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Economic Aspects of Access to Medicines after 2005:

Product Patent Protection and Emerging Firm Strategies in the Indian Pharmaceutical Industry

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This study has been commissioned by the CIPIH, WHO. The views expressed in this study are the views of the author and do not represent those of the CIPIH, World Health Organization or the United Nations University.

List of Abbreviations

APIs	Active Pharmaceutical Ingredients
ARV	Anti -Retroviral
CDRI	Central Drug Research Institute
CII	Confederation of Indian Industries
CRAM	Contract Research and Manufacturing
CSIR	Council for Scientific and Industrial Research
DPCO	Drug Price Control Order
EMRs	Exclusive Marketing Rights
FDA	Food and Drug Administration
FERA	Foreign Exchange Regulation Act
FICCI	Federation of Industries and Chamber of Commerce of India
GDP	Gross Domestic Product
GMPs	Good Manufacturing Practices
HAL	Hindustan Antibiotics Limited
IBEF	India Brand Equity Foundation
IDMA	Indian Drug Manufacturers Association
IDPL	Indian Drugs and Pharmaceuticals Limited
IICT	Indian Institute for Chemical Technologies
IPA	Indian Pharmaceutical Alliance
LDCs	Least Developed Countries
MNC	Multinational Corporation
NCEs	New Chemical Entities
NDDS	New Drug Delivery Systems
NPPA	National Pharmaceutical Pricing Authority
OECD	Organization for Economic Co-operation and Development
OPPI	Organization of Pharmaceutical Producers of India
PhRMA	Pharmaceutical Manufacturers Association of the US
PLC	Public Limited Company
PRDSF	Pharmaceutical Research and Development Support Fund
R&D	Research and Development
TRIPS	Trade-Related aspects of Intellectual Property Rights
WTO	World Trade Organization

Executive summary

CENTRAL FOCUS OF THE INVESTIGATION AND METHODOLOGY

01 January 2005 marks the end of the transition period granted by the Agreement on Trade Related Aspects of Intellectual Property Rights, 1995 (the TRIPS Agreement) to developing countries to comply with its provisions on pharmaceutical product patents. From this date onwards, pharmaceutical firms can obtain full scale patent protection on their products in major markets in developing countries, such as India, and also prevent local firms from manufacturing generic copies of their patented products.

Theoretically, compulsory licensing, as provided for under the TRIPS Agreement, or merely the threat of its use, could be used as a price-leveraging instrument in developing countries. But the introduction of product patent protection in countries such as India may have far-reaching consequences on access to medicines at affordable prices in a large number of developing and least developed countries. Indian pharmaceutical firms, have in the past, offered strong price competition through the production of cheaper generic versions of drugs patented elsewhere. In this context, the Doha Declaration on the TRIPS Agreement and Public Health, 2001 and the decision on the implementation of Paragraph 6 of the Doha Declaration, adopted by the WTO countries on 30 August 2003 have tried to further the means by which developing countries can export drugs through compulsory licenses to least developed countries that do not have adequate local manufacturing capacities.

Equitable pricing could result from the Doha Declaration and the 30 August Mechanism if LDCs without adequate manufacturing facilities would be able to use the 30 August 2003 mechanism to obtain supplies from India or a different developing country under a compulsory license. But in practice, apart from the legal hurdles involved in such a compulsory license (see Grace, 2003 for a discussion), there is a possibility that these compulsory licenses may not make much economic sense for potential generic producers (in terms of market size and profits involved in such supply), thereby reducing the potential of this mechanism to serve as an instrument to induce price competition in the global market.

The study aims at investigating what the effect of the introduction of product protection for pharmaceuticals in India is likely to have on:

- The pricing of new medicines in the Indian domestic and third country markets? The investigation of this question focuses specifically on the pricing and business strategies of brand name and generic producers in the new environment, particularly in respect of Africa.

- How important this change will be, when compared to other factors affecting access to new medicines, especially for diseases that disproportionately affect India and other such countries?

- To what extent can compulsory licensing still be an economically feasible alternative for generic producers?

The original contribution of the study is a survey of 103 Indian firms, complemented with insights from case study interviews conducted to supplement information gathered in the survey. The scope of this study is limited to ***analyzing emerging firm strategies of Indian firms as a response to a gradual transition to product patent protection***, and not to predict or to assess India's present legal situation and issues therein related to the full implementation of its product patent protection regime. Therefore, data collected in the survey was mostly for a time period of 2000 to 2004, in order to be able to assess emerging firm strategies.

In addition, a variety of other data sources were employed, including secondary sources and case studies that rely considerably on scientific expertise perception of scientists. Secondary research consisted of a detailed review of existing literature including general documents on access to medicines and international developments related to the TRIPS Agreement and policy documents and papers on the impact of product patent protection on the Indian pharmaceutical industry.

Based on the secondary research and semi-structured interviews, a structured questionnaire was completed. A background report on the Indian pharmaceutical industry and emerging prospects and strategies from 2005 onwards was prepared to assist in identifying the main issues. The 103 firms that participated in the survey were chosen using a purposive probability sampling technique from a list of companies' generated for purposes of this study using major Indian databases like the *India Info line* and *Pharmabiz* (export potential, R&D investments and total sales were used as the three main parameters to arrive at the ranking for the list generated for the survey).

The questionnaire administered to participating firms was designed with the aim of generating as much information as possible on:

- Firm demographics, such as employment status, net sales turnover, focus of pharmaceutical activities, ownership structure of the firm, and main firm policies on various issues;
- Emerging R&D and business strategies and how these are affected by increased intellectual property protection in India, especially those on product patents; and,
- Firm views regarding the viability of compulsory licensing as a supply mechanism for least developed countries, and the circumstances under which they would consider this option as contained in the Indian Patent (Amendments) Act of 2005.

STUDY STRUCTURE

This study considers the following questions. Section 2 is an analysis of innovation in the Indian pharmaceutical industry. This section traces the origins, the strengths and weaknesses of the innovation system in the

pharmaceutical sector in India, and its industrial structure and activities, in order to establish the importance of the Indian industry for access to medicines in the developing world today. This section also arrives upon a categorization of firms in the Indian industry, based on empirical data, which is used in the rest of the study to draw conclusions on various issues. Section 3 discusses the main changes that are forcing a transition in the industry today, of which the introduction of product patent protection is the main one. The main issues that are still in the open despite the enactment of the Indian Patent (Amendments) Act of 2005 are also discussed at length in this section. Section 4 contains an in-depth analysis of the emerging firm strategies, for both, business and R&D, based primarily on the firm-level data collected. Special attention has been paid to two questions, namely: (a) whether the August 30 mechanism (which is the basis for Section 92(A) of the Indian Patent (Amendments) Act, 2005), offers sufficient financial incentives for Indian firms to act as suppliers of cheaper versions of patent drugs in a way analogous to the pre-2005 scenario, and (b) what the impact of increased intellectual property protection is on various aspects of pharmaceutical R&D in the Indian industry. Section 5 of the study analyses the different factors that affect access to medicines in the Indian market and in the developing world, and the feasibility of the compulsory licensing mechanism as contained in the 30 August 2003 decision to deal with these issues. Section 6 contains conclusions and policy recommendations.

A SUMMARY OF MAIN RESULTS

Product patent protection in India is emerging to be a very decisive factor in determining access to medicines, both in India and other third countries in Africa. The survey shows that Indian firms will face severe challenges to adapt to the emerging patent regime while (a) operating in an industrial and regulatory climate that still is not fully geared towards its needs in the light of tough international competition, and; (b) coping with the losses induced by the restrictions placed on them by the new patent regime. This is in keeping with earlier studies on the topic such as Fink (2000) and Chaudhuri, Goldberg and Jia (2004), which show that the losses to the Indian industry in certain segments following India's full scale TRIPS compliance are very high. Therefore, emerging strategies of Indian firms will continue to be dictated mostly by survival needs and not by issues related to access to medicines of the general public, whether in India or other least developed countries.

Is it too early for assess emerging firm strategies in India? The answer to this question lies in the negative. Some of the major changes, such as extension of patent protection from 14 years to 20 years, were already introduced in earlier amendments to the Patent Act (in 2002), and the survey shows that Indian firms have been preparing for India's product patent regime over time, and their strategies have been devised to help them cope with the emerging regime. The general sentiment in the industry is well summarized by a quote: "There is big trouble ahead for those who have not planned for post-2005" (Sridharan, 2005, quoting the MD, Divi Labs).

Indian firms are adopting a combination of cooperative and competitive strategies, in order to adapt and as well as capitalize on opportunities created by the new patent regime. The study has categorized firms in the

Indian pharmaceutical industry into three main groups, based on empirical data collected, and identified the main strategies and their triggers in each one of the three firm groups. Emerging firm strategies in the Indian industry portray a scenario that is is very different from what was observed in several Latin American countries, where local firms mainly adopted a cooperative strategy upon entry of foreign MNCs, thereby leading to their acquisitions by the latter, resulting in steeper increase in prices of drugs. The behavior of the Indian industry is more in keeping with what one would expect to see in an environment where a well-to-do local industry with clearly established areas of expertise is faced with strong international competition. Newer technologies and evolving market structures (in this case, as induced by the product patent regime and strong competition from global firms) almost always create new market segments and niches with many opportunities for specializations that the Indian industry will be quick to capitalize upon, although this will also be accompanied by a high degree of consolidation in the industry in the coming years.

The study also found a very high correlation between export intensity and R&D investments in the Indian pharmaceutical sector. Firms that had greater revenues from exports were able to invest a larger amount on R&D.

Should there be cause for concern that Indian firms are focusing so little on health priorities of the developing world? Is this a counter-intuitive result? Two factors seem to be instrumental in motivating innovation trends amongst Indian firms. Firstly, export demand plays a large role in shaping innovation strategies of Indian firms. Secondly, Indian firms are hard-pressed to survive amidst little government support and tremendous external pressures of global competition. Given that almost all Indian firms fully fund their own research activities through their profits; their concern is primarily on investing into drugs that assure them maximum returns. Both these factors result in an emphasis on R&D investment into global diseases. Therefore, this finding, although disappointing is not counter-intuitive.

The results of the survey on the impact of TRIPS Agreement on restricted access to technologies in the pharmaceutical sector show that Indian firms do face several difficulties with India's TRIPS compliance in this regard, and have also had to abandon some R&D projects in recent years. This preliminary evidence calls for a more systematic assessment of issues, such as: (a) the relative importance of IPRs when compared to other factors that affect firm-level decisions on whether or not to take up new R&D projects; and (b) if there are research projects under this regime that were not undertaken mainly due to IPR issues, do the other benefits of granting such IPRs offset these costs/ losses.

A last set of questions relate to the responses of group 3 firms to the survey. In many cases, responses of group 3 firms seem somewhat implausible (see Tables 5 to 14). The main explanation for their responses, as gathered through case study interviews that were conducted with the firms, is cognitive dissonance. There is a pervasive lack of information in the group 3 firms regarding the impact of product patent protection, Schedule M and opportunities that can be made use of by them, the patent application

processes and emerging business opportunities. These account for the far-fetched answers, to a large extent.

POLICY RECOMMENDATIONS

Several policy recommendations follow from the analysis for action, both at the international and Indian level. At the international level, the main recommendations are as follows:

1. To explore evidence of patents on restricted access to technologies in developing countries and to advise countries to how to balance intellectual property rights-competition law interface in this regard.

2. To advise the innovative developing countries on strengthening existing systems of health innovation and LDCs on how to build innovation systems while dealing with the effects of full-scale TRIPS compliance.

3. To generate awareness that IPRs may not necessarily be an impetus to innovation.

4. To advise countries on enacting procedures that expedite the use of compulsory licensing provisions under 30 August 2003 Decision. These should be directed towards rectifying distortions both on the demand side (LDCs) and the supply side (developing countries with manufacturing capabilities). On the supply side, countries need advice on kinds of incentive structures for private sector that promotes their continued engagement in such activities.

Policy recommendations for action at the Indian level that follow from the analysis are as listed below:

1. The Indian government needs to invest extensively in strengthening existing institutions such as local competition enforcement agencies, patent examiners, an informed judiciary which is more attuned to the public health and local industry needs in a country like India, and price control mechanisms in order to promote access to medicines in the local market and other LDCs.

2. The patent regime incorporates several major TRIPS flexibilities. But it also contains several provisions that are open to different sets of interpretations and therefore whether all the flexibilities that are permissible under the TRIPS Agreement will be used by India in day-to-day practice or not, is still much in the open.

3. Other rules affecting the industry, such as those on data exclusivity should be enacted only after taking into consideration the interests of the generics industry and the scope of its impact. If the generic industry in India is curbed further, a large amount of cheap supply of medicines at very competitive prices will be seriously affected.

4. The government should apart from providing an expedient administrative procedure for the implementation of Section 92(A) of the Act, create a higher level of awareness amongst the local industry on the option of

compulsory licensing to supply to other least developed countries. This could result in a more conducive attitude amongst the firms to deal with requests from other least developed countries in future.

5. The government should, in a concerted effort with the industry, plan ways in which to reduce bottlenecks to pharmaceutical R&D in the local Indian context. These will be very helpful to aid the industry to devise and implement strategies for survival.

6. The government should strengthen its activities in terms of identifying key areas where there is potential (for example, clinical research) and invest in development of these facilities systematically.

7. Promotion of R&D into diseases of the developing world, as the survey goes on to show, will remain a public good problem, irrespective of the capacities in the pharmaceutical sectors in developing countries. The government of India (either singularly or in collaboration with other governments in developing countries) should initiate more public R&D programmes that utilize the strengths of the Indian industry to find cures for neglected diseases.[1]

[1] There are already several such programmes in which the Government of India is involved. This recommendation is to augment these efforts further.

Acknowledgements

This study has been funded by Commission on Intellectual Property Rights, Innovation and Health (CIPIH) of the World Health Organization. I am thankful to a wide range of people who helped make the empirical investigation and my field visit to India extremely successful. I begin by thanking my colleagues at UNU-INTECH, Prof. Banji Oyeyinka and Kaushalesh Lal, for their help in refining the questionnaire design and survey techniques. I also extend my gratitude to Dr. Charles Clift, Secretary to the Commission, for his support in organizing the India trip. Without the help of Dr. Mashelkar and his office, all the interviews with government offices and departments in New Delhi would not have been possible. I am extremely indebted to the offices of the Indian Pharmaceutical Alliance and the Organization of Pharmaceutical Producers of India for obliging me with all their help. Mr. D. G. Shah's office, especially Ms. Lourdes Fernandez, offered enormous support services and extensive hospitality during my stay at Bombay, including helping in fixing meetings with a wide range of companies in and around Bombay. Mr. Homi Bhabha, Director of the Organization of Pharmaceutical Producers of India, helped organize a joint meeting with the members of their Industrial Policy and Licensing Committee members.

I am thankful to Mr. B. N. Sampath Kumaran for helping with organization and general infrastructure relating to the field trip. In Bangalore, I am thankful to the members of the office of the Karnataka State Chamber of Commerce for organizing a public seminar, where interaction will members of the state pharmaceutical and biotechnology companies, and governmental councils was made possible. My thanks also go to Mr. Mukund of Dr. Reddy's Laboratories, who organized almost an entire day of meetings and inspection of the Dr. Reddy's Laboratories Research Centre and Corporate Facilities in Hyderabad. I am also thankful to Multidimensions India Ltd., for having helped with the questionnaire survey of the Indian pharmaceutical industry. I am also grateful to Jamie Love, Cptech, USA, for taking the time to discuss the implications of 30 August 2003 Mechanism and compulsory licensing in least developed countries.

I am very grateful to Dr. Charles Clift, CIPIH, Jean Lanjouw, University of Berkeley, and Prof. Banji Oyeyinka, UNU-INTECH for comments on earlier drafts of this study.

Lastly, I thank Eveline in de Braek, UNU-INTECH and Richard Horne for editorial assistance.

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1 Introduction

Competitive processes that drive new-economy industries in many sectors centre on the protection of R&D efforts through intellectual property rights, and on resulting technological change (Evans and Schmalensee, 2002). The pharmaceutical industry, although one such industry, also confronts us with a plethora of issues that run far beyond shaping technological change. Patent protection guarantees profits to inventors in return for investing in the production of socially useful information by granting a temporary monopoly on the product. The patent holder therefore, can prohibit all others from copying the patented product and offering it in the market for a lower price, during the life of the patent. As a result, two diverging questions of public health – that of providing wider access to medicines to all those who need it at affordable prices, and that of granting incentives to invest in the research and development of new therapeutic products (Lanjouw, 2002, p. 4) – are intertwined and can sometimes run contrary to one another in the short-term or mid-term.

Public policy in most countries worldwide has been very sensitive to this trade-off between patent protection and restricted access even historically (See Correa, 2000). Data on OECD countries shows that patent protection for pharmaceutical products was introduced within countries only when their GDP per capita had reached a sufficiently high rate (Ibid.). But the Agreement on Trade Related Aspects of Intellectual Property Rights (hereafter, the TRIPS Agreement) does not allow the developing and least developed countries to retain the opportunity of doing so, since it obliges all member countries of the World Trade Organization to introduce patent protection on pharmaceuticals within transition periods recognized under the Agreement (Chang, 2002; Correa, 2005).[2]

This is one of the main reasons for increasing divisiveness on the impact of higher levels of intellectual property protection as contained within the TRIPS Agreement. The TRIPS Agreement contains several provisions that enforce stronger intellectual property protection on all member countries. These are mainly contained in Articles 27(1), 27(3) (b), 28, 30 and 31(a) to (f) of the Agreement (See Correa, 2001 for a discussion). At the start of the Uruguay round of negotiations, very few developing countries offered both process and product patent protection to the extent specified under the TRIPS Agreement.[3] Post-1995, as more and more developing countries became TRIPS compliant, the possibility that generic producers from developing

2 Developing countries have to comply with the pharmaceutical patent provisions of the Agreement as of 01 January 2005, whereas LDCs have an extended transition until 2016 to implement pharmaceutical patent protection in their local contexts (see footnote 9 below).

3 Although information available with the WTO Secretariat shows that at the date of entry of the TRIPS Agreement, there were less than 20 developing and least developed countries that did not provide for product patent protection (Watal, 2001, p. 8), the extent of protection within national laws in developing countries varied and in very few instances extended to the twenty years as specified by the TRIPS Agreement (See Watal, 2001).

countries offer price competition to the global pharmaceutical industry in the newly-patented drug categories has been reducing. The South African and Brazilian cases on the HIV/AIDS drugs poignantly drew attention to this dilemma and the limitations faced by developing countries to deal with the steadily increasing burden of disease internally given their inadequate finances (Grace, 2003). These cases have also shown that competitive supply of medicines can play a key role in lowering the market price of patented drugs. In the South African case on HIV/AIDS, a significant reason for the fall in prices was the threat of low cost supplies from generic producers from countries such as India.[4] The threat from generic companies that were able to manufacture ARV drugs at a much cheaper price have been a critical factor in the reduction in prices of these drugs in several other least developed countries ever since the South African case[5] - many firms, such as Merck and Co., Bristol Myers Squibb Co., Glaxo Smithkline PLC and Abbott labs have recently announced steep price reductions for their ARV drugs (Ganslandt et al, 2005, p. 208).[6]

1.1 Trends and Developments in the International Intellectual Property Rights Regime

01 January 2005 marks the end of the transition period granted by the TRIPS Agreement to the developing countries on pharmaceutical product patents. From this date onwards, pharmaceutical firms can obtain full scale patent protection on their products in major markets in developing countries, such as India, and prevent local firms from manufacturing generic copies of their patented products. This brings to the fore a very important question: given that the local pharmaceutical industry in developing countries can no longer offer price competition by manufacturing generic versions of drugs patented elsewhere at cheaper prices, what impact will this have on access to medicines in third countries, such as those in Africa?

