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# THE SECTORAL SYSTEM OF INNOVATION OF INDIAN PHARMACEUTICAL INDUSTRY

**Sunil Mani**

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**ABSTRACT**

The paper undertakes a detailed mapping out of the sectoral system of innovation of India's pharmaceutical industry. The industry is one of the most innovative industries in the Indian manufacturing sector. The innovation system of the industry has three strong pillars: very pro active government policy regime especially with respect to intellectual property right, strong government research institutes and private sector enterprises which have invested in innovation. The TRIPS compliance of the intellectual property right regime making it mandatory for pharmaceutical products to be patented has not reduced the innovation capability of the industry although it has not made them work on R&D projects that may lead to the discovery of drugs for neglected diseases of the developing world. Although the innovation system has the capability to develop new chemical entities the two main components of the innovation system, namely the enterprises and the Government Research Institutes does not appear to be having all the requisite capabilities to bring a new drug to the market. Although the state has been very proactive with respect to this industry, this is an area where public policy support is still required.

**Key words**: Sectoral system of innovation, pharmaceutical industry, TRIPS, innovation

**JEL Classification**: O31, O34 and O38

**Introduction**

It is generally held that firms in developing countries such as those in India does not necessarily innovate in the sense of doing R&D that results in the release of new products and processes. At best they are assumed to be introducing incremental innovations defined as adaptation of known technologies to local conditions as these may be new to the Indian firms although not new to the universe in which these firms are located. Consequent to this line of thinking measuring innovation using conventional indicators such as R&D expenditures, patent grants, technology-content of exports has always been problematic. Although this is the general rule, there are certain notable exceptions in terms of firms creating new technologies on their own. The pharmaceutical industry in India, despite the copycat image that is heaped on it rightly or wrongly, has managed to be one of the most innovative among the country's manufacturing establishments. Indian pharmaceutical companies enjoyed two 'home-grown' advantages namely, much cheaper manufacturing facilities and world-class medicinal chemistry skills, honed by years of reverse engineering. The industry is currently one of the fastest growing and is a major recipient of US patents. For such an industry, the concept of a sectoral system of innovation makes eminent sense. Against this perspective, the purpose of this paper is to attempt at mapping out the sectoral system of innovation of India's pharmaceutical

industry. Such an exercise would allow us to identify the sources of innovation in the industry.

The paper is structured into four sections. The first section outlines some important features of this industry. The second section maps out the sectoral system of innovation (SSI) of the industry and focuses on three components of the SSI. The third section measures the performance of the innovation system in terms of a number of, albeit, conventional indicators. The fourth and concluding section sums up the main findings of the paper.

## 1. Features of India's pharmaceutical industry

The pharmaceutical Industry in India is one of India's foremost science-based industries with wide ranging capabilities in the complex field of drug manufacture and technology. The country produces pharmaceutical formulations and over 400 active chemicals used in the manufacturing of drugs (namely Active Pharmaceutical Ingredients). A wide range of pharmaceutical machinery too is available in the country. The value of the pharmaceutical market in India was U.S.$ 6.0 billion in 2004 representing two per cent of global market, and ranking fourth in terms of volume and thirteenth in value terms. . The industry has been exhibiting an excellent growth performance especially over the last decade. The structure of the industry is such that that an entire range of firms according to type of ownership (foreign and Indian) and according to scale (large, medium and small) occupy the manufacturing landscape of this industry.

The industry has three key characteristics that are worth examining:

- The industry is dominated by formulations;
- The industry is very active in the world-wide market for generics; and
- The country is self sufficient in most drugs as judged by a growing positive trade balance;

## i. Domination of formulations

The Indian pharmaceutical industry is divided into two broad categories on the basis of form/usage into bulk drugs[1] and formulations. The industry is dominated by formulations (Figure 1). Although it is the development of the bulk drugs sector that is actually the most important achievement of the pharmaceutical industry in India and it has led to the transformation of the industry (Chaudhuri, 2005)

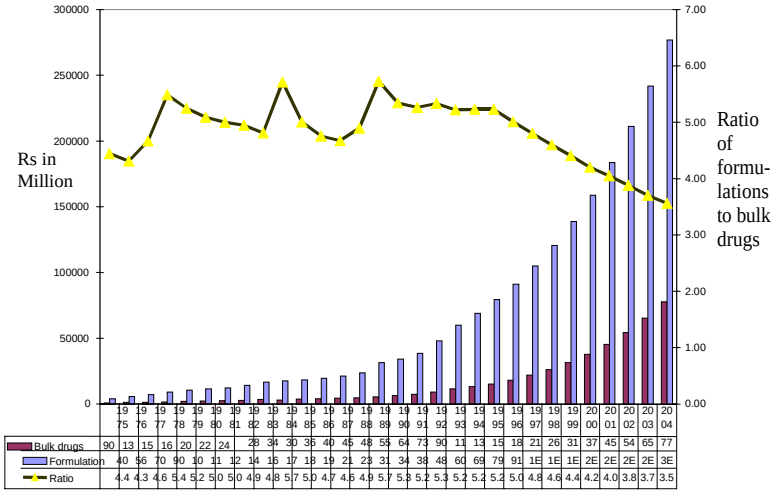


**Figure 1: Structure of Indian pharmaceutical production, 1975-2004**

Source: Chaudhuri (2005)

Chaudhuri divides the entire history of pharmaceutical production in the country into three phases. The first phase is up the early 1970s, the second phase covers the late 1970s through the 1980s and the third phase refers to the period since the 1990s. The salient features of the three phases are summarized in Table 1.

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1 Bulk drugs are the active pharmaceutical ingredients (API), which are used to manufacture formulations. APIs cannot be directly administered to the patients and other substances called excipients are added to stabilize the formulations. This end product, which includes the API and the excipient is referred to as a formulation.

**Table 1: Salient features of the pharmaceutical industry over the three phases**

| Phase | Ownership | Patent regime | Nature of drug prices | Import dependence |
|---|---|---|---|---|
| I (till the early 1970s) | Foreign companies | Product and process patents were recognised | High | High for essential bulk drugs |
| II (the late 1970s and the 1980s) | Growth of a strong indigenous production sector | Only process patents were recognized under the new patent law | Moderate due to the availability of cheaper alternatives from domestic companies Further the industry | Increased production of bulk drug and formulations has substituted imports. started exporting as well |
| III (since the 1990s) | Continued growth and consolidation by an indigenous production sector | For most of this, same as phase II. The patent regime made TRIPS compliant since January 1 2005. | Same as Phase II. The National Pharmaceutical Pricing Authority (NPPA) was established to monitor prices of 74 bulk drugs and to revise them periodically. | Net exports as a percent of exports increased from 37.3 in 1990-91 to 90.8 in 2002-03. |

Source: Chaudhuri (2005)

**ii. The country is very active in the world market for generics**

A generic drug is identical, or bioequivalent to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use. Although generic drugs are chemically identical to their branded counterparts, they are typically sold at substantial discounts from the branded price. Generics account for around 14 per cent of the healthcare market worldwide (Figure 2) and they are growing at a phenomenal rate. The recent growth in the generics market has been largely fuelled by the patent expiry of several blockbusters, and with around $12bn of innovative drugs coming off patent by 2008 in

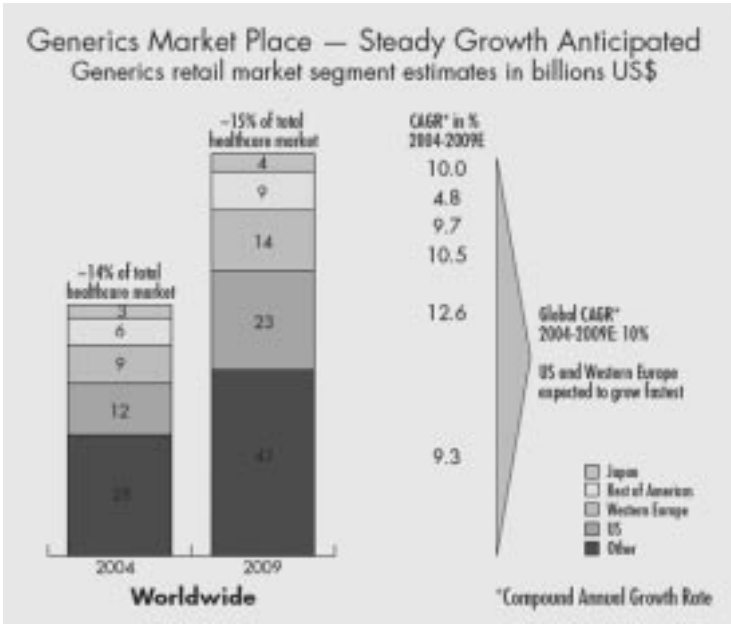


**Figure 2: Size of the generics market worldwide**

Source: Drug Discovery and Development,

http://www.dddmag.comShowPR.aspx? PUBCODE=016&ACCT= 1600000100&ISSUE= 0511& origreltype =cvs& RELTYPE= pr&ProdCode = 00000000&PRODLETT=G (accessed on 11/08/06)

