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Exploitative and Explorative Learning as a Response to the TRIPS Agreement in Indian Pharmaceutical Firms: Some Implications for Other Developing Countries

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Abstract

The intellectual property regime forms an important part of any government's economic and industrial policies. It is an important regulatory instrument not only affecting industry and market structure but also influencing firm level learning strategies, especially in knowledge based industries like pharmaceuticals. Given its crucial role, the strengthening of patent laws as a result of the Trade Related Intellectual Property rights (TRIPs) agreement presents a significant institutional change for developing country industry. This paper analyses Indian pharmaceutical firms response to the strengthening of patent law.

The research in this paper shows that Indian pharmaceutical firms responded to disruptive regulatory change by developing competencies incrementally as well as radically. Ambidextrous capability development involved *explorative* investment in R&D to develop innovative product R&D competencies and in parallel also involved *exploitative* use of existing process R&D capabilities. This explorative and exploitative learning in Indian pharmaceutical firms has wider implications for firms from other developing countries facing similar TRIPS challenges.

Keywords: Innovation, learning, capability, pharmaceutical industry , R&D

1 Introduction

In recent years World Trade Organisation (WTO) agreements have played a key role in reducing the tariff and non tariff barriers of international trade. Its agreements have emerged as a backbone of the globalisation process, instrumental in setting uniform rules and regulation for trade in goods and services all over the world.

Two–thirds of WTO members (around 146 countries) are 'developing' and 'least developed' countries and their industries will certainly be affected by the emerging 'trade' regimes. It is clearly evident that changes in the 'rules of the game', specifically the strengthening of IPR regimes, will exert significant pressure upon sectors like pharmaceuticals, chemicals and agro-chemicals that have long enjoyed protection and an assured domestic market (Das and Nair, 2000). In such industries access to technology is relatively difficult. New product development in knowledge based industries is highly professionalized and involves specialised technological R&D activities.

The learning process involved in development of pharmaceutical manufacturing and R&D capabilities is complex compared to most other sectors. The large multinational firms that dominate this sector create a significant proportion of knowledge and through patents effectively control the diffusion of knowledge. These firms conduct most of their activities in developed countries and prefer direct investment to licensing when producing abroad. Therefore most developing countries have built domestic pharmaceutical industries by adopting weak patent laws which allowed them to overcome patent barriers in acquisition of patented knowledge. But TRIPS will now severely effect these countries' pharmaceutical industries.

Most of the literature on the patent system in developing countries has either: focused on socio economic issues like drug pricing and welfare cost (Lanjouw, 1996;Watal, 2000; Pangariya, 1999; Nogues, 1993); investigated the link between patent system strengthening and technological development (Sequeria, 1998; Kumar, 2003; D'Este, 2002): or analysed the effects of strong patent system on output and trade performance of the industry (Weisburst and Scherer, 1995; Felker et al., 1997).

This paper addresses the impact of changing patent law on the learning process of catch-up firms in a developing country (India) and employs a capabilities approach to study industry and firm response to the strengthening of patent law. The proprietary-product-process grid (Fig 2) developed by Forbes and Wield (2002) is used for analysing technology paths taken by Indian firms in response to the emerging TRIPS regime.

Analysis of Indian pharmaceutical industry response to patent law strengthening reveals that firms have adopted an ambidextrous capability development approach (O'Reilly and Tushman, 2004; Tushman and O'Reilly, 1996). Indian firms have aggressively entered the generics market in advanced regions like US and Europe exploiting existing capabilities in process R&D while in parallel firms have invested in explorative capability development in innovative areas of pharmaceutical R&D such as new chemical entities and new drug delivery systems.

According to March (1991) exploration includes search, variation, risk taking, experimentation, discovery and innovation while exploitation includes refinement, choice, efficiency, implementation and execution. Thus, ambidextrous capability development approach has allowed Indian firms to exploit strengths of existing process R&D capabilities and at the same time to develop innovative R&D competencies. This response by Indian industrial firms has important managerial and policy implications for firms and industries in other developing countries which are facing the same TRIPS challenge.

Sections 2-4 introduce the key background, section 2 presenting the characteristics of the Indian pharmaceutical industry, the focus of this research. Section 3 focuses on the various issues related to the patent system, illustrating differences between the evolution of patent systems in advanced and developing countries. It also discusses the Trade Related Intellectual Property Rights agreements (TRIPS) and its consequences on patent regulation around the world. Section 4 reviews the literature regarding changes to patent systems and impacts on the domestic pharmaceutical industry in different countries. Sections 5-7 go on to analyse transformations in Indian firms using three case studies, using strategic mapping techniques to characterise the R&D trajectories and learning strategies of these firms. Section 5 introduces the three cases, of leading Indian firms, which are analysed and discussed in section 6. Section 7 presents some conclusions

2 The Indian pharmaceutical industry

The Indian pharmaceutical industry is the thirteenth largest in the world in terms of market output; accounting for a market of about US$ 2.5 billion (Ramani, 2002). It is ranked as the most advanced pharmaceutical industry amongst developing countries and one of India's best science-based industries. The Indian pharmaceutical industry has developed wide ranging capabilities in the complex field of drug process development and production technology. It is well ahead of other developing countries in process R&D capabilities and the range of technologically complex

medicines manufactured. The Indian pharmaceutical industry comprises 250 large units which include public sector, Indian companies and foreign subsidiaries and 8000 small scale units. These 250 large units have close to a 70% share of pharmaceutical activity and therefore dominate the Indian pharmaceutical sector

The Indian government adopted a new Patents Act in 1970, which laid the foundations of the modern Indian pharmaceutical industry. It removed product patents for pharmaceuticals, food and agro-chemicals, allowing patents only for production processes. The statutory term for production processes was shortened to five years from grant or seven years from application. The 1970 Patent Act greatly weakened intellectual property protection in India, particularly for pharmaceutical innovations. It started the era of reverse engineering where firms developed new products by changing their production processes. The availability of trained manpower, comparative ease of imitation and a strong chemistry base among Indian research institutes supported the manufacturers and gave the Indian pharmaceutical industry its current profile.

