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TRIPS, TECHNOLOGY AND EXPORTS: EVIDENCE FROM THE INDIAN PHARMACEUTICAL INDUSTRY

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ABSTRACT

This is an empirical and historical study of the co-evolution of policy, technology and exports in the Indian pharmaceutical industry. The study considers the causes and implications of reforms and changes in the policy framework in the Indian pharmaceutical industry, particularly capacity and capability development for research and innovation and their consequent impact on exports under different patent regimes. The paper studies the R&D behavior and export performance of 20 major Indian pharmaceutical firms during 1996-2008. In our research while scrutinizing the impact of WTO on the exports the correlation of exports with the R&D intensity of Indian firms was well established and the degree of dependence and explanation of variables was done with the help of bivariate correlation matrix and stepwise regression technique while taking Exports as dependent variable and Investment, Profits and R&D as independent variables. The rise in the Drug Master Files (DMF) with US FDA also reflect the export vigorisity and R&D capability of Indian Pharma in USA market. A trend analysis of rising DMF Numbers has been prepared to justify the trend and direction of Indian Exports in the US market. This paper sheds light on the strong inter-linkage between technological changes and exports of Indian Pharmaceutical Sector. The results indicate that the Indian Pharmaceutical firms adept at reverse-engineering of brand name drugs have an opportunity to enter the global generic market for off-patent drugs.

KEYWORDS
Exports, Innovation, New Chemical Entities, TRIPS.

INTRODUCTION

There is widespread agreement on the importance of technological progress for economic growth (1). Technological change increases the productivity of land, labour and capital, reducing costs of production and improving the quality of outputs. The ability to be internationally competitive also depends on having up-to date technology. In open economies this is not only necessary for export development but is also vital for domestic production which serves local markets (UNCTAD 2007). The value of goods and services that countries trade increasingly resides in their intellectual content, technology, Research and Development (R&D) and human creativity that is sought to be protected by intellectual property rights (IPRs) (Chaddha 2005).

Thus under the new international order advocated by World Trade Organization (WTO) IPRs are fast emerging as "global currency for power". For the first time in international law the agreement on Trade Related Aspect of Intellectual Property Rights (TRIPS) sets out procedures that governments must provide under their domestic law so that IPRs can be effectively enforced. Particularly for Pharmaceuticals, TRIPS require that developing countries should provide for product and process patents with a patent term of 20 years w.e.f. January 1, 2005 (Chaddha 2005).

Ever since India gained its independence in 1947, the Indian government has taken many initiatives to encourage public, private as well as foreign investments in pharmaceutical Research and Development with an ultimate aim to make drugs available to the masses at affordable prices (Chataway and Chaturvedi 2006). The decade of the 1970s has been of great importance to the IPR, which witnessed a "process revolution" through concerted effort at acquisition of technological capability fostered by a favourable policy environment, especially a weak patent regime. Through the decades of 1970s and 1980s, the IPR reached new heights of process capabilities to "knock off" any new drug with a non-infringing process and market them at low prices (Ray 2008).

This allowed the domestic industry build up considerable competencies and offer a large number of cheaper "copycat" generic versions legally in India at a fraction of the cost of the drug in the West, as long as they employed a production process that differed from that used by the patent owner (Green 2007).

In fact, India was a leading bulk drug exporter in the international market in the late eighties but lost that position to china as it started undercutting India's prices and entering the world market. Now after a dull phase, Indian Pharmaceutical firms are reviving as quality exporters of bulk drugs (2) and formulations (3). It is because of Indian firms increasing its Research and Development efforts and adopting international standards in drug manufacturing. Exports of pharmaceuticals have consistently outstripped imports (Economic Survey 2009-10). The top five destinations of Indian pharmaceutical products are the USA, Germany, Russia, the UK and China. Using empirical evidence from firm level investigations, this paper shows how Indian firms have evolved from reverse engineering outfits operating under the process patent regime to technologically advanced and sophisticated organizations capable of catering to diverse international markets in the product patent regime.