France, Germany and the UK alone, this trend is expected to continue. For generics companies, speed to market with the right molecules is a critical success factor and that means being flexible, competitive and fast to capitalise on new opportunities. Originator companies, meanwhile, facing dwindling pipelines are being called on to show increasing creativity in their handling of key product expiries. Several large pharma firms have already begun buying into and owning generics businesses and with traditional generics companies trying their hands at proprietary brands, conventional lines of demarcation are blurring.

According to research by London-based researcher Global Insight, Indian drugmakers will have a 33 per cent share of the global generics market by 2007, compared with 4 per cent in 2005.

There are four main factors that helped Indian pharmaceutical manufacturers to emerge as important generics manufacturers.

First, is the Indian Patents Act of 1970 This Act has been in force since 1972 until December 31, 2004. As per this Act, the Indian parliament granted patent rights only to manufacturing processes, rather than to the end products themselves. Indian pharmaceutical firms were able to take new drugs developed abroad, reverse-engineer the manufacturing process and begin churning out generics. Consequent to these local firms went from controlling 30 percent of the Indian drug market in 1972 to 77 percent in late 2004. Developing-world consumers, and even some in Western markets, enjoyed the benefits of low prices and the quick introduction of the latest wonder drugs. At present the country exports generic drugs to nearly 200 countries. Chaudhuri (2005) has provided us with detailed analysis of the contribution of the pre 2005 Indian patent regime towards the building up of a generics industry in the country.

Second, research in India costs 40 per cent less than in the U.S. The cost of developing a drug from scratch in India could be as low as

$100 million while it is up to $1 billion in the West. In other words the industry has a significant and sustainable cost advantage over international peers;

Third, is the availability of skilled work force with strong chemistry skills;

Fourth, India has the largest number of US FDA approved manufacturing plants outside the USA. It has the largest number of Drug Master Filings (DMF) outside the US.[2] Indian companies are also the leading companies participating in Para IV challenges.[3]

**(ii) The country is self sufficient in most drugs:**

Until 1988, the industry was experiencing a negative trade balance (Figure 3). The trade balance turned positive since 1989 and has started steadily increasing from 1997 onwards. This shows that the country is fairly self sufficient in most drugs and pharmaceuticals. This self-sufficiency is a very good indicator of the country's growing technological capability in this industry.

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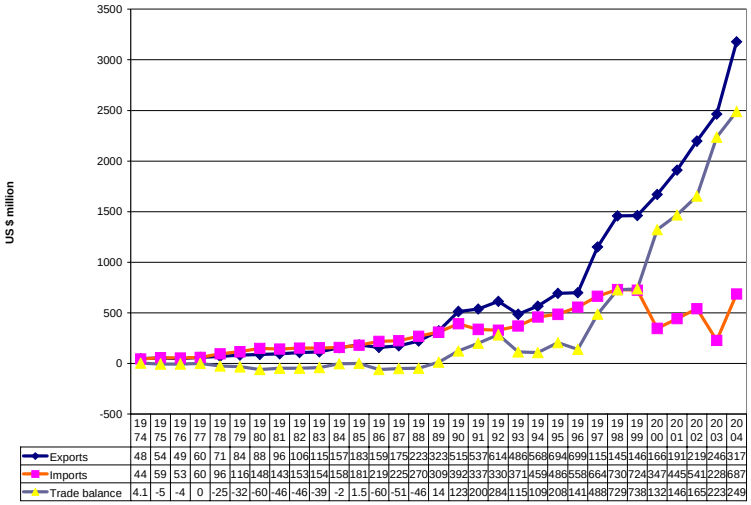
2 A master file (MF) is a voluntary submission to the Food and Drug Administration (FDA) that may be used to provide confidential, detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more drugs. Those on file with the Center for Drug Evaluation and Research (CDER) are referred to as drug master files (DMF's). The master file is used to provide support information and data for an NADA, ANADA, INADA, Export Application, or other master files

3 Once a patent challenge is successful, the challenger gets 180 days exclusivity period for sales of the generic drug, something that can dramatically improve the fortunes of Indian generic pharma companies. These legal battles, however, are unpredictable and risky. DRL had earlier won a legal battle against Eli Lilly, and enjoyed a six-month exclusivity for fluoxetine capsules, a generic version of Lilly's anti-depressant Prozac.




| | 1974 | 1975 | 1976 | 1977 | 1978 | 1979 | 1980 | 1981 | 1982 | 1983 | 1984 | 1985 | 1986 | 1987 | 1988 | 1989 | 1990 | 1991 | 1992 | 1993 | 1994 | 1995 | 1996 | 1997 | 1998 | 1999 | 2000 | 2001 | 2002 | 2003 | 2004 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Exports | 48 | 54 | 49 | 60 | 71 | 84 | 88 | 96 | 106 | 115 | 157 | 183 | 159 | 175 | 223 | 323 | 515 | 537 | 614 | 486 | 568 | 694 | 699 | 115 | 145 | 146 | 166 | 191 | 219 | 246 | 317 |
| Imports | 44 | 59 | 53 | 60 | 96 | 116 | 148 | 143 | 153 | 154 | 158 | 181 | 219 | 225 | 270 | 309 | 392 | 337 | 330 | 371 | 459 | 486 | 558 | 664 | 730 | 724 | 347 | 445 | 541 | 228 | 687 |
| Trade balance | 4.1 | -5 | -4 | 0 | -25 | -32 | -60 | -46 | -46 | -39 | -2 | 1.5 | -60 | -51 | -46 | 14 | 123 | 200 | 284 | 115 | 109 | 208 | 141 | 488 | 729 | 738 | 132 | 146 | 165 | 223 | 249 |

**Figure 3: Trends in trade balance of pharmaceutical products, 1974-2004**

Source: Chaudhuri (2005), p. 45

## II. Mapping of the sectoral system of innovation

The paper adopts a sectoral system of innovation perspective introduced by Malerba (2004). The framework involves mapping out the boundaries of the innovation system in terms of the specific agencies of the government dealing with telecommunications development, the policy framework, the equipment suppliers, the service providers and the regulatory agency and tracking the knowledge flows between these various actors within the system. According to Malerba (2004), every sectoral system of innovation has at least three blocks: (i) knowledge, technological domain, and boundaries; (ii) actors, relationships and networks; and (iii) institutions. These three blocks may be elaborated as follows. First, knowledge plays a central role in innovation. It has to be

absorbed by firms through their differential abilities accumulated over time. Knowledge differs across sectors in terms of domains. One knowledge domain refers to the specific scientific and technological fields at the base of innovative activities in a sector. The boundaries of sectoral systems are affected by knowledge base and technologies. Second, sectoral systems are composed of heterogeneous actors. Firms are the key actors in the generation, adoption, and use of new technologies. Actors also include users and suppliers who have different types of relationships with the innovating, producing or selling firms. Other types of agents in a sectoral system are non-firm organizations, government agencies, local authorities, and so on. In various ways, they support innovation, technological diffusion, and production by firms, but again their role greatly differs among sectoral systems. Third, in all sectoral systems, institutions play a major role in affecting the rate of technological change, the organization of innovative activity and performance. Innovation greatly differs across sectors in terms of sources, actors, features, boundaries and organization.

The following figure (Figure 4) maps out the sectoral system of innovation. There are essentially five components to the sectoral system. In broad terms they are (i) Policy and strategic direction; (ii) The Intellectual Property Right Regime; (iii) Human resource development or the supply of scientists and engineers;[4] (iv) Technology generating sector; and (v) The manufacturing sector.