A number of quantitative studies have shown that the abolition of product patents in chemicals and pharmaceuticals facilitated the development of local technological capability in Indian pharmaceutical firms (e.g. Fikkert, 1993; Haskar, 1995; Kumar and Saquib, 1996)They have shown incredible skills in reverse engineering R&D and now account for 70% of bulk drugs and 80% of formulations produced (Hamied, 1993). By 2000 out of the top ten firms, in terms of market share, six were Indian. (OPPI, 2001). Thus the Patent Act of 1970 and government investment in the drug industry infused life into the domestic pharmaceutical industry. Indigenous capability development in the Indian pharmaceutical industry represents one of the most successful cases of self reliant development in knowledge based industries from developing countries.

However the signing of WTO agreements has put the Indian pharmaceutical industry at the threshold of a major transformation. The 1999 Patents Act strengthens patent protection along the lines specified by the TRIPS agreement. It introduced the recognition of product patents for pharmaceuticals, food products, agro chemicals and micro organisms. Among other changes, increases in the life of patent from the existing seven years to 20 have important implications for drug related healthcare issue.

For many decades intellectual property rights issues have been contentious. Now with the signing of the TRIPS agreement, they have become highly debated and controversial.

3 WTO and Patents – Trade Related Aspects of Intellectual Property Rights

Over the years advanced countries have strengthened their patent system whereas developing countries, with different needs and priorities, set up weak patent laws or reduced the strength of their patent systems. The TRIPS agreement is now instrumental in universalising the standards of intellectual property rights all over the world, framing equal 'rules of the game' for advanced as well as developing countries. It is the most important instrument to date concerning intellectual property protection. It covers the seven IPRs: copyright and related rights, trademarks, geographical indications, industrial designs, patents, layout-designs of integrated circuits, and undisclosed information.

3.1 Strength of Patent system and its economic implications

The broad argument put forward in support of a strong patent system relates to the issue of development and economic growth. Researchers claim that there is a tendency in industry to under invest in R&D and patent protection is one of several alternatives of appropriation that act as an encouragement for industry to invest in R&D. Therefore intellectual property rights provide an incentive to spur innovation (Kanwar and Evenson, 2003; Arrow, 1962).

Mazzoleni and Nelson (1998) summarise four broad theories put forward to explain the purpose of patents: patent protection motivates inventions, induces development and commercial inventions, promotes disclosure of inventions, and enables orderly development of broad prospects. It is argued that the strong patent system stimulates innovation by granting the innovator a limited period of exclusive control of the right to use, manufacture and sell the innovation. A patent affects invention and innovation principally through its effects on the rate of imitation. If patent protection and the resultant period of exclusive rights delays imitation, that would be a stimulus for firms to invest in R&D. However Mazzoleni and Nelson (1998) point out that the effectiveness of patent protection varies from industry to industry and in most industries patents are not an important incentive for firms to invest in R&D. It is also argued that patent incentives to innovation will be at the expense of society as the exclusive rights conferred by the patent system enables the innovator to charge monopolistic prices during the lifetime of the patent (Arrow, 1962; Nordhaus, 1962; Scherer, 1972).

IPR and developing countries

In the context of developing countries arguments about the influence of patent systems focus on foreign direct investment, technology transfer and trade.

It is argued that the stronger patent systems promote technological development by encouraging the acquisition of technology through market mediated mechanisms like technology licensing and foreign direct investment (Ferrantino, 1993; Smith, 2001). The fear of imitation and reverse engineering will prevent the transfer of technology in the case of a weak patent system.

Another important argument put forward in support of strong patent systems is that it promotes technology transfer through MNCs establishing R&D subsidiaries (Ferrantino, 1993; Mansfield, 1994). However Kumar (1996) suggests that availability of abundant trained low cost human resources and scale of ongoing R&D in the specialised knowledge fields of MNCs appear to be more important considerations for location of R&D than strength of the IPR regime.

The arguments supporting weak patent regimes argue that the weak protection of IPR helps cheap acquisition of technology through imitation or reverse engineering. Several studies of East Asian countries have pointed out the importance of non market mediated mechanisms like imitation in facilitating firm level technological learning (Hobday, 1995; Nelson and Pack, 1999; Lall, 2000; Amsden, 1989).

TRIPS agreement and its implications

The broad regulatory framework advocated by the TRIPS agreement will now guide and control the pharmaceutical industry in WTO member countries. In the case of pharmaceuticals and agro chemicals, patents will now be granted both for products and processes for inventions in all fields of technology, subject to the classical criteria of patentability i.e. novelty, non obviousness (or inventive step) and usefulness (or capability in industrial application)The patent term will be twenty years from the date of application, applicable to all members of the WTO. Importantly in the case of a dispute on infringement, the responsibility of proving innocence lies with the accused rather than in proving the infringement of the accused by the patent holder.