PREVIOUS STUDIES AND THE NEED OF THE PRESENT STUDY

A number of studies have been done so far to study the penetration of domestic firms in the foreign markets. Sterlacchini (1999) studied the innovative activities of small firms in Italy and found that activities such as design, engineering and pre production developments were important in positively influencing exports. Chaudhary (2005) has found that the tendency of Indian firms have been to move up the value chain and target higher value added market segments through innovation and investments. Chadha (2005) reveals that innovative environment is likely to encourage exports. Greene (2007) while studying the impact of Indian pharma on US markets verified that Indian companies have made tremendous strides in the U.S. market and companies like Ranbaxy are major sources of generic drugs. The Indian companies also enjoy comparative advantages in cost, strength in reverse engineering skills, and number of U.S. FDA approved plants located in India. Ray (2008)

while studying the learning and innovation of Indian Pharmaceutical Industry to meet the global expectations maintained that although India has reached impressive heights of technological maturity in pharmaceuticals, but it is yet to arrive at the global frontiers of cutting edge drug discovery research. This can only be achieved through sustained technological effort and continued R&D. However all these studies either cater to pre liberalisation phase or do not capture the TRIPS regime and export behaviour of Indian firms in the competitive era unleashed by foreign firms in the new product patent regime.

OBJECTIVES AND HYPOTHESIS OF THE STUDY

The paper aims to find out the increase in export intensity of Indian Pharmaceutical firms and the causes explaining such increase.

HYPOTHESIS

H_1 The exports of Indian Pharma as a Percentage to Net Sales have increased for the period 1996-2008.

Thereafter the study scrutinizes the stimulators of Exports viz. R&D, Profits and Investments and investigates the impact of such stimulators on exports through causal analysis. Thus the following set of hypothesis can be drawn:

H_2 Increase in R&D positively and significantly affects exports of Indian Pharma.

H_3 Increase in Profits positively and significantly affects exports of Indian Pharma.

H_4 Increase in Investment positively and significantly affects exports of Indian Pharma.

H_5 Increase in Profits positively and significantly affects exports of Indian Pharma.

Finally the paper examines the impact of rising Drug Master files on Indian Pharma Exports. The hypothesis drawn from this objective is:

H_6 Increase in DMFs positively affects exports of Indian Pharma.

METHODOLOGY

The study has been made by analyzing the economic behavior of 20 major pharmaceutical Companies comprising around 50 % of Indian pharmaceutical market during 1996 to 2008. The paper also encapsulates the export performance of Indian Pharma in the pre TRIPS period. The companies included in the study are Cipla, Ranbaxy, Glenmark, Dr. Reddy's, Lupin, Piramal Healthcare, Wokhardt, Aurobindo, Torrent, Indswift, Orchid, Alembic, IPCA, Unichem, Glenmark, JB Chemicals, Medicaps, Divi, Zandu and Cadila Healthcare. In our research while scrutinizing the impact of WTO on the exports, the correlation of exports with the R&D, Investment and Profit intensity of Indian firms was made and the degree of dependence and explanation of variables was done with the help of Step wise Regression technique. Since USA is the largest export destination for Indian Pharmaceuticals and constitutes around $1/4^{th}$ of total pharmaceutical exports, we have studied the rise in the Drug Master Files (DMF) with US FDA that reflect the R&D capability and bulk drug export vigorisity of Indian Pharma. A trend analysis of rising DMFs has been prepared to justify the trend and direction of Indian bulk drug exports in the US market.

Changes at the micro level are supplemented by macro analysis. Existing literature has been used to analyse the causes and effects of the legal and policy changes of last four decades on the growth and evolution of this industry. Literature and data has been sourced from Centre for monitoring Indian Economy (CMIE) Prowess database, the Annual Reports of the various pharmaceutical companies and their websites, the Ministry of Commerce and Industry, and reports/papers published by Individual organizations and authors. In addition, industry journals, trade journals, and industry associations' publications are also referred to.

THE PATENTS ACT, 1970

The origins of the pharmaceutical industry in India can be traced back to the colonial (pre-independence) era (4). But right from its origin through the decades of the 1950s and 1960s, the industry remained largely dominated by foreign firms and drug prices were among the highest in the world. Approximately 99 percent of all pharmaceutical products under patent in India at the time were held by foreign companies (Green 2007). Further, India was dependent on imports for many of the essential bulk drugs. The import dependence constricted consumption in a country deficient in foreign exchange and inhibited the growth of the industry.

In the 1970s, India introduced complex laws and policies to regulate the pharmaceutical industry, to counteract monopoly abuses by multinationals and to promote local industry. The reforms included changes to foreign exchange regulations, price controls, industrial licensing and, most important of all, the non-recognition of pharmaceutical product patents. The Patents Act, 1970, which came into effect in 1972, represented a significant change in the legal and technological regime and had an enormous impact on the technological evolution of the pharmaceutical industry in India. It started the era of reverse engineering, where firms developed new products by simply changing a few steps in their production processes (Chataway and Chaturvedi).