Specifically, the introduction of product patent protection in the Indian market may have far-reaching implications on access to medicines at affordable prices in a large number of developing and least developed countries, because Indian pharmaceutical firms presently produce and supply both bulk drugs and finished formulations in the global market at very competitive rates.[7] The Indian pharmaceutical industry is amongst one of the

4 For a detailed discussion of the case, see Berger (2004), p. 16-18.

5 In these cases, it was the threat of generic production (and importation) by other Asian manufacturers that proved to be a more effective negotiation tool in reducing rates of the ARV cocktail far below those achieved by UNAIDS in direct negotiations with pharmaceutical firms that held patents on them. In this context, Grace (2004) notes that price wars induced by generic manufacturers brought down the price of the triple therapy from 10,000 US $ to US $ 350 in an year (at p. 15).

6 Merck and Co. has recently announced to sell its two drugs – Norvir and Kaletra at prices at which the company would not make any profit (Wall Street Journal, 2001, cited in Ganslandt et al, 2005, p. 208).

7 See Grace (2004), p. 7; also see Jongysur-Vevey (2004); Fink (2001) and Shah (2004) among others.

largest industries within developing countries and accounted for 8% of the global output in terms of the volume and ranked 13th in terms of value in 2004 (IBEF and Ernst and Young, 2004a, p. 8).[8] The industry is reported to have had an overall production value of US$ 7 billion in the year 2003 (ibid). The export potential of the industry has steadily been on the increase over the past decade. As Table 1 below shows, it has risen gradually from 2179 crore rupees to 14,600 crore rupees, making it the second largest export industry within India today. Its main export regions are USA, Germany, Russia, UK and China, although a more detailed country-wise division of exports from the Indian pharmaceutical industry as available with the Export Promotion Wing of the Indian Patent Office (CHEMEXCIL) is listed in Annex 2. India also has the largest amount of FDA approved drug manufacturing facilities outside of the USA (OPPI, 2003). Indian firms account for 90% of raw material supplies to the governmental pharmaceutical organization of Thailand for its ARV manufacturing activities, all of the raw material supply for the three main ARV producers in South Africa and along with China, and also dominate the ARV supply scenario for Brazil (Grace, 2004, p. 14).

Table 1: Value of imports and exports of drugs and pharmaceuticals from 1994-1995 to 2003-2004

Year	Total Imports	Total exports (in Crore Rupees)
1994-95	1527.00	2179.00
1995-96	1867.00	2337.00
1996-97	2358.00	4090.00
1997-98	2711.04	5419.00
1998-99	3047.34	6152.00
1999-2000	1502.03	7230.16
2000-2001	2032.47	8729.89
2001-2002	2581.23	10475.87
2002-2003	1102.50	11925.00
2003-2004*	3155.61	14600.00

*Estimated

Source: Indian Drug Manufacturers' Association, 2004.

In theory, compulsory licensing, as provided for under the TRIPS Agreement, or the threat of its use, could be used as a price-leveraging instrument in developing countries to ensure affordable access to patented medicines. The Doha Declaration on the TRIPS Agreement and Public Health, adopted by the WTO in 2001 (WT/MIN(01)/DEC/W/2), was in many ways a triumph for developing countries seeking to enforce the legitimacy of public health over stronger intellectual property protection in the pharmaceutical sector. The Declaration extends the transition period to least developed countries to implement the pharmaceutical patents provisions of the TRIPS Agreement until 2016.[9] Paragraph 6 of the Declaration reads as follows:

8 The IBEF (Indian Brand Equity Foundation) is a public-private partnership between the Ministry of Commerce, Government of India and the Confederation of Indian Industry (CII).

9 The Declaration thus has an over-riding effect on Article 65(4) of the TRIPS Agreement which provided that countries that did not have product patent

> We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing, under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

The Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (Decision No. WT/L/540), adopted by the WTO countries on 30 August 2003 has tried to further the contents of Paragraph 6. The Decision makes it clear that the obligation of a developing country to produce predominantly for the local market will be waived if the importing country which is a least developed country/developing country seeking to import drugs manufactured under the said license satisfies the terms laid out by Paragraph 2 of the Decision. Paragraph 2 makes the compulsory license incumbent upon: (a) the lack of local capacity to manufacture; (b) a condition that the compulsory license issued by the exporting member will be only for the amount needed by the importing member; and, (c) a notification to the TRIPS council by the importing member for the grant of a license for a national emergency or other circumstances of extreme urgency or a case of public non-commercial use. This allows developing countries to export drugs through compulsory licenses to other least developed countries that cannot manufacture them locally.

Paragraph 11 of the Decision also instructs the TRIPS Council to initiate work on the preparation of such an amendment to Article 31, so that it can be adopted within 6 months. This deadline of 31 March 2005 has recently been missed by member countries negotiating at the WTO due to differences between countries as to whether translation from a waiver into an amendment should be literal or whether it can have technical changes (Intellectual Property Watch, 2005).

For the impact of the Doha Declaration and the 30 August Mechanism to be realized, not only should LDCs be able to take complete advantage of delaying patent protection on pharmaceuticals in their national frameworks, LDCs without adequate manufacturing facilities should also be able to use the mechanisms introduced 30 August 2003 decision to obtain supplies from India or a different developing country under a compulsory license expeditiously. But in practice, apart from the legal hurdles involved in issuing such a compulsory license (see Grace, 2003 for a discussion), there is a possibility that these compulsory licenses may not make much economic sense for potential generic producers (in terms of market size and profits involved in such supply), and thus, may reduce the potential of this mechanism to serve as an instrument to induce price competition in the global market.

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protection at the time of joining the TRIPS Agreement can exercise the option of delaying the introduction of product patents until 01 January 2005.

1.2 Study Objective

This study aims at investigating what the effect of the introduction of product protection for pharmaceuticals in India is likely to have on:

- The pricing of new medicines in the Indian domestic and third country markets? The investigation of this question focuses specifically on the emerging pricing and business strategies of brand name and generic producers in the new environment, particularly in respect of Africa.

- How important this change will be, when compared to other factors affecting access to new medicines, especially for diseases that disproportionately affect India and other such countries?

- To what extent can compulsory licensing still be an economically feasible alternative for Indian generic producers, post-2005?

Between 1995 and 2005, several studies have sought to predict the impact of full-scale TRIPS compliance on the Indian market in general and strategies of Indian firms in particular (See for example, Subramanian, 1995; Arvind, 1995; Lanjouw, 1998; Watal, 1999; Fink, 2000; Chaudhuri, Goldberg and Jia, 2004; and Grace, 2004). These studies have each examined various aspects of the patent landscape and its impact on the Indian industry using different methodological techniques, in order to predict the impact of product patent protection on the Indian pharmaceutical industry. In one of the earliest studies on the topic, Lanjouw (1998) analyses how the introduction of product patents for pharmaceuticals may benefit or adversely affect India. She bases her analysis on information obtained over a period of six months, September 1996-March 1997, in India through interviews with a wide range of people in the pharmaceutical sector. Through this and documents supplied by various pharmaceutical organizations and governmental agencies, she tries to predict whether one might expect or not expect to see changes occurring.

Fink (2000) examines the impact of patent protection on the behavior of pharmaceutical multinationals and the market structure in India. His analytical approach builds around the calibration of a theoretical model to actual data from the Indian pharmacy market, to answer the hypothetical question of what the market structure would look like, if India allowed product patent protection on pharmaceuticals. He concludes that in case new on-patent drugs are newer varieties of off-patented products in the same therapeutic class, it will not have a large impact on prices of drugs. But if they are altogether new products, of which off-patent generic versions are not available, price rises associated with such products may be high (see p. 29). The model also shows that the simulated welfare losses for the Indian consumers were quite large (p. 30).

Grace (2004) analyses the importance of pharmaceutical supplies from India and China for access to medicines on a global scale. In doing so, she presents a review of the strengths, weaknesses, opportunities and responses of the Indian firms to changes in intellectual property protection, mainly the introduction of product patent protection. The analysis is based on secondary data supplemented with select interviews conducted with

informants in order to confirm information taken from reports (Grace, 2004, p. 10).

More recently, Chaudhuri, Goldberg and Jia (2004) use detailed product-level data sets from India to conduct a case study of Quinolones in India, to show the potential adverse welfare effects of the TRIPS Agreement on the Indian industry. They estimate that "in the absence of any price regulation or compulsory licensing, the total welfare losses to the Indian economy from the withdrawal of the four domestic product group in the fluoroquinolone sub-segment would be on the order of US$ 713 million, or about 118% of the entire systemic anti-bacterials segment in 2000" (p.1).

This study uses a firm-level survey of 103 firms as its central focus to derive results on emerging R&D and business strategies in the Indian pharmaceutical industry, in order to deal with India's impending product patent protection regime (see section 1.3 on methodology). An innovation system-oriented and policy-relevant innovation survey at the firm level is complex and not too many such surveys have been conducted in the pharmaceutical sector in India. Firm level innovation surveys generally aim at gathering information on innovation inputs (both R&D and non-R&D oriented) and outputs (usually in terms of products or processes of innovation) (Smith, 2005, p. 161). Thus, firm level surveys incorporate the exploration of critical aspects of innovation, such as sources of innovative ideas, impetus to innovation, interactions between various actors in the innovation system, external inputs to innovation and so on (Ibid). A common weakness of earlier innovation surveys was that they were weakest in precisely the features of greatest utility: few innovation surveys carried out in the 1990s, for example, were consciously designed for policy-relevance (Oyelaran-Oyeyinka et al, 2004). To avoid this, the main focus in the firm level survey conducted for this study has been on learning and innovation processes in Indian pharmaceutical firms and how these will be affected by stronger intellectual property protection and not so much on innovation inputs and outputs. The information generated in the firm level survey is used to analyze emerging firm strategies, both for R&D and business, and their impact on access to medicines in India and third countries in Africa. While doing so, the study also seeks to generate evidence for several theoretical predictions made in earlier studies on introduction of product patent protection in India.

1.3 Scope, Methodology and Time Frame of the Study

The original contribution of the study is a survey of 103 Indian firms, complemented with insights from case study interviews conducted to supplement information gathered in the survey. The scope of this study is limited to ***analyzing emerging firm strategies of Indian firms as a response to a gradual transition to product patent protection***, and not to predict or to assess India's present legal situation and issues therein related to the full implementation of its product patent protection regime. Therefore, data collected in the survey was mostly for a time period of 2000 to 2004, in order to be able to assess emerging firm strategies. A more in-depth discussion of the sample size and distribution, and its representativeness of the Indian pharmaceutical industry have been undertaken in Section 2.2.

In addition, a variety of other data sources were employed, including secondary sources and case studies that rely considerably on scientific expertise perception of scientists. Secondary research consisted of a detailed review of existing literature including general documents on access to medicines and international developments related to the TRIPS Agreement and policy documents and papers on the impact of product patent protection on the Indian pharmaceutical industry.

A range of semi–structured interviews with experts in the area of pharmaceutical innovation and intellectual property rights were conducted as the second step in order to firstly, help clarify the structure and content of the study framework and secondly, to refine and provide content validation to the survey questionnaire.

Based on the secondary research and semi-structured interviews, a structured questionnaire was completed. A background report on the Indian pharmaceutical industry and emerging prospects and strategies from 2005 onwards was prepared to assist in identifying the main issues. The 103 firms that participated in the survey were chosen using a purposive probability sampling technique (see discussion in section 2.2), from a list of companies' generated for purposes of this study using major Indian databases like the *India Info line* and *Pharmabiz* (export potential, R&D investments and total sales were used as the three main parameters to arrive at the ranking for the list generated for the survey).

The questionnaire consisted of five main parts: firm demographics, R&D issues and emerging strategies for process and product technologies, collaboration and inter-linkages, finance, and lastly, emerging marketing and business strategies. These sections were designed with the aim of generating as much information as possible on:

(a) Firm demographics, such as employment status, net sales turnover, focus of pharmaceutical activities, ownership structure of the firm, and main firm policies on various issues;

(b) Emerging R&D and business strategies amongst firms in response to a transition towards increased intellectual property protection in India, especially the introduction of product patents; and,

(c) Firm views regarding the viability of compulsory licensing as a supply mechanism for least developed countries, and the circumstances under which they would consider this option as contained in the Indian Patent (Amendments) Act of 2005.

The study was initiated in October 2004 and the questionnaire survey and fieldwork for the study was carried out in the months of December 2004 and January 2005. Most of the information presented in this study was collected during fieldwork in India: in addition to the questionnaire survey, interviewees and major organizations in India working with the pharmaceutical industry, such as the Organization of Pharmaceutical Producers of India (OPPI), the Indian Pharmaceutical Alliance (IPA), the Indian Drug Manufacturers Association (IDMA), the Confederation of Indian Industries (CII) and the

Federation of Industries and Chamber of Commerce of India (FICCI), all provided documents that have served as inputs in the analysis. Wherever possible, annual reports were collected for over a period of three years from all firms interviewed.

1.4 Study Structure

This study considers the following questions in the forthcoming sections. Section 2 is an analysis of innovation in the Indian pharmaceutical industry. This section traces the origins, the strengths and weaknesses of the innovation system in the pharmaceutical sector in India, and its industrial structure and activities, in order to establish the importance of the Indian industry for access to medicines in the developing world today. This section also arrives upon a categorization of firms in the Indian industry, based on empirical data, which is used in the rest of the study to draw conclusions on various issues. Section 3 discusses the main changes that are forcing a transition in the industry today, of which the introduction of product patent protection is the main one. The main issues that are still in the open despite the enactment of the Indian Patent (Amendments) Act of 2005 are also discussed at length in this section. Section 4 contains an in-depth analysis of the emerging firm strategies, for both, business and R&D, based primarily on the firm-level data collected. Special attention has been paid to two questions, namely: (a) whether the August 30 mechanism (which is the basis for Section 92(A) of the Indian Patent (Amendments) Act, 2005), offers sufficient financial incentives for Indian firms to act as suppliers of cheaper versions of patent drugs in a way analogous to the pre-2005 scenario, and (b) what the impact of increased intellectual property protection is on various aspects of R&D in the Indian industry. Section 5 of the study analyses the different factors that affect access to medicines in the Indian market and in the developing world, and the economic feasibility of the compulsory licensing mechanism as contained in the 30 August 2003 decision to deal with the issue. Section 6 contains conclusions and policy recommendations.

2 Innovation in the Indian pharmaceutical industry

Innovation literature views innovation as an interactive process of "... [l]earning and knowledge creation through which new problems are defined and new knowledge is developed to solve them" (Lam, 2005, p. 124). Innovation processes differ largely based on factors such as the sector concerned, field of knowledge, type of innovation, historical period and the country concerned (Pavitt, 2005, p. 87). But fundamentally, nature and intensity of interactions between the various actors in the innovation processes shape the ability of the system to grasp and use scientific and new technological developments; whatever be the initial triggers to such interactions. There is no common accepted theory of innovation in firm level processes, as a result of which it has been proposed to divide innovation into three overlapping processes: the production of scientific and technical knowledge, the translation of knowledge into working products and processes and the response to and influence of market demand on innovation (Ibid: p. 88).

2.1 Genesis of an "indigenous" Indian pharmaceutical industry: a brief historical overview

The Indian government's vision to reduce dependency on multinational firms for drugs, especially antibiotics, marks the starting point of building self-sufficient local production facilities in the pharmaceutical sector. Three critical changes, mainly attributable to India's socialist vision in the 1960s and 1970s, were instrumental in this regard – the setting-up of government-held companies to boost local pharmaceutical production of drugs, the Drug Price Control Order and finally, the Indian Patent Act of 1970. The government also initiated other industrial policies to augment these major changes, such as restrictions on foreign direct investment that also played a role.

As a result of the provisions of the Indian Patent Act of 1970, the number of patents granted per year within India fell by three quarters between the years 1970-71 and 1980-81 (Lanjouw, 1998, p. 4). The Drug Price Control Order, since it set a ceiling on the overall profits of pharmaceutical companies, acted as an added disincentive. It was harshly criticized by multinational companies operating in India at that time on grounds that it will reduce the incentives for investments in the sector (Ramani et al, 2001). The criticism also found basis in reality: when the Order came into force, multinational companies operating in India lost interest in expanding their operations in the Indian market, which included R&D efforts, due to the low profit margins involved (Ibid). The local industry on the other hand, was quick to take cue from the flexibilities contained in the Patent Act: they developed extensive skills in chemistry-based reverse engineering which forms the core of their product and process development skills until today. Over a period of time in the 1980s and 1990s, even when the Price Control Order reduced its coverage, the threat of reverse engineering by Indian firms kept subsidiaries of multinational firms operating in India from introducing new products in the Indian market.[10] In contrast, the policy initiatives that placed restrictions on foreign direct investment and on other technological aspects did not result in promoting any significant technology spillovers between the MNC

[10] Several firm executives from subsidiaries of multinational companies who were interviewed underscored the point that the ability of Indian forms to produce generic copies of successful drugs was a big factor in their lack of interest to introduce innovative drugs that had huge markets in other Western countries in India. Lanjouw (1998) presents several examples on this point – Indian companies were able to introduce copies of Ciprofloxacin within seven years of its introduction in India, Glaxo was similarly faced with several local competitors on the very day it introduced its drug Ranitidine (Zantac) in India (at p. 9). Even in the case of off-patent drugs, MNCs operating in India have been wary of Indian competence to replicate drugs and create price competition in the local market. A good case is that of Teramycin (Oxytetracyclin), a patent on which was held by Pfizer that expired in the 1960s. Despite the expiry of the patent, Pfizer did not want to share the know-how with Indian companies, for fear of strong price competition in the local generics market. Dr. Sarabhai Laboratories, the first Indian firm to produce Tetracyclin, did so through reverse engineering skills (Pers. Comm, D.G. Shah, 13 January 2005).

subsidiaries based in India and the local Indian firms, although they promoted small and medium-sized enterprises in the pharmaceutical sector.[11]

These changes brought about radical transformations in the foreign versus local firm ratio in the Indian market gradually. In the year 1970, the domestic sector was virtually non-existent, with 15% of Indian firms as against 85% foreign firms in the local market. In terms of retail sales value, in 1970, only two firms in the top ten firms were Indian and the rest were subsidiaries of multinational companies (See Lanjouw 1998, p. 3 and Table 1 on p.39). This ratio of 15% Indian firms to 85% foreign firms in 1970 grew to 50% each of Indian and foreign firms by 1982, which further increased to 61% Indian firms versus 39% foreign firms by the year 1999 (OPPI, 2000). Of the top 10 firms in 2001, eight were Indian firms and only two were subsidiaries of multinational companies. This trend of having Indian companies dominate the list of top ten companies in the market continues even today. In addition to the export potential of the industry that has already been discussed in Section 1, on the domestic front, the sale of retail formulations in the domestic market reached an estimated US$ 4.3 billion in the fiscal year 2003, and was dominated by Indian companies which held a market share of 75% (IBEF and Ernst and Young, 2004a, p 8). The industry growth rate over the 1990s has, on an average, been around 15% for bulk drugs and 20% for formulations (IBEF and Ernst and Young, 2004a).

