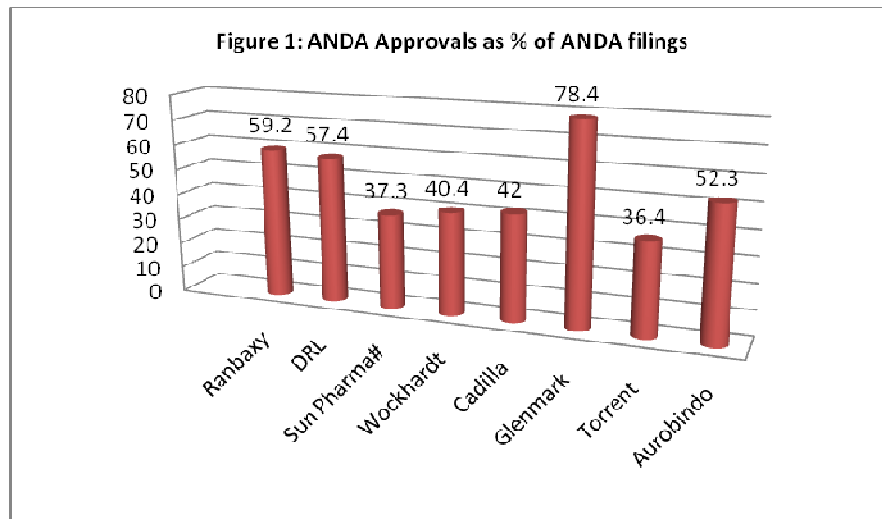
**Table 9: Cumulative ANDA filings by selected leading pharmaceutical companies in post-TRIPS period**

Company	2004	2005	2006	2007	2008	2009
Ranbaxy	150	183	197	239**	240**	241
DRL	52	65	77	117	122	144
Sun Pharma	11	33	62	107	142	179
Wockhardt	7	13	39	47	57	67
Cadilla	12	25	36	62	81	92
Glenmark	--	7	18	28	51	71
Torrent	--	1	4	6	11	32
Aurobindo	2	24	51	100#	128	147

Source: Annual Reports, \*as on 31st March \*\*as on 31st Dec. # as on 31st July

Figure 1 shows that these leading companies have been getting a good percentage of their ANDA filings approved. Another thing worth mentioning is that most of these companies have been getting more than 35 percent of their ANDA filings approved.

The above results clearly highlight that the Indian companies are investing funds on filing DMFs and ANDAs and the trend depicts an increase in filings in the post-TRIPS period. It proves our hypothesis that patents in pharmaceuticals have improved in post TRIPS period.



## 5. Results and Discussion

Three hypotheses have been tested in this study:

**H1:** R&D activity of Pharmaceutical companies/industry has improved in the Post-TRIPS period.

**H2:** Exports of Pharmaceutical companies/ industry has improved in the Post-TRIPS period.

**H3:** Patenting activity of Pharmaceutical companies/ industry has increased in the post-TRIPS period

These results show that growth of R&D of the industry as a whole is more in the latter period i.e., post-TRIPS period (6.56) as compared to pre-TRIPS period (4.89). In addition to that most of the sample pharmaceutical companies showed the most impressive increase in their R&D intensities over the period 1998-2008. The implication which comes out from this analysis is that these firms have realized the need of R&D in post TRIPS period and as such they have been increasing the percentage of R&D expenditure. The above results show that R&D activity of Pharmaceutical industry as well as of companies has improved in the Post-TRIPS period.

The results of Exports of Pharmaceutical industry in the Post-TRIPS period. Industry level analysis shows that the growth rate has been 5.29 percent per annum in pre-TRIPS period and 5.67 percent per annum in post-TRIPS period which shows that exports have increased more in post-TRIPS period. Company level analysis show that export intensity of all the nine firms has been increasing in post TRIPS period. Many of these firms have been exporting more than one-half of their sales turnover. It appears that for these companies, foreign markets are equally important as their domestic market and this gave them the impetus to improve their operating efficiencies. The above results show that Exports of Pharmaceutical firms have improved in the Post- TRIPS period.

Regarding patenting, that pharmaceutical industry seems to respond better in post-TRIPS period. The results show that the patents in drugs and pharmaceutical industry have grown at a higher rate of 6.06 percent per annum as against the 5.57 percent growth of total patents granted. Majority of the sample pharma companies got patents after 2000. This may be attributed to the fact that the process of acquiring patents takes a few years. One of the plausible reasons could be filing of patents immediately after India adhered to the TRIPS agreement.

The present study like a number of earlier studies reports an Increase in R&D and R&D intensity in the post TRIPS period. The study by Gupta (2000) highlights that after the establishment of WTO, there is a greater effort by the Indian R&D organizations to obtain patents in USA. Kubo (2004) opines that R&D intensity and patent to R&D ratio has increased in India after 1995 for large pharmaceutical firms. Grace (2004) is of the opinion that most successful firms investing an increasing amount in R&D including in partnership with MNCs, and with increasingly positive results. Dhar and Gopakumar (2006) also accept that there has been an increase in the R&D spending of some of the leading firms, in particular, Ranbaxy and Dr Reddy's. As a result, R&D intensities of the firms have improved

significantly. The study by Chaturvedi and Chataway (2006) further corroborates that Indian firms are investing in R&D not only for new drug discovery but also for developing capabilities to assimilate and exploit knowledge available externally.