Following were the main features of Patent Act, 1970.

- The Drugs (and food and those manufactured by chemical processes) could be patented only for a new method or process of manufacture, not for the products as such (5).
- The protection for the processes of manufacturing the drug would be for seven years from the date of filing the application or five years from the date of the grant of The Patents (Lalitha 2002).
- Patentee can import the patented drug and has no obligation to produce it locally (Exim Bank Study 2007).
- In case of process patent the burden of proof lies with alleged infringer.

The result was that the MNCs lost their market domination. From around 60 per cent market share in the late 1970s, their share declined to 40 per cent by the early 1990s (Table 1).

TABLE 1: MARKET SHARE OF INDIAN AND FOREIGN COMPANIES IN PHARMACEUTICAL INDUSTRY OF INDIA

Year	MNCs (%)	Indian Companies (%)
1952	38	62
1970	68	32
1978	60	40
1980	50	50

1991	40	60

Source: Sudip Chaudhary, The WTO and the Indian Pharmaceutical Industry, OUP, 2005

The older firms such as Ranbaxy and Cipla saw dramatic growth essentially after the revision of the Patents Act. Their ranks in the domestic retail market were respectively 43rd and 56th in 1971, way behind the MNCs such as Glaxo, Pfizer, Hoechst, Lederle, Ciba, May & Baker, Abbott, Sandoz, Boots, Smith Kline and French which dominated the industry those days. Today Ranbaxy is the largest company and Dr. Reddy's is the 2nd largest company in the domestic market, and only one MNC (Glaxo Smith Kline) has sales comparable to them (6).

The favourable environment also attracted the entry of a number of new firms. Among the top companies, Sun Pharmaceuticals, for example, was set up in 1983 and Dr. Reddy's Laboratories in 1984. A large number of specialized bulk drugs manufacturers, set up since the 1970s–particularly in the 1980s–contributed immensely to the transformation of the Indian Pharmaceutical Industry. The more prominent among them are Shasun (set up in 1976), Morepen Laboratories (1984), Aurobindo (1986), Neuland Laboratories (1986), Divi's Laboratories (1990), Orchid Chemicals and Pharmaceuticals (1992), and Hetero (1993) (7).

From over 2200 units in 1969- 70, the size of Indian pharmaceutical industry increased to nearly 24000 in 1995-96. Many of them were small-scale units and were receiving number of incentives from the Government, including reservation of drugs for exclusive production. Many of them have commenced their operations specializing in generics production (Chaudhary 2005).

Exports also started increasing steadily. From a meager $54.3 million in 1974-5, exports of drugs and pharmaceuticals increased to $536.6 million in 1990-91 and to 694.0 million in 1994-95. Till 1987-8, imports were larger than exports except for a few years. But with the steady growth in domestic production and exports, the country has become a net exporter since 1988-9 (Table 2).

TABLE 2: EXPORTS OF INDIAN PHARMACEUTICAL INDUSTRY

Year	Exports	Imports	Trade Balance	Trade Balance as a % of Exports
1973-74	47.9	43.8	4.1	8.5
1974-75	54.3	59.1	-4.7	-8.7
1980-81	96.3	142.6	-46.3	-48.1
1988-89	322.9	308.6	14.3	4.4
1990-91	536.6	336.6	200	37.3
1991-92	613.7	329.9	283.8	46.2
1992-93	486.2	371.1	115.1	23.7
1993-94	567.9	459.1	108.8	19.2
1994-95	694	486.3	207.7	29.9

Source: Sudip Chaudhary, The WTO and the Indian Pharmaceutical Industry, OUP, 2005

TRIPS AGREEMENT AND PATENT (AMENDMENT) ACT, 2005

The year 1995 recorded another milestone for the Indian pharmaceutical sector. The WTO came into effect in 1995. One of the agreements negotiated under WTO was for the Trade Related aspects of Intellectual Property Rights TRIPS. Since India is a founder member of WTO, India automatically became a signatory of the TRIPS agreement.