2.1.1 Initiation of government-held pharmaceutical companies

In the 1960s, the government set up several companies to explore local production of pharmaceuticals, with a special emphasis on antibiotics. The Hindustan Antibiotics Limited (HAL) and the Indian Drugs and Pharmaceuticals Limited (IDPL) were most prominent amongst the twelve companies set up across the country for this purpose. The main policy pursued by the government in these companies was to import the penultimate intermediate required for bulk drug manufacture, so that the last step of the reverse engineering process could be conducted within India to create local active pharmaceutical ingredients. Today, the Karnataka Antibiotics and Pharmaceuticals Ltd, based in Bangalore, and Rajasthan Drugs and Pharmaceuticals Ltd, based in Jaipur, are the only government companies that are still fully operational. All the other companies have either been wound up or have been classified as "sick" companies, owing to management problems and lack of modern technology. Notably, the once-prominent Indian Drugs and Pharmaceuticals Ltd (IDPL), classified amongst the top 20 companies in the country in the 1980s, is now a sick company with no manufacturing activities. The government is presently trying to revive the Hindustan Antibiotics Ltd (HAL), which has also been classified as a sick company (Interviews, KAPL).

Despite their gradual decline, government companies had interesting spin-off effects on the creation of a local pharmaceutical industry. They helped

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[11] Studies on the topic note that the only noticeable technology spillovers in the 1980s and the 1990s in the Indian industry were between various MNC subsidiaries (see Feinberg and Majumdar, 2001).

both in technology absorption and manpower training (Reddy, 2003). Some of the major companies, such as IDPL, led to increased entrepreneurship by ex-employees of these companies in the local areas where they were based.[12] A large reason for the pharmaceutical hub around the Hyderabad/ Secunderabad areas is to be contributed to IDPL. Secondly, the governmental policy on reverse engineering triggered off an emphasis on building local chemistry skills for pharmaceutical manufacturing within the country.

2.1.2 Price control in India

Subsidiaries of multinational companies operating in India commonly imported bulk drugs into the country and formulated them into deliverable forms such as tablets and syrups (Interviews). The imports were the primary reason for the higher drug prices in the Indian market, but these were not easily substitutable, since locally produced bulk drugs were considered to be of inferior quality (see Ramani, 2001). The urgent need to ensure cheaper prices of drugs locally during the Indo-China war of 1964 resulted in the Drug Price Display Order, enacted under the Defence of India Act. After the war, the desire to keep prices at the 1963 levels formed the basis of the government's decision to enact a national Drug Price Control Order under the Essential Commodities Act.

Since then, the Drug Price Control Order (hereafter, the DPCO) is the main regulatory mechanism to control the prices of drugs in the country and is monitored by the National Pharmaceutical Pricing Authority (NPPA). The 1970 DPCO Order had the effect of bringing all drugs that were in the local market in India under immediate price control. The 1970 DPCO has undergone several revisions until today. It was first revised in 1979, based on the Hathi Committee Report. The 1979 DPCO not only brought down the number of drugs under price control to a total of 349, it also laid down categories of drugs, for purposes of imposing price control. Formulations were classified into category 1 (where margin of expected cost was 40%), category 2 (with a margin of expected cost at 55%), category 3 (with the margin of expected cost at 100%) and a de-controlled category. The 1979 DPCO was replaced once again by a new DPCO of 1986, based on the Kelkar Committee recommendations. The DPCO 1987 had the effect of further reducing the number of drugs under price control from 349 to 174. Only categories 1 and 2 were retained from the earlier DPCO of 1979 for drug control purposes. Category 1 now contained all drugs for national Tuberculosis eradication, Leprosy, Malaria, Blindness and Trachoma, with a government mark-up of 75%. The remaining bulk drugs were classified under category 2.

The 1995 DPCO brought down the scope of price control further, to only 76 drugs. Of these, two were subsequently removed from price control and therefore as of today, only 74 drugs are under price control in India. The 1995

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[12] Many successful private firms emerged as employee spin-offs. For instance, a former employee of Indian Drugs and Pharmaceuticals Limited (IDPL) established Dr. Reddy's Laboratories, which is now amongst the top three Indian pharmaceutical firms (Reddy, 2003).

DPCO is to be succeeded by the National Pharmaceutical Policy of 2002. The National Pharmaceutical Policy of 2002 contains several important policy changes, such as the further reduction of the number of drugs under price control to 28 from 74 (as under the 1995 Policy), the setting up of a Pharmaceutical Research and Development Support Fund (PRDSF) to boost national R&D efforts, a permit for 100% foreign investment in the pharmaceutical sector, abolition of industrial licensing for all bulk drugs, intermediates and formulations and lastly, automatic approval for foreign technology agreements through the Reserve Bank of India (National Pharmaceutical Policy, 2002). Unfortunately, the implementation of this policy is presently in a state of limbo. Triggered off by a stay on the application of the 2002 Policy within the state of Karnataka by the State High Court, a petition to investigate the validity of the judgment is pending in the Supreme Court. The ultimate implementation date and effectiveness of the policy when implemented will both be determined by the decision of the Supreme Court in this regard.

2.1.3 Changes to the patent regime

The Indian Patent Act of 1970 (that came into force in 1972) weakened the amount of patent protection applicable to the pharmaceutical sector to a very large extent. The changes relating to duration of protection and licensing were amongst the most significant. The Act excluded product patent coverage for pharmaceutical products completely, and limited process patents to a period of seven years (or five years from the date of sealing of the patent, whichever was shorter). The provisions on "local working" and licensing of rights contained in the Act limited the scope of process patents further (Fink, 2000). The Act provided that any pharmaceutical process on which a local patent was obtained, had to be "worked" in India within three years from the date of sealing of the patent. After three years of sealing, the patent owner was subject to the provision on "licensing of rights", i.e., the patent owner was obliged to license his process to a local manufacturer in cases where the patent was not locally worked for a royalty not exceeding 4%.[13] The government also had the authority to grant a compulsory license on a process after three years from the date of sealing of the patent, if the product was not available locally at "reasonable" rates. The Drug Price Control Order was primarily responsible for determining these rates and when a compulsory license was granted, the royalty rate for such a license was to be set by the government in all cases where the process patent owner and the licensee could not agree upon a rate between themselves. The Act also provided that the burden of proof in cases of patent infringement rested on the patent owner.

2.1.4 Other factors

The Foreign Exchange Regulation Act of India (FERA) imposed several investment and ownership restrictions on multinational companies, some of which are now to be relaxed under the National Pharmaceutical Policy of

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[13] The royalty rate of 4% stood in stark contrast to normal royalty rates of 10-15% (Lanjouw, 1998, p. 51).

2002.[14] Other restrictions on the import of finished formulations, high tariff rates, ratio requirements (that is, imports of bulk drugs had to be matched by purchases of domestic sources at a fixed ratio) and equity ceilings on foreign participation also played a role in discouraging the multinational companies in India (Lanjouw, 1998, p. 4). Many of these were standard measures that the Indian government used across industrial sectors to promote local entrepreneurship.

2.2 Firm groups based on empirical data

Presently, the Indian pharmaceutical industry is a heterogeneous mixture of firms split between the organized and unorganized sectors (Ramani, 2002). Its major constituents are subsidiaries of large multinational firms and a large Indian industry comprising of large, medium and small-sized firms that also extend to garage operations. As against the commonly quoted figure of 20,000 manufacturing units in the pharmaceutical sector, a recent expert committee set up by the government of India has clarified the number of active units on the basis of drug manufacturing licenses issued (Expert Committee, 2003, p. 3). According to the Committee, the total number of manufacturing units engaged in the production of both bulk drugs and formulations within India is not more than 5877.[15] Of these, only around 300 companies account for over 95% of the total domestic market, the rest are marginal players.

Three main associations represent most of India's pharmaceutical companies: the Organization of Pharmaceutical Producers of India (OPPI), the Indian Pharmaceutical Alliance (IPA) and the Indian Drug Manufacturers' Association (IDMA).[16] The OPPI was first started by the subsidiaries of major MNCs operating in India. Today, its membership is mixed, wherein several wholly Indian companies are active members of the OPPI (see Annex 3). The Indian Pharmaceutical Alliance, on the other hand, is a consortium of the top 9 Indian companies. The Indian Drug Manufacturers Association (IDMA) is the largest represented Association of pharmaceutical manufacturers with over 580 members, and these are large, medium and small manufacturers of active pharmaceutical ingredients and formulations as also intermediates, allied products.[17] Membership in these associations is not exclusive; there are several companies that are members of the IPA and the OPPI and the IDMA at the same time, and several others, which have dual memberships.

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14 For example, the National Pharmaceutical Policy contains a permit for 100% foreign investment in the pharmaceutical sector (See discussion in Section 2.1.2).

15 This can be further broken up into 1333 bulk drug units, 4534 formulation units, 134 large volume parenteral units and 56 vaccine-manufacturing units.

16 There are also other associations that are active in representing pharmaceutical companies in India, but these are comparatively smaller and therefore have not been mentioned here.

17 More information on the IDMA can be obtained from www.idma-assn.org. Membership of IDMA is mainly split between Maharastra (252 member companies), Gujurat (38 member companies), Tamil Nadu (44 member companies), West Bengal (150 companies), Haryana (14 Companies and other states (79 companies).

Using the country-level data collected, Indian pharmaceutical companies can broadly be classified into three main categories each, based on both their structural characteristics and emerging R&D and business strategies.[18] A key determinant of the classification is the annual sales turnover of firms, since that determines their export potential, ability to invest into R&D, devise marketing and R&D strategies and access other markets.

The first group of firms (hereafter, group 1) comprises of large-scale pharmaceutical firms that are both subsidiaries of MNCs in India or wholly-owned Indian firms. Group 1 includes firms like Ranbaxy, which is the largest pharmaceutical company in the country, also ranked in the top 100 companies worldwide; Cipla, which is the largest producer of generic drugs in India with around 800 products in the market (Interviews). These firms, in an effort to gear themselves up to India's new product patent protection regime, are allocating large amounts of their profits for R&D expenditure.[19] A major driver for the internal firm policies group 1 companies over the past decade has been the entry into global regulated markets, although they also supply to the local Indian market and other semi-regulated markets worldwide. In the classification for purposes of this study, companies that can be classified into group 1 have an annual sales turnover of more than 300 crore rupees. Group 1 companies have extensive brand marketing networks for their brands that help in creating and promoting brand identity of their products amongst consumers across the country.[20]

The second group of companies (hereafter, group 2) comprises of pure generic manufacturers whose ability to do product development is very limited. These companies supply predominantly to the Indian market as well as to other semi-regulated and unregulated markets. Firms classified as group 2 have an annual sales turnover between 100-300 crore rupees.

The third and final group of companies (hereafter, group 3) are those that mainly perform contract research and manufacturing (CRAM) for bigger Indian companies, both local and MNCs. Companies that fall into group 3 have an annual turnover of less than 100 crore rupees annually. These companies are the true local players – their main marketing strength is their well-embedded local connections that help them supply their products to local and municipal hospitals, local doctors and dispensaries within the districts in which they operate or at best, within the state boundaries of the state that they are based in. These firms generally use their contacts with the local medical community in these institutions to further their business. This stands in contrast to the extensive marketing networks of group 1 companies that operate across the country. Group 3 companies have no R&D investments whatsoever, given their small scale of operations. Investments

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18 I thank Mr. Dilip G. Shah, President, Indian Pharmaceutical Alliance for taking out the time and helping me to organise the data collected through the firm-level survey to arrive at this classification.

19 See Lanjouw and Cockburn (2001, p. 281) who make a similar point regarding the top 20 firms in the Indian pharmaceutical industry.

20 For a more detailed discussion on brand identities and marketing tactics in the Indian industry, see discussion in Section 5.1.1.

are made only for modernization and upgrading of facilities in order to meet standards of good manufacturing practices.

Table 2 below contains an approximate group-wise representation of companies in the Indian industry, based on country-level data collected for this study. The total number of companies is taken to be approximately 6000 (the expert committee's calculation of 5877 as rounded off to 6000), in order to show the spread of companies across the three main firm groups. As the Table shows, the number of companies that fall into groups 1 and 2 differ slightly depending on whether one classifies on the basis of formulation activities or production of active pharmaceutical ingredients.

Table 2: Indian pharmaceutical firms: a group-wise representation

Firm Break-up	Formulations	API Production
Group 1	25 firms	100 firms
Group 2	275 firms	200 firms
Group 3	5700 firms	5700 firms
Total	6000 firms	6000 firms

Source: WHO-INTECH survey conducted by author, 2005

A total of 103 firms chosen through a purposive probability sampling technique took part in the country-level empirical survey conducted for this study.[21] Of these 31 belonged to Group 1, 27 to Group 2 and 44 to Group 3. In the rest of the sections of this study, the firm survey will be used, in conjunction with other data collected through documents and interviews during the field visit, to draw conclusions on the emerging firm strategies in the Indian industry. A complete list of firms that participated in the survey is contained in Annex 2. Interviews were conducted with a select group of firms that participated in the survey, industry representatives and governmental counterparts (See Annex 1).

2.3 Nature of innovation, strengths and weaknesses of the Indian industry

India is a prime example of an "innovative developing country" (Morel et al, 2005, p. 2; Mashelkar, 2005). The term "innovative developing countries" refers to developing countries that have demonstrated a significant promise in carrying out activities in health innovation (ibid.). Major strengths of the Indian pharmaceutical industry include: a cost-competitive manufacturing base that extends to clinical studies, extensive skills in chemistry and process development, ability to manufacture over 50% of the bulk drugs needed for

[21] Very simply put, the purposive probability sampling (PPS) technique refers to a method of choosing firms in such a way that the key representatives of the industry are taken into account in the survey completely (purposive) and the rest of the population is chosen at random. In this survey, since group 1 firms are key representatives of the Indian pharmaceutical industry, the effort has been to cover them to the fullest extent possible. Firms from groups 2 and 3 have been chosen at random from the ranking list created for the study based on export potential, total sales and R&D investments.

its pharmaceutical production activities locally, the emergence of a promising biotechnology industry, availability of local scientists and R&D personnel of a high scientific quality and a wide network of R&D (CII, 1999; IBEF and Ernst and Young, 2004a, p. 2; Grace, 2004, p.18).

Indigenous local capacity in the sector was built through a combination of right policy environment, access to international technology, education and promotion of entrepreneurship, among other factors (see Mashelkar, 2005). Yet, since the main impetus to build a local pharmaceutical industry in India came from a perspective that sought to encourage the local production of drugs at affordable prices, and not from a focus on inventive activities *per se*, the industry has several weaknesses in addition to its strengths as it stands today.

2.3.1 Major strengths of the Indian industry

The focus on incremental innovation as opposed to novel inventions in the Indian industry has often come under scrutiny. A major criticism levied against the Indian pharmaceutical industry is that its focus is mainly on reverse engineering and the production of generic versions of successful drugs world-wide (Lanjouw, 1998). It has also been pointed out that the industry does not spend much on R&D – the R&D expenditure of the group 1 companies is presently around 6% of the annual turnover on an average and is projected to rise up to 10% by the year 2010.[22] This when compared to what we know from pharmaceutical firms in western countries is not much at all. Lastly, it has also been pointed out that most R&D activities that Indian firms engage in are minor modifications of pharmaceutical products developed in foreign (mainly western) countries, and that very little R&D effort has been devoted towards the development of any new drugs (Fink, 2000, p. 9). On the basis of all these reasons, it is often claimed that the Indian industry is not invention-based, aiming at the production of new chemical entities, but rather innovation-based, aiming at producing incremental modifications of existing drugs.

However, R&D efforts and process and product innovation in the Indian industry are not isolated phenomena as projected by many scholars, but well inter-linked. Adaptive and incremental innovation activities are non-trivial activities. Reverse engineering, for instance, presupposes a deep understanding of the processes and products in the pharmaceutical industry. As Kline and Rosenberg (1986) observe, quite often *design* is the initiating point of innovation. What Indian firms do presently falls clearly in this domain. They further note that innovation has three major aspects to it: (a) innovation is not a linear process but one involving many interactions and feedbacks in knowledge creation; (b) innovation is a learning process that involves several inputs at the same time; and lastly, (c) on-going innovation processes can be initiating factors to invention processes that involve formal R&D (Kline and Rosenberg, 1986). This observation also fully applies to the pattern of expanding R&D activities of Indian firms. Whereas a large spectrum of Indian firms are still active as generic manufacturers and whereas a large part of the

22 See discussion in Section 4.1 on this point.

R&D is focusing on incremental innovations, such as novel drug delivery systems (NDDS) and novel combinations, the emphasis on original R&D is gradually increasing within the industry.[23] Several group 1 companies are very good examples of this, but there are also group 2 companies, such as Matrix Labs, which help underscore this transition in the Indian industry (See Box 1 below).

Box 1: Matrix laboratories

Matrix Laboratories is an Indian company that started out with a new management that laid a strong R&D and GMP emphasis in 2000. The company has, since then, seen a rapid metamorphosis: from an annual turnover of 40,000 crore rupees and a net profit of 4 crore rupees in 2000, to an annual turnover of 560,000 crore rupees with a net profit of 130 crore rupees in 2004. Today, Matrix Labs is one of the 10 largest pharmaceutical exporters in the country.

Matrix's R&D strategies: Matrix's main research focus is on developing non-infringing propriety processes for the production of APIs, in order to establish its position as a global supplier of APIs to major generic companies in regulated markets. Their API process development got a major impetus with the success of their non-infringing process on *Citalopram* (an anti-depressant), as a result of which the company is the sole exporter of the API to western Europe today. They have recently extended their development work into formulations. Their formulations business is complementary to their API business: the formulations use the APIs that Matrix internally produces and is done through contract research for their consumers abroad to whom they normally sell their APIs as well. The profits generated by the success in process development are also being invested into joint collaborations for NCE development. Matrix Labs has a partnership with a Japanese firm, Arigin Technologies for clinical Phase 1, 2 and 3 studies for NCE development. Presently, Matrix has an internal R&D strength of 200 employees, out of total employee strength of 1750 employees. Of this, 120 employees work only on process development, 70 employees are in analytical division and around 10 employees work in their intellectual property cell. Since their main aim is to have proprietary technologies, the intellectual property cell is actively involved in conducting research on all existing process patents, product patents and formulation patents that affect their development strategies worldwide, as well as on planning their patent strategies. They also plan to venture into biotechnology-based research, mainly in the area of peptides, in the near future.

Matrix's marketing strategies: Matrix's main focus is on exporting to regulated markets, from which it gets about 90% of its total revenues. 65% of their total output is exported to regulated markets (US and Europe), 10% are exported to semi-regulated markets and 25% is aimed at the local market. Their main marketing strategy, in both APIs and formulations, is to not emerge as competitors to major global and local generic companies, but to offer complementary services.