4 The areas are medicinal chemistry; combinatorial chemistry; Bioinformatics and structure based molecular modelling, Genomics and proteomics, Clinical pharmacology, and Regulatory toxicology.

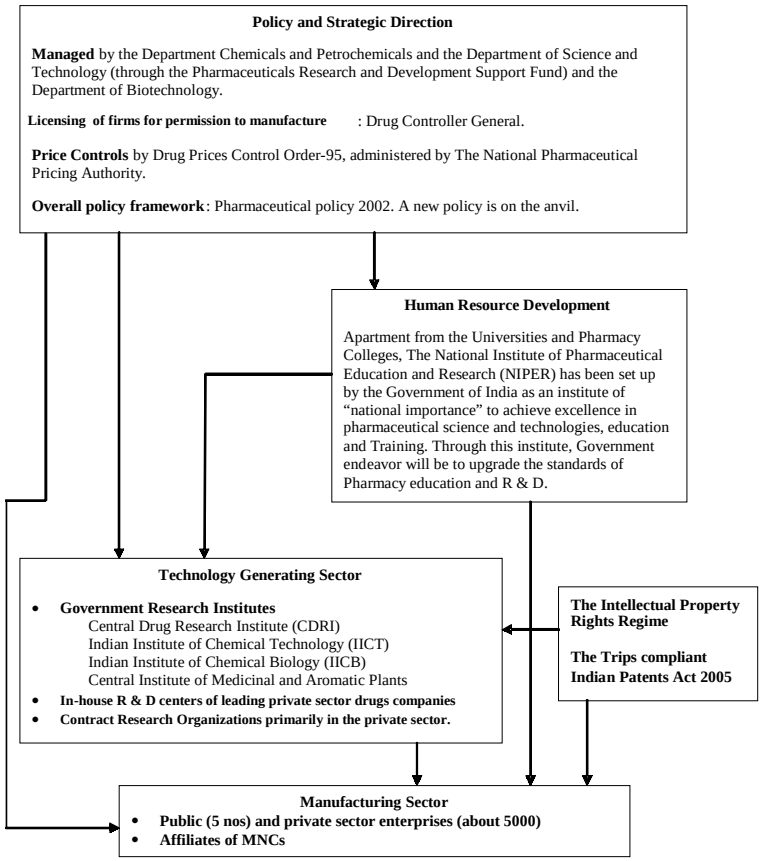



**Figure 4: Sectoral System of Innovation of the Indian Pharmaceutical Industry (c 2006)**

Source: Own Compilation

The three important components of the SSI are: (A) the public policy support; (B) the manufacturing enterprises primarily in the private sector; and (C) Government Research Institutes (GRIs). We deal with each of these components in some detail below:

**(A) The public policy support**

The market conduct or behaviour of the pharmaceutical industry in the country is subjected to the following policy framework. These could be classified as:

- Overall policy framework towards the development of pharmaceutical industry;
- Intellectual Property Right or patent regulations;
- Price regulations; and
- Product and quality regulations.

**(a) Overall policy framework**: The overall policy framework governing the industry up to this time has been the Indian Pharmaceutical Policy of 1994.This is because the new drugs policy formulated by the government in 2002 could not be implemented due to litigation involving it; hence the policy of 1994 still continues to be in force. The present Policy known as the Draft National Pharmaceuticals Policy, 2006[5] has been necessitated due to several developments that have taken place during the course of last few years as well as to address some of the major concerns as highlighted above. Price regulation of the essential medicines is an important component of this policy. However several other matters having a close bearing on the pharmaceuticals sector have also been included. Since the purpose of the present paper is to analyse the sectoral system of innovation of the Indian pharmaceutical industry,

5 Department of Chemicals and Petrochemicals, http://chemicals.nic.in/npp_circulation_latest.pdf (accessed on 11/08/2006)

we will focus our attention only on those aspects of the policy that explicitly deals with the promotion of innovation. The major policy initiatives in this area are summarized below:

i. Promotion of pharmaceutical R&D through the provision of fiscal incentives;

ii. Promotion of R&D intensive companies;

iii. Establishment of a pharmaceutical Research and Development Support fund (PRDSF); and

iv. Development of orphaned drugs

In the following we discuss the details of each of these four policy initiatives.

**i. Fiscal incentives for R&D:** a) The benefit of 150 per cent weighted exemption (under section 35{2AB} of the Income Tax Act of 1961)[6] is to be continued till 31st March, 2015; b) This deduction is to be extended to depreciation on investment made in land and building for dedicated research facilities, expenditure incurred for obtaining regulatory approvals and filling of patents abroad and expenditure incurred on clinical trials in India; c) Reference Standard (sample under test) would be exempted from import duty; d) Reference books to be imported for R&D would be exempted from import duty; and e) Presently there are 101 specified instruments (list 28) required for R&D purposes, which are exempt from import duty. With the ever-changing requirements new instruments are required to be imported. These instruments based on the certification of DSIR would also be exempt from import duty. The fiscal incentives are at present only available up to 31st March 2007. Since R&D activity has to be carried over long periods of time, fiscal

6 Income Tax Department, Government of India, http://www.taxmann.com/TaxmannDit/DisplayPage/dpage1.aspx?md=2&typ=se&yr=2006&ch=(accessed on 11/08/06)

incentives would be granted over a longer period of time extending up to 10 years i.e., up to 31st March 2015.

**ii. R&D Intensive Companies (Gold Standard Companies)**: The Pharmaceutical Research and Development Committee headed by Dr R A Mashelkar in its report submitted to Government in November, 1999 recommended that R&D intensive companies fulfilling certain conditions should be given price benefits for the drugs under Drug Price Control Order (DPCO). It specified certain norms in this regard and termed these as the gold standards. Since six years have elapsed since this report was submitted it has been considered proper to revise these norms. The revised norms are as under: a) Invest at least 3 per cent of the annual sales turnover on R&D or Rs 500 million per annum, (average of last 3 years) whichever is higher on research facilities. b) Employment of at least 200 scientists in India (MScs or PhDs employed at least for one year). c) Own and operate manufacturing facilities in India which have been approved by at least two reputed foreign regulatory agencies (US, Europe, Japan, Canada, Australia, Israel, South Africa etc) d) Have filed at least 10 patent applications in India based on research done in India Companies fulfilling the above norms would be eligible for the benefit of 200% weighted deduction under 35(2AB) till 31st March, 2015 Additional incentives under price control measures may also be considered to such companies by Department of Chemicals and Petrochemicals.

**iii. The Pharmaceutical Research and Development Support Fund:** At present, the Pharmaceutical Research and Development Support Fund (PRDSF) has a corpus of Rs. 1500 million (where only interest income is available for spending) is utilized for funding R&D projects of research institutions and industry in the country. It is not adequate to meet the present day and the emerging requirements of this sector and there needs to be sufficiently augmented over the next five years. It has been decided to convert it into an annual grant of Rs. 1500

million, and thereafter it would be suitably increased further in a phased manner over a period of next five years. Priority would be given for R&D in case of diseases which are endemic to India like malaria, tuberculosis, hepatitis-B,leishmania (kala-azar),HIV/AIDS etc.

**iv. Development of orphaned drugs**: The Central Drug Research Institute (CDRI) has over time developed a number of drug technologies, which could not be commercially produced and marketed. Efforts will be made to identify such technologies with a view to enabling them to reach the market.

Further, the following two initiatives implied in the new draft policy has also further implications for promotion of innovation in the industry. They are: (i) abolition of industrial licensing for bulk drugs, intermediates and formulations; and (ii) automatic approval for foreign technology agreements through RBI.