TRIPS provides a three-stage frame for countries such as India which did not grant Product Patent rights in pharmaceuticals when TRIPS came into force on 1 January 1995;

i. Introduction of a facility ('mail box') from 1 January 1995 to receive and hold product patent applications in the fields of pharmaceuticals (and agricultural chemicals). Such applications will not be processed for the grant of a patent until the end of 2004. But Exclusive marketing Rights (EMRs) can be obtained for that application if a patent has been granted in some other WTO member country and the application has not been rejected in the country as not being an invention (8).

ii. Compliance, from 1 January 2000, with other obligations of TRIPS, namely, those related to the rights of The Patentsee, term of patent protection, compulsory licensing, reversal of burden of proof and so on.

iii. Introduction of full product patent protection in all fields including pharmaceuticals from 1 January 2005. All the product patent applications held in the mail box are also required to be taken up for examination from 1 January 2005.

Compliance with the TRIPS requirements has taken substantial time in India. This reflects the significant opposition to TRIPS in India. An Ordinance was actually introduced on 31 December 1994 to implement these provisions. But the ordinance lapsed because it could not be followed up with the necessary legislation within the stipulated six weeks time required. The panel set up by the Dispute Settlement Body (DSB) of the WTO asked India to comply with the requirements by April 1999. Again a Bill was introduced and this time it was passed in the Rajya Sabha on 22 December 1998, but the Bill could not come up for consideration in the Lok Sabha.

Ultimately an Ordinance was promulgated followed by an Act passed in March 1999. The Patents (Amendment) Act, 1999 amended the Patents Act, 1970 with retrospective effect from 1 January, 1995 to implement mail box facilities and EMRs as mentioned in (i) above. Another Bill was introduced in the Rajya Sabha in December 1999 to bring about the other changes in The Patents regime as mentioned in (ii) above. The Bill with a few changes was approved by the Parliament in May 2002. the Patents (Amendment) Act, 2002 came into force on 20 May 2003.The Patents (Amendment) Act, 2002 made 64 amendments to the Patents Act, 1970 relating to terms of patents (20 years), exceptions to exclusive rights, compulsory licensing, and so on.

A third Amendment was necessary by the end of 2004 to replace the EMR system and to introduce product patent protection as mentioned in (iii) above. The Patents (Amendment) Bill, 2003 was introduced in the Parliament in December 2003. Before this Bill could be passed, Lok Sabha was dissolved. A full-fledged product patent regime has been introduced in India from 1 January 2005 through a presidential decree The Patents (Amendment) Ordinance 2004 which was issued issued on 26 December 2004. The provisions of the Ordinance were essentially the same as those of the Bill of 2003. As required under the law, the Ordinance was followed up with the necessary legislation and the Patents (Amendment) Act, 2005 was passed by the parliament in March 2005 and received the assent of the President on 4th April, 2005.

To meet its TRIPS obligations, India amended its patent law on March 22, 2005, abolishing its "process" patents law and reintroduced Western style "product" patents for pharmaceuticals, food, and chemicals. This action effectively ended 36 years of protection for Indian pharmaceutical companies and stipulated that Indian companies selling copycat drugs must pay foreign patent holders a "reasonable" royalty for copies sold in the Indian market. The amendment made reverse engineering or copying of patented drugs illegal after January 1, 1995. The Act allowed for

only two types of generic drugs in the Indian market: off-patent generic drugs and generic versions of drugs patented before 1995. The Amendment grants new patent holders a 20-year monopoly starting on the date The Patents was filed and, without a compulsory license, no generic copies can be sold during the duration of The Patents (Green 2007). The WTO also required India to establish a "mailbox" where patent applications could be filed between 1 January, 1995 and 2005.

The Act encouraged significant numbers of foreign pharmaceutical companies to participate in the Indian market and, in 2005 foreign drug producers filed approximately 8,926 patent applications to cover their patented drugs sold as generics in the Indian market. On the contrary The Patents Act of 1970 had discouraged The Patents Activity in the country. The number of patents granted per year fell by three-quarters over the following decade, from 3,923 in 1970-71 (of which 629 were to Indian applicants, 3,294 to foreign applicants) down to 1,019 in 1980-81 (349 Indian, 670 foreign) (Lanjouw 1997).