The TRIPS agreement became effective on 1st January, 1995. All pharmaceutical inventions for which patent applications were sought in any WTO member nation from 1994 onward have been covered by TRIPS obligations. In sum, all developing countries had to make available patent protection for pharmaceutical inventions from 1995 onwards. For developing countries these changes in patent regulations are of

key importance given the well documented relationship between patent, pharmaceutical products and health care policy.

4 Patents and the pharmaceutical industry

The pharmaceutical industry is among the most R&D intensive, measured by the percentage of sales devoted to such activities (PhRMA, 2004). This industry is significantly different from other high tech industries in that the R&D process has different phases, all stringently controlled by regulation, therefore taking 10-15 years from initial discovery to commercialisation. Pharmaceutical R&D is a very costly and risky process. Effective IPR protection is seen by the pharmaceutical industry as critical to recoup its large R&D expenditures. Patents have the ability to provide strong appropriation and profit maximisation by conferring limited monopoly rights to inventors. So the strength of the patent regime plays an important role in pharmaceutical firm's strategic decision making.

Most developing countries have built domestic pharmaceutical industries by adopting weak patent laws which provide protection only to production processes, not products. This allowed the manufacturing of the same product albeit with small modifications in production processes, starting the trend of reverse engineering in developing countries. On the basis of reverse engineering countries developed domestic pharmaceutical industries. Countries such as India and China have developed enough capability to produce active pharmaceutical ingredients and are now exporting drugs to other developing countries as well as to the highly regulated generic markets in advanced countries.

Now due to the TRIPS agreement, for the first time all countries are required to provide protection to both process and product inventions. This strengthening of patent law will certainly restrict reverse engineering and imitative R&D. Absence of product protection played a crucial role in the development of the domestic pharmaceutical industry and will be severely affected by TRIPS (Watal and Mathai, 1995).

The Indian pharmaceutical firms will not be allowed to reverse engineer new technologies or molecules without formal licenses from patent holders. This means that a main source of molecules for Indian industry will be blocked. Most of MNC pharmaceutical firms who hold the patents for new technologies or molecules have already established a presence in the Indian market and those who have not are preparing plans to enter the Indian market. The challenge facing the industry is to make a transition from the era of protectionism to an era of global competition.

4.1 Implications of strengthening the patent law and its effects on pharmaceutical industry

As described in section 1, pharmaceutical industries in developing countries have been the subject of a range of empirical studies on the influence of patent regime strengthening, focused on socio economic issues like pricing of the drugs and welfare cost; the link between strengthening of the patent system and technological development; and, the effects of strong patent systems on output and trade performance. But not enough attention has been paid to the impact of changed patent law on learning processes involved in building technological capabilities in pharmaceutical firms from developing countries and resultant responses from firms to transform their competencies.

Most research examining the effects of changes in patent law on pharmaceutical industries has focused on investigating the link between strengthening the patent system and technological development of pharmaceutical industries (Sequeria, 1998; Kanwar and Evenson, 2003). For instance Sequeria (1998) found that in general a strong patent system did not influence the development of production capabilities but had a marginal influence on the rate of accumulation of innovative capabilities through reorienting the 'culture' of the industry towards attaching greater importance to innovation.

Some studies have analysed the effects of patent system in output and trade performance of the industry. In the case of Italy (Weisburst and Scherer, 1995) and Hungary (Felker et al., 1997) bulk pharmaceutical production growth rate declined after the introduction of a strong patent system. In the Italian case the modest trade surplus in pharmaceuticals of $40.6 million in 1979 was converted into a trade deficit of $827 million by 1988 (Challu, 1995) and within a decade of strengthening the patent regime Italy lost domination over its drugs export market to other countries. Studies have consistently shown that strong patent systems are associated with increasing foreign firm market share.

Similarly Madanmohan and Krishnan, (2003) suggest that in the case of Indian pharmaceutical firms response to changes in patent law, the predominant strategy of Indian firms is to build capacity to achieve scale economics while the other preferred strategy is to stabilise and control the environment through developing alternative technology paths.

In the case of Indian pharmaceutical firms the important constituent of alternative technological paths is innovative process and product R&D. Therefore this research focuses on the learning processes adopted by Indian pharmaceutical firms to