**(b) The Patent regime**: It is now fairly well accepted that it is the provisions of the Indian Patents Act of 1970, and especially the fact this Act did not recognize product patents but only process patents, that allowed Indian pharmaceutical companies to reverse engineer and manufacture at significantly lower costs. But with the country becoming a member of the WTO in 1995, the patent regime has been made TRIPs compliant. This TRIPS compliance in very specific terms have led to the introduction of the following set of measures;

- The EMR (Exclusive Marketing Rights) provision was introduced with retrospective effect from January 1, 1995 (self-expunging provision which will be void on January 1, 2005)

- This transitional arrangement entailed India to provide for a mailbox mechanism for accepting product patent applications and for examining and granting EMRs till the time it accords recognition to product patents;

- Minimum patent term increased from 14 to 20 years
- Reversal of burden of proof from patent holder to alleged infringer
- The provisions relating to compulsory licensing have been modified to suit the public health requirements and also to comply with TRIPS.
- Introduction of product patents relating to Chemicals, Drugs, Medicines and Food Products
- Provision for pre-grant objection to patents has been diluted; and
- Grace period in case of publication of inventions;

The potential effect of these amendments on the innovative behaviour of the domestic industry is now hotly debated. One of the most important consequences is about the availability and prices of many essential drugs. Henceforth some of these drugs can only be manufactured under an explicit licence. According to Ramani, Pradhan and Ravi (2005), the Indian pharmaceutical firms have three choices open to them in a post TRIPS compliant regime. These are:

i. They can focus on products that are either off patent (essentially the generics market);

ii. They can collaborate with Western MNCs and biotech companies (two areas that are likely to witness an increase in collaborations are clinical trials and R&D outsourcing) and;

iii. They can focus on innovations that the MNCs will not be interested in; that is mainly 'tropical' or developing world diseases.

Although a bit too early to clearly measure whether the three possibilities are actually happening, there is enough evidence to show that (i) and (ii) are indeed happening. We will discuss this in some more detail in the subsequent sections. In the present we analyse, albeit briefly,

the efforts undertaken by Indian pharmaceutical companies towards R&D in neglected but tropical diseases. This discussion is very largely based on Chaudhuri (2005).

The Indian private sector started investing in R&D for developing new drugs since the mid 1990s when TRIPS came into effect. According to current estimates there about 15 domestic pharmaceutical companies that are active in drug research and they have or are in the process of establishing new research centres with new drug discovery research (NDDR) as the major objective. The total R&D expenditure for the development of new drugs by Indian companies has increased from Rs 6.73 billion in 2002-03 to Rs 10.02 billion in 2003-04 and a number of new chemical entities (NCEs) have been developed which is at different stages of development. Since they do not have all the skills or the financial wherewithal required to engage in the entire process of drug development, they have adopted a strategy to develop new molecules and license out the molecules to the MNCs at early stages of clinical development. Consequent to this the Indian companies are effectively not targeting neglected diseases, but only those, which interest the MNCs. At this point, it is necessary to mention that the government has taken some initiatives for collaborative research to synergise the strengths of publicly funded R&D institutions and the Indian pharmaceutical industry. The only one area where some progress has been made is in the development of an anti-TB molecule (Lupin's development of the NCE LL 4858 is a case in point). However no special efforts have been made for the development of new drugs for most of the neglected diseases (such as malaria, HIV/AIDS, Chagas disease, Dengue fever, Leishmaniasis and Leprosy).

**(c) Price regulations**: Drug prices in India are among the lowest in the world (and imports are therefore negligible). This is because of several reasons. The first is that only product patents and not process

patents (for pharmaceuticals) are so far recognized under Indian law. Therefore Indian manufacturers can make bulk drugs and formulations by "reverse engineering" of the overseas patented medicines, reducing R&D expenses and also avoiding royalty payments. Further, Indian labour costs are low compared to overseas levels. India also has a large pool of technical and managerial personnel and does not need management skills from overseas. Most of the plant and equipment required is made locally. Most importantly a measure of statutory price control for bulk drugs and formulations operates in India. Certain drugs (known as scheduled drugs, as they are listed in the First Schedule to the Drug Price Contol Oder (DPCO). The DPCO was introduced in 1970, but has since been modified three times, the latest one being in 1995. Over time the number of drugs under price control has been significantly reduced from 370 in 1979 to just about 25 in 2005. Non-scheduled drugs can be priced freely, subject to some restrictions. The National Pharmaceutical Pricing Authority (NPPA) administers the price control regime.[7] The Government can exempt certain products from price control if they are new drugs discovered in India or bulk drugs produced from the basic stage by a new process discovered in India or drugs manufactured by small-scale industries (capital investment below a certain level) and sold under their own brand names. The most important problem with respect to price monitoring is the absence of an appropriate price index. The government has been depending on IMS Health-AC Nielsen, (formerly ORG) for tracking data on retail sales both in volume and value terms. Therefore, having a pharmaceutical price index on the lines of the Consumer Price Index or Wholesale Price Index is being considered. Though details of the proposed index were not available, it is said that

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7 The functions of the NPPA, inter alia, are to: (i) implement and enforce the provisions of the Drugs (Prices Control) Order in accordance with the powers delegated to it; (ii) monitor the availability of drugs, identify shortages, if any, and to take remedial steps; and (iii) collect/ maintain data on production, exports and imports, market share of individual companies, profitability of companies etc, for bulk drugs and formulations.

the government could create an index by having a basket of drugs whose prices would be benchmarked to a base year. It could then monitor any changes in their prices in relation to the index. However, the therapeutic segments that would form the basket would have to be decided. Also, whether the index would monitor prices of only generic drugs or include patented drugs as well would also have to be finalised.

**(d) Product and quality regulations:** The Drugs and Cosmetics Act of 1940 and its subordinate legislation Drugs and Cosmetics Rules (DCR), 1945 govern this aspect. The conduct of clinical trials- a growing area of importance is actually governed by this legislation. The government has decided to amend the DCR and has emphasised the incorporation of Good Clinical Practices (GCP) protocols and to make it legally binding to stress on the safety aspect of the patients and strict accordance to ethics. Towards this direction the Department of Science and Technology (Government of India) established national Good Laboratory Practices (GLP) Compliance Monitoring Authority, with the approval of the Union Cabinet on April 24, 2002. GLP-compliance certification is voluntary in nature. The GLP in India are compliant with OECD norms and principles. Industries/test/ facilities/laboratories looking for approval from regulatory authorities before marketing them may apply to the National GLP Compliance Monitoring Authority for obtaining GLP Certification. So far there are only five Indian laboratories that have received this certification (Table 2).

**(B) The manufacturing enterprises**

There has been confusion on the total number of pharmaceutical units in the country. This has been variously estimated to be about 19, 203 licensees. Citing the arguments and data provided in the Mashelkar Committee on drug regulatory issues, Chaudhuri (2005) argues that there are about 5877 pharmaceutical units in the country. This is because the number of pharmaceutical companies would be less than the number of licensees because manufacturing licenses are given to specific units and

**Table 2: Profile of Indian laboratories with GLP certification**

| Sl. No. | Test facility | Areas of expertise | Year of recognition |
|---|---|---|---|
| 1 | International Institute of Biotechnology and Toxicology (IIBAT) | Physical-chemical testing<br>Toxicity studies<br>Mutagenicity studies<br>Environmental toxicity studies on aquatic & terrestrial organisms<br>Studies on behavior inwater, soil and air; bioaccumulation<br>Residue studies<br>Studies on effects on mesocosms and natural ecosystems<br>Analytical and clinical chemistry testing<br>Studies on natural enemies and predators | 2004 |
| 2 | Dr. Reddy's Laboratories Limited, Discovery Research | Physical-chemical testing<br>Toxicity Studies<br>Mutagenicity Studies<br>Analytical and Clinical Chemistry Testing | 2004 |
| 3 | Jai Research Foundation | Physical-chemicalTesting<br>ToxicityStudies<br>Mutagenicity Studies<br>Environmental Toxicity Studies on Aquatic and Terrestrial Organisms<br>Studies on Behaviour in Water, Soil and Air; Bioaccumulation<br>Residue Studies<br>Studies on Effects on Mesocosms and Natural | 2004 |

*cont'd....*

| | | | |
|---|---|---|---|
| | | Ecosystems<br>Analytical and Clinical Chemistry Testing | |
| 4 | Orchid Chemicals and Pharmaceuticals Limited | Physical-chemical Testing<br>Safety Pharmacology and Pharmacokinetic Studies<br>Toxicity Studies<br>Mutagenicity Studies<br>Analytical and Clinical Chemistry Testing | 2005 |
| 5 | Advinus Therapeutics Private Limited | Physical-chemical Testing<br>Toxicity studies<br>Residue studies<br>Mutagenicity Studies<br>Analytical and Clinical Chemistry Testing<br>Environmental toxicity studies on aquatic & terrestrial organisms | 2005 |

Source: National Good Laboratory Practice Monitoring Authority, http://indiaglp.gov.in/TestFacility.htm (accessed on January 25, 2006).

many companies have multiple manufacturing units. The structure of the drugs manufacturing sector in India is presented in Table 3.

