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Performance of the Indian Pharmaceutical Industry in Post-TRIPS Period: A Firm Level Analysis

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The Indian Pharmaceutical Industry has shown the strongest performance in post- TRIPS period. Not only did the industry improve its production performance seen in the previous decades, the industry turned into a net foreign exchange earner during the decade in question. Under this backdrop, the present paper examines the impact of new Patent Act on Pharmaceutical Industry of India especially on R&D. This paper seeks to evaluate the performance of a few leading Pharmaceutical Firms especially in terms of their ANDA filings and approvals as well as DMF filings with USFDA in post-TRIPS period.

Field of Research: TRIPS, ANDA Filings, ANDA Approvals, DMF Filings with USFDA

1. Introduction

The pharmaceutical industry is an exciting industry worldwide with growth rate of 8% and a turnover of around US$ 650 billion. In terms of value, the major constituents are the United States (US) (48% share), European Union (EU) (28%share) and Japan with a share of 12%, and the rest of the world, including India, contributes around 20%. However, in terms of volume, the share of the rest of the world is approximately three times larger. An example in this regard, is India, which ranks 4th in terms of volume with a share of 8% in the world pharmaceutical market and only 13th in terms of value. The annual turnover of the Indian pharmaceutical industry is approximately, US$ 19 billion.

The period of the 1995-2008 (i.e the Post-TRIPS period) saw the strongest performance of the Indian pharmaceutical industry on several fronts. Not only did the industry improve its production performance seen in the previous decades, and that too by a significant margin, the industry turned into a net foreign exchange earner during the decade in question. The Indian pharmaceutical industry, now a $19 billion industry, has shown tremendous progress.

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India now ranks 3rd worldwide in volume and 13th in value. Also country shows excellent performance in export. Indian exports to more than 200 countries around the globe including the highly regulated markets of US, Europe, Japan and Australia. India exported drugs worth around US$ 8 billion in 2008-09, most of which to the US and Europe, followed by Central and Eastern Europe, Latin America and Africa. The trend of patent filing in our country has tremendously increased. A total of 35,218 patent applications were filed, 6040 from domestic and 29,178 from foreign applicants in the last fiscal year.(Economic Times, Jan.7,2009). India stood at 18th position according to their number of PCT international applications (IAs) filed in 2008.

Indian pharmaceutical industry is entering an era in which it is becoming a global hub for R&D activities, which may be in the area of new drug discovery. Indian pharmaceutical industry has also been increasing the R&D expenditure significantly in the recent years. With an increase in R&D spending, Indian companies could file large number of Drug Master Files and Abbreviated New Drug Application (ANDA) with US-FDA. Indian Pharma 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.

In the above backdrop, the paper is an attempt to trace the changing context of innovation and technological developments in Indian pharmaceutical firms in the recent past.The present paper examines the Performance of the Indian Pharmaceutical Industry in Post- TRIPS period by evaluating the performance of a few leading pharmaceutical companies by analyzing a few growth indicators like sales, profits, R&D expenditure, Patents granted by USPTO, ANDA filings and approvals with USFDA in Post- TRIPS period, DMF filings with USFDA in Post- TRIPS period and global DMF Filings.

2. Objectives of the Study

The main objectives of the paper are:

1. To evaluate the performance of a few leading pharmaceutical companies especially in terms of their ANDA filings and approvals as well as DMF filings with USFDA in post-TRIPS period.
2. To evaluate the R&D expenditure of a few leading pharmaceutical companies in post-TRIPS period
3. To evaluate the patents granted to a few leading pharmaceutical companies by USPTO in post-TRIPS period.

3. Significance of The Study:

The growth of Indian Pharmaceutical industry in terms of a few parameters has been envisaged in a few studies but a firm level comprehensive work on the growth of Indian Pharmaceutical industry taking many parameters simultaneously has not been done so

far. This study aims at providing a comprehensive view of the growth of Indian Pharmaceutical industry by doing firm level analysis in the post-TRIPS period.