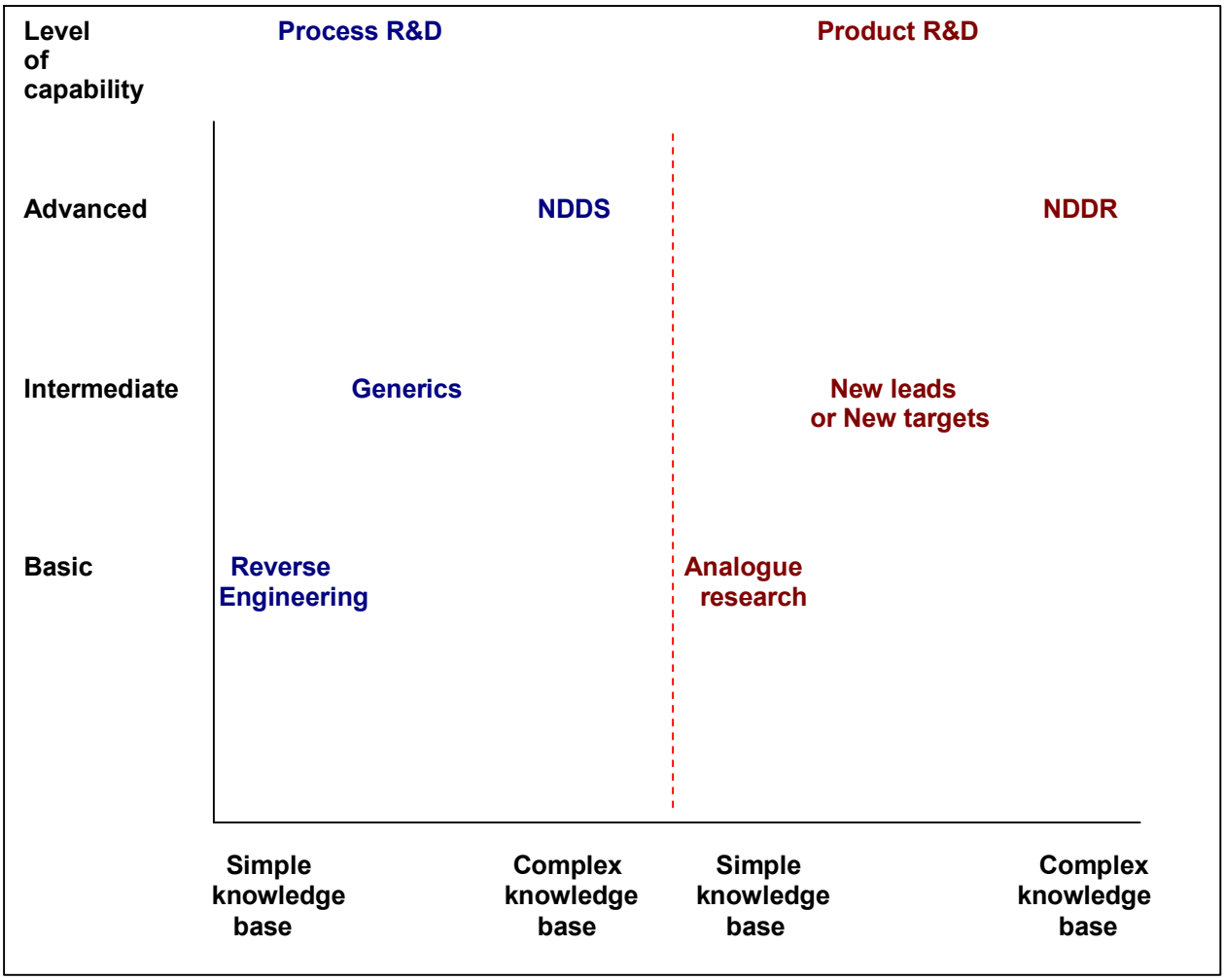
transform from imitative R&D to innovative R&D as a response to changes in patent law.

4.2 The challenge of innovative R&D

Indian pharmaceutical firms are applying different adaptive strategies particularly vertical integration, capacity addition, brand acquisition strategy, marketing channel integration strategy and R&D integration strategies as a response to change in patent law (Madanmohan and Krishnan, 2003). However, the most ambitious and challenging strategy is to develop new competencies for innovative R&D. In the pharmaceutical industry innovative R&D involves new chemical entities or new drug delivery systems. This represents an enormous challenge for firms given the infrastructural and financial resources involved in innovative R&D and more importantly the difference of knowledge bases involved in innovative and imitative R&D.

The fig 1 presents our classification of the knowledge base and respective levels of capability in process and product pharmaceutical R&D, built as a means of analysing the Indian pharmaceutical industry. It maps the changing R&D skills and capabilities of innovative Indian pharmaceutical firms.

Fig 1 Classification of process R&D and product R&D and the Indian pharmaceutical industry



In the case of pharmaceutical R&D, process and product R&D capabilities can be differentiated on the basis of the complexity of knowledge base which can be characterised as basic, intermediate and advanced levels.

Basic level innovative capability is taken as the ability to make minor adaptations to production and assimilate technology (Bell and Pavitt, 1993). Intermediate innovative capability is the ability to generate incremental technical change in product design, quality and production processes and the ability to search and evaluate external sources of technology. Advanced innovative capability is the ability to generate new product and process innovations. Knowledge base can be categorised as simple and complex based on the nature of technological challenges involved in development of products and the capabilities required to develop those products.

In the case of process R&D, the capabilities in reverse engineering, generic R&D and new drug delivery systems are mapped in figure 1 as basic, intermediate and innovative. Reverse engineering involves copying the manufacturing process using

indigenous sources of technology while generic R&D includes producing the product with non-infringing and innovative processes. New drug delivery systems (NDDS) involve the development of technology to introduce a drug at diseased site in a novel way.

In the case of product R&D analogue research, new targets or new leads and original NCE research can be characterised as basic, intermediate and advanced level capabilities.

The distinction between the ability to produce a product by imitation or ability to copy technology or use the given technology and capability to generate it or create and change technology, have profound implications in pharmaceutical R&D. The process of technological learning and of progressing from imitation and reverse engineering to establishing a genuine indigenous innovative capability must now be done differently from the past.

In the new environment, Indian firms adopted an ambidextrous capability development approach to develop new competencies, as we illustrate below using a grid divided into four quadrants based on product-process-proprietary dimensions that provides a framework to track the technological strategies of firms (fig 2). Proprietary capability comes from knowledge that is distinctive to the firm. The test of proprietary knowledge is whether or not it permits the firm to add value ahead of its competitors. In some cases this proprietary capability takes the form of intellectual property formally owned by the firm: patents, trademarks, designs, copyright.