**Table 3: Structure of India's Pharmaceutical Industry**

| | Type of enterprise | Number of enterprises |
|---|---|---|
| 1. | Bulk drugs | 1333 |
| 2. | Formulations | 4354 |
| 3. | Large Volume Parenterals | 134 |
| 4. | Vaccines | 56 |
| | Total | 5877 |

Source: Mashelkar Committee (2003), p. 49

According to Chaudhuri (2005), the bulks drug industry resembles that of a perfectly competitive industry with no one firm accounting for a significant share. Most of the units in this sector belong to the small-scale sector. Large private sector companies, on the contrary, dominate the formulations industry. See Table 4.

**Table 4: Top twenty companies in the retail pharmaceutical market in India, 2004**

| Rank | Sector | Comapny | No. of products | Annual sale in Rs.million | Market share (%) 2004 |
|---|---|---|---|---|---|
| 1 | Indian | Cipla | 707 | 11285 | 5.51 |
| 2 | MNC | Glaxo Smith Kline | 205 | 11143 | 5.44 |
| 3 | Indian | Ranbaxy | 437 | 9190 | 4.48 |
| 4 | Indian | Nicholas Piramal | 449 | 8720 | 4.25 |
| 5 | Indian | Sun Pharma | 350 | 6738 | 3.29 |
| 6 | Indian | Dr Reddy's | 183 | 4988 | 2.43 |
| 7 | Indian | Zydus-Cadila | 330 | 4959 | 2.42 |
| 8 | Indian | Aristo Pharma | 175 | 4760 | 2.32 |
| 9 | MNC | Abott India | 87 | 4735 | 2.31 |
| 10 | Indian | Alkem Labs | 310 | 4477 | 2.18 |
| 11 | MNC | Aventis | 44 | 4367 | 2.13 |
| 12 | Indian | Lupin | 274 | 4165 | 2.03 |
| 13 | Indian | Micro Labs | 461 | 3903 | 1.9 |
| 14 | Indian | Wockhardt | 238 | 3776 | 1.84 |
| 15 | Indian | Torrent | 150 | 3747 | 1.83 |
| 16 | Indian | Novartis India | 127 | 3725 | 1.82 |
| 17 | Indian | Alembic | 169 | 3432 | 1.67 |
| 18 | Indian | Unichem Labs | 189 | 3430 | 1.67 |
| 19 | Indian | USV | 86 | 3390 | 1.65 |
| 20 | MNC | Pfizer | 29 | 3274 | 1.6 |

Source: Chaudhuri (2005), p. 17.

One of the most important features of the industry is the fact that it is largely dominated by domestic private sector enterprises. In fact there are only five MNCs in the top 20 and not a single public sector enterprise figure in the list. The two public sector enterprises, Hindustan Antibiotics established in 1954 and the Indian Drugs and Pharmaceuticals established in 1961, played an important role in creating a domestic private sector pharmaceutical industry (Chaudhuri, 2005, p. 34). This is best summed up by Smith (2000, p 33)

"Before HAL opened its doors, the domestic pharmaceutical industry was all but nonexistent. Furthermore, India's universities had no provisions for the type of specialized training required by pharmaceutical companies. HAL's founders took the initiative and laid a considerable part of the foundation that supports today's local and MNC subsidiary drug companies. HAL created a demand for inputs in the form of skilled labor, specialized capital, and relevant services, and provided the critical mass for local pharmaceutical production, created jobs for tens of thousands, spurred innovation, and sparked industrial development in up and downstream businesses. These contributions eventually rendered India a favorable environment for pharmaceutical production, research, and distribution".

However currently both these units are declared as "sick" or financially distressed companies by the Board for Industrial and Financial Reconstruction (BIFR) and are practically non-existent.

The amended patent law (1972) and the policy of positive discrimination towards indigenous companies vis-à-vis MNCs ensured that domestic companies currently (2004) account for nearly three quarters of the pharmaceutical market (Figure 5).

Although the data on market shares provided in Table 4 appears to give an indication that the market is fairly competitive, this is really not the case. The reason being the pharmaceutical industry is not a

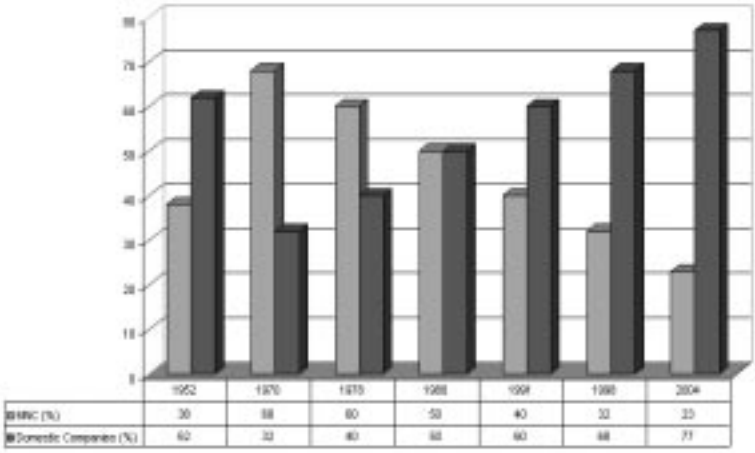

**Figure 5: Market shares of Foreign and Indian Companies in the Indian pharmaceutical industry, 1952-2004**

Source: Chaudhuri (2005), p. 18

homogenous one but fragmented into different therapeutic segments such as tranquilizers, analgesics, antibiotics, vitamins etc. Each of these segments is a not substitute for each other. In fact the concentration ratios are much higher within a specific therapeutic group. For instance, Chaudhuri (2005) shows that, if one takes the various sub groups within antibiotics, the degree of concentration is much higher.

Another important structural aspect has been the increased number of mergers and acquisitions in the industry. In the period from January 2004-when Ranbaxy formalized its purchase of RPG (Aventis) for $80 million, making it the fifth-largest generics supplier in France-until October 2005, Indian firms made 18 international acquisitions (KPMG, 2006). Glenmark, Jubilant Organosys, Nicholas Piramal and Ranbaxy each acquired two overseas businesses during this time, but the biggest Indian buy was Matrix Labs' acquisition of Belgium's Docpharma for $263 million in June 2005. It is generally held that the pharmaceutical

enterprises are currently the most aggressive overseas investors of all Indian industries. Several reasons[8] could be attributed to this mergers and acquisition spree. They are for the need to:

- Improve global competitiveness;
- Move up the value chain;
- Create and enter new markets;
- Increase their product offering;
- Acquire assets (including research and contract manufacturing firms, in order to further boost their outsourcing capabilities) and new products; and
- Consolidate their market shares

**(C) Government Research Institutes**

According to Chaudhuri (2005), of the total pharmaceutical R&D expended in the country, nearly two thirds is contributed by the industry and the remaining by the GRIs primarily under the management of the Council of Scientific and Industrial Research (CSIR). Of the small number of new drugs that were developed by Indian inventors a lion's share were the products of research done at the Central Drug Research Institute (CDRI). CDRI is considered to be one of the few public sector organizations in the world, which have its own drug development infrastructure. Over the years it has developed and licensed to other private sector enterprises ten new drugs. Unfortunately most of the drugs according to Chaudhuri (2005) did not survive in the market owing to strong competition from MNCs.

Apart from the CDRI, which is directly connected with drug research, the CSIR system has 20 other laboratories that are engaged in some form of pharmaceutical research or other. The annexure lists these

8 See KPMG (2006), p.25

labs with their areas of competence. Four of these led by the CDRI have been very active in drug research as indicated by the fact that they together account for a quarter of both Indian and foreign patents secured by the CSIR system (Table 5).