4. Review of literature

Enough literature is not available on the growth of Indian Pharmaceutical industry taking many parameters simultaneously. Limited research has been there covering firm wise ANDA filings and approvals, DMF filings and approvals with USFDA. Whatever literature is available is in the form of papers/articles published in pharma magazines and studies showing growth of Indian pharmaceutical industry by taking a few parameters only. 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 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.

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. Sunil (2006) in his working paper 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. 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).

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. Gupta (2007) feels that the 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

The results of research study (2007) by EXIM Bank's Occasional Paper Series explores that favourable Government policies along with industry / firm level initiatives have helped the industry to post high growth rates over the years. 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. Chaturvedi and Chataway (2006) highlight that Indian firms are adapting to the changing environments. 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.

Sharma (2008) explores that India is now emerging as a preferred supplier of Active Pharmaceutical Ingredients (APIs) to many global companies for considerations beyond costs. 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. From the literature review, it can be seen that till recently there has not been enough research covering firm wise ANDA filings and approvals, DMF filings and approvals with USFDA. The present study tries to shed light on this un-treaded area of Indian Pharmaceutical research.

5. Data Collection

The paper is based on Secondary data mainly taken from annual reports of Pharmaceutical companies included in the paper. In addition Pharma websites like pharmabiz.com and Pharma magazines were considered. The study would use data from the annual reports of 8 leading firms of the industry to comment on their performance since the Agreement on TRIPS became operational in India, i.e. 1995.

6. Data Analysis

The present study has taken some of the leading pharmaceutical firms' and has used the following indicators: i) sales, ii) net Profits, iii) R& d expenditure, iv) ANDA and DMF Filings for analyzing the performance of Indian Pharmaceutical industry:

Table I. Sales of the leading Pharmaceutical Firms (Rs in Crores)

Year	Ranbaxy	Dr Reddy	Sun Pharma	Worhhardt	Cadila Healthcare	Glenmark	Torrent	Cipla	Aurobindo
1998	1334	332	234	276.2	286	80	347.5	514.4	295
1999	1560	411.7	322	328	345	100	300	617.1	550
2000	1737	481	440	357	457	138	413	759.3	746
2001	2055	1098	613	649	452	200	400	967	996
2001	2820	1641	789	678	528	286	395	1437	1036
2003	3534	1807	892	1023	935	371	386	1842	1190
2004	3615	2008	983	1342	1091	381	430	2090	1341
2005	3537	1913	1185	1561	1090	612	472	2482	1159
2006	4059	2408	1636	1720	1276	758	677	2891	1472
2007	4185	6419	2136	1729	1450	1253	882	3438	2250
2008	4461	4923	3357	2650	1681	2009	969	3998	2435
Growth Rates	**2.03**	**2.91**	**2.79**	**2.39**	**2.21**	**3.18**	**3.31**	**2.25**	**1.94**

Source: Annual Reports

6.1: Sales

The Table IV indicates that most of the top ten firms of the industry saw significant increases in their sales. Almost all the firms, experienced very high growth of sales during period 1995-2008 for which data have been presented in the Table I. The growth was remarkable for the period 2000-08. Inter firm comparision show that the highest growth rate for sales has been highest for Torrent followed by Glenmark and Dr Reddy's Lab.

Table II: Net Profit of the leading Pharmaceutical firms(Rs in Crores)

Year	Ranbaxy	Dr Reddy	Sun Pharma	Worhhardt	Cadila Healthcare	Glenmark	Torrent	Cipla	Aurobindo
1998	117	51	56	51.8	34	11	32	102	24
1999	197	53	59	46.8	44	13	34	115	50
2000	183	60	84	46.8	47	22	46	133	75
2001	252	145	135	102	61.8	22.5	41	179	68
2001	624	455	168	109	67.2	23	50	235	69
2003	795	364	249	111	86.5	33	52	248	103
2004	529	283	316	112	142.9	42	64	307	127
2005	224	66	396	211	131.4	107	53	410	36
2006	381	211	574	302	165	88	65.8	608	70
2007	618	1177	784	386	205	310	112.9	668	229
2008	1049	475	1487	139	236.2	632	155.52	702	291
	2.80	3.58	3.26	3.13	2.43	3.86	3.15	2.57	3.14

Source: Annual Reports

6.2: Net Profits

In terms of net profits the growth rate has been highest for Glenmark followed by Dr Reddy's Lab and Torrent (Table II).