In the case of pharmaceuticals a 'patentable' product or process certainly allows value addition in a firm's portfolio compared with competitors and therefore in the grid the proprietary dimension for pharmaceuticals takes the form of process or product patents formally owned by the firm. In the grid capability to manufacture bulk drugs or API (active pharmaceutical ingredient) will occupy the process- non proprietary quadrant while branded formulations will represent the product non proprietary quadrant. The manufacturing of active pharmaceutical ingredient is basic ability to produce the drug in powder or raw form while the branded formulation involves preparing the drug in different dosage forms. Generic drugs in advanced markets like the US and Europe occupy the process-proprietary grid whilst new chemical entities or new drug delivery systems will occupy the product-proprietary quadrant. Generic R&D involves the development of product with non-infringing and novel 'patentable' process and which allows firm to add value in comparison to competitors. New chemical entity development involves the ability of the firm to conduct research and develop innovative patentable drugs in form of new therapies or improvement in current therapies as a cure for diseases while new drug delivery system (NDDS)

involves the development of technology to introduce a drug at a disease site in a novel way

Fig 2 Product- Process-Proprietary Grid (adapted from Forbes and Wield, 2002)

Product **Branded formulations** **II**	**New chemical entities** **New Drug delivery systems** **IV**
Process **I** **Bulk drugs** **(Active Pharmaceutical Ingredient)** **Non-proprietary**	**III** **Generic drugs** **Proprietary**

5 Indian pharmaceutical firms

The paper now reports on our investigation of the response of Indian pharmaceutical firms to the new IPR environment, focusing on three firms: Alpha, Beta, and Gamma. The three cases were chosen from a group of six firm case studies undertaken between 2000 and 2004. The primary data was collected through interviews with R&D presidents, senior scientists and IPR managers working in these firms. The secondary data is mainly based on annual reports, analyst presentations and business news magazines.

5.1 Alpha laboratories

Alpha Laboratories Limited, India's largest pharmaceutical firm, is ranked amongst the top ten generic companies in the world. Like other Indian pharmaceutical firms, Alpha's early focus was chemical synthesis, or reverse engineering of known compounds. Alpha rapidly developed a strong expertise in process R&D and prepared several dosage formulations of drugs with cheap alternative processes.

The changing dynamic of the domestic pharmaceutical market resulting from the emerging product patent regime prompted Alpha's globalisation strategy with the company's top management setting up a mission to move from a turnover of $300

million in 1993 to US$1 billion in 10 years. Alpha's major focus was the generics market in advanced countries and to cater to those markets the company began developing indigenous innovative production processes for drugs.

Generics strategy

In the 1980s Alpha began focusing on developing novel production process that would let it side-step other company's process patents. In 1985 Alpha found a novel way to manufacture the anti-ulcerant Ranitidine, the world's best selling drug and the generic version of 'Zantac'. However, the real breakthrough in process R&D came with the development of an innovative novel process for Cefaclor. The molecule was owned by a MNC firm through a patent the firm had obtained in 1979. Alpha started work on developing a new seven stage process for the production of Cefaclor in 1988. The number of steps involved in synthesis of product, their potential for hazardousness and associated cost made the product too expensive for the Indian market. Also the MNC firm had filed more than 70 patents for process improvements to protect the drug from generic competition. But after spending three years and nearly 2 million $US, Alpha emerged as the only other manufacturer of Cefaclor. Subsequently in 1992 Alpha started a joint venture with the MNC firm for the manufacture and supply of Cefaclor. This success proved important for Alpha's globalisation strategy and entry into innovative R&D.

Based on the globalisation strategy Alpha entered the US market in 1995. In 1996, Alpha acquired a New Jersey based firm and started a joint venture with another US based firm for marketing Ranitidine in US. Such agreements helped Alpha in establishing manufacturing operations in the US and allowed the company entry into US generic markets. More importantly, Alpha started applying for patents all over the world for innovative production processes developed indigenously by the company's R&D teams. This enabled Alpha to market almost a third of its major products internationally and maintain a steady increase in net foreign exchange earnings throughout the 1990s. The experience gained also developed the company's regulatory skills needed to obtain approvals for its products under the Abbreviated New Drug Applications (ANDAs) scheme in the US. Since 1995, it has filed for 127 ANDA and has received 81 approvals; the highest for an Indian company (see Table 1).

In 1998 Alpha established a 100 percent subsidiary in the US and started marketing products under its brand name. Within just four years of starting its US operations, Alpha touched the US $ 100 million mark in the US. By 2003, Alpha reached a position among the top 10 biggest players in the US generics market

Table 1 Alpha's generic product filings

Year	DMF (Drug Master Files)	ANDA
Till 1999	**16**	**49**
2000	**6**	**12**
2001	**8**	**15**
2002	**7**	**25**
2003	**9**	**26**
Total	**44**	**127**

Alongside the US, Alpha began spreading its operations in Europe. In 1995 it set up a manufacturing plant in Ireland and opened a subsidiary in the UK. In 2004 Alpha acquired the fifth largest generics company in France.

The success of Alpha's globalisation strategy is reflected in its world wide expansion. The company's products are now sold in more than 100 countries, manufacturing operations exist in seven countries and ground presence in 34 countries. In 2003, Alpha achieved annual turnover of US$ 972 million and registered robust growth of 27%. Overseas markets contributed 76% of total turnover, out of which advanced markets like USA/ Europe accounted for more than 50%.