Matrix has recently acquired Vorin labs, Medicorp technologies, Vera Labs, Fine Drugs & Chemicals and a formula's facility of Sigma Labs, Nasik. Their facilities are

23 See Amsden (2003) who notes the same in relation to emerging industries in South East Asia.

approved by MCC, MCA and TG, and they are also planning to get FDA approval for their facilities this year.

Source: Field interviews conducted by author with Dr. G.S. R. Anjaneyulu, President R&D, and Dr. B. Mohan, Senior General Manager R&D, Matrix Laboratories.

2.3.2 Major pressures on the industry

Several pressures are working in tandem on the Indian industry, apart from that of India's full-scale compliance with the TRIPS Agreement, which is discussed in detail in the next sub-section.

Although its strength lies in the way the industry is able to thrive beyond mere production of generics, expand and tap into modern technologies, like health biotechnology, it also has some significant shortcomings. Many of these flaws, as already mentioned, can be attributed to the fact that the emphasis was mainly on building a system of production and not on a system of innovation. As a result, there is a lack of strong links between universities, research institutes and other major actors in the local system of innovation. Out of the 103 firms surveyed, only 31 firms admitted to having local collaborators whereas 72 firms had no local collaborations of any form. Table 3 contains the average ranking of intensity of local collaboration by the firms (where 1 = weakest and 5= strongest) as ranked by the firms who admitted to having local and foreign collaborations. As the table shows, those firms which collaborate have very collaborative linkages with other institutions, both local and foreign.

Table 3: Collaborative links: local and foreign

Links/Firm Group	Group 1	Group 2	Group 3	Total
Local	4.07(14)	3.86(7)	3.70(10)	3.90(31)
Foreign	3.69(13)	3.38(8)	2.89(9)	3.37(30)

Note: Figures in parenthesis refer to the number of firms
Source: WHO-INTECH Survey conducted by author, 2005

Also notably, amongst the firms that admitted to having collaborations, most were in the area of research as opposed to product development. Health biotechnology is one prominent area of research where Indian firms are collaborating with smaller biotechnology firms. Many contract research collaborations exist between large pharmaceutical companies and smaller biotechnology firms (See Table 7 of this study). But in the mainstream pharmaceutical sector (and also in the biotechnology sector), there is a dearth of high quality R&D in university departments, partly due to bureaucratic and financial constraints (CII, 1999, p. 20). Research institutes fare much better than universities on the question of finances and human capital for conducting pharmaceutical research, notable amongst which are institutes like the Council for Scientific and Industrial Research (CSIR), the Central Drug Research Institute (CDRI) and the IDMR. Several of these public research institutes are also very active partners in international public-private partnerships.

Yet, many of the firms that were interviewed admitted to having no local collaborations at all even with the public research institutes, due to the difficulties they face in speedy and efficient performance. Matrix Laboratories, for example, commended the facilities at the Indian Institute for Chemical Technologies (IICT) for sample analysis, but expressed the problems in working with them given the laxity of service and lack of competitive spirit. Since IICT takes a week to analyze samples, firms like Matrix Labs feel that such long delays reduce their competitiveness (interviews).

This is inconsistent with experiences in several other developed countries which have very good sectoral systems in pharmaceutical biotechnology, where interactions between industry-universities-public research institutes and the movement of human capital between these institutions have been critical in building and strengthening the innovation system over time. In these countries, it has been observed that interactions usually involve a range of contract research, collaborative research arrangements with the industry in the research and patenting stages (Chiesa and Toletti, 2004; see also Oliver 2004). Amongst the several motives for interactions between industry-university-PRIs, the most important ones are the provision of additional funds for specific forms of biotechnology-based research and knowledge exchange through collaborative research arrangements (Meyer-Krahmer and Schmoch, 1998). Both these aspects seem to be much weaker in the Indian industry as it stands today.

The lack of minimum good manufacturing practices applicable across the industry, and adequate regulatory enforcement of such standards is another major issue for the industry. In recent years, there have been several contrasting estimates on the extent of spurious/counterfeit drugs produced in and exported by the Indian pharmaceutical industry. These estimates vary between 0.5% (as presented by State authorities within India) and 35% (ascribed to WHO studies). The pharmaceutical companies are wary of the fact that such claims undermine the reputation of the Indian industry as a producer and exporter of quality drugs. As a response to these complaints, the Indian government set up an Expert Committee in 2003 to investigate the validity of these claims and to assess the threat of spurious/counterfeit drugs produced in India. In addition to clarifying the validity of these claims,[24] the Expert Committee on Spurious Drugs noted, among others, that the enforcement of the Drugs and Cosmetic Act is far below satisfactory levels in many Indian States. Within the local market, low quality drugs that can be sold at lower prices by the smaller marginal companies depress the prices of drugs and in extreme cases, lead to a 'market for lemons' where consumers are not able to differentiate between good quality and low quality products.

To avoid doubts on the quality of Indian drugs in international markets and the artificial depression of prices within the local market, group 1 companies, especially those represented by the Indian Pharmaceutical Alliance, have lobbied for a law enacting good manufacturing practices since 2000.

24 In response to a query by the Indian government, the WHO clarified that there is no WHO study that concludes that 35% of the world's spurious drugs are produced in India (Expert Committee Report, 2003).

Schedule M of the Drugs and Cosmetic Act contains this regulatory initiative and is in the process of being implemented. There are several small-scale units that belong to group 3 that will find it hard to implement the quality standards specified under Schedule M. It is because of this that the IDMA, which represents group 3 companies to a large extent, has been very active in voicing opposition to Schedule M standards and their implementation.[25]

There are other gaps in the innovation system that could critically affect the performance of the industry post-2005. These include the lack of patent-related training at universities, and large regulation gaps in very important areas such as clinical testing and biotechnology (Ramani, 2002). The government of India is in the course of taking action on several of these aspects that require immediate attention, and the impact of these changes in fostering innovation remains to be seen.

Table 4: Areas of government support critical to industry

Firm Group	Speed of processing patent applications	Enabling R&D environment	Reduce price control	Access to land for expansion	Patent Amendment Act, 2005
Group 1	3.17 (29)	3.66 (29)	3.66 (29)	3.41 (29)	3.17 (29)
Group 2	3.23 (22)	3.36 (22)	3.23 (22)	3.23 (22)	2.82 (22)
Group 3	3.18 (38)	3.26 (38)	3.26 (38)	3.05 (37)	3.05 (37)
Total	3.19 (89)	3.42 (89)	3.38 (89)	3.22 (88)	3.03 (88)

Note: Figures in parenthesis refer to the number of firms
Source: WHO-INTECH survey conducted by author, 2005

While India is being promoted heavily as a clinical outsourcing hub, there are several regulatory aspects that may thwart India's potential in clinical sciences. Regulations preventing animal testing within the country, for instance, were until recently a big hindrance to Phase II clinical trials. Schedule Y rules of the Drugs and Cosmetics Act that have been recently revised through a Notification of 20 January 2005 relax several of the cumbersome regulations on conducting clinical trials in India, but the scientific and technological capabilities required for Phase II and III of clinical trials are very few and far between in the country, although these are steadily on the increase.[26] Recent initiatives include the setting up of three centres for clinical research in the country by the global firm, Quintiles and also expansion of operations within Indian companies to include performance of clinical research on a contract basis, such as Clinigene by Biocon (Maria and Ramani, 2004). Other global majors, such as Eisai, have

25 Due to pressure from the small scale units, the introduction of Schedule M has been delayed for sometime now. But recently, the Ministry for Small Scale Industries has rejected a plea of the small scale drug manufacturing sector for further modification of Schedule M (See Mathew, 2005).

26 The NCE license agreement between Dr. Reddy's Laboratories and Schwarz AG (See Table 5) that has now been abandoned was in fact, for conducting Phase II and II clinical trials of the NCE only, since these facilities were not available within the country at that time (Field interviews conducted by authors with firm executives of Dr. Reddy's Labs).

also opened three centres for clinical R&D in India (D'silva, 2005). Yet, industry interviews show that added government support towards helping Indian clinical test procedures meet international standards could go a long way in tapping this potential to its fullest. Table 4 above contains the survey responses of firms surveyed as to the areas in which governmental support would be critical to the industry. The firms rated each one of the factors from 1 (not important) to 5 (most important). As the table shows, each one of the factors identified therein was seen by the firms to be of above average importance (2.5).

A simpler framework for the regulation of biotechnology is another one of such requirements. The multi-level regulatory framework established by the Government of India for biotechnology comprises of administrative procedures under the Department of Biotechnology under the Ministry of Science and Technology (for approval to invest in technology activities) and the Drug Controller of India, under the Ministry of Health (for evaluating pharmaceutical products including recombinant products) (See Ramani, 2002 for a discussion). In order to simplify procedures and reduce bottlenecks in biotechnology research, the Mashelkar Committee appointed by the government has recently drafted rules for governing recombinant products (Biospectrum, 2005). The government can also help increase the potential of the nascent venture capital industry in India, with an emphasis on the pharmaceutical industry (see for example, Nishith Desai Associates, 2003; also see Charya, 2005).

3 Status of product patent protection in India: open and contentious issues[27]

Indian compliance with the TRIPS Agreement has proceeded in several stages up until now. The Patents (Amendment) Act, 1999 introduced the mail box system and set up a system of exclusive market rights (hereafter, EMRs) to be retrospective from 01 January 1995, in conformity with the TRIPS Agreement. The Patent (Amendment) Act, 2002 introduced 64 changes to the Patent Act of 1970, the most important ones of these being the extension of patent term from 14 to 20 years, and the reversal of burden of proof from patent holder to alleged infringer (see People's Commission, 2003). The final set of changes to make India's patent regime comply with the TRIPS Agreement *in toto* were first contained in the Indian Patent Ordinance of 2004, that has now been replaced by the Indian Patent (Amendments) Act of 2005.

Survey results indicate that most group 1 and 2 firms were very aware of the implications of India's accession to the World Trade Organization in 1995: that India's patent regime will inevitably have to conform to the TRIPS Agreement, thereby placing restrictions on several kinds of activities from 01 January 2005 onwards. Company representatives interviewed from group 1 and 2 firms

27 The bare Act versions of the Patent Act, 1970 and all the subsequent amendments to the Act and Patent Rules analysed in this section were taken from the official website of the Government of India: http://www.patentoffice.nic.in/ipr/patent/patents.htm

clearly indicated the fact that their strategies for both R&D and business have been in a slow-but-steady transition over the past few years, in order to enable them to cope with the changing legal environment and threat of stronger international competition (interviews).

3.1 Indian patent (amendments) Act, 2005

The Indian Patent (Amendments) Act, 2005 seeks to complete India's full-scale compliance with the TRIPS Agreement. The Act has the effect of invalidating Section 5 of the Indian Patent Act, which granted only process patents for food, medicines and other drug substances. As a result, reverse engineering possibilities available to the pharmaceutical industry will only be limited to those drugs that are off-patent. The Act also introduces Section 92 (A) on compulsory licensing, in keeping with 30 August 2003 Decision of the WTO. Section 92 (A) of the Act deals with compulsory licensing of pharmaceuticals for export purposes. This is meant to facilitate the Indian industry to continue supplying cheaper generic versions of patented drugs to those LDCs that do not have adequate domestic manufacturing capabilities. The Patent (Amendments) Act of 2005 was preceded by an earlier 2004 Patent (Amendments) Ordinance that was different in several aspects from the Amendments Act of 2005 that has now been enacted. For example, the 2004 Ordinance provided for exclusive marketing rights (hereafter, EMRs) that were to be effective under the same terms under which they were granted, and also laid out the power of the government to sell or distribute the article for which the EMR was granted and to direct that the EMR-based product be sold at a regulated price (Section 24 D). The Patent (Amendments) Act, 2005 has now omitted Section 24 of the original Patent Act.

3.2 Use of TRIPS flexibilities in India's patent regime: a discussion of outstanding issues

The Patent (Amendments) Act, 2005 and its full scale effects on India has been a very controversial topic, and it is estimated that its implementation may take about two to three years to be fully implemented in the domestic context (Sridharan, 2005). On the whole, the regime introduces several important TRIPS flexibilities that have been proposed for developing countries in the context of pharmaceutical patent protection (See for example, the report of the UK Commission on Intellectual Property Rights). But on the question of whether the IPR design is in fact one that is pro-development oriented, especially in a country that has a promising domestic pharmaceutical industry (Barton, 2003), the regime poses a cause for concern on several fronts.[28]

28 Several aspects, such as parallel imports, have not been considered in this section, since they fall beyond the scope of this study. See Chaudhuri (2005) among others for a discussion.

3.2.1 Criteria of patentability and its enforcement

Criteria of patentability will play a key role in determining which inventions are patentable in India, who the patentees are, what they will be allowed to do and what is 'legal' for the other market players. In the aftermath of the Patent Ordinance of 2004, the provisions that dealt with the definition of patentability (Section 3) and the grounds on which a patent can be revoked (Section 64), which was almost left unaltered in the Ordinance, had become a major concern for the industry.[29] Taken in conjunction with the Glivec EMR, which was one of India's first EMRs in the pharmaceutical sector (see Box 2 below), it led to widespread fear that the patent regime may not be adequate to deal with the issue of "evergreening" of patents (or grant of secondary patents). The main worry of the Indian industry was that if the patent regime allowed the grant of patents on crystalline versions of known molecules or on combination patents, as popular in several developed countries, such patents would have the effect of delaying the entry of generics, which would have an automatic effect of reducing the product profiles of the Indian generic companies.[30]

Box 2: The Glivec EMR

Glivec, India's first exclusive market right in the pharmaceutical sector was granted to Novartis, for the anti-cancer drug, Glivec. The EMR given to Glivec is on a beta crystalline version of the compound imatinab mesylate, which was challenged by Indian generic producers of the drug. The generic companies challenged the EMR on grounds that the compound imatinab mesylate was a derivative of a molecule that was known prior to 1995, and therefore does not qualify for patent protection. At the time when the EMR was granted, several Indian companies were producing generic versions of Glivec, including, Cipla, Ranbaxy and Sun Pharmaceuticals.

Natco Laboratories, Hyderabad, which is now the only firm allowed to manufacture the compound locally, sells one capsule for 75 rupees (US$ 1.5), whereas Glivec was priced at US $30 per capsule in the Indian market (a box of 100 capsules sold by Natco is priced at Rs. 10,800 as opposed to Glivec's price of $3600 for 100 capsules). Natco's brand is called Veenat 100 Imatinib Capsules. A

[29] Sections 3 and 64 dealt mainly with the definition of patentability in the Patent Act of 1970. In Section 3, "new use for a known substance" was listed as subject matter that was not patentable. The Patent Ordinance of 2004 left Section 64 unchanged, and replaced the term "use" in this section with the term "mere use", which it was felt, widens the scope of patentability in the Act (Chaudhuri, 2005, p. 10).

[30] Two good examples are the patent granted to Aventis on Fexofenadine Hydrochloride and to Novatis on Oxcarbazepine. Aventis was granted a patent on Fexofenadine Hydrochloride, an anti-histamine, in 1979 (US Patent number 4,254,129). The first patents in the normal course would have expired after a 20-year period, in 1999. But the company obtained a second patent in 1996 claiming that it was a "substantially pure compound", extending the patent life to 2006. Similarly, Novartis was granted a patent on Oxcarbazepine (a central nervous system (CNS) drug) in 1970 (US Patent number 3,642,775). Subsequently, Novartis obtained a second patent (US 20,030,190,361) in 2003 on the same, claiming a "particle size" of certain specifications (Source: D. G. Shah, IPA).

case filed by Natco on this matter is pending in the Supreme Court right now, and the situation will be clarified only when a judgment on the matter is passed.

Source: Field interviews conducted by author with Mr. Nannapaneni, Chairman and MD, and Mr. A. V. Satyanarayana, Advisor, Corporate Technical Laboratories, NATCO Laboratories.

The Patent (Amendments) Act of 2005 has tried to deal with this problem to a large extent by amending Section 3 of the original Patent Act. Section 3 (d) now reads as follows:

> "(d) the mere discovery of a new form of a known substance which does not result in the enhancement of the know efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a know process, machine or apparatus unless such know process results in a new product or employs at least one new reactant.
>
> Explanation – For the purposes of this clause, salts, esters, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy."

The Patent (Amendments) Act of 2005 has also extended the grounds on which a patent can be opposed in the pre-grant period. These are now contained in Section 25 of the 2005 Act. The earlier Ordinance had come under criticism on this point, since it reduced the grounds for pre-grant opposition of patents to only two (from the nine grounds listed in the original Act of 1970). The 2005 Act has now retained the nine grounds listed in the original Act of 1970 (with some modifications) and also added two more grounds of pre-grant opposition: on the lack of disclosure or no disclosure of source of geographical origin of biological material and another on the presence of indigenous knowledge, oral or written, of local and indigenous communities in India in the invention (see Sec. 25(j) and (k)).

Despite the presence of such provisions, the capacity of the Patent Office in India, and the awareness of patent examiners of these issues will play a key role in determining how these provisions in the Patent Amendments Act of 2005 will be interpreted and enforced. There is reason to believe that the lack of capacity in India's patent offices may have more far-reaching consequences for the local industry in terms of patent litigation following grant of patents that should not have been granted, than for the mailbox applicants, as is often claimed (Chaudhuri, 2005).

3.2.2 Data protection and data exclusivity

There is a clear distinction between keeping information secret (data protection) and doing approvals and clinical work "relying" exclusively on the original patent holder's data submitted to obtain regulatory approval for

the patented product (data exclusivity). Article 39(3) of the TRIPS Agreement places a requirement upon member countries to provide protection to regulatory data under specific circumstances. Data exclusivity, a relatively new form of protection, is one such form of protection and it refers to the protection of pharmaceutical registration files that contain data submitted by pharmaceutical companies to regulatory agencies, such as the US Food and Drug Administration and the European Agency for the Evaluation of Medicinal Products (EMEA), for the purposes of obtaining market approval of patented drugs (Pugatch, 2004). Grant of data exclusivity prevents generic companies from using the test data submitted by the original patent holder to regulatory authorities to prove bioequivalence of the generic version of the products. In practice, data exclusivity terms, since they are granted from the date of introduction of a particular product in a given market, may have the effect of extending the monopoly term of the patent holder beyond the term of the patent and delaying the entry of generics. The general practice in the USA is to grant five years of data exclusivity, whereas the EU grants a ten year data exclusivity period. Assuming hypothetically that a developing country like India granted data exclusivity of five years, this would mean the following in reality. A product for which a patent was granted in 1995 is valid until 2015. But if this product is introduced in the Indian market in 2013, then data exclusivity in Indian law would protect the regulatory data submitted by the company until 2018 (5 years from introduction), thus delaying the entry of generics (and extending the product monopoly) by three more years than the twenty years granted under the patent.

There seems to be no clear economic justification as to why data exclusivity should be granted to firms that already avail a patent protection term of 20 years globally for their products. It has been argued that data exclusivity allows firms to rely on some form of protection when they introduce their products, especially since they cannot be sure whether all countries will grant effective patent protection. But this form of "back-up" protection mechanism seems to be unnecessary, especially since the TRIPS Agreement has circumscribed the ability of countries to deny patent protection under normal circumstances to a very large extent. Furthermore, in the light of recent evidence which suggests that strong levels of intellectual property protection may not have such a direct bearing on the decision of pharmaceutical companies as to when they introduce their products in different markets world-wide (Lanjouw, 2005), one wonders if data exclusivity can be defended on this basis. In fact, grant of data exclusivity terms seems to contravene principles of bioethics, since it forces generic manufacturers who wish to introduce generics before the expiry of data exclusivity periods to generate their own test data through the conduct of clinical trials.