INCREASE IN EXPORT INTENSITY

To know the increase in Export intensity we have measured data from 1996 to 2008 in terms of R&D as a percentage of net sales. Chaudhary (2005) and Kale (2006) have made similar efforts for the period before 2002.The twenty companies listed in table 5.1 earned export revenue worth Rs. 908.5 crore 1996 and Rs.15548 crore in 2007-08 and aggregate amount of Rs. 77440.98 crore for the twelve year period between 1996-2008. The Exports as a percentage of Net Sales were 28.5% for the twenty companies in the year 1996 and rose to nearly 46% in 2005 and fell down slightly to 41.08% in the year 2008. The overall trend shows the increase in export intensity of Indian Pharmaceutical Industry. Hence H_1 is proved.

TABLE 3: EXPORTS AS A PERCENTAGE TO NET SALES (VALUE IN CRORE)

Year	Exports	Net Sales	Exports as a Percentage to Net Sales
1996	908.5	3191	28.5
1997	1265	4584.74	27.59
1998	1451	5371.9	27.01
1999	2007	5951	33.73
2000	2538	7811	32.49
2001	3397.7	9649	35.21
2002	4722	12111	38.99
2003	6209	14597	42.54
2004	7833	17393	45.04
2005	8190	17969	45.57
2006	9660	22095	43.72
2007	13711	33082	41.45
2008	15548	37846	41.08

Source: CMIE

HIGHER R&D INTENSITY LEADS TO HIGHER EXPORTS

Strong process R&D and low manufacturing cost helped the Indian companies to further penetrate into the export markets. Between 2001 and 2005, Formulation Exports from India posted a compounded annual growth rate of 20% (EXIM bank Study 2007). An increase in a pharmaceutical firm's innovative activities enhances its export competitiveness. This means that the more a firm invests in R&D, the more likely it is to increase its exports revenue. The table 4 reveals a high degree of correlation between Exports and R&D. The table 5 depicts the impact of R&D on export through Regression analysis while taking exports as dependent variable and R&D, Profit and Investment as independent variables.

TABLE 4: CORRELATION MATRIX TABLE FOR EXPORTS, INVESTMENT, R&D AND PROFITS

		Exports as a % to Net Sales	R&D as a % to Net Sales	Investment as a % to Net Sales	Profits as a % to Net Sales
Exports as a % to Net Sales	Pearson Correlation	1	.865(**)	.291	.570(*)
	Sig. (2-tailed)		.000	.334	.042
	N	13	13	13	13
R&D as a % to Net Sales	Pearson Correlation	.865(**)	1	.155	.380
	Sig. (2-tailed)	.000		.613	.200
	N	13	13	13	13
Investment as a % to Net Sales	Pearson Correlation	.291	.155	1	-.096
	Sig. (2-tailed)	.334	.613		.754
	N	13	13	13	13
Profits as a % to Net Sales	Pearson Correlation	.570(*)	.380	-.096	1

	Sig. (2-tailed)	.042	.200	.754	
	N	13	13	13	13

** Correlation is significant at the 0.01 level (2-tailed).

* Correlation is significant at the 0.05 level (2-tailed).

TABLE 5: REGRESSION EQUATION FOR DETERMINANTS OF EXPORTS (9)

Variables	B	t	R Square
(Constant)	22.482	8.174	
R&D	3.336	5.710	.748

Dependent Variable: Exports

Independent Variables: R&D, Profit and Investment

The equation shows that β for R&D comes at 3.336 which is very high compared to the β value of other variables. The t-value of R&D comes at 5.710 (highly significant). Value of all other variables has been noted insignificant reflecting lower't'. R&D thus is the most relevant determinant of exports of Indian Pharmaceuticals.

An increase in a pharmaceutical firm's innovative activities enhances its export competitiveness. This means that the more a firm invests in R&D, the more likely it is to increase its exports revenue. Ranbaxy developed a new process to manufacture Eli Lilly's Cefaclor, which led to forming an alliance between the two companies (Dhar and Rao 2003). Ranbaxy also developed a Novel Drug Delivery System (NDDS) for Bayer's Ciprofloxacin, which was licensed to the innovator for a substantial sum. Today, Ranbaxy derives around 75 per cent of its revenues from exports. Lupin, the world's largest producer of ethambutol, an anti-TB drug, generated 35 per cent of its sales in overseas markets in 2002. Dr Reddy's Labs, the second largest producer of ranitidine, an antiulcerant, generates around 60 per cent of its sales from exports. India has become known as the pharmacy of the world for cheap medicines. After all, it was the Indian pharmaceutical industry that forced the price drop of antiretrovirals to poor countries from around $12,000 to around $350 per capita (Aggarwal 2004). The results show that H_2 is proved but H_3, H_4 and H_5 are disproved.