The globalisation strategy allowed Alpha an opportunity to learn about the competitive practices required to succeed in intermediate markets. The globalisation of business has helped Alpha in deriving benefits of economies of scope and scale in larger markets, facilitated the expansion and diversification of its product portfolio and aided development of competencies in innovative research and regularity areas.

Innovative R&D

Alpha laboratory's initial forays into innovative R&D activities began in the early 1990s. Initial R&D effort was focused on formulating bulk drugs into dosage forms and on developing cheap processes to synthesize bulk drugs.

On the heels of its success with Cefaclor and roughly in tandem with the vision 2003 exercise, Alpha stepped up its R&D expenditures from 2% of sales to 5%. Alpha started establishing state-of-the-art multi-disciplinary R&D facilities in India. The company's new strategic intent was to ascend the research value chain and accordingly it began to establish capabilities in the areas of discovery research, delivery systems and clinical research.

Alpha decided to focus on NDDS (Novel Drug Delivery Systems) and NDDR (New Drug Discovery Research) as key anchors of innovative R&D. Alpha critically reviewed its R&D competencies and adopted a two stage approach, beginning with development of NDDS platform first, then NDDR. Thus development of capabilities in NDDS will act as a stepping stone to development of NDDR capabilities. Focus on NDDR/NCE (New Chemical Entities) is for long term value building and on NDDS for medium term growth.

Alpha gradually changed R&D focus from process R&D to new initiatives in NDDR and NDDS. Over the years Alpha has increased R&D intensity to 6 % of sales, showing consistent commitment towards innovative R&D (Table 2). It has emerged as one of the largest investors in R&D in the Indian pharmaceutical industry with R&D investment of $US 57.46 million in 2003.

In the last decade Alpha R&D investment gained momentum as company started funding basic research involved in finding new chemical entities through the revenues generated from generics.

Table 2 Alpha's R&D intensity and investment (Source: Annual Reports 1999-2003)

Year	R&D intensity	R&D investments ($US million)
1993-94	5.9	6.29
1994-95	5.1	12.62
1995-96	5.3	13.16
1996-97	4.3	15.24
1997-98	3.9	16.74
1998-99	3.6	16.91
1999-00	3.6	19.57
2000-01	4.2	26.54
2001-02	3.8	26.82
2002-03	5.2	39.78
2003-04	6.1	57.46

In 1999 Alpha registered its first success in innovative R&D with the development of once-a-day dosage for the Ciprofloxacin molecule. This improvement in dose administration promised greater patient-compliance compared to multiple dosages offered by the patent holder, a MNC firm and hence was a major step forward.

The development of the once-a-day formulation became Alpha's first major innovative R&D product. Alpha licensed the technology to a MNC firm for US$10million for further development and marketing in select markets. In 2004 the MNC successfully launched 500mg and 1gm once-a–day formulation in US, based on delivery technology platforms developed by Alpha, thereby triggering the milestone and revenue sharing payments.

Alpha's new drug discovery R&D focus now includes urology, anti-infective, respiratory, anti-inflammatory and metabolic disorders segments. By 2003 Alpha had 7 molecules in different stages of development.

Table 3 Alpha's R&D employee strength (Source: Annual Reports, 1999-2003)

Year	Total number of people	No. of people in R&D	Scientists
1994-95	4703	325	
1995-96	4478	380	
1996-97	6131	456	
1997-98	5655	443	
1998-99	5469	498	330
1999-00	5347	490	410
2000-01	5784	512	410
2001-02	6424	580	474
2002-03	6297	700	583
2003-04	6797	919	650

Over the years Alpha consistently increased its R&D strength by recruiting scientists from Indian as well overseas academia and industry (Table 3). It has also set up a US R&D facility to focus on three areas: clinical research, regularity affairs and to give commercial inputs on diseases, targets and compounds to be pursued.

Thus Alpha is aiming to achieve significant business presence in proprietary prescription products in advanced markets by 2012 and is therefore investing in innovative R&D by exploiting existing process R&D capabilities.

5.2 Beta Ltd

Beta is now ranked among the top ten companies in India and has developed comprehensive expertise in manufacturing and marketing of pharmaceutical and biotechnology products. Beta's product portfolio includes pharmaceuticals (bulk drugs and formulations), medical nutrition, agro-sciences and hospitals. Beta set up its first formulation plant in 1977 and established a bulk drug plant in 1983.

The turnover of Beta in 2003-04 was $US 160 million. Of that international sales contributed 57%, the European market contributing 37%, the US market 10% with remaining 10% from the rest of the world

Beta's post 2005 strategy is based on three dimensions: research and development; domestic business; and, international business. In 2000, Beta split the pharmaceutical business from the agro-chemical, IV Fluids and hospital business:

Beta Life Sciences and Beta Ltd. The aim of this restructuring exercise was to allow Beta Ltd to concentrate more on building skills and capabilities in the pharmaceutical business while Beta Life Sciences focused on managing businesses related to agricultural sciences and hospitals. The company is moving ahead with a business strategy which involves innovative R&D to move up the value chain in both the generics and biotechnology segments.