In the post-TRIPS period the performance of the Indian pharmaceutical industry improved significantly on several fronts. The industry improved its production performance by a significant margin. The Pharmaceutical industry turned into a net foreign exchange earner during the Post-TRIPS era. India is fast emerging as a powerhouse of API production. The growth was remarkable for the period 2000-08. R&D Expenses have increased at a higher rate in the Post-TRIPS period growing at a rate of 6.56 against 4.89 in Pre-TRIPS period. According to industry reports, the share of Indian companies in the total drug master files (DMF) filed with the US FDA increased to 50 per cent in 2007 from 14 per cent in 2000. Indian companies have been at the forefront, both in terms of DMF and ANDA filings.

## 6. Recommendation for future research

Future research should be focused on in depth study of patenting activity, R&D and exports by taking case studies of some selected pharmaceutical companies. A study based on technology management strategies used by these sample firms can be of great help for the policy makers as well as for the pharmaceutical firms.

## References

- Bell, M and K.Pavitt (1993) "Technological accumulation and industrial growth: contrasts between developed world and developing countries", *Industrial and corporate change*, Vol.2, no.2, pp157-210 Business Standard 2009 "Pharma companies on DMF filing spree" Sept 2009.
- Business Line (2006) "Indian pharma companies top DMF filings" Aug. 2006.
- Chadha, A. (2005) "TRIPS and Patenting Activity: Evidence from the Indian Pharmaceutical Industry", National University of Singapore, Department of Economics, working paper no 0512 retrieved from <http://nt2.fas.nus.sg/ecs/pub/wp/wp0512.pdf>.
- Chadda, A. (2006) "Destination india - the right choice for the pharmaceutical industry", *Delhi Business Review* Vol. 7, No. 1 (January - June 2006) pp 1-8
- Chaudhuri, S. (2007) "Is Product Patent Protection Necessary in Developing Countries for Innovation? R&D by Indian Pharmaceutical Companies after TRIPS" Working Paper Series WPS No. 614/ September 2007 retrieved from <http://www.iimcal.ac.in/res/upd/Sudip20Wp20614.pdf>.
- Chaturvedi, K. and Chataway, J., (2006) , " Innovation In The Post-Trips Regime In Indian Pharmaceutical Firms: Implications For Pharmaceutical Innovation Model", *International Journal of Business Innovation and Research* , Volume 1, Number 1-2 , pp 27-50.
- Dhar, B. and Gopakumar, K.M. (2006) "Post-2005 TRIPS scenario in patent protection in the pharmaceutical sector: The case of the generic pharmaceutical industry in India" the UNCTAD/ICTSD Project on Intellectual Property Rights and Sustainable Development November.

- Export Import Bank of India (2007) "Indian Pharmaceutical Industry: Surging Globally", Occasional Paper No 119, Quest Publications.
- Express Pharma, (2008) "The preferred API partner" 16-30 Sept.
- Grace, C. (2004) "The Effect of Changing Intellectual Property on Pharmaceutical Industry Prospects in India and China: Considerations for Access to Medicines", DFID Health system resource centre: London 2004
- Gupta, Desh Bandhu, (2007), "Exciting Opportunities for the Indian Pharmaceutical Industry", Indian Chemical Engineer, Vol. 49 No. 2 April-June 2007, pp. 154-157
- Kubo, K. 2004 "Product patents and vertical integration in the Post- TRIPS Indian Pharmaceutical Industry", retrieved from <http://are.berkeley.edu/jobmarket/ken.pdf>.
- Lall, S (1987), Learning to industrialize: the acquisition of technological capability by India, London : Macmillan press.
- Lanjouw, J. O. (1998) "The introduction of pharmaceutical product patents in India: Heartless exploitation of the poor and suffering?" NBER working paper No.6366, National Bureau of Economic Research, Cambridge.
- Lanjouw, J.O., and Cockburn, I.M. (2001) "New pills for poor people? Empirical evidence after GATT", World Development, 29(2) February, 265-289.
- Lanjouw, J.O., and MacLeod, M. (2005) "Statistical trends in pharmaceutical research for poor countries", CIPIH Working Paper.
- Mishra P., and Chandra T. (2010) "Mergers, Acquisitions and Firm's Performance: Experience of Indian Pharmaceutical Industry", Eurasian Journal of Business and Economics 3(5), 111-126.
- Pradhan, J.P. (2006) "Strengthening Intellectual Property Rights Globally: Impact on India's Pharmaceutical Exports", ISID Working Paper No 2006/02.
- Ravi Kiran and Mishra, Sunita (2010) "New IPR Regime and Challenges of the Small Pharma Industry", Interdisciplinary journal of Contemporary Research in Business, Vol.1, No 10. pp 42-60.
- Ravi Kiran and Sunita Mishra (2009) "Performance of the Indian Pharmaceutical Industry in Post- TRIPS Period: A Firm Level Analysis", International Review of Business Research Papers, Vol.5, No. 6, pp 148-160.
- Ravi Kiran and Mishra, Sunita (2009) "Changing Pragmatics of The Indian Pharmaceutical Industry in Pre and Post-TRIPS Period" International Journal of Business & Management, Vol. 4, No 9, pp 206-220.
- Reddy, S. (2006) "The Costs to India of Complying with World Intellectual Property Rights: Effects on the Pharmaceutical Industry and Access to Drugs" Economics Thesis.
- Wendt, R. A. (2000) "The Pharmaceutical Industry in India", in Handelshoejskolen i Koebenhavn. Institut for Informatik, International Development Studies, Roskilde University Working Paper No. 24, pp 18 [www.ruc.dk/isg\\_en/](http://www.ruc.dk/isg_en/)