Furthermore, a reading of Article 39(3) of the TRIPS Agreement shows that although there is a requirement to provide protection to regulatory data under specific circumstances, it is not necessary that this protection is granted in the form of data exclusivity (Watal 2001; Correa, 2002; Chaudhuri, 2005). Article 39(3) gives countries the choice to countries to decide upon the form of protection.

India has not had a strict regime that protected secrecy of data submitted by pharmaceutical companies to regulatory agencies. Many MNCs hold the

view that this has helped the generics industry immensely to reverse engineer and make cheaper versions of drugs (Interviews). The general practice amongst Indian generic companies has also been to use the data submitted by the original manufacturer to prove bioequivalence. Presently, a committee set up by the Government of India is presently examining the extent of data protection that should be afforded to the pharmaceutical industry.

3.2.3 Pharmaceutical exports to LDCs with little or no manufacturing capabilities

Section 92A of the Patent (Amendments) Act of 2005 deals with the extremely important issue of compulsory licensing for export of patented pharmaceutical products in certain exceptional circumstances, in an effort to put into place a regulatory mechanism in line with 30 August 2003 decision of the WTO. The earlier Section 92 A as contained in the Patent Ordinance of 2004 had been criticized on grounds that it requires even LDCs under the extended transition period up to 2016 to grant the compulsory license, and that this ran contrary to the extension given to LDCs under the Doha Declaration to LDCs to delay introduction of patents on pharmaceuticals until 2016 (See IPA, 2005; Chaudhuri, 2005). The Patent (Amendments) Act, 2005 has tried to correct this now. Section 92(A)(1) of the Act reads as follows: ... [p]rovided compulsory license has been granted by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India."

3.2.4 Compulsory licensing for the local Indian market

The Patents (Amendment) Act, 2005 has had the effect of omitting Sections 22 to 24 of the original Indian Patent Act, as a result of which Section 24 C that dealt with compulsory licenses has also been repealed (this contained the provision on granting of a compulsory license in case a patent was not "worked" locally). Section 84 of the Indian Patent Act of 1970 still continues to be in force with some minor modifications. Section 84 (1) provides that any time after the expiry of three years from the date of grant of a patent, any person interested may make an application to the Controller alleging that the reasonable requirements of the public with respect to the patented invention is not available to the public at a reasonable price and request for the grant of a compulsory license to work the patented invention. Section 85 deals with matters that need to be taken into account in granting compulsory licenses, such as the nature of the invention, the measures taken by the patentee to make full use of the invention, the ability of the applicant to work the invention to public advantage, and the capacity of the applicant to undertake the risk in providing capital to work the invention if it were to be granted. The Act of 2005 also contains provisions that incorporate Article 31's implementation in the local context, such as the grant of a compulsory license to remedy anti-competitive practices identified through administrative or judicial procedures (see Section 90(1)(ix) below). Section 90(1)(vii) of the Act has been amended to also cater to demands of export.

Section 90(1)(vii) to (ix) read as follows:

"(vii) that the license is granted with a predominant purpose of supply in the Indian market and that the licensee may also export the patented product, if need be in accordance with the provisions of sub-clause (iii) of clause (a) of sub-section (7) of section;

(viii) that in the case of semi-conductor technology, the license granted is to work the invention of public non-commercial use;

(ix) that in the case the license is granted to remedy a practice determined after judicial or administrative process to be anti-competitive, the license shall be permitted to export the patented product, if need be."

This could prove to be very effective tool in the hands of the judiciary to control anti-competitive practices in the pharmaceutical sector in India.

3.2.5 Protection of research tools

Section 47 of the original Patents Act of 1970 contains a research exemption for patented inventions (see Section 47 (3)). This section, which can be interpreted as applicable for both academic and commercial research, has been left unmodified by all subsequent amendments to the patent regime. But three major changes introduced in the Amendments of 2002 affect the patenting of research tools for biomedical and biotechnological inventions in India. These are as follows:

- The Patent Act has extended the scope of patentable inventions to a method or process of testing during the process of manufacture, including those in biochemical, biotechnological and microbiological areas.[31]

- Section 3 of the Patent Act that deals with inventions that are not patentable was amended in 2002 to include any process for the diagnostic or therapeutic treatment of human beings or for a similar treatment of animals or plants (See Section 3(i)).

As a result of these provisions, biomedical research tools are patentable under Indian patent law. Medical, diagnostic and therapeutic kits/ tools are not patentable only when they are for the treatment of human beings or animals or plants.

4 Emerging R&D and marketing strategies

The Indian market is highly fragmented, with not one firm holding over 10% of the domestic market. In the year 1998, Glaxo-Welcome, Cipla and Ranbaxy together held 14.4% of the total formulations market (CII, 1999, p. 25). The

[31] See "Salient Fratures of the Patents (Amendment) Act, 2002 and the Patent Rules, 2003", downloadable from: www.patentoffice.nic.in/ipr/patent/salient_f.htm

6000 odd companies that comprise the Indian industry are faced with extremely different constraints while trying to evolve strategies to deal with product patent protection, even apart from the uncertainties created by the outstanding issues in the Indian Patent (Amendments) Act, 2005. Therefore, although most firms interviewed during the survey admitted to having foreseen at least some of the consequences of extending product patent protection to pharmaceuticals in India, India's full-scale TRIPS compliance is viewed differently by each group of companies in a different way, depending on how it affects their business interests and options.

A large number of strategic options have been suggested (and promoted) as the way ahead for Indian firms, both by the government of India and also by agencies within India that are actively involved in industry analysis and growth. These include: focusing on original R&D activities, such as vaccines, and genetics research in addition to incremental product and process innovation; focusing on newer opportunities in the generics market, such as biogenerics;[32] expanding into other areas such as clinical trials and herbal remedies/botanical medicines; specializing activities in order to benefit from outsourcing venues for contract research and manufacturing (CRAM);[33] using collaborative ventures in both R&D and marketing to their advantage; among several others.

4.1 Emerging R&D strategies in the Indian industry

R&D investment has been steadily on the increase amongst Indian companies. According to estimates, Indian firms spent a total of US $80 million on R&D in the year 2001, and approximately 90% of the Indian R&D investments come from the top 11 companies (IBEF and Ernst and Young, 2004a, p. 13). Yet, the average R&D expenditure in the pharmaceutical sector in India, although growing at 18% internally over the past five years is only 1.9% of the total sales, as against 8-10% spent by the global pharmaceutical companies.

From the results of the empirical survey and case study interviews conducted with a cross-section of the firms shows that each one of the three firm groups are using a combination of competitive and collaborative options to deal with pressures imposed by India's full scale TRIPS compliance. At the outset, three sets of predictive observations can be drawn that apply to each group respectively, given the various pressures that the industry faces.

32 Before 2007, a drug market of around $60 billion will be open for generic competition world-wide (Grace, 2004, p. 20; also see CII, 1999, Annex 5). A large part of the biogenerics market will also open up to generic competition (Schellekens and Ryff, 2002).

33 This option promotes the use of India's cost advantages in manufacturing and conducting contract research at various stages of the pharmaceutical innovation process to attract investment from western pharmaceutical companies.

Table 5: Emerging firm strategies: a categorization[34]

Firm group	Drivers	R&D Strategies
Group 1	• Entry and establishment in regulated markets • Realization that gains of entry are higher than initial costs to overcome barriers to entry • Need to strengthen product portfolios to insure against greater global competition	• Greater investment into R&D through revenues earned by product sales in regulated markets • Higher innovation in generics, new products and processes and bulk drugs.
Group 2	• Taking advantage of business opportunities created by the shift in focus of group 1 companies to regulated markets • Need to strengthen competitive advantages, to make use of CRAM opportunities	• Active supply of off-patent generics to the semi-regulated and unregulated markets, by setting up manufacturing plants outside India or strengthening supplier partnerships • Focus on establishing themselves as niche players for contract research by choosing specific areas that give them competitive advantage: e.g., clinical research, domestic marketing. • Moving up the industry's value chain gradually.
Group 3	• Survival in the light of Schedule M of the Drugs and Cosmetics Act and India's full fledged TRIPS compliance	• Upgrading facilities to Schedule M standards in order to continue manufacturing for group 1 and 2 companies.

Source: WHO-INTECH survey conducted by author, 2005

Group 1 firms, which are capable of investing into R&D, are keen on having their own intellectual property protection in order to establish themselves within India and other regulated markets worldwide. The pharmaceutical activity of firms in this group can be classified into two main categories: generics and R&D. On the generics front, not only are the firms venturing into innovative options, such a specialty generics, the firms are also keenly developing their own marketing infrastructure within India and in other regulated markets. This requirement to set up marketing infrastructure abroad is the driving force behind several international acquisitions and alliances. The experience of group 1 companies has been that while the entry barriers to regulated markets for the supply of generics are very high, the monetary

34 Sridharan (2005) presents a similar categorization of the industry split into three main groups: the innovator, the collaborator and the endangered.

returns and the ease of business that follows entry into these markets are both higher than in the semi-regulated and unregulated markets worldwide.

The added profits earned by the sale of generic products in regulated markets is one of the main reasons for the significant increase in R&D amounts spent by group 1 Indian firms, and this is expected to increase over time. Group 1 companies in India are therefore choosing a mix of cooperative and competitive strategies to deal with challenges and opportunities post-2005.[35] Although most Indian companies clearly acknowledge that producing the next new blockbuster NCE in India is still some way off, most competitive strategies adopted by these companies are centered on enhancing their R&D focus. These include: development of non-infringing processes, research on new chemical entities, generics and specialty generics[36] for regulated markets, novel drug delivery systems and biopharmaceutical research (Interviews; IBEF and Ernst and Young, 2004a, p. 11). Cooperative strategies are predominantly focused on increasing internal technological competitiveness and higher revenues from more sales in regulated markets by tapping the marketing networks of the non-Indian partners through collaborations.

Group 2 companies, which have an annual turnover between 100-300 crore rupees and have little or no investment capabilities to indulge in R&D, will predictably, remain pure generic suppliers, or at best, shift to product development that involves minor modifications. Their main focus will be on specializing in order to make use of emerging opportunities for contract research and manufacturing. Towards this end, companies in group 2 will try to establish themselves as niche players in contract research and manufacturing by choosing specific areas where they can be competitive. Some of these companies that are quite high up in the profitability chain presently are also planning to expand their activities and gradually move into regulated markets following the example of group 1 companies, thereby climbing up the industry value chain. A good example of such a company in group 2 is Ajantha Pharmaceuticals, which now has a big presence in Russia, a manufacturing plant in Ukraine and is seeking gradual entry into regulated markets.

In group 3 companies, contrary to popular misconceptions; it will mainly be the enactment of Schedule M of the Drugs and Cosmetics Act on minimum GMPs for Indian firms that will force unviable units to close down, as opposed to introduction of product patent protection. This segment of the industry will perhaps witness maximum consolidation in the next decade. Although many of the group 3 firms are also strategically aiming to benefit from contract manufacturing, either for larger Indian firms or even for foreign firms post-2005, only those who can upgrade their plants to at least to the GMP

35 This is mainly applicable to the Indian firms in Group 1. The subsidiaries of MNCs that belong to this group are also planning to expand operations or entering into collaborative arrangements, but as discussed in more detail in Section 6, are waiting to see progress under the Indian Patent (Amendments) Act, 2005.

36 Speciality generics are generics of reformulated older molecules, but made using new drug delivery technologies.

standards as contained in the Schedule M of the Drugs and Cosmetics Act will tend to benefit. Even such a generalization has to be made with a note of caution, since the standards contained in Schedule M of the Indian Drugs and Cosmetics Act are much below the WHO standards on GMPs. In this context, it remains unclear as to whether group 3 companies that do upgrade their facilities to the standards specified under Schedule M can indeed target contracts for manufacturing from MNCs/ firms operating outside India. In order to be able to manufacture for foreign partners from regulated markets, standards of foreign inspectors such as USFDA will need to be met by group 3 firms, which are much more stringent than both the Indian and WHO standards on GMPs. It therefore seems more likely that most such companies which do adhere to GMP standards as specified by Schedule M will perform contract manufacturing for group 2 companies in India who are looking at filling in the demand for generics in the unregulated and semi-regulated markets or foreign partners directly from the unregulated and semi-regulated markets. Alternatively, group 3 companies that comply with Schedule M will also supply to companies that are targeting the domestic Indian market.

Table 6: Main competitive strategies adopted by Indian firms

Strategy	Examples
Specialty generics	Several development initiatives at both Cipla and DRL are actively focusing on the development of specialty generics.
No infringing processes	Ranbaxy's non-infringing process on Cefuroxime Axetil enabled Ranbaxy to be its sole seller for almost one and a half years in the US market. Matrix Laboratories has developed its own non-infringing process on Citalopram and is the sole exporter of the API to Europe presently.
Novel drug delivery systems	Ranbaxy has licensed its NDDS on ciprofloxacin to Bayer AG that is under consideration in the USA right now. It is also actively involved in developing NDDS in several other therapeutic areas such as gastric retention.
New chemical entities	Ranbaxy licensed out its NCE RBx 2258 for the treatment of cancer to Schwarz Pharma AG. This NCE has now been dropped from clinical trials. Dr. Reddy's had licensed out its molecule for the treatment of Diabetes (Balaglitazone) to Novo Nordisk in 1997, for carrying out toxicology studies that form part of Phase II clinical trials. This

	molecule also had to be dropped from clinical trials due to toxicity issues.

Source: Field interviews conducted by author, 2005

Tables 6 and 7 contain an illustrative list of major competitive and cooperative strategies emerging in the Indian industry. In-licensing arrangements are a major cooperative strategy for group 1 and 2 companies and Table 6 lists some examples of in-licensing agreements that Indian firms have entered into. As mentioned, Indian firms are, in some cases, also using in-licensing agreements to acquire new technologies. For example, in the agreement between Zydus Cadilla and Fermenta Biotech, the Zydus Cadilla has the "... [e]xclusive rights for the commercialization of this technology, with manufacturing assistance being provided by Fermenta Biotech Ltd." (IBEF and Ernst and Young, 2004a, p. 26).

Table 7: Main collaborative strategies adopted by Indian firms

Strategy	Examples
In-licensing arrangements	Nicholas Parimal and Roche agreement on launching Roche's products dealing with cancer, epilepsy and AIDS in the local market (CII, 1999, p. 23). Agreement between Ranbaxy and K. S. Biomedix Ltd accords Ranbaxy exclusive marketing rights for TransMID, a biopharmaceutical product used in the treatment of brain cancer in India with an option to expand this to China and other South East Asian countries (IBEF and Ernst and Young, 2004b, p. 26). Agreement between Zydus Cadilla and Fermenta Biotech Ltd (A subsidiary of Duphar Interfran Ltd) that gives Zydus process technologies to manufacture Lisinopril and Benazepril exclusively within India.
Collaborative R&D	Glaxo SmithKline and Ranbaxy have a collaborative R&D arrangement for the development of new drugs in the areas of infective diseases and diabetes. Cipla has established an R&D deal with a smaller biotechnology firm, Avestagen Laboratories to produce the biogeneric drug for Artritis, *N-Bril*. Ranbaxy and Avestagen Laboratories have collaboration for the production of NCEs using biotechnological techniques.

	Avenstagen has collaboration with Astrazeneca Research Facility to help develop their TB Dots products.
Contract research	Biocon's subsidiary Syngene performs a large range of contract R&D activities for pharmaceutical firms world-wide
	Avestagen Laboratories, also a biotechnology firm, performs R&D for European pharmaceutical companies.

Source: Field interviews conducted by author, 2005; IBEF and Ernst and Young, 2004b.

Table 8 below contains the responses of survey respondents on emerging R&D strategies. The table shows, in a group-wise classification, the number of firms that are considering each one of these strategies as R&D options post-2005.

Table 8: Emerging R&D strategies

Firm group	Collaborative research	Custom synthesis and drug development	In-licensing	Clinical trials	Focus to generics	Focus to more basic research	API supply	Contract manufactu ring	Focus more innovative
1	11	1	2	5	10	1	3	1	5
2	6	2	2	6	5	5	1	3	2
3	6	1	4	7	15	4	2	4	9

Source: WHO-INTECH survey conducted by author, 2005
Note: Total firms that responded to this question = 40

4.2 Impact of patents on R&D, and emerging patenting strategies of Indian firms

Under the new Indian patent regime, biomedical research tools are patentable in India (see discussion in Section 3.2.5). There are two exceptions to this. Firstly, there is a research exemption for patented inventions (Section 47 (3) of the original Act), which can be interpreted to be applicable for both academic and commercial research. Secondly, medical, diagnostic and therapeutic kits/ tools are not patentable *only when* they are for the treatment of human beings or animals or plants.

Legal and economic literature on the impact of stronger intellectual property protection has pointed out that stronger intellectual property protection can, instead of promoting innovative activities, limit access to knowledge that is necessary for society to indulge in innovative activity, by restricting access not only to inventions but also to research tools and processes. There is evidence of firms creating patent portfolios and holding up research in cases where progress is dependent on access to their inventions (Jaffe, 1999 cited in Dumont and Holmes, 2002, p. 154). These concerns have been deepened by strong patent rights acquired by firms that cover not only inventions related to genes, but also genes and proteins themselves and fundamental research tools, apart from entire living organisms (Primo et al, 1998).

Empirical evidence on this topic is limited and controversial, although some studies have been conducted on the topic in the recent past, albeit mainly in developed countries (see Thumm, 2003, Walsh et al, 2003). The topic assumes atleast as much importance in the context of developing countries, especially those that are trying to/have been able to develop significant local capacity in the pharmaceutical (and also biotechnological) sectors.

Will India's full-scale TRIPS compliance result in restricting access to technologies to the local pharmaceutical industry? To test this, the survey posed the question whether firms face increased difficulties in accessing new technologies that are required for their activities after India started its phased compliance with the TRIPS Agreement over the past few years. A total of 43 firms felt that access to new technologies have become more difficult after India started implementing its compliance with the TRIPS Agreement. Of these, 12 belonged to group 1, 11 belonged to group 2 and 20 to group 3. But of the 43 firms that did face difficulties in accessing new technologies after India began complying with the TRIPS Agreement, only 28 firms admitted to having abandoned R&D projects due to patent protection. Of these, 11 belonged to group 1, 7 to group 2 and 10 to group 3 (see Table 9). Interviews with firm executives revealed that projects that were abandoned were done so mainly because (a) firms faced difficulties in terms of high costs for licensing and (b) firms realized ex-post that the results of their R&D would infringe patents filed for by competitors on the same compounds/ processes (interviews).