Generics strategy

Biotechnology is Beta's R&D thrust area and with three exclusive products in the market, the company has been the front runner in the biotechnology research. From the early 1990s, the company spent 20-30% of its total R&D budget on biotech. In 1995 Beta formed a joint venture with a German firm to manufacture hepatitis B vaccine and in 2000 launched its first biotech product, a hepatitis B vaccine. This joint venture helped the company to develop staff trained in biotechnology R&D and provided access to crucial know-how. In 2001 Beta indigenously produced a drug called erythroprotein (EPO) for severe anaemia. Erythroprotein was produced using genetic engineering methods, for the first time in India. However for Beta an important milestone in biotech R&D came with development of human insulin. In 2003, Beta launched human insulin, the first human insulin to be made indigenously by an Indian company. The company is fourth in the world – the first outside US and Europe – to develop, manufacture and market this life saving drug used in diabetes

Beta started targeting international markets in the late 1990s. It entered the UK market in 1998 by acquiring a UK based company and in 2003 acquired another UK based pharmaceutical company. Beta is also investing £1 million to up-grade the UK pharmaceutical plant as the company's largest overseas manufacturing base and a future manufacturing base for Beta's European operations. In the UK, Beta is now the largest Indian pharmaceutical company and ranked among the top 10 generic pharmaceutical companies.

In 2004 Beta took over the business of a German pharmaceutical company to enter Germany, the largest generic drug market in Europe. This acquisition gave Beta increased depth in product portfolio and helped the company strengthen its presence in European.

Table 4 Beta's generic product portfolio (Source: Annual Report, 2003)

Year	ANDA (Abbreviated New Drug Applications)	DMF
2001-02	1	2
2002-03	6	23
2003-04	10	7
Total	17	32

Beta recently launched its US operation by starting Beta Americas Ltd and now has its own marketing and regulatory teams based in the US. Beta's US strategy is based on launching formulation products through the ANDA route and by 2003 had filed 17 ANDA applications with USFDA (see Table 4). The focus is on ANDA rather than to file drug master files (DMF) as it doesn't intend to sell Active Pharmaceutical Ingredients (APIs) in US and Europe markets. Beta currently sells four products in the US – ranitidine, enalapril, bethanecol chloride and captopril.

Currently 80% of Beta's international business comes from the developed US and European markets, while 20% comes from the rest of the world.

Beta plans to make a foray into global markets on the strength of its biotechnology product portfolio. Building on these biotechnology capabilities Beta aims to develop competencies in genomics and proteomics to support its ambitious new drug discovery programme.

Innovative R&D

Beta set up its R&D centre in 1994 and entered the field of new drug discovery research in 1997From 1998, Beta has been consistently investing into its R&D activities and is one of the top R&D investors in the Indian pharmaceutical industry (see table 5).

Table 5 Beta's R&D intensity (Source: Annual Report, 1999-2003)

Year	R&D intensity	R&D investments ($US Million)
1998-99	10.9	10.27
1999-00	4.6	9.66
2000-01	7.2	8.94
2001-02	6.2	8.51
2002-03	6.2	9.527
2003-04	7.9	12.57

Although Beta embarked on its innovative R&D programme a little later than its major Indian competitors it achieved impressive results in the chosen therapeutic research area: anti-infectives. By 2003 Beta had 3 molecules in different stages of development.

Like other innovative Indian pharmaceutical firms Beta's innovative R&D strategy is based on using techniques of analogue research to find new chemical entities.

However, unlike other Indian companies, Beta has decided to focus only on the anti-infective therapeutic segment, as the main thrust area in new drug discovery R&D. Beta's drug discovery programme has yielded several lead molecules one of which, a broad spectrum antibacterial, has completed Phase I clinical trials and is entering the next phase of trials. Beta's has built in-house clinical research facilities and a sixteen-member team is working on further development phases to commercialisation. The team successfully undertook Phase III clinical trials for human insulin project according to international guidelines. The clinical research team has also successfully completed Phase I clinical trials as well as preclinical studies for Beta's new chemical entities.

Table 6 Beta's R&D employee strength (Annual Report, 2003)

Year	Total number of people	Number of people in R&D
2000-01	2300	220
2001-02	2700	300
2002-03	2805	350
2003-04	2928	400

To summarise, Beta is focusing on innovative R&D, biotechnology products, and internationalised business as pillars of its post 2005 strategy. Over the years Beta has consistently invested impressively in R&D and emerged as one of the top R&D spenders on Indian scene. It is tapping into the generics and bio-generics market, employing existing capabilities in chemical as well as biotechnology process R&D.

5.3 Gamma

Gamma has emerged as the first Indian pharmaceutical company to discover a new chemical entity and license it to a MNC pharmaceutical firm. In the last decade it has consistently ranked amongst the top ten pharmaceutical firms in India. Now the company has 15 manufacturing plants in India, 2 plants in UK and 1 in China. It has set up 23 subsidiaries for distributing and marketing pharmaceutical products in domestic and international markets. GAMMA which started as a bulk drug manufacturer in the 1980s, moved to a formulation-focussed company in early 1990s, upgraded itself as a US focused pharmaceutical company in the mid 1990s, and now evolving into 'a research based international company'.

GAMMA started as a bulk drug company and later moved into the formulations business. In 1986 it started operations on branded formulations and within a year launched Norilet, GAMMA's first recognised brand in India. Big success came with launching of Omez, Omezaprozole which GAMMA managed to launch at half the prices of other brands prevalent in the Indian market at that time. GAMMA successfully reverse engineered many popular patented drugs to expand its therapeutic presence and, GAMMA became the first Indian company to export bulk drugs or API to Europe within a year of its inception.

With India's shift from a process patent regime to the post-2005 product patent regime, the broad strategy of GAMMA is to develop new molecules for licensing through innovative R&D and target advanced markets for speciality generics products.