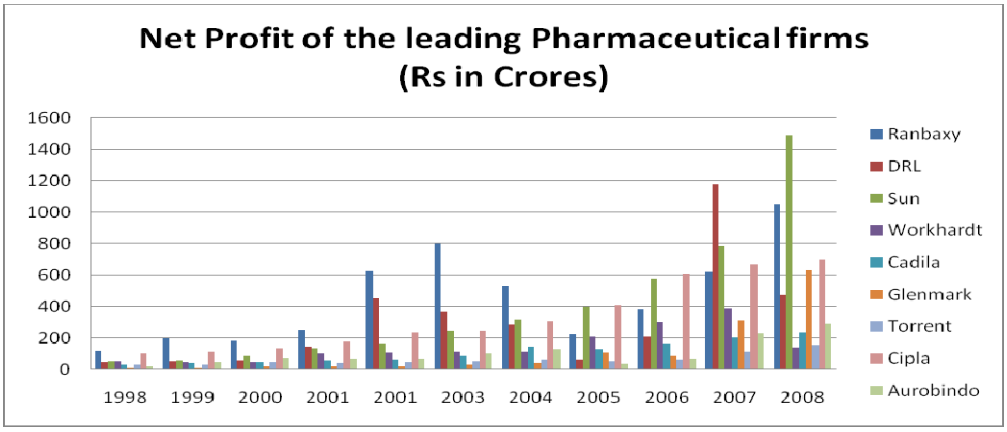
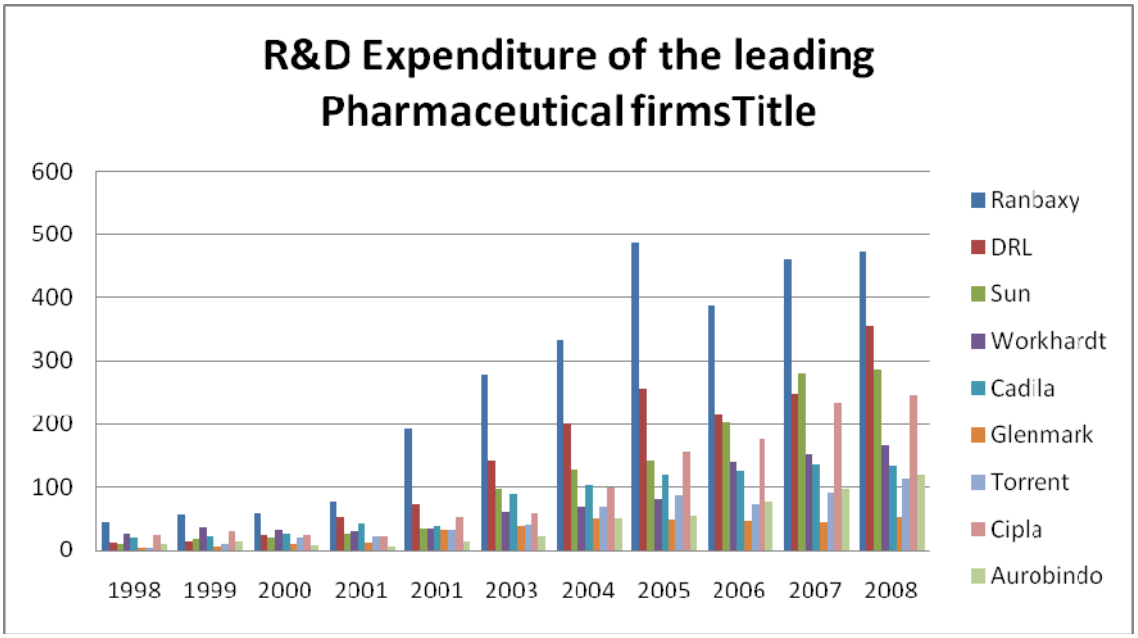