DMF FILINGS

Indian firms have been filing Drug Master Files (DMFs) internationally primarily to gain entry into regulated markets. Taking lead from Chaturvedi and chataway (2006), we have done a comprehensive survey of India companies filing patents i.e DMFs in the overseas markets particularly USA for the period 1996-2008.

A Drug Master File (DMF) is a submission to the Food and Drug Administration (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 (Malhotra 2008). For exporting Bulk Drug to USA, Indian companies are required to file a Drug Master File (DMF). The company filing a DMF is required to submit detailed information on kind of equipment, location of the plant, description of production facility, process chemistry, raw material specifications, stability data, impurity profile and so on.

Followings are the types of DMF.

- **Type I** Manufacturing Site, Facilities, Operating Procedures, and Personnel (no longer applicable)
- **Type II** Drug Substance, Drug Substance Intermediate, and Material Used in Their Preparation, or Drug Product
- **Type III** Packaging Material
- **Type IV** Excipient, Colorant, Flavor, Essence, or Material Used in Their Preparation
- **Type V** FDA Accepted Reference Information

The documentation to register drugs is extremely detailed and often is very expensive to provide such dossiers such as DMFS or ANDAS, etc. The review procedures of such documentation are very stringent and do not permit any low cost approach. The complete process details, site plans and all intricate details are demanded and have to be provided (10). The cost of filing a DMF can be up to USD 200, 000 depending on the product (the steps involved, the processes, the number of tests to be done etc).

The increase in DMF Filings is the important barometer of rising Bulk Drug Exports from India. India is rapidly emerging as a trusted outsourcing destination for not only generic drugs but also high-end, difficult to manufacture innovator/patented drugs. Indian companies have been at the forefront in leveraging the increased outsourcing demand for APIs/Intermediates, which is reflected in the aggressive DMF filings made by Indian companies (IBEF 2008) (11).

TABLE 6: DMF FILINGS (TYPE II) BY INDIA

Year	DMF Filings
1998	32
1999	26
2000	33
2001	47
2002	55
2003	115
2004	160
2005	233
2006	267
2007	274

Source: Data downloaded, sorted and tabulated from US FDA Website www.fda.gov/CDER/dmf/index.htm visited on 19 December, 2008

In 12 years span India filed 1242 (Type II) DMF Applications which shows active penetration of Indian pharmaceutical Sector into other part of the world. The share of Indian companies in the total DMFs (Type I, II, III & IV) filed with the US FDA increased to 42 per cent in 2007 from 10 per cent in 1998. The total number of 3911 DMFs were filed globally between 1998 and 2007 with US FDA.

India filed 1242 DMFs during this period and accounted for around one third of drug master files (DMFs) in USA. China's share of DMF filings is less than one-third of that of India and is around 9% of global filings. The highest number of DMFs verifies the fact that India has out surpassed its traditional rival China in terms of seizing this opportunity effectively.

While analysing the individual companies' performance which are part of our sample, some interesting facts came into light. Dr. Reddy is ranked first in US DMF filings from India (123 Type II Active US DMFs) and ranked number three in US DMF filings globally. Aurobindo pharma (119), Cipla (115) and Ranbaxy (93) ranked second, third and fourth respectively. Three companies have more than 100 DMFs and seven companies have more than 50 DMFs, which reveal towering performance of Indian Pharmaceutical Industry in the export front.

TABLE 7: LIST OF INDIAN COMPANIES INCLUDED IN OUR SAMPLE HAVING TYPE-II (ACTIVE) DMF FILINGS (1998-2007)

DMF Holder	No. of DMF
Dr Reddy's Labortaries	123
Aurobindo Pharma Limited	119
Cipla Ltd	115
Ranbaxy	93
Lupin	72
Cadila healthcare Limited	61
Orchid	53
IPCA Labortaries Ltd	42
Wokhardt	42
Divi labortaries Limited	33
Glenmark Generics Ltd	30
Alembic Limited	22
Unichem	13
Ind Swift Labortaries Ltd	12
Torrent	10
Piramal Healthcare	8
Zandu	2

Source: Data downloaded, sorted and tabulated from US FDA Website www.fda.gov/CDER/dmf/index.htm visited on 19 December, 2008.