Table 9: Impact of TRIPS agreement on access to technologies

Firm group/Issue	More difficult access to technologies because of TRIPS	Abandoned R&D projects
1	12	11
2	11	7
3	20	10
Total	N = 43	N=28

Source: WHO-INTECH survey conducted by author, 2005

The survey also asked the firms to identify factors responsible for difficulties in accessing new technologies. The respondents were asked to rank each one of the reasons contained in Table 10 from 1 (weakest) to 5 (strongest). As Table 10 shows, all reasons ranked from significant to very significant (above 2.5), with royalty stacking being a reason that is relatively less important than multiple patents, restricted access due to too many patents on research inputs and high licensing fees. Furthermore, the survey response to this question also shows that group 2 firms are much more sensitive to the increasing number of patents, restricted access and the high licensing fees involved in carrying out incremental innovations as a result of India's TRIPS compliance.

Table 10: Reasons for difficulties in accessing new technologies after India's TRIPS compliance

Firm group/Effect	Too many patents on research inputs needed for R&D	Restricted access due to contractual difficulties	Royalty stacking in licensing contracts	High licensing fees
1	3.17 (12)	3.33 (12)	2.33 (12)	3.33 (12)
2	3.91 (11)	3.64 (11)	2.55 (11)	3.91 (11)
3	3.35 (20)	3.55 (20)	2.79 (19)	3.58 (19)
Average mean/ Firm total	3.44 (43)	3.51 (43)	2.60 (42)	3.60 (42)

Source: WHO-INTECH field survey conducted by author, 2005

The findings tabulated in Table 10 and the interviews with company executives suggest that the Indian industry's reaction is different from that of the US industry, where Walsh et al. (2003) noted that "Notwithstanding concerns about the proliferation of IP on research inputs and about the ability of rights holders to limit access to upstream discoveries and promising research targets the problem was generally considered to be manageable…Many of our responding firms suggested that if a research tool was critical, they would buy access to it." (p. 322-323). Interviews with company executives in the Indian industry shows that the industry finds high licensing fees is a very important issue. Furthermore, firms (both group 1 and 2 firms) also expressed the difficulties in devoting large sums on evaluating intellectual property of third parties on API, process and product patents (Interviews). The firms focusing on generics also said they had to invest

resources in exploring the possibility that the products that they have been producing until now are covered by newly issued secondary or combination patents that would restrict their export opportunities (see for example, Box 3 of the study).

This preliminary evidence calls for a more systematic analysis on the impact of TRIPS compliance on restriction of access to technologies to firms in developing countries. Three issues will be of specific importance in exploring this question:[37]

(a) Can accumulated IPR positions by firms in developed countries that have a lead technological advantage be used to prevent serious competition from industries in developing countries in innovative activities at the frontier?

(b) What sort of bargaining anomalies could result from monopolistic positions, information issues and transaction costs when one talks of such licensing arrangements between firms across the globe? Specifically, what are the transaction costs faced by firms in developing countries where "working solutions" such as infringements and invalidating patents in courts is not common?[38] How are these affected when firms on both sides do not have IP assets to trade that interest them mutually, in *quid pro quo* relationships?

(c) How important are IPR restrictions when compared to other factors that affect firm-level decisions on taking up new R&D projects? If there are research projects under this regime that were not undertaken mainly due to IPR issues, do the other benefits of granting such IPRs offset these costs/ losses?

4.2.1 Patenting Strategies of Indian Firms

Patenting activities have clearly been on the rise in India, accompanied by a growing realization that it is a primary factor in leveraging global competition to their advantage. According to Morel et al (2005), when the top 25 countries worldwide are ranked in order and analyzed for all US patents issued where atleast one inventor is from a given subject country, India ranked third highest (see Table 2, p.4). They further find that the number of US patents per GDP per capita in India is 0.912, second only to USA and Japan (ibid.). Despite this, since the Indian Patent Act of 1970 clearly under-emphasized the importance of patenting in the pharmaceutical sector, patenting is a relatively new phenomenon in the Indian pharmaceutical sector and there is a need to enhance awareness regarding the implications and potential of patenting amongst a large number of smaller firms in sector.

Emerging patenting strategies of Indian firms fall into two broad categories – positive patenting and defensive patenting. Most Indian firms that perform

37 Some of these issues are considered at length in Gehl Sampath (2005).

38 In India, one could suppose that the research exemption applies for commercial research as well and this is a good working solution, but there seems to be a need for clarification on this, either through a legislative amendment or a court ruling on the topic.

innovative R&D are presently following a mixed strategy of both positive and defensive patenting. Positive patenting refers to the patenting strategy where firms use the patent system to secure their own products that are presently based on NDDS or polymorphs or novel combinations in Indian and other markets. Cipla, for example, has filed for 166 patents world-wide, whereas Ranbaxy has the third largest ANDA filings in the USA for 2004 (Interviews). Other Indian companies like Dr. Reddy's Labs are also filing up to 15-20 ANDAs in the US market each year (IBEF and Ernst and Young, 2004a). At the same time, several firms are aggressively adopting defensive patenting strategies, where they apply for patents in order to prevent others from obstructing their R&D activities. Defensive patenting, as one company executive put it, is to ensure that "...someone else should not be able to stop us from developing our own processes".

Matrix Laboratories is another example of a firm that follows a mixed strategy for patenting. The company has filed 38 patents involving 36 inventions in the last three years. Their positive patenting strategy is to secure their proprietary rights on the innovative processes they create worldwide. Their defensive patenting strategy, on the other hand, has been motivated by their experience in the past few years, where they had to abandon research at the commercialization stage because their process had been filed for by someone else. As part of this strategy, they have tried to ring fence entire areas of process development, so that developing the same/ similar process is rendered a very hard task for outsiders (interviews).

Box 3: CIPLA: a group 1 firm focusing on generics

Cipla is a company that has been in the top 10 Indian companies for many years now, but has as its vision, the introduction of cheaper generic versions of drugs patented world-wide into the Indian market in order to promote affordability. In keeping with its vision, the company has since 1972, introduced approximately 40 drugs that are know worldwide but not in the Indian market, at affordable prices.

Cipla presently supplies generics of ARV drugs to 90 countries worldwide, including Brazil, Congo, Malawi and Senegal. Yet, the company does not have a base outside India, either for corporate management or production, unlike other major Indian companies. The company relies on alliances and partnerships with local agents in the importing countries for the sales of its products. Whereas Cipla fixes the price for its products while contracting with the local agents, the company does not take responsibility for the prices at which the local agents/partners sell the drugs in the importing countries.

Cipla also follows a mixed patenting strategy, although one could argue that this is predominantly defensive. The company has filed for 166 patents worldwide until now, all of which are either defensive patents, or patent applications for NDDS or new polymorphs. Cipla's patenting strategy also includes contesting formulation patents of other foreign firms, such as Combivir (by GlaxoSmithkline). Cipla recently took GlaxoSmithkline to court in the UK on grounds of "lack of novelty" for its patent on Combivir (GB2235627), which Cipla claimed was a combination of its earlier two ARV products, AZT (patent expiry date 2005) ands Lamivudin (patent expiry date 2007). Cipla won the case in the UK in 2004.

Another example of Cipla's patenting strategy is the case of Perendoperal. The

originator of the product has several patents on Perendoperal, yet Cipla has come up with Perendoperal Monohydrate, a patent on which is not covered by the originator and has applied for patents on Perendoperal Monohydrate.

Source: Field Interviews conducted by author, Cipla, January 2005.

4.2.2 R&D on health priorities of the Indian population and other parts of the developing world

It has been argued that patents are very essential to secure returns on R&D investments, since the costs of developing a new drug run into hundreds of million dollars, whereas the drugs can be copied very easily.[39] An offshoot of this argument has also been that increased intellectual property protection can create higher incentives for pharmaceutical firms to invest in health priorities of the developing world (See for example, Kremer, 2002; Lanjouw, 1998).

Although the evidence available until now on the issue is not systematic, it points out to the fact that private intellectual property rights promote research only into drugs and therapies with large expected returns. In 1996, WHO estimated that whereas 50% of all global health R&D was conducted by the private sector, less than 5% of this was spent on diseases of importance to low income countries (WHO, 1996). In 1999, Pecoul et al reported similarly that out of 1233 drugs licensed worldwide between 1975 and 1997, only 13 were for tropical diseases of which five were for veterinary diseases (Pecoul et al, 1999).

In India too, private sector investment in health priorities of the developing world has been scarce, even before 2005. A study conducted by Lanjouw and Cockburn (2001) also surveyed top 20 Indian firms as to their extent of R&D investment into neglected diseases. Their finding was that the large firms in India that are investing into R&D are doing so on global illnesses, which may also be found in developing country markets (p. 280-281). Therefore, an important issue while talking of emerging R&D strategies in the light of product patent protection in India is whether increased intellectual property protection in the sector does translate into higher incentives for the local Indian industry to undertake R&D on health priorities of the Indian market or the developing world generally?

Out of the 103 survey respondents, 15 of the firms reported to have all their activity (research, product development, or generic manufacturing) focused on local disease conditions, 16 reported to have 50% of their entire work on local disease conditions, and 62 of them had less than 25% to no activity at all on local disease conditions. Table 11 below shows a break-up based on firm groupings.

39 See for example, Angell (2004); Bale (1998), p. 637.

Table 11: Research amongst Indian firms on local disease conditions

FIRM GROUP	All research on local conditions	50% research on local conditions	Less then 25% research on local conditions
1	3	6	17
2	2	1	19
3	10	9	25
Total	15	16	62

Source: WHO-INTECH survey conducted by author, 2005.

More specifically, the survey revealed that in most cases, the firms had two kinds of perceptions of what "research on local conditions" constituted. Firstly, many firms were of the view that diseases like diabetes, different kinds of heart ailments and oncology constituted a "local condition", on grounds that there are several million Indians who were affected by these diseases. Secondly, while some firms focus on infectious diseases, they are not focusing on neglected diseases.[40] Amongst the three group 1 firms who reported to have all of their research on local conditions, the details of the research were: Alkem Labs (antibiotics and anti-fungal research), Nicholas Parimal (anti-pyretic and anti-inflammatory products) and Wockhardt (since their main products are anti-viral, anti-fungal, anti-bacterial and pain management).[41]

It seems unlikely that higher levels of intellectual property protection in India will translate into higher incentives for firms to conduct R&D into health priorities of the Indian or other developing countries' markets automatically. This is because export demand clearly shapes innovation strategies to a very large extent in all three firm groups in India. The survey asked firms to rank the extent to which export demand shapes their innovation strategies (ranked on a scale from 1 (least important) to 5 (most important)). The responses of firms to this question are as tabulated in Table 12 below. It shows that firms in all three groups admit to a very strong influence of export demand on their innovation strategy. On a comparative scale, group 1 is most sensitive to export demand while devising innovation strategies (with an average mean of 3.89), with group 2 following closely (with an average mean of 3.81).

40 This gaping divide between infectious diseases and neglected diseases has been noted in several other studies. Lanjouw (2002) cites a study of the Medecins sans Frontieres conducted in 2001 to make the same point. According to the 2001 study that reviewed drugs in development by PhRMA, only two drugs were related to the most neglected diseases although 137 of them were focused on infectious diseases (Lanjouw, 2002, p. 13).

41 The data collected in the field survey was corroborated by the interviews too. Interviews with firms, such as Dr. Reddy's Laboratories, also revealed a similar trend. Although one of the five major areas of R&D at Dr. Reddy's Labs is infectious diseases, this work is not focused on neglected diseases.

Table12: Influence of export demand in shaping innovation strategy

Firm Group	Extent to which innovation strategy is shaped by export demand	Number of firms who responded to the question
1	3.89	28
2	3.81	21
3	3.60	35
Average mean/ Total number of firms	3.75	84

Source: WHO-INTECH survey conducted by author, 2005

Some notable exceptions do exist, although they are few and far between.[42] These are in the area of vaccines and a novel research centre set up by Astrazeneca in Bangalore. Indian biotechnology firms have made a head start in vaccine production; the biggest success being the development of a hepatitis B vaccine by Shantha Biotech in collaboration with other local institutes (Kumar et al, 2004, p. 31).[43] Bharat Biotech and Serum Institute of India are also active in production of Hepatitis B vaccine (Ibid). On the pharmaceutical side, Astrazeneca Plc has established a laboratory and clinical research centre in Bangalore to focus on tuberculosis research. This US$ 40 million facility has already commenced its R&D programme in association with local biotechnology firms like Avestagen. Ranbaxy, another large Indian firm, is also involved in developing new anti-malaria drugs.

4.3 Emerging Business Strategies

Indian firms are also choosing a mix of marketing strategies to tackle increasing market pressures. These include:

(a) *In-licensing and out-licensing alliances*: In-licensing alliances allow Indian companies to launch the products of MNCs within the local market through their efficient distribution and sales networks. For the MNC that out-licenses the molecule, the arrangement can bring about regular royalty at minimum investments with a wider geographical coverage for its products (IBEF and Ernst and Young, 2004a, p. 26).

(b) *Co-marketing alliances*: These are alliances where two drug firms market the same product using a distinct brand name, in order to build up brand identity and loyalty and capture a larger share of the market.

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42 Note that this section only looks at R&D on neglected diseases in the private sector in India. There are several efforts in the public sector, especially those relating to the activities of the public research institutes in local and international collaborations, that are beyond the scope of this analysis. See Chaudhuri (2005) for a more detailed discussion of these ventures.

43 Shantha Biotech has a WHO certification since 2002 as well as a contract with the UNICEF for a supply of 8.5 million doses of the vaccine (Kumar et al, 2004, p. 31).

(c) *Outsourcing*: Given that the global clinical market is estimated to be around US$ 5 billion, clinical outsourcing has been promoted as a lucrative strategy for the Indian industry. India has several advantages to indulge in clinical research, such as cost advantages and genetically varied populations for clinical studies being some.

(d) *International acquisitions*: Larger Indian pharmaceutical companies have been making acquisitions in western countries in order to increase their presence in export markets. Good examples are Ranbaxy's acquisition of RPG Aventis's French subsidiary, Wockhardt's acquisition of CP Pharmaceuticals in the UK and Esparma GMBH in Germany (IBEF and Ernst and Young, 2004a, p. 18).

(e) *Setting up production facilities*: The Dabur-Abbott Alliance in oncologics is a good example in this context. This is a marketing alliance where Abbott's role is to market the generics produced by Dabur from their UK-based facility in the regulated markets of the EU and USA (Pers. Comm, Mr. Burman, CEO, Dabur Research India). Several other Indian companies have set up production facilities abroad.

(f) *Entering into marketing alliances abroad:* Several other firms rely on marketing alliances abroad instead of setting up subsidiaries or production facilities. For example, Cipla's marketing strategy is to rely on alliances and partnerships with firms abroad.

Table 13 below contains the survey responses of the firms on the main business strategies being considered in the industry. Predominantly, group 1 firms are looking at diversifying and expanding operations. Their business model is one that focuses on multiple markets and diverse portfolios in order to get the best prices for their products so that they can invest more into innovative R&D (Sridharan, 2005). Group 2 firms are also looking at a similar model, but in the semi-regulated and unregulated markets. Group 3 firms, on the other hand, are limited not only in terms of their investment and quality of production, but also in terms of marketing capabilities. Therefore, as the table shows, a large number of firms in group 3 are also planning to make the shift to herbal medicines, since the standards for manufacture in the herbal medicines sector are perceived to be less stringent than those in under Schedule M of the Drugs and Cosmetics Act.

Table 13: Main business strategies of Indian firms

Firm Group	In-licensing alliances	Co-marketing alliances	Focus on Generics	Focus on herbal medicines	Perform contract R&D
1	9	6	8	10	4
2	6	4	4	7	2
3	7	10	8	14	4

Source: WHO-INTECH survey conducted by author, 2005

4.3.1. Business strategies for regulated, semi-regulated and unregulated markets

Amongst the 103 firms surveyed, 42 export to Africa and these firms belonged to all three firm groups. But the 40 firms that were exporting to the European Union and North America predominantly belonged to Group 1 and some to Group 2. 42 firms export to other Asian countries, but these firms were once again as in the case of Africa, equally divided between all groups.

Although this indicates that a large proportion of the firms surveyed belonging to all three groups were supplying to African countries and other least developed countries and developing countries until now, there is a gradual and on-going transition in the industry structure vis-à-vis supplies to African countries presently, which will continue well into the future. The better to do pharmaceutical firms that belong to Group 1 are, as already discussed in earlier sections, making large investments in R&D targeted at global diseases and focusing on regulated markets, to ensure profitable returns. This is accompanied by a marked movement of group 1 companies from the unregulated and semi-regulated markets to regulated markets. This trend will continue with group 1 firms tending to focus on getting a larger share of global regulated markets, giving secondary importance to semi-regulated and unregulated markets. But group 2 companies will be quick to fill in the profitable opportunities that are being created by the shift of group 1 companies from unregulated to regulated markets. Some firms in Group 3 will also make this transition and benefit from the possibility to export to semi-regulated and unregulated markets.

Annex 4 contains country-data from CHEMEXIL on export statistics of Indian firms in the pharmaceutical and chemical sectors. The figures contained in the country-data support the conclusions drawn in this section.

5 Constraints and options to improve access to medicines in the local and international market

The question of access of medicines is almost always directly linked to affordability in much of the literature on the topic, as a result of which introduction of product patents has become almost synonymous with higher drug prices and therefore, with more limited access to medicines. However, such a direct link between product patent protection and higher drug prices is hard to draw. The impact of intellectual property rights on developing countries will differ from one country to another depending on its level of development (Mashelkar, 2005). Whether or not product patent protection leads to higher drug prices (and therefore limited access) depends on several factors, which includes (Gehl Sampath, 2004):

(a) Nature of competition posed by the local industry;

(b) Presence of off-patent therapeutic substitutes in a given category of newly patented products;

(c) Nature and effectiveness of price control in the local market;

(d) Amount of essential medicines under patent protection.

Additionally, recent literature on the topic has constantly underscored four determinants of access of medicines: geographical accessibility, physical availability, acceptability and affordability (Guimier et al, 2004, p. 7). Of these, whereas geographical accessibility and physical availability are both dependent on how drug markets are structured and how distribution systems work, acceptability is more dependent on marketing and affordability depends on the capability of consumers to pay (Ibid; also see Ganslandt et al, 2005).

5.1 Access to medicines in the local Indian market

Will product patent protection in India automatically increase the availability of new drugs within the local market? Most executives from subsidiaries of large MNCs who were interviewed in the study were very optimistic about the introduction of newly patented products in the Indian local market from 2005 onwards. But they made it conditional on the full-scale implementation of the Indian Patent (Amendments) Act of 2005. If these drugs are in fact made available within the country, it is very likely that the newly patented drugs will be expensive, at least in the therapeutic categories where there are no generics available to offer price competition (Fink, 2000). But the definition of patentability, as contained in the Indian Patent (Amendments) Act of 2005 will also play a very large role in determining the nature of competition that Indian firms will be able to put up in the generics market. As discussed in Section 3.2 earlier, Section 3 of the original Act has been amended under the Act of 2005 to prevent patents that merely re-combine pre-1995 molecules. But the new Section 3 contains an explanation that reads as follows: "For purposes of this clause, salts, esters, ethers, polymorphs, metabolites….shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy." This puts much of the onus on the patent examiners and/or courts in case of litigation in India.

In cases where there are indeed newly patented products with no generic price competition in a given therapeutic category, the critical question will be: how many Indian people will be able to access them? In these cases, even if one/some Indian firms create NDDS or other novel applications, it is not likely to be of much help if a foreign firm/ MNC holds the molecule patent.