**Table 5: Foreign and Indian patents granted to CSIR Labs engaged in drugs research, 2003-04**

| | India | Foreign |
|---|---|---|
| CDRI | 7 | 5 |
| CIMAP | 7 | 29 |
| IICB | 4 | 5 |
| IICT | 24 | 39 |
| Total for the above | 42 | 78 |
| Total for CSIR | 275 | 212 |

Source: Computed from CSIR Website

### III. Performance of the innovation system:

It is already seen above that India has demonstrated strong innovation capabilities in developing manufacturing processes, thanks to the old patent regime. Conventional measures of measuring innovation are unlikely to show the real innovation potential of pharmaceutical companies, as most of these reverse engineered processes may not have been done through a formal R&D route. Hence there is a strong case for developing non-conventional measures to portray the innovation capability of this sector. However before attempting at some non-conventional measures, we start with the innovation record of the industry using conventional measures such as R&D expenditure and patents and we start with the R&D investments.

**Table 6: Trends in R&D expenditure in the Indian pharmaceutical industry** (Rs in Millions)

| | Public Sector | Private sector | Small scale | Total | Gowth rate(%) |
|---|---|---|---|---|---|
| 1989-89 | 46.06 | 501.651 | 16.733 | 564.444 | |
| 1989-90 | 54.158 | 579.674 | 32.272 | 666.104 | 18.01 |
| 1990-91 | 118.934 | 598.727 | 38.211 | 755.872 | 13.48 |
| 1991-92 | 168.313 | 756.592 | 52.763 | 977.667 | 29.34 |
| 1992-93 | 79.652 | 1053.509 | 58.653 | 1191.814 | 21.90 |
| 1993-94 | 71.416 | 1217.206 | 85.479 | 1374.101 | 15.29 |
| 1994-95 | 57.813 | 1600.268 | 153.832 | 1811.913 | 31.86 |
| 1995-96 | 48.432 | 1938.869 | 179.111 | 2166.412 | 19.56 |
| 1996-97 | 44.402 | 2618.954 | | 2663.356 | 22.94 |
| 1997-98 | 46.318 | 2828.556 | | 2874.874 | 7.94 |
| 1998-99 | 49.018 | 3725.958 | | 3774.976 | 31.31 |

Source: Department of Science and Technology (Various issues)

The exercise is conducted at two levels. First we analyse the overall R&D expenditure (Table 6) and this is followed by a more firm-level analysis (Table 7).

The overall R&D expenditure has increased, on an average, by 21 per cent per annum. One of the more interesting conclusions that can be derived from Table 5 is that it is the private sector, which accounts for over 85 per cent of the R&D expenditures. The share of the small-scale sector too has shown some increases and in 1995-96 (the latest year for which such data are available) stood at around 8 per cent. The small-scale sector is entirely in the private sector and so if one adds the small-scale sector data to that of the private sector, latter's share is even higher. The reduction in public sector's share is to be explained by the fact that two leading public sector enterprises, HAL and IDPL, as mentioned above, are financially speaking distressed.

The firm-level analysis (Table 7) further confirms that even with in a short period of time the R&D expenditure of the firms under

consideration have actually trebled although the research intensity for all the firms together have increased only slightly. However many of the leading firms have increased their research intensities thus prompting us to believe that the firms are responding to the challenges posed by a TRIPS compliant innovation regime.

**Table 7: R&D expenditure of leading Indian pharmaceutical firms (Rs in Crores)**

| | 2001-02 | | 2003-04 | |
|---|---|---|---|---|
| | R&D | R&D Intensity (%) | R&D | R&D Intensity (%) |
| 1. Ranbaxy | 77 | 3.6 | 276 | 6.1 |
| 2. Dr Reddy's Laboratory | 111 | 7.1 | 226 | 13.0 |
| 3. Sun Pharma | 34 | 4.4 | 108 | 10.2 |
| 4. Cadila Health Care | 42 | 7.1 | 88 | 7.6 |
| 5. Wokhardt | 30 | 4.4 | 60 | 6.2 |
| 6. Cipla | 22 | 3.5 | 57 | 2.9 |
| 7. Nicolas Piramal | 10 | 1.2 | 56 | 4.4 |
| 8. Lupin | 54 | 5.6 | 46 | 3.7 |
| 9. Aurobindo Pharma | 13 | 1.3 | 46 | 3.5 |
| 10. Torrent Pharma | 22 | 5.1 | 40 | 8.9 |
| 11. Glenmark Pharma | 12 | 4.7 | 37 | 9.8 |
| 12. Biocon India | 7 | 4.4 | 23 | 4.4 |
| 13. USV Ltd | 12 | 3.3 | 21 | 0.4 |
| 14. Alembic | 14 | 2.3 | 20 | 3.2 |
| 15. IPCA Labs | 8 | 1.8 | 17 | 2.6 |
| 16. Sushan | 9 | 2.3 | 11 | 4.0 |
| 17. Cadila Pharma | 9 | 2.3 | 10 | 2.4 |
| 18. Unichem | 10 | 3.3 | 8 | 2.2 |
| Total | 496 | 4.0 | 1150 | 4.7 |

Source: Lok Sabha Unstarred Question no: 1916, http://164.100.24.208/lsq14/quest.asp?qref=19536 (accessed on March 15 2006)

Despite this high growth the R&D expenditure incurred by Indian firms is only a very small percentage of what is expended by foreign firms (Figure 6).

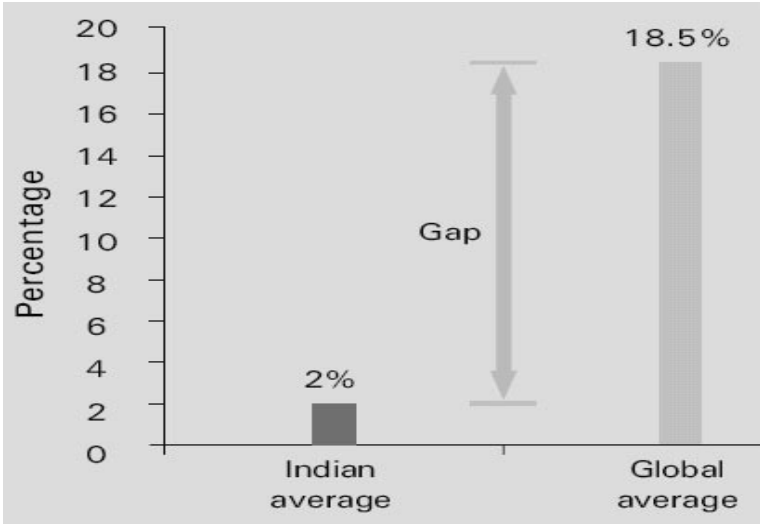


**Figure 6: R&D intensity of Indian and Western MNCs, 2001**
Source: KPMG (2003)

Indian companies have been active patenting entities in the US as far as pharmaceutical technologies are concerned (Table 8). Pharmaceutical patents now (2000-2004 period) account for over 20 per cent of all patents granted to Indian inventors. An important finding is that the number of pharmaceutical patents granted to Indian inventors has actually increased significantly during the latter period. This means that the impending TRIPS compliance of India's patent regime has actually made the Indian inventors more innovative. This fact is hardly realised in the Indian literature on this issue.[9]

9 Even the rather conservative "Economist" of London in one of its most recent stories on the Indian pharmaceutical industry had the following caption "Mere copycats no longer, Indian firms are flaunting their research skills". See Economist (2006), http://www.economist.com/business/displayStory.cfm?story_id=5476754

**Table 8: Patenting performance of India in pharmaceutical technology classes in the US**

| | India | China | South Africa | Brazil | All Indian patents in the US | Share of Indian Pharma patents in all Indian patents |
|---|---|---|---|---|---|---|
| 2000 | 36 | 8 | 5 | 4 | 110 | 33 |
| 2001 | 46 | 20 | 4 | 0 | 174 | 26 |
| 2002 | 48 | 19 | 5 | 3 | 239 | 20 |
| 2003 | 72 | 24 | 7 | 9 | 329 | 22 |
| 2004 | 44 | 23 | 1 | 1 | 347 | 13 |
| Total During 2000-2004 | 246 | 94 | 22 | 17 | 1199 | 21 |
| Total During 1995-1999 | 56 | | | | 316 | 18 |

Note *Based on US Patent Class 424, Drug, Bio-Affecting and Body Treating Compositions (includes Class 514))
Source: USPTO (2005)

It is also interesting note that most of the Indian patents (excluding individually owned patents) have been granted to private sector enterprises (Table 9), although the network of government research institutes under the CSIR is also a strong contender.