Table III: R&D Expenditure of the leading Pharmaceutical Firms (Rs in Crores)

Year	Ranbaxy	DRL	Sun	Workhardt	Cadila	Glenmark	Torrent	Cipla	Aurobindo
1998	43	11	10	25.6	19.2	3.1	4.2	23	9.2
1999	55	13.27	18	36.24	21.27	5.2	10	30	14.4
2000	57	23	20	32	25	10.2	20	23	8
2001	77	51	25	30	42	12	22	22	6
2001	192	74	34	34	38	31	31	52	14
2003	276	141	97	60	88	37	40	57	22
2004	331	199	127	69.3	103	48.7	67.3	98.4	49
2005	486	254	143	81.1	119	46.7	87.4	155	54
2006	386	215	202	138	124	45	74	176	77
2007	460	246	279	152	134	43	91	232	97
2008	471	353	287	165	133	51	113	244	118
Growth Rates	**2.23**	**2.35**	**2.69**	**2.85**	**2.20**	**1.82**	**2.13**	**2.86**	**3.03**



6.3: R& D Expenditure

In terms of R&D Expenditure Ranbaxy has always spent higher expenditure as compared to other Pharmaceutical Companies, but in terms of Growth rates, the highest growth has been recorded by Aorobindo, followed by Cipla and Workhardt (Table III).

6.4: Firm wise Analysis of Patents in terms of ANDA and DMF Filings

Table IV. Patents granted to the leading Pharmaceutical Firms by USPTO

	Ranbaxy	DRL	Torrent	Aurobindo	Workhardt	Sun
Pre 1995	7	0	0	0	0	0
1995	1	0	0	0	0	0
1996	1	0	0	0	0	0
1997	2	1	0	0	0	0
1998	5	2	0	0	0	0
1999	4	7	0	0	0	0
2000	4	7	1	0	0	0
2001	8	3	3	0	0	0
2002	7	7	1	2	0	2
2003	8	1	3	0	3	2
2004	11	0	0	3	2	0
2005	7	0	0	1	2	1
2006	12	2	1	3	4	4
Total	**77**	**30**	**9**	**9**	**11**	**9**

Source: Annual Reports, USPTO www.uspto.gov/web/offices/ac/ido/ oeip/taf/asgstca/inx_stc.htm,

In 2008, Ranbaxy in USA, six ANDAs were submitted. Ranbaxy has the largest basket of products in the US market with 141 approved drugs and another 98 marketing applications pending for approval (Table IV).

Table V: Increasing Number of ANDA Filings from India (Firm-wise)

Firm	Upto 2004	2005	2006	2007	2008	2009
Ranbaxy	150	33	14	42	6	
Dr.Reddy's	52	13	12	33	22	37
Sun Pharmaceutical Inds. Ltd	11	22	29	45	31	38
Wockhardt	7	6	26	8		
Cadilla healthcare	12	13			18	
Glenmark Pharmaceutical Ltd	--	7	11	10	23	30E
Torrent Pharmaceutical Ltd	--	1	3	2	5	21
Aurobindo	2	22	27	31	46	19*

Source: Annual Reports, * FY 2008-09 and Q4 2008-09 Unaudited Results

Table: VI ANDA Approvals as on 31-3-08

Company	ANDA Filings as on 31-3-08	ANDA Approvals as on 31-3-08
Ranbaxy	241	142
Dr.Reddy's	122	70
Sun Pharmaceutical Inds. Ltd #	142	53
Wockhardt	--	23
Cadilla healthcare	81	34
Glenmark Pharmaceutical Ltd	51	40
Torrent Pharmaceutical Ltd	11	4
Aurobindo	128	67

Source : Annual Reports, #Sun Pharma and Caraco

6. 4. 1: ANDA Filings

Ranbaxy: In 2008, Ranbaxy in USA, six ANDAs were submitted. Ranbaxy has the largest basket of products in the US market with 141 approved drugs and another 98 marketing applications pending for approval. The year 2007-08 saw the first of technology based ANDA filings from Sun Pharma, with technology sourced from SPARC Ltd. As on 31-3-08, between Sun Pharma and Caraco, 142 ANDAs were filed, whereas ANDAs for 53 products are now approved.This compares with 29 products last year, including tentative approvals for 8 products. A total of 215 patents have been have

been filed so far, of which 59 were granted. Till March 08, the company has 101 filings for DMF and CEP.