Several other factors will also be critical in determining access to medicines for the Indian population in the mid-term or long-term, apart from product patent protection issues. Some of the main ones that require immediate attention in the Indian context are discussed here. Others, such as health infrastructure and distribution systems, availability of adequate financial resources, rational selection of medicines, are all very important but are beyond the scope of this study.[44]

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[44] In this context, refer to a recent study conducted by the National Pharmaceutical Pricing Authority of India (NPPA) on the availability and prices of

5.1.1 Competition law issues and compulsory licensing for the domestic Indian market

As already noted in Section 3.2, the provision of the original Indian Patent Act of 1970 that linked the grant of a compulsory license to "working a patent" locally has now been deleted. Despite the provisions in the Act that still preserve some of the rigor of compulsory licensing, Indian administrative authorities, including the judiciary, have very little experience in dealing with patent-related issues and disputes. The global pharmaceutical industry, on the other hand, has proved to be fertile ground for anti-competitive practices many of which are promoted by accumulation of patents by firms, such as coercive bargaining, hold-up effects, and unfair terms in license agreements between firms that share research results (see for example, Correa, 2000). Although India has an enabling competition law framework in place, there is a lack of awareness of issues in intellectual property-competition policy interface that practices in the industry may give rise to. As a result, it is highly likely that post-2005, Indian competition enforcement agencies will be over-whelmed by the magnitude and diversity of competition law issues in the pharmaceutical industry.

In addition to competition issues posed by the entry of global pharmaceutical players into the Indian industry, marketing practices within the Indian market create a large potential for collision between medical representatives of pharmaceutical firms and doctors/ hospitals, in order to influence the brands of drugs that are prescribed.

The general practice amongst Indian firms was to produce their drugs under brand names. Business strategies therefore, were mainly aimed at promoting brand names to consumers. Lanjouw (1998) notes, "... [e]arly entrants with strong brands seem to have a persistent advantage in the market." Since the market operated with immense product differentiation with each firm offering the same/similar product under a different brand name, and since there is virtually no information for the consumer to differentiate amongst the various brands of the same products, quality control is through a firm's reputation and doctor's prescription of certain brands over others (Interviews).

This creates the scope for a typical vertical restraints problem that can only be dealt with by an efficient competition law framework. For example, Dr. Reddy's Laboratories holds a dominant market position for their Nimersulide brand Nice: the brand controls 70% of the market, a large part of the success being attributable to the presence of extensive brand marketing networks with thousands of sales representatives. Indian companies also indulge in giving large margins to retailers in order to promote their brands (Interviews), and it is common practice that most of the large firms in group 1 have

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medicines in India. The study shows that almost 50% of the patients avoid seeking service from government hospitals due to poor quality of services and non-accountable medical practices although services are highly subsidized and although 97% of the patients confirmed that drug availability in governmental centres is not a big problem. See VOICE and NPPA (2002).

extensive brand marketing networks for their brands. Cipla, for example, has a sales force of around 2500 representatives within India. Smaller firms that may have equally good products at competitive prices but no marketing infrastructure may end up with insufficient profits, due to the difficulties of marketing their products. The emerging cooperative in-licensing alliances between MNCs and large local firms need to be viewed against this reality. They may, in fact, help thwart competition from smaller firms within the Indian industry that do not have large marketing infrastructure, even within those therapeutic categories where generic price competition is possible. The costs of these practices, if they continue uncontrolled, will eventually be borne by the uninformed consumer in the Indian market.[45]

In an effort to eliminate these price distortions related to high retail trade margins in the sector, a recent decision of the government of India (08 January 2005) has had the effect of bringing all drugs and medicines (other than traditional medicines) under the maximum-retail price based excise assessment. This has brought about an end to the earlier practice of levying excise duty on drugs on the ex-factory price, which meant that companies could make significant profits by selling drugs at prices that were much higher than the ex-factory price and thus offer significant margins to traders to promote their products (Nagendranath, 2005).

The dependence on the medical professionals to prescribe brands to patients goes beyond generic products. Since the normal practice amongst Indian doctors is to rely on drugs that are published in major British medical journals, like the Lancet, Indian firms fear the situation that when they do come up with completely new products, they may not be able to market them. A good example of this is Cipla's Kelfar, a new drug introduced in 1995 (See discussion in Chaudhuri, 2005, p. 18). This deferiprone drug was very hard to promote within India, although it was a good substitute for the only other deferiprone drug in the market, produced by Novartis at the time (ibid). According to Cipla's MD, Dr. Hamied, drugs like Kelfar failed to capture the local market because of the reaction of Indian doctors (Pers. Comm, Dr. Hamied, 2005).

The usual practice of the judiciary of using cases from USA and Europe to substantiate decisions will only exacerbate the situation and may go against the interests of the Indian industry and public health concerns of the people. India also does not have a large number of qualified and experienced patent examiners. The lack of qualified patent examiners and the time lapse between the grant of a patent and its publication in the official Gazette that the industry can access are other issues that need immediate attention (Interviews).

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[45] The 2002 study conducted by VOICE and NPPA on the availability and prices of medicines in India also found that more than 60% of the patients consult chemists rather than doctors to decide which medicines to buy (See VOICE and NPPA, 2002).

5.1.2 Price control and its effectiveness post-2005

According to government authorities, price rise in prices of medicines that are under price control is only 1%, whereas drugs that are not under price control have an average price rise of around 7% in the past decade (Pers Comm., G. S. Sandhu). Yet, there are several problems with price control and its scope as it is operating in India presently that undermines its effectiveness.

1. Previous experience with price control shows the acute trade-off between accessibility and affordability. Previous experience in India on price control has shown that both local Indian companies and MNCs do not find the introduction of drugs in price-controlled categories lucrative. Therefore when price control was imposed on a particular drug, more often than not, they either discontinued its production or created other deviations.

2. The Price Control Order relies mainly on ORG data to assess prices, which takes into account only retail prices.[46] Institutional sales, such as those to hospital segments are completely left out. Therefore, prices of drugs for very important diseases, such as AIDS and Cancer, are left out of the scope of the Order, since most of the drug supply in the case of these diseases is institutional and escapes the economic criteria of the Order.

3. The drug categories in the Order are completely out-dated. Although the criteria was meant to prevent cartels of drug manufacturers from exploiting consumers, the present Order relies on 1990 selection of drugs. As a result, Naproxyn, an analgesic is still under price control for several years now, although other analgesics, such as Ibuprofen and Diclofenac are not.

4. The categories of illnesses listed in the Price Control Order are outdated, and does not contain any reference to neglected diseases. These need to be re-defined so that neglected diseases and other important health priorities get sufficient attention under the price control mechanism.

5. The price control mechanism as it operates today, does not effectively control the prices of imported drugs. The practice under the Order for imported drugs had been to allow a margin over "landed" costs (cost of the drug/ API when it lands on Indian territory). This practice has been problematic in the past because it is hard to monitor price collusions between the Indian importer and exporter of the raw materials/drug. Previously, subsidiaries of MNCs operating within India have used this loophole to claim inflated prices for raw materials imported from their parental companies into India (Feinberg and Majumdar, 2001, p. 430). This problem will become much more acute from 2005 onwards, since patented products do not have to be produced locally.

For the price control mechanism to be effective to help in dealing with price rises accompanied with product patent protection in the local Indian market, these issues need to be eliminated. The government of India has presently constituted a Sandhu Committee that is looking into these matters in great

46 ORG-MARG is India's premium market surveillance and consulting firm, whose audits provide detailed product-level information based on monthly retail sales.

detail. The aim of the committee is to reinforce accessibility of drugs in the post-2005 scenario by re-defining the categories and basis for price control (Pers. Comm., G. S. Sandhu).[47]

5.2 Access to medicines in the international market: the compulsory licensing option

Even if the legal and regulatory hurdles over compulsory licensing were to be sorted out, as Grace (2003) rightly identifies, the option poses two pertinent economic issues for firms in a third country like India:

(a) Does the compulsory license issued by a least developing country serve as an economically feasible incentive for an Indian firm to invest in the development of a copy of the patented product?

(b) If the active pharmaceutical ingredients required for the product are not available easily, is the market large enough to attract the firm to invest in the production of active pharmaceutical ingredients?

To be able to test these preliminary conclusions at least partially, the survey respondents were asked whether Section 92 (A) of the Indian Patent Ordinance (now Section 92 (A) of the Act) offered an economically lucrative option for them to retain their export sales. Of the 103 firms, only 25 firms thought it was an economically lucrative option, whereas 78 firms did not think so. Of the 25 firms who answered in the positive, a group-wise classification reveals that only 6 belonged to Group 1, only 4 to Group 2 and notably, 15 firms belonged to firm Group 3. The common reason given by firms in group 1 and 2 for not considering it a lucrative option was that it increased the procedural hassles associated with such exports enormously, and this was not considered worthwhile, especially since the economic returns from such exports were very low. Group 2 firms also mentioned the constraints posed by the fact that their product range may be very different than those that might be in demand for imports by LDCs under such a license. These firms also expressed that the economic returns of investing in securing supplies of APIs that are different from those that they normally require for their activities or investing into reverse engineering efforts that may not be profitable to them beyond the said compulsory license to an LDC may not be profitable enough for them to consider. A common reason quoted by the 15 firms of Group 3, who were willing to supply to least developed countries under a compulsory license was that the decreased competition for exports to LDCs will enable them to strengthen their export potential. Table 14 below contrasts the general exports of firms in all three groups to Africa until now versus firm perceptions on how many of them would still find it lucrative to supply under Section 92(A) of the Indian Patent (Amendments) Act, 2005, as generated by the survey. Amongst the firms surveyed, 42 out of 103 firms export drugs to African countries presently: 15 of these are group 1 companies, 12 of these are group 2 companies and 15 were group 3 companies. But in response to the question whether they would still find it

47 In this context, an amendment to Schedule H of the Drugs and Cosmetics Act has also recently been enacted.

lucrative to supply generic versions of drugs patented in India post-2005 to African countries, not only did the total number of firms willing to consider the option reduce to 25 firms, the group-wise division changed drastically. Of the 25 firms who are willing to consider this option, only 6 belong to group 1, 4 to group 2 and 15 to group 3.

Table 14: Comparison between present exports to Africa and export projections of firms under section 92(A) of the new patent regime.

Firm Group	Present exports to Africa	Projections of future export intentions under sec. 92(A)
Group 1	15	6
Group 2	12	4
Group 3	15	15
Total	42	25

Source: WHO-INTECH survey conducted by author, 2005

From the survey data and case study interviews, and the on-going industry transition between regulated, semi-regulated and unregulated markets, it seems that compulsory licensing will be a better incentive for companies to continue and produce drugs that they were already manufacturing pre-2005. But companies may not have the incentive to engage in reverse engineering or organizing API production and produce new products only for export to LDCs under compulsory licenses, since this may not translate into a commercially viable proposition. More specifically, the following conclusions can be drawn on the question of viability of compulsory licensing as an economically feasible alternative for Indian firms:

(a) Firms in groups 1 and 2 will most likely continue to supply under compulsory licenses to LDCs so long as these products were those that they were manufacturing as generics pre-2005, although group 2 firms will generally be keener.

(a) In the case that the demand is for generic versions of newly patented drugs (that is, products that were not being manufactured by Indian firms in generic versions until 2005), firms in Groups 1 and 2 may consider supplying the least developed countries market under compulsory licenses. Group 2 firms will be keener even in this case, but they may be limited by process technologies and bulk drug requirements required, especially if the products that are under demand are very different from what are currently being exported by Group 2 firms to semi-regulated or unregulated markets. Least developed countries will have a better chance with Group 1 companies in the case of newly patented drugs if they could aggregate demand regionally (see Grace, 2003).

(b) Group 3 companies that answered in the positive are companies which have little or no experience in exporting pharmaceutical products mainly because they were not able to match up to competition from other Indian firms in Groups 1 and 2 before 2005. They see the export restrictions created by India's product patent protection as an opportunity to enter LDC markets. This may not be a very feasible option, since most of these companies do not even have facilities that are Schedule M compatible presently.

On the demand side, countries in Africa that have used compulsory licensing as a mechanism to improve access to medicines have required most help in negotiating royalties (Pers. Comm., Jamie Love, 2005). But up until now, there is no African country that has invoked the 30 August 2003 decision (ibid). There is also considerable skepticism as to whether countries may do so in the future, given the political pressures on countries not to issue such licenses.

Despite this, resolution of the legal issues associated with the implementation of Paragraph 6 of the Doha Declaration and sufficient proactive support by the Indian government may help the industry align its views vis-à-vis such compulsory licensing opportunities.

6 Conclusions and policy recommendations

Several conclusions emerge from the field survey of the Indian pharmaceutical industry and emerging firm strategies that need discussion and offer a large scope for future research. These are presented here along with major policy recommendations, both general to the international community and specific to the Indian government.

6.1 Firm size and emerging strategies: a discussion of the main results

Product patent protection in India is emerging to be a very decisive factor in determining access to medicines, both in India and other third countries in Africa. The survey shows that Indian firms will face severe challenges to adapt to the emerging patent regime while (a) operating in an industrial and regulatory climate that still is not fully geared towards its needs in the light of tough international competition, and; (b) coping with the losses induced by the restrictions placed on them by the new patent regime. This is in keeping with earlier studies on the topic such as Fink (2000) and Chaudhuri, Goldberg and Jia (2004), which show that the losses to the Indian industry in certain segments following India's full scale TRIPS compliance are very high. Therefore, emerging strategies of Indian firms will continue to be dictated mostly by survival needs and not by issues related to access to medicines of the general public, whether in India or other least developed countries.

Is it too early for assess emerging firm strategies in India? The answer to this question lies in the negative. Some of the major changes, such as extension of patent protection from 14 years to 20 years, were already introduced in earlier amendments to the Patent Act (in 2002), and the survey shows that Indian firms have been preparing for India's product patent regime over time, and their strategies have been devised to help them cope with the emerging regime. The general sentiment in the industry is well summarized by a quote: "There is big trouble ahead for those who have not planned for post-2005" (Sridharan, 2005, quoting the MD, Divi Labs).

Indian firms are adopting a combination of cooperative and competitive strategies, in order to adapt and as well as capitalize on opportunities created by the new patent regime. The study has categorized firms in the Indian pharmaceutical industry into three main groups, based on empirical data collected, and identified the main strategies and their triggers in each

one of the three firm groups. Emerging firm strategies in the Indian industry portray a scenario that is is very different from what was observed in several Latin American countries, where local firms mainly adopted a cooperative strategy upon entry of foreign MNCs, thereby leading to their acquisitions by the latter, resulting in steeper increase in prices of drugs. The behavior of the Indian industry is more in keeping with what one would expect to see in an environment where a well-to-do local industry with clearly established areas of expertise is faced with strong international competition. Newer technologies and evolving market structures (in this case, as induced by the product patent regime and strong competition from global firms) almost always create new market segments and niches with many opportunities for specializations that the Indian industry will be quick to capitalize upon, although this will also be accompanied by a high degree of consolidation in the industry in the coming years.

The study also found a very high correlation between export intensity and R&D investments in the Indian pharmaceutical sector. Firms that had greater revenues from exports were able to invest a larger amount on R&D.

Should there be cause for concern that Indian firms are focusing so little on health priorities of the developing world? Is this a counter-intuitive result? Two factors seem to be instrumental in motivating innovation trends amongst Indian firms. Firstly, export demand plays a large role in shaping innovation strategies of Indian firms. Secondly, Indian firms are hard-pressed to survive amidst little government support and tremendous external pressures of global competition. Given that almost all Indian firms fully fund their own research activities through their profits; their concern is primarily on investing into drugs that assure them maximum returns. Both these factors result in an emphasis on R&D investment into global diseases. Therefore, this finding, although disappointing is not counter-intuitive.

The results of the survey on the impact of TRIPS Agreement on restricted access to technologies in the pharmaceutical sector show that Indian firms do face several difficulties with India's TRIPS compliance in this regard, and have also had to abandon some R&D projects in recent years. This preliminary evidence calls for a more systematic assessment of issues, such as: (a) the relative importance of IPRs when compared to other factors that affect firm-level decisions on whether or not to take up new R&D projects; and (b) if there are research projects under this regime that were not undertaken mainly due to IPR issues, do the other benefits of granting such IPRs offset these costs/ losses.

A last set of questions relate to the responses of group 3 firms to the survey. In many cases, responses of group 3 firms seem somewhat implausible (see Tables 5 to 14). The main explanation for their responses, as gathered through case study interviews that were conducted with the firms, is cognitive dissonance. There is a pervasive lack of information in the group 3 firms regarding the impact of product patent protection, Schedule M and opportunities that can be made use of by them, the patent application processes and emerging business opportunities. These account for the far-fetched answers, to a large extent.

6.2 Policy Recommendations

Several policy recommendations follow from the analysis for action, both at the international and Indian level. At the international level, the main recommendations are as follows:

1. To explore evidence of patents on restricted access to technologies in developing countries and to advise countries to how to balance intellectual property rights-competition law interface in this regard.

2. To advise the innovative developing countries on strengthening existing systems of health innovation and LDCs on how to build innovation systems while dealing with the effects of full-scale TRIPS compliance.

3. To generate awareness that IPRs may not necessarily be an impetus to innovation.

4. To advise countries on enacting procedures that expedite the use of compulsory licensing provisions under 30 August 2003 Decision. These should be directed towards rectifying distortions both on the demand side (LDCs) and the supply side (developing countries with manufacturing capabilities). On the supply side, countries need advice on kinds of incentive structures for private sector that promotes their continued engagement in such activities.

Policy recommendations for action at the Indian level that follow from the analysis are as listed below:

1. The Indian government needs to invest extensively in strengthening existing institutions such as local competition enforcement agencies, patent examiners, an informed judiciary which is more attuned to the public health and local industry needs in a country like India, and price control mechanisms in order to promote access to medicines in the local market and other LDCs.

2. The patent regime incorporates several major TRIPS flexibilities. But it also contains several provisions that are open to different sets of interpretations and therefore whether all the flexibilities that are permissible under the TRIPS Agreement will be used by India in day-to-day practice or not, is still much in the open.

3. Other rules affecting the industry, such as those on data exclusivity should be enacted only after taking into consideration the interests of the generics industry and the scope of its impact. If the generic industry in India is curbed further, a large amount of cheap supply of medicines at very competitive prices will be seriously affected.

4. The government should apart from providing an expedient administrative procedure for the implementation of Section 92(A) of the Act, create a higher level of awareness amongst the local industry on the option of compulsory licensing to supply to other least developed countries. This could result in a more conducive attitude amongst the firms to deal with requests from other least developed countries in future.

5. The government should, in a concerted effort with the industry, plan ways in which to reduce bottlenecks to pharmaceutical R&D in the local Indian context. These will be very helpful to aid the industry to devise and implement strategies for survival.

6. The government should strengthen its activities in terms of identifying key areas where there is potential (for example, clinical research) and invest in development of these facilities systematically.

7. Promotion of R&D into diseases of the developing world, as the survey goes on to show, will remain a public good problem, irrespective of the capacities in the pharmaceutical sectors in developing countries. The government of India (either singularly or in collaboration with other governments in developing countries) should initiate more public R&D programmes that utilize the strengths of the Indian industry to find cures for neglected diseases.[48]

[48] There are already several such programmes in which the Government of India is involved. This recommendation is to augment these efforts further.