**Table 9:Distribution of Indian patenting organizations in pharmaceutical technologies in the US, 2000-2004**

| | Share |
|---|---|
| Council of Scientific and Industrial Research | 46 |
| Ranbaxy Laboratories | 19 |
| Dabur Research Foundation | 10 |
| Dr Reddy's Research Foundation | 9 |
| Panacea Biotec | 4 |
| Wockhardt | 3 |
| Biocon | 3 |
| Torrent | 3 |
| Aurobindop | 3 |
| Total | 100 |

Source: USPTO (2005)

There are several instances of real innovations by Indian pharma companies. Of the various instance, although a small number by Western standards, two stand out. The first one is by Dr. Reddy's Laboratories (DRL) which entered into agreements in 1997 and 1998 with global pharmaceutical giant Novo Nordisk to license molecules for further development. The second one is by the country's largest pharmaceutical company, Ranbaxy, when it licensed its technology for an innovative drug delivery system for ciprofloxacin, named Cipro-OD, to Germany's Bayer, which owned the patent to the drug. (OD stands for once a day, which was Ranbaxy's innovation.)[10]

India's strength in this area, as in information technology (IT), is its talent pool. According to some estimates the country has 122,000

10 This information is based on Knowledge@Wharton (2005)

chemists and chemical engineers graduating each year and the compensation that needs to be paid to these scientists are much lower than that in the West. Goldman Sachs, an investment bank, estimates that India's overall research-and-development costs are one-eighth of Western levels.

Even so, no domestic company yet has the financial clout to become a big drug innovator. This is because new drug development is a highly uncertain affair with far more failures than successes. The cost of developing a new drug to be marketed worldwide is usually put at about $1 billion. Two of the leading Indian pharma companies, Ranbaxy and Dr Reddys Laboratories are in the process of doing R&D with a view to developing and marketing their own proprietary drugs in the near future. Given its high quality talent pool and tremendous cost advantages an area where the industry has immense potential is in R&D outsourcing or contract research deals. This will be discussed in detail in the next section.

Given that much of the pharmaceutical production in the country is of generic in nature, conventional indicators such as R&D investments and patents are not really good measures to gauge the innovativeness of this industry. Drug Master Files (DMFs) and Abbreviated New Drug Applications (ANDA) approved by the USFDA can be taken as a good indicator of the innovation capability of generic manufacturers. Systematic data on county-wise number of DMF and ANDA applications approved are not available from the Office of Generic Drugs of the USFDA. The total number of ANDA applications approved by the USFDA is presented in Figure 7. It is estimated that approximately a third of these have gone towards Indian companies.[11]

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11 According to Agres (2005) Indian companies were responsible for submitting nearly 21% (73 of 350) of all abbreviated new drug applications (ANDAs) to the FDA last year. This is expected to increase to about a third of the anticipated 500 ANDAs in 2005, according to a report by Credit Lyonnais Securities. Further the Indian firms now account for 35 percent of Drug Master File applications. The DMF filing gives details about a company's facilities for manufacturing, processing, and storing drugs.

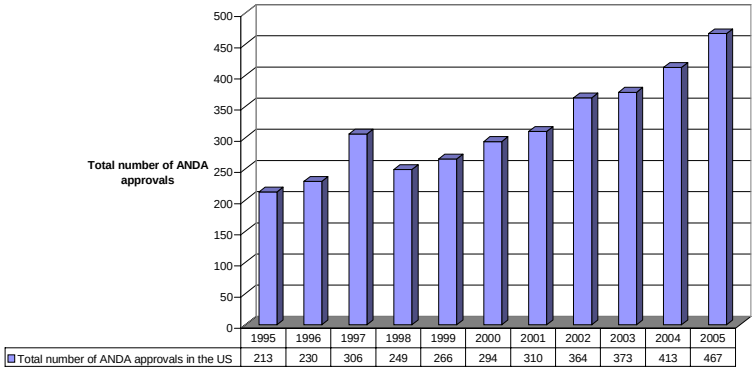


**Figure 7: Total number of ANDA applications approved in the US, 1995-2005**

Source: Buehler (2005)

**Growing contract research**

There are two dimensions to this. First, is R&D outsourcing by Western MNCs to Indian entities and second is the growth of clinical trials.

R&D outsoucing is being done primarily to minimize the expenses, time and risk involved in R&D. The estimations from industry sources reflect that the cost of bringing one new molecule into the market amounts to USD 1 billion. The European Federation of Pharmaceutical Industries and Associations (EFPIA) estimates that, on an average out of 10,000 molecules developed in laboratories, only one or two will successfully pass all stages of drug development and be commercialised. Pharmaceutical companies looking for effective solutions, thus, prefer outsourcing to low-cost, developing countries rather than persisting with expensive R&D efforts in the West. Alliances with local companies, contractual outsourcing arrangements and establishing local subsidiaries

are good options for enterprises thinking of utilising the strong intellectual potential in India and indeed in China too. "Contract research organisations (CROs) are a popular option and carry out medical and scientific studies on a contractual basis for multiple clients," says Frost & Sullivan Industry (http://pharmaceuticals.frost.com). These outsourcing activities in developing countries amount to 20.0 to 30.0 per cent of total global clinical trials. Access to specialised skills in both countries and work hours on a 24/7 basis underpins their competitive advantage. In addition, better management from the start reduces development risks.

Recent amendments to Schedule Y of Drugs and Cosmetics Rules of India, 1945, signify a progressive attitude on the part of the Indian Government, clarifying the environment for clinical research in the country attain international standards in pharmaceutical research.

India, at the moment, is the most preferred destination for clinical research because of its heterogeneous huge but treatment naïve patient population; English-speaking western educated investigators (physicians) and track record of sincerity in meeting regulatory and recruitment timelines, and most importantly well accepted good quality auditable data. While the global pharmaceutical companies are increasing their clinical trial investments in India, many small and big regional pharma companies are considering India in their drug development initiatives. There is a perceptible change in the old mindset of people - from skepticism to acceptance - of the capability, skill-sets and quality of data in Indian trials.

Cost-effectiveness, competition and the increased confidence on capabilities and skill sets have propelled many global pharmaceutical players (Pfizer, Novartis, Astra Zeneca, Eli Lilly, GSK, Aventis, Novo Nordisk to name but a few) to expand their own clinical research investment and infrastructure in India. Evaluating the business progression and futuristic projections of top notch services firm like

Ernst & Young, McKinsey, Strategic Associates etc, while global pharmaceutical companies and Contract Research Organisations (CRO) are opening up their branches / offices, the small biotech, pharmaceutical and Research and Development (R&D) companies are looking for preferred partners to conduct their research activities in India. The report captures the striking regulatory change i.e. the amendment of Schedule Y (2005), which is a step towards harmonizing the Indian regulatory framework with international Good Clinical Practice (GCP) for all the stakeholders in clinical research including the sponsors, CROs, Site Management Organisations (SMOs), Institutional Ethics Committees (IECs), Investigators and the subjects participating in clinical trials in India

The country can accommodate these business expansions because of the availability of huge talent pool of Investigators and clinical research professionals.

India's growth in pharmaceutical and biotech manufacturing, and contract research supported by IT skills has led to promising outsourcing business in various other segments including Clinical trial data management, statistical analysis.

The clinical research industry in the country is currently valued at $100 million (• 83 million) and is almost doubling each year, reflecting the shifting focus of the pharmaceutical outsourcing industry to Asia. The findings are published in a recent report analyzing the clinical research industry and 33 leading contract research organizations (CROs) in India, put together by US pharmaceutical consulting firm, Proximare[12].

A previous barrier to outsourcing to India has been that companies are worried about probable loss of control in processes and proprietary

12 In fact there are no official sources of data on the number of contract research oroganizations in India.

knowledge and delays due to regulatory hold-ups. Recent amendments to Schedule Y of Drugs and Cosmetics Rules of India, 1945, signify a progressive attitude on the part of the Indian Government, clarifying the environment for clinical research in the country. Executives at large and small pharmaceutical and biotech companies are increasingly becoming intrigued about India and how they can leverage it to launch high quality products in a quicker and more cost-effective manner.