Cadila: Cadila has built up a robust generic pipeline for the US market. As on 31-3-08, out of 81 cumulative ANDA filings, Cadila has 34 product approvals and 15 of them have been launched in the market. The company filed around 18 ANDAs and received approval for 12 ANDAs in FY08. In 2007–08, Company Dr Reddy filed 19 ANDAs in US including10 Para IV filings. Dr. Reddy's has filed 122 cumulative ANDAs as of 31March 2008. 2007–08 also saw the highest number of approvals for the Company's ANDA filings: 13 final approvals from the US and 4 from Canada, in addition to 7 tentative approvals from the US. Wockhardt: Wockhardt is amongst the top five companies globally to have received 23 abbreviated New Drug Application(ANDAs) approvals from the United States Food And Drug Administration (USFDA) in 2008. As of 31March 2008 Company has got approval for 38+ products abbreviated New Drug Application(ANDAs) approvals from the United States Food And Drug Administration (USFDA) .

Glenmark: Glenmark's focus on strategic planning and development has generated a robust pipeline in varying stages of maturity. In 2007–08 alone, Glenmark filed 23 abbreviated New Drug Application with (ANDAs) with the USFDA of which seven were paragradh IV filings . As of 31March 2008 Company has filed 51 cumulative ANDAs & it has got approval for 38 products so far. Regarding APIs, till date the Company filed over 30 US Drug Master Files(DMFs), filed seven Canadian DMFs,and several EDMFs. In 2007–08, 8 USDMFs and 5 CEPs were filed. As on 31 March 2008, the Company has made cumulative filings of 37+ Global DMFs, with 30 in the US.

Aurobindo: Aurobindo filed highest number of ANDAs from India in 2007-08. In the same year it also filed highest number of DMFs from India. As on 31-03-08, a total of 128 ANDAs were filed and 67 were approved with the USFDA. A total of 318 patents have been have been filed so far. In 2007-08, 46 ANDAs were filed & ANDAs for 17 products were approved for the US.

Torrent: As at March 08, 11 ANDA and 6 DMFs were filed in US and 17 new product Dossiers completed in the European Union. Five processes for APIs were developed and transferred to plant during the year. 588 patents filed for NDDS technology, drug discovery projects and innovative process of API & formulations for various markets and 163 have been granted so far.

6.4.2 Drug Master File

DMFs are typically filed for supplying bulk drugs or active pharmaceutical ingredient (API). A Drug Master File (DMF) is a submission to the US Food and Drug Administration (US-FDA) that may be used to provide confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more human drugs. The submission of a DMF is not required by law or FDA regulation. A DMF is submitted solely at the discretion of the holder. The

information contained in the DMF may be used to support an Investigational New Drug Application (IND), a New Drug Application (NDA), an Abbreviated New Drug Application (ANDA), another DMF, an Export Application, or amendments and supplements to any of these. However, a DMF is not a substitute for an IND, NDA, ANDA, or Export Application. It is not approved or disapproved. Technical contents of a DMF are reviewed only in connection with the review of an IND, NDA, ANDA, or an Export Application.