As we have mentioned above the company filing a DMF is required to submit detailed information on kind of equipment, location of the plant, description of production facility, process chemistry, raw material specifications, stability data, impurity profile and so on. To satisfy the US FDA's regulatory requirements, dedicated plants need to be set up at huge costs. It would cost much more than what a plant following WHO GMP ("Good Manufacturing Practices") or that following the guidelines in EU countries would cost. Certification is not a onetime process. Once granted, it requires the maintenance of pre specified norms throughout (Chaudhary 2005).

In other words an US FDA plant requires about six times the cost of an ordinary plant, which most small Indian Pharmaceutical companies have. The cost of such plant for even a simple bulk drug may cost around USD 3-5 million in India (excluding documentation and other costs incurred on exports). Most of the Indian companies which have set up such dedicated bulk drug facilities for the US market have invested atleast USD 10 million. To have a reasonably good portfolio of bulk drugs, the cost of plant and maintenance would be around USD 20 million. (Table 8)

TABLE 8: THE COST INDEX OF PRODUCTION PLANT

Type of Plant	Cost Index
Ordinary (Not following GMP)	50
GMP	100
EU	200
US FDA	300

Source: Cecile H Miles, "Differential Pricing & Financing of essential drugs: Experience with Generic Drugs", Ranbaxy Laboratories Ltd, Mimeo.

India has one of the largest numbers of FDA approved bulk drug plants in the world outside of USA. The table below clarifies that here was no such production facility before 1985. The ten years spanning 1985 to 1995 saw coming up of only 11 such plants (only 1 by 1990), whereas the post WTO period (1998-2005) witnessed mushrooming of such facilities and number shot up to 119.

Table 9: FDA Approved Indian Plants

Year	Annual	Cumulative
1985	0	0
1990	1	1
1995	10	11
2000	33	44
2005	75	119

Source: Ministry of Commerce & Industry, 2008

Globally India is way ahead to its arch rivals China and Italy in terms of FDA approved facilities. India had 75 approvals in 2005-06 as compared to 55 and 27 of that of China and Italy respectively.India is the world's fifth largest producer of bulk drugs. Demand for bulk drugs has grown at a CAGR of 31 per cent since 2000-01 to reach US$ 2.8 billion in 2005-06. India's bulk drug/API exports accounts for 21% of India's pharmaceutical industry, which, in contrast to many developed countries is significantly higher as bulk drugs are mainly manufactured for internal consumption. Bulk drugs exports grew robustly by 28% CAGR between 2001-02 and 2007-08 to reach an estimated USD 4.2 bn (OPPI and Yes bank Study 2008). Hence the H_6 is proved.

CONCLUSION

This paper set out to investigate the augmentation of Research and Development activities due to TRIPS and consequent increase in exports of India's pharmaceutical industry. The periodisation from pre-trips to post-trips era has been immensely useful in encapsulating technological

and capability development as well as export behavior of the Indian pharmaceutical industry during different policy regimes. The statistics and other qualitative data presented in this paper confirm the strong inter linkage between R&D and exports of Indian Pharmaceutical Industry. Indian companies are responsible for most of the increase in patent filings in the US in the form of rising DMFs reflecting qualitative modifications and adjustments in its R&D capabilities in the production of exportables. The paper indicates that an efficient policy-package promotes the creation of new technology and knowledge on the one hand, and on the other facilitates promotion of exports.

ENDNOTES

(1)Neoclassical theory, new endogenous growth theories, and evolutionary growth theories which draw inspiration from Schumpeter all emphasize this.
(2) Bulk drugs are active chemical ingredients used to manufacture formulations or finished products.
(3) Formulation - means the same as Product - an active ingredient processed with other materials or formulants to make it easier to apply and/or more effective.
(4) The modern Indian Pharmaceutical Industry was founded partially because of British efforts and rest because of Indigenous backlash. The Bengal Chemical and Pharmaceutical Works (BCPW) was founded by Prafulla Chandra Ray, a staunch nationalist in 1892. In 1903, Raj Mitra, Shri BD along with Prof. A.S. Kotibhaskar and Prof. T.K.Gajjar founded Alembic in Gujrat.
(5) The Patents Act, 1970, Section 5.
(6) Annual reports of various companies, 2009.
(7) Companies' websites.
(8) The Patents (Amendment) Act, 1999, Sections 24A &24B
(9) All the variables are as a % to net sales.
(10) Report of the Task Force, Ministry of Commerce & Industry, 2008, p. 90
(11) IBEF Pharmaceuticals Market & Opportunities, 2008, p. 5

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