## IV. Conclusions

India's innovation system is dominated by the pharmaceutical industry. The industry has achieved self-sufficiency in most drugs, although a number of active pharmaceutical ingredients are still being imported. It is very well understood that the old patents regime has enabled the pharmaceutical industry to enhance its domestic technological capability. This capability to reverse engineer known pharmaceutical products have given some of the firms sufficient learning to engage in the development of NCEs in a TRIPS compliant product patent regime. However none of the firms are doing research on the neglected diseases. In sum, the TRIPS compliant patent regime does not appear to have dampened the innovation capability of the domestic pharmaceutical industry, and on the contrary they have both increased their research budgets and patenting. However none of the components of the sectoral system of innovation has sufficient knowledge and capability in the entire sequence of doing research, developing a molecule and introducing a new drug in the market. In fact our study shows that this is an area where public policy ought to be focusing upon.

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**Annexure : Indian GRIs engaged in drug research and their respective areas of core competence**

| Sl. No | Name of the laboratory | Areas of competence |
|---|---|---|
| 1 | Central Drug Research Institute (CDRI, Lucknow) | Drug discovery to development, synthetic/natural product chemistry, combinatorial chemical synthesis, molecular modelling, HTS, structural biology, broad-based biological screening, pharmacology, pharmaco-kinetics, toxicology, phase I clinical studies, chemical and fermentation technology, quality control and standardization, proteomics, medicinal chemistry, molecular and cell biology, pharmacology, and phytochemicals/herbal drugs/nutraceuticals research. |
| 2 | Indian Institute of Chemical Biology (IICB, Kolkata) | Synthetic/natural products/medicinal chemistry, infectious diseases, cellular physiology, drug designing, molecular modelling, molecular biology, biotechnology, cell signals for oncogene expression and metabolic diseases, immunology, human genetics, genomics, proteomics, bioinformatics, molecular and cell biology, pharmacology, phytochemicals/nutraceuticals. |

| Sl. No | Name of the laboratory | Areas of competence |
|---|---|---|
| 3 | Indian Institute of Chemical Technology (IICT, Hyderabad) | Synthetic and natural products chemistry, chemical /process engineering, combinatorial/medical chemistry, asymmetric synthesis for chiral drugs, custom synthesis, computer-aided modelling and drug design, glyco-therapeutics, peptides and peptido-mimetics, enzyme mimics (drug delivery systems), pharmacology, pre-clinical toxicity pharmacokinetics, toxicology, phytochemicals/herbal drugs/ nutraceuticals research, quality control and formulation. |
| 4 | Indian Institute of Microbial Technology (IMTECH, Chandigarh) | Molecular and cell biology, microbial genetics, immunology, structural biology, protein engineering, fermentation technology, culture type depository, microbial gene bank, bioinformatics, proteomics, molecular and cell biology. |
| 5 | Institute of Genomics and Integrative Biology (IGIB, Delhi) | Genomics & Molecular Medicine, Predictive medicine, Genome Informatics (in-silico biology), Bio-informatics, Pathway modelling, Proteomics structural biology, Comparative Genomics & Gene Expression, Immunology and molecular genetics of respiratory disorders including allergy, Nucleic Acids & Peptides, Bioactive molecules of medicinal importance |

| Sl. No | Name of the laboratory | Areas of competence |
|---|---|---|
| 6 | Regional Research Laboratory (RRL-Jammu) | Agrotechnology, synthetic (chiral) and natural product chemistry, herbal drugs, select biological screening, bioprospecting, microbial biodiversity for industrially useful enzymes, genetic fingerprinting, identification/authentication of medicinal plants, fermentation technology, quality control and standardization of herbal drugs, establishment of medicinal plants gene bank, bioinformatics, pharmacology phytochemicals/herbal drugs/nutraceuticals research. |
| 7 | Central Institute of Medicinal and Aromatic Plants (CIMAP, Lucknow) | Agrotechnology of economically important herbs, process technology for phytochemicals, herbal drugs, nutraceuticals, genetic finger printing of plants/herbs, plant bioinformatics, genetic improvement, bioprospecting, molecular and cell biology, quality control and formulation. |
| 9 | Centre for Cellular and Molecular Biology (CCMB, Hyderabad) | Advanced molecular and cell biology, biotechnology, sperm-associated proteins/fertility-potential of sperm, DNA-fingerprinting, signal transduction, eye diseases, hepatitis vaccine, microbial genetics, transgenics, anti-microbial proteins, genomics, proteomics molecular and cell biology |

| Sl. No | Name of the laboratory | Areas of competence |
|---|---|---|
| 10 | National Chemical Laboratory (NCL, Pune) | Synthetic chemistry, tissue culture, biotechnology, industrial microbiology, nanoparticle technology, smart polymer gels, chemical/process engineering, process/enzyme/fermentation technology, combinatorial chemistry, medicinal chemistry, quality control and formulation |
| 11 | Institute of Himalayan Bioresource Technology (IHBT, Palampur) | Identification, collection, isolation and characterization of plants and microbes chemical and molecular characterization of bioactives, genomics, tissue culture, agro-technology of medicinal plants, phytochemicals/herbal drugs/nutraceuticals research, and chemical/process engineering |
| 12 | Industrial Toxicology Research Centre (ITRC, Lucknow) | In vitro test systems for bio-evaluation/identification of molecules or neurological disorders and antioxidant activity, complete toxicity evaluation in small animals; identification and action mode of hazardous toxicants/pollutants, diagnostics for toxicants/pollutants; safety evaluation/preventive measures for environmental/industrial hazards, and quality assessment of drinking water |

| Sl. No | Name of the laboratory | Areas of competence |
|---|---|---|
| 13 | National Botanical Research Institute (NBRI, Lucknow) | Pharmacognosy, ethnopharmacology, herbal drugs (authentication, standardization, characterization), nutraceuticals, agro-technology of medicinal plants, plant bioinformatics, genetic characterization and genetic improvement of economically important plants, proteomics, transgenics, molecular and cell biology, pharmacology phytochemicals/herbal drugs, quality control and formulation |
| 14 | Central Salt & Marine Chemicals Research Institute (CSMCRI, | Bioactives from plants, cultivation of desert economic plants and their value addition, sea weed cultivation, phycocolloids and marine microbes, biotechnology, synthetic chemistry and drug intermediates desalination water treatment technology for pure water for drinking, low sodium and plant/herbal salt |
| 15 | Regional Research Laboratory (RRL, Jorhat). | Bioactives from plants, drugs and drug intermediates, isolation and characterization of active molecules and analytical services |
| 16 | National Institute of Oceanography (NIO, Goa) | Collection and identification of marine flora and fauna, biological screening (antimicrobial, anticancer, oxytocic, anti-inflammatory, anti-fouling cytotoxic, antimalarial, antiosteoporotic antiviral, immunomodulatory) and marine natural product chemistry for the identification and structure elucidation of active molecules |

| Sl. No | Name of the laboratory | Areas of competence |
|---|---|---|
| 17 | Regional Research Laboratory (RRL-Thiruvananthapuram) | Synthesis of drugs/drug intermediates, natural product isolation, biological screening, chemical finger printing, herbal drugs, nutraceuticals, bioprocess/enzyme technology and phytochemicals. |
| 18 | Central Food Technological Research Institute (CFTRI, Mysore) | Nutraceuticals, health-promoting effects of spices/herbs/foods (antioxidants, digestion-stimulants, anti-inflammatory), traditional remedies, food-safety/nutritional toxicology, nodal codex food laboratory, animal and plant cell culture, PCR probes and biosensors, phytochemicals/nutraceuticals research,quality control & formulation, toxicology and bioprocess/enzyme/fermentation technology |
| 19 | Central Leather Research Institute (CLRI, Chennai) | Controlled drug delivery systems, collagen-based biomaterials, skin biology |
| 20 | Central Glass and Ceramics Research Institute (CGCRI, Kolkata) | Ceramic membrane technology based water purification technologies, Ceramic based bio-medical implants |
| 21 | National Environmental Engineering Research Institute (NEERI, Nagpur) | Water purification, diagnostic kits etc. |

Source: http://www.csir.res.in/External/Utilities/Frames/achievements/main_page.asp?a=topframe.htm&b=leftcon.htm&c=../../../Heads/achievements/major_achievements.htm (accessed on March 18 2005)

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