One-third of all Drug Master Files with US-FDA come out of Indian facilities. India now has the highest number of FDA-approved plants (approx. 73). Fifteen percent of the scientists in big Pharma companies in America working in drug discovery laboratories are of Indian origin. Forty percent of people who work on the shop floor of the worldwide generic pharmaceutical industry are of Indian origin, and the best developers of generics are also of Indian origin. (Industry Highlights, January 2007)

Table VII: Increasing Number of DMF Filings with USFDA (Firm-wise)

Firm	Upto 2004	2005	2006	2007	2008	2009
Ranbaxy	16	13	15	13	6	
Dr.Reddy's	55	9	17	23	23	21
Sun Pharma. Inds. Ltd		7				15
Wockhardt			10			
Cadilla healthcare	12	16			8	
Glenmark Pharma. Ltd			7	11	8	15E
Torrent Pharma. Ltd	--	1st	3	2	6	15
Aurobindo	5	30	51	43	12	11*

Source: Annual Reports * FY 2008-09 and Q4 2008-09 Unaudited Results

Table VIII: DMF Filings as on 31-3-08

Company	DMF Filings with USFDA as on 31-3-08	Global DMF Filings as on 31-3-08
Ranbaxy		271
Dr.Reddy's	127	281
Sun Pharmaceutical Inds. Ltd		101
Wockhardt	8	
Cadilla healthcare	59	
Glenmark Pharmaceutical Ltd	30	37+
Torrent Pharmaceutical Ltd	6	23
Aurobindo	122	1017

Source : Annual Reports

Dr Reddy's Laboratories Ltd, with the largest API pipelines in the Indian Pharma industry, has filed 23 DMFs with the USFDA in 2007-08. This took the total number of DMFs on file with the USFDA to 127 as at the end of March 2008.FRegarding APIs, the Company filed 54 DMFs in 2007–08. Of these, 23 were filed in US, 9 in Canada, 13 in Europe and 9 in other countries. As on 31 March 2008, the Company has made cumulative filings of 281 DMFs, with 127 in the US**.**

Ranbaxy Laboratories, a leading pharmaceutical company of India, continued with its focus on developing innovative, environment friendly and cost-effective technologies for high-value APIs. The Company filed 271 Drug Master Files, comprising 48 APIs across various countries as on 31-3-08. Till 185 patents were filed and 12 were granted.

Aurobindo: Aurobindo filed highest number of DMFs from India in 2007-08. As on 31-03-08, a total of 128 ANDAs were filed and 67 were approved with the USFDA. A total of 318 patents have been have been filed as on 31-3-08. As on March 2008, the company has 122 filings for US DMF and 1017 Global DMF Filings .

Torrent: As at March 08, 6 DMFs were filed in US and 17 new product Dossiers completed in the European Union. Five processes for APIs were developed and transferred to plant during the year. 588 patents filed for NDDS technology, drug discovery projects and innovative process of API & formulations for various markets and 163 have been granted so far

India continues to lead in the number of drug master files (DMF) filed with the US Food and Drug Administration (FDA). In the first quarter of 2006, Indian companies like Ranbaxy, Aurobindo Pharma and Cipla accounted for 31.7% of the total DMFs filed with USFDA. This is a continuation of the trend witnessed in the past couple of years according to which Indian companies account for a third of the DMFs filed with the USFDA. Aurobindo filed highest number of DMFs from India in 2007-08.

Table IX: Share of Indian Companies in the Total DMFs filed with the US FDA

Year	India as % of Global
2000	14.5
2001	18.6
2002	21.1
2003	30.7
2004	37.9
2005	39.8
2006	43.9
2007	48.7

Source: US FDA

7. Conclusion:

The period of the 1995-2008, i.e, the post-TRIPS period 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 the Post-TRIPS era. India is fast emerging as a power house 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 5.07 against 3.88 in Pre-TRIPS period.

Inter firm comparison show that the highest growth rate for sales has been highest for Torrent followed by Glenmark and Dr Reddy's Lab. In terms of net profits the growth rate has been highest for Glenmark followed by Dr Reddy's Lab and Torrent. In terms of R&D Expenditure Ranbaxy has always spent higher expenditure as compared to other Pharmaceutical Companies, but in terms of Growth rates, the highest growth has been recorded by Aorobindo, followed by Cipla and Workhardt.

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.

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