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ANNEX 2: List of firms that participated in the empirical survey

Sl. no	Company Name
1	Micro Labs Limited Bangalore
2	Glenmark Pharma
3	Dr.Reddy
4	Aurobindo
5	Alkem Labs
6	Ind-Swift Laboratories Limited
7	Strides Arcolab Limited
8	Alembic
9	Novartis
10	Nicholas Piramal
11	Orchid
12	Morepen
13	Pfizer Ltd
14	Ranbaxy
15	Cipla
16	Glaxo S.K
17	Wyeth
18	Lupin
19	Torrent
20	Sun Pharma
21	Cadila
22	J.B.Chemicals & Pharmacutical
23	Ipca Laboroties
24	Wockhardt
25	Matrix
26	Unichem
27	Zydus Group
28	Aventis
29	Abbott
30	Biocon
31	Merck
32	Ambalal Sarabhai Enterprises

33	Arvind Remedies
34	Fdc Ltd
35	(Dabur) Ayurved Ltd
36	Zandu Pharma
37	Torrent Gujarat
38	Aarti Drugs
39	Kopran
40	Dishman
41	Emcure Pharmaceuticals
42	Netcare
43	Neuland Labarotories
44	Indoco Remedies
45	German Remedies
46	Astra Zenaca
47	Jagsonpal Pharmaceutical Ltd
48	Blue Cross
49	Core
50	Panacea
51	Divis
52	Rpg Lifesience
53	Shasun
54	Fullford
55	Ajanta
56	Natco
57	Solvay
58	Pharma Chemico Laboratories
59	Aimil
60	Mdc Pharmaceuticals (P) Ltd
61	Eisen Pharmaceutical Co.(Pvt) Ltd
62	Juggat Pharma
63	Relish Pharma
64	Sanjivani Remedies Limited
65	Medicamen Biotech Limited
66	Capsugel India Limited
67	Anglo French

68	K.A.P.L
69	Bal Pharma Ltd
70	Natural Capsules Lmt
71	Daurala Oraganics Ltd
72	Ozone Pharmaceuticals Ltd
73	Ttk Healthcare Lmt
74	Gujarat Terce
75	Jen Burkt
76	Suven Life Scince
77	Thems Medicare
78	Lincoln
79	Lyka Labs
80	Advik
81	Ahlcon Paraenterals India Ltd
82	Venkat Pharma
83	Krebs Biochem
84	Malladi Drugs
85	Geno Pharma
86	Zenith
87	Bharat Serums
88	Tablets(India)Limited
89	Ankur Drugs
90	Alpha Drugs
91	Veronica Labs
92	Li-Taka Pharmaceutical Limited
93	Bio-Ved Pharmaceuticals
94	Guj.Them's
95	Granules India
96	Elder Health Care Pharma
97	Flamingo Pharma
98	Chemech
99	Arch Pharma
100	Anuh Pharma
101	Wintac
102	Jupiter Biosciences

103	Mangalam

Annex 3: Organisation of Pharmaceutical Producers of India, Member Companies

Ordinary members	Martin & Harris Pvt. Ltd.
Abbott India Ltd	Merck Ltd.
AHP Manufacturing B.V.	Nicholas Piramal India Ltd.
Aristo Pharmaceuticals Ltd.	Novartis India Ltd.
Associated Capsules Pvt. Ltd.	Novo Nordisk India Pvt. Ltd.
Astrazeneca Pharma India Ltd.	Organon (India) Ltd.
Aventis Pasteur India Pvt. Ltd.	Para Pharmaceuticals Ltd.
Baxter (India) Pvt. Ltd.	Pfizer Ltd.
Bayer Pharmaceuticals Pvt. Ltd	Procter & Gamble Hygiene and Health Care Ltd.
Becton Dickinson India Pvt. Ltd.	Ranbaxy Laboratories Ltd.
Boehringer Ingelheim India Pvt. Ltd.	Raptakos, Brett & Co. Ltd.
Boots Piramal Healthcare Pvt. Ltd.	Reckitt Benckiser (India) Ltd.
Bristol-Myers Squibb Company	Roche Scientific Company (India) Pvt. Ltd.
Dabur Pharmaceuticals Ltd.	RPG Life Sciences Ltd.
Dey's Medical (U.P.) Pvt. Ltd.	Sandoz Pvt. Ltd.
Dr. Reddy's Laboratories Ltd.	Sangfroid Remedies Ltd.
East India Pharmaceutical Works Ltd.	Sanofi-Sythelabo India Ltd.
Eli Lilly and Company (India) Pvt. Ltd.	Serdia Pharmaceuticals (India) Ltd.
Ethypharm LL Pvt. Ltd.	Shreya Life Sciences Pvt. Ltd.
Fulford (India) Ltd.	Solvay Pharma India Ltd.
Galderma India Pvt. Ltd.	SPIC Pharmaceuticals Division
German Remedies Ltd.	Suven Life Sciences Ltd.
GlaxoSmithKline Consumer Healthcare Ltd.	UCB India Ltd.

GlaxoSmithKline Pharmaceuticals Ltd.	Unichem Laboratories Ltd.
Hindustan Lever Ltd.	Walter Bushnell Ovt. Ltd.
Intervet India Pvt. Ltd.	Wander Ltd.
Johnson & Johnson Ltd.	Wockhardt Ltd.
Laboratories Griffon Ltd.	Wyeth Ltd.
Lupin Ltd.	
Affiliated Members	
Ernst and Young Pvt. Ltd	Quintiles Spectral (India) Ltd.
Health World India (a division of Bates India Pvt. Ltd.)	Rabo India Finance Pvt. Ltd.
ORG IMS Research Pvt. Ltd	Sudler & Hennesey Pvt. Ltd.
Ogilvy & Mather Pvt. Ltd.	Yes Bank Ltd.
Associate Members	
Bi Ltd.	Hindustan National Glass & Industries Ltd.
Colorcon Asia Pvt. Ltd.	Indian Aluminium Co. Ltd.
Extrusion Processes Ltd.	PRS Permacel Pvt. Ltd.
GMM Pfaudler Ltd.	Schott Glass India Pvt. Ltd.
Gujarat Glass (P) Ltd.	

Source: OPPI 2005

Annex 4: CHEMEXIL DATA

COUNTRY-WISE EXPORT STATISTICS OF DRUGS PHARMACUETICALS, FINE CHEMICALS AND CRUDE DRUGS

FOR THE YEARS 2001-02, 2002-03 AND 2003-04

(Rs. In millions)

REGION/COUNTRY	2001-02	2002-03	2003-04
EAST ASIA			
Ameri Samao	1.4	0.0	1.2
Australia	872.3	797.4	876.4
Br. Virgin IS	1.5	0.0	0.0
Brunei	0.0	10.9	4.9
Cambodia	290.0	419.2	328.6
China P. Rep.	3819.9	4490.0	4483.9
Chinese Taipei	689.5	866.5	904.3
Christmas Is.	0.5	0.0	0.0
Cocos Is	5.5	2.2	4.1
Fr. Guiana	1.0	15.0	3.9
Fiji IS	28.7	97.8	41.3
Guam	12.7	7.9	1.9
Hong Kong	3425.1	3325.0	3622.7
Indonesia	729.7	668.8	817.1
Japan	1512.8	2419.1	3076.0
Kiri Bati Rp.	3.8	5.2	0.2
Korea Dp. Rep.	378.2	476.0	426.4
Korea Rep	1066.5	1585.2	1271.6
Lao Pd. Rep.	9.3	13.2	3.1
Macao	18.7	35.5	54.7

Malaysia	619.1	925.3	1249.1
Myanmar	508.0	654.0	696.5
Mongolia	4.8	9.0	6.6
Nauru Rep.	0.6	0.0	0.0
New Caledonia	0.0	0.1	0.2
New Zealand	235.3	253.7	249.7
Papua N Gna	66.9	101.7	66.4
Phillipines	699.3	1159.8	1281.2
Singapore	2011.6	2122.5	2165.5
Solomon IS	3.7	4.2	5.6
Thailand	1513.8	1169.8	2197.2
Vanuatu Rep.	0.5	4.1	19.6
Vietnam Soc. Rep.	2143.1	2757.6	2506.4
TOTAL	**20673.8**	**24396.7**	**26366.3**

COUNTRY WISE EXPORT STATISTICS OF DRUGS, PHARMACEUTICALS, FINE CHEMICALS AND CRUDE DRUGS

FOR THE YEARS 2001-02, 2002-03 AND 2003-04

(Rs. In millions)

Region/Country	2001-02	2002-03	2003-04
SOUTH ASIA			
Afghanistan	75.1	230.3	1013.0
Bangladesh	1273.5	1702.7	1916.6
Bhutan	0.4	3.8	21.2
Iran	1277.5	1110.4	2165.0
Maldives	92.4	103.6	157.0
Nepal	1509.1	1673.4	1607.5
Pakistan	877.3	1059.3	1158.5
Sri Lanka	1526.8	2262.7	2311.3
Wallis F. Is.	0.5	0.3	2.3
TOTAL	**6632.6**	**8146.5**	**10352.4**

(Rs. In millions)

Region/Country	2001-02	2002-03	2003-04
WEST ASIA			
Bahrain IS	49.4	33.9	52.8
Iraq	342.4	499.3	195.1
Israel	647.3	1226.9	1819.2
Jordan	439.8	617.4	907.9
Kuwait	55.4	40.8	41.6
Lebanon	5.5	32.2	36.2
Muscat/Oman	125.1	145.9	274.7

Qatar	24.3	51.1	43.7
Saudi Arabia	414.9	552.9	455.7
Syria	382.9	467.5	726.6
U.A.E.	1419.8	2038.9	2139.2
Yemen Rep.	469.9	510.7	384.5
TOTAL	**4376.7**	**6217.5**	**7077.2**

COUNTRY-WISE EXPORT STATISTICS OF DRUGS PHARMACUETICALS, FINE CHEMICALS AND CRUDE DRUGS

FOR THE YEARS 2001-02, 2002-03 AND 2003-04

(Rs. In millions)

Region/Country	2001-02	2002-03	2003-04
AFRICA			
A.R.E/Egypt	623.5	563.7	647.2
Algeria	134.3	213.6	506.3
Angola	199.6	303.7	411.8
Aruba	0.0	0.0	0.5
Benin	384.3	704.3	311.7
Botswana	6.4	5.2	3.2
Burundi	32.1	89.1	118.3
Burkina Faso	47.2	129.9	129.9
C Afri Rep	1.1	4.1	14.0
Cameroon	223.8	376.9	337.9
Canary Is	0.1	0.0	0.0
Cape Verde Is	0.2	0.0	0.2
Chad	10.4	31.3	98.6
Congo P. Rep	542.9	1016.9	802.3
Comoros	2.1	2.9	2.1
Djibouti	26.5	83.0	91.1
Equtl Guinea	3.1	1.4	4.4
Eritrea	0.0	0.0	52.7
Ethiopia	361.9	401.3	653.7
Gabon	13.5	10.0	1.8
Gambia	17.5	25.3	38.2

Ghana	708.0	939.7	939.1
Guinea	555.2	860.3	504.4
Guinea Bisu	66.7	116.1	29.9
Cote D'Ivoire	89.4	113.8	134.4
Kenya	1131.9	1184.9	1200.5
Lesotho	3.3	6.4	7.3
Liberia	54.6	58.3	63.1
Libya	12.6	2.2	3.8
Madagascar	72.7	88.7	197.5
Malawi	108.4	134.6	169.2
Mali	74.5	170.6	110.4
Mauritania	3.4	17.6	27.8

Region/Country	2001-02	2002-03	2003-04
Mauritius	197.8	290.2	310.4
Morocco	83.8	164.1	74.7
Mozambique	134.5	363.2	231.4
Namibia	21.2	30.1	42.7
Niger	194.0	399.0	198.1
Nigeria	3790.3	3670.9	3647.8
Reunion	8.4	22.0	11.0
Rwanda	46.0	52.1	62.0
Senegal	79.9	118.8	79.9
Seychelles	8.2	11.9	14.2
Sierra Leone	97.0	97.2	132.9
Somalia	46.4	110.2	115.1
South Africa	887.0	1121.5	1551.0
Sudan	306.6	422.2	616.1
Swaziland	7.3	5.6	30.5
Tanzania	404.7	569.4	623.9
Togo	24.5	26.2	62.1
Tunisia	44.0	36.0	35.5
Uganda	590.8	777.2	902.5
Zaire Rep.	60.1	41.7	0.0
Zambia	181.2	250.6	378.9
Zimbabwe	160.8	311.9	285.2
TOTAL	**12885.7**	**16547.8**	**17019.2**

COUNTRY-WISE EXPORT STATISTICS OF DRUGS PHARMACUETICALS, FINE CHEMICALS AND CRUDE DRUGS

FOR THE YEARS 2001-02, 2002-03 AND 2003-04

(Rs. In millions)

Region/Country	2001-02	2002-03	2003-04
EAST EUROPE			
Albania	43.2	54.8	86.6
Armenia	5.2	8.4	7.4
Azerbaijan	21.4	58.5	92.7
Belarus	60.4	180.6	172.2
Bosnia-Herzegovina	0.2	29.7	5.6
Bulgaria	67.0	64.0	135.8
Croatia	47.6	51.2	89.4
Czech Rep.	183.6	187.0	422.0
Estonia	6.5	3.1	10.1
Georgia	33.1	34.5	44.1
Hungary	253.7	376.2	828.9
Kazakhstan	102.5	563.4	484.7
Kyrghyzstan	26.2	6.0	30.4

Latvia	41.6	43.8	76.3
Lithuania	32.5	83.5	216.7
Macedonia	4.5	16.6	24.1
Moldova	47.4	107.0	64.0
Poland	451.0	685.9	716.4
Romania	117.2	162.7	292.2
Russia	4810.8	5176.5	6250.3
Slovak Rep.	42.6	60.2	194.3
Slovenia	93.4	323.3	638.8
Tajikistan	17.1	46.8	44.6
Turkmenistan	68.4	72.5	67.0
Ukraine	1121.9	1512.0	1991.4
Uzbekistan	71.5	89.4	173.4
Yugoslavia F. Rep.	71.4	53.7	94.7
TOTAL	**7852.1**	**10051.3**	**13254.1**

COUNTRY WISE EXPORT STATISTICS OF DRUGS PHARMACUETICALS, FINE CHEMICALS AND CRUDE DRUGS

FOR THE YEARS 2001-02, 2002-03 AND 2003-04

(Rs. In millions)

Region/Country	2001-02	2002-03	2003-04
WEST EUROPE			
Andorra	0.0	3.9	0.1
Austria	149.2	221.0	296.8
Belgium	702.2	899.8	997.4
Channel Is.	7.8	0.5	0.0
Cyprus	270.6	288.9	287.3
Denmark	578.7	613.4	652.1
Faroe Is.	0.0	0.0	1.9
Fr Polynesia	0.0	0.7	0.0
Finland	104.9	480.8	853.7
France	1326.7	1361.3	1743.9
German F. Rep.	5033.5	7808.9	8831.2
Greece	117.1	140.0	143.1
Greenland	0.0	0.3	7.1
Iceland	45.9	122.5	329.5
Ireland	512.0	728.5	584.4
Italy	1198.4	1764.0	2601.7
Liechtenstein	10.2	7.3	5.9
Luxembourg	0.0	4.8	3.0
Malta	57.5	122.2	208.7
Marshall Is.	0.0	1.6	3.5
Monaco	0.0	0.0	9.3

Netherlands	1935.6	2441.0	2618.1
Norway	62.3	33.9	64.8
Portugal	138.6	342.9	239.2
Spain	1691.0	2052.7	2782.4
Sweden	63.4	89.6	127.3
Switzerland	1566.5	1418.9	1553.4
Turley	795.3	1193.4	1884.8
U.K.	2821.8	4301.1	4712.1
TOTAL	**19179.0**	**26443.9**	**31542.7**

COUNTRY-WISE EXPORT STATISTICS OF DRUGS PHARMACUETICALS, FINE CHEMICALS AND CRUDE DRUGS

FOR THE YEARS 2001-02, 2002-03 AND 2003-04

(Rs. In millions)

Region/Country	2001-02	2002-03	2003-04
NORTH AMERICA			
Canada	1492.0	2556.8	3729.3
U.S.A.	16411.7	22008.4	21046.7
TOTAL	**17903.7**	**24565.2**	**24776**

Region/Country	2001-02	2002-03	2003-04
LATIN AMERICAN COUNTRIES			
Argentina	633.8	677.3	1096.2
Bolivia	26.4	63.0	86.9
Brazil	3504.8	3674.4	3805.8
Chile	320.6	267.3	273.7
Colombia	404.6	576.2	761.0
Cuba	26.3	20.4	63.8
East Timor	0.0	0.0	11.4
Guatemala	181.4	128.6	184.0
Mexico	1495.7	2636.0	3259.2
Panama C Z	10.9	23.6	0.3
Panama Rep.	52.3	62.2	32.8
Paraguay	108.7	147.0	68.1
Peru	239.9	296.7	302.6
Pitcairan Is	0.0	1.1	0.0

Sao Tone	0.9	0.0	0.3
Surinam	0.6	2.8	11.7
Venezuela	191.3	211.6	185.2
Virgin Is. U.S.	15.1	3.9	12.6
TOTAL	**7213.3**	**8792.1**	**10155.6**

COUNTRY-WISE EXPORT STATISTICS OF DRUGS PHARMACUETICALS, FINE CHEMICALS AND CRUDE DRUGS

FOR THE YEARS 2001-02, 2002-03 AND 2003-04

(Rs. In millions)

Region/Country	2001-02	2002-03	2003-04
OTHER AMERICAN COUNTRIES			
Antigua	0.2	8.4	8.2
Anguila	0.0	0.0	10.3
Bahamas	4.5	13.4	42.3
Barbados	2.2	2.1	6.1
Belize	1.0	3.2	5.6
Cayman Is	0.8	3.0	1.3
Costa Rica Is	83.2	129.2	283.0
Domic Rep	101.6	172.2	126.9
Domica	30.8	23.7	15.2
Ecuador	16.4	33.6	142.8
El Salvador	22.9	15.9	92.0
Grenada	0.0	0.0	1.3
Guadeloupe	1.5	8.3	4.4
Guyana	23.0	80.5	54.0
Haiti	146.4	298.6	160.0
Honduras	97.8	215.8	95.2
Jamaica	54.0	65.5	66.3
Martinique	0.4	0.2	1.6
Montserrat	0.8	0.5	1.0
Netherlands Antil	47.0	71.2	9.7
Nicaragua	41.7	6.3	51.2
Nieu Is	0.0	0.0	3.4

Puerto Rico	78.7	68.2	641.7
St. Helena	0.0	0.4	0.0
St. Kitt NA	0.0	0.4	4.5
St. Lucia	2.0	3.1	4.2
St. Vincent	0.0	0.0	0.0
Tonga	5.0	5.2	4.1
Trinidad	97.5	172.0	119.1
Turks C Is	9.9	18.1	6.9
Uruguay	679.7	542.5	384.0
West Samoa	11.3	10.0	0.0
TOTAL	**1560.3**	**1971.5**	**2346.3**