Generics strategy

GAMMA strengthened its Indian operation by acquiring a small Indian pharmaceutical firm in 1999 and merging with a subsidiary in April 2000. GAMMA post-merger was a fully integrated pharmaceutical company, covering the full spectrum of pharmaceutical products, which included bulk drugs, intermediates, finished dosages, chemical synthesis, diagnostics and biotechnology. The merger had primary aim of supplying APIs (active pharmaceutical ingredient) to the technically demanding markets of North America and Europe and the merged GAMMA gained entry into value added generics business in the regulated markets of APIs.

GAMMA began its major international operation by entering Russia through a joint venture with a local pharmaceutical firm in 1992 which GAMMA converted in 2002 into its 100% subsidiary. GAMMA started targeting the US generics market by building a state of art manufacturing facility in 1994. In three years it filed its first abbreviated new drug application (ANDA) in 1997 for Ranitidine 75mg tablets. Improving on that, in 1999 it submitted a Para IV application for Omeprazole. Para IV application signifies the patent challenge route involving a development of non-infringing process and invalidating existing patent to gain an exclusive marketing right for a limited period of time. But the big achievement of GAMMA's generics foray came in 2001 when it became the first Indian company to launch a generic drug, Fluoxentine with 180 day market exclusivity in US. As a result of market exclusivity GAMMA's international sale of Fluoxentine 40mg, a generic version of Eli Lilly's Prozac increased massively. The generic turnover touched $23.2 million for the third quarter of 2001, with Fluoxentine contributing 87% of these sales.

In January 2003, GAMMA launched 400, 600 and 800 mg Ibuprofen tablets in the US under its own brand name. Ibuprofen became the first generic product to be marketed under GAMMA brand name and thus represented a significant step in its efforts to build a strong and sustainable US generic business. Direct marketing of Ibuprofen was the first step in building GAMMA's fully fledged commercial organisation in the US market.

In 2002, GAMMA started its European operation by acquiring two pharmaceutical firms in UK. These acquisitions allowed it to expand geographically and gave company an opportunity to enter the European market.

By 2003 GAMMA filed 56 DMFs (drug master files) and 35 ANDA applications with USFDA, showing strong capabilities in innovative process R&D and regulatory management (see Table 7).

In 2004 GAMMA acquired a US based private generic company specialised in dermatology products giving it access to products and proprietary technologies in dermatology

Table 7 GAMMA' generic product filings (Source: Annual Report, 2003)

Year	DMF (API)	ANDA (Formulation)
Till 2000	**18**	
2001	**8**	**8**
2002	**14**	**14 (Para IV - 10)**
2003	**16**	**13**
Total	**56**	**35 (Para IV – 24)**

Innovative R&D

Recognising the importance of innovative basic research in the post 2005 Indian scenario, GAMMA built its Research Foundation in 1992, exclusively dedicated to research for new drug discovery. It was the first organisation in the Indian pharmaceutical private sector to begin basic research.

The companies which are part of GAMMA group commit sizeable resources to support this state of the art Research Foundation. For two years from 1991 to 1993 GAMMA invested heavily in building the physical infrastructure and from 1993 it started recruiting R&D staff. At the beginning, GAMMA's drug discovery research strategy revolved around analogue research and created initial success for the company. It has consistently increased the R&D intensity of the firm over the years but this gathered momentum in the early 2000s as it started spending over 5% of its turnover on R&D compared to the industry average of 2-3% (Table 8). During 2003-04 GAMMA increased its investment in R&D to about 10% of total revenue. This is the highest R&D investment to sales ratio in the Indian pharmaceutical industry.

Table 8 Gamma's R&D investment (Source: Annual Report, 1999-04)

Year	R&D intensity	R&D investments ($US Million)
1998-99	2.15	3.22
1999-00	2.69	4.15
2000-01	4.22	9.23
2001-02	6.29	20.76
2002-03	7.7	27.71
2003-04	10	39.75

GAMMA evaluated its R&D capabilities and hired scientists to fill knowledge gaps (see table 9). It focused on hiring fresh scientists to work in discovery R&D and identified Indian students studying abroad on doctoral and post doctoral courses as one of the main source of talent.

Table 9 GAMMA's R&D employee strength (Source: Annual Reports, 1998-2003)

Year	Total number of people	Number of people in R&D
1998-99		
1999-00	2100	229
2000-01		
2001-02	5500	500
2002-03	5852	725
2003-04		

GAMMA currently has 8 NCEs in various stages of development. Research is focused towards anti-cancer, anti-diabetes, cardiovascular drugs and anti infectives. It is pursuing the clinical development of three molecules on its own while a fourth molecule is now licensed for development by a Danish MNC. This is in line with GAMMA's strategy of investing in own discovery molecule up to Phase II and then pursuing licensing opportunities. Through this route it is building in-house capabilities for drug development as well as enhancing the value of new chemical entities.

In 2000, GAMMA set up a lab in the US dedicated to discovery and design of novel therapeutics. The primary aim of the lab is to conduct drug discovery using molecular genomics and proteomics approaches for next generation drugs.

GAMMA raised the funds for international expansion of R&D through IPO (initial public offering) in US. In 2001 it completed its US initial public offering of a US$132.8 million ADS (American depository shares) issue and listed on the New York Stock Exchange. The funds collected from US IPO were diverted into the international expansion of R&D

From 2004, GAMMA licensed molecules to MNC firms and these licensing agreements have also proved to be effective source of learning. Apart from financial gains these partnerships gave GAMMA an opportunity to learn new capabilities through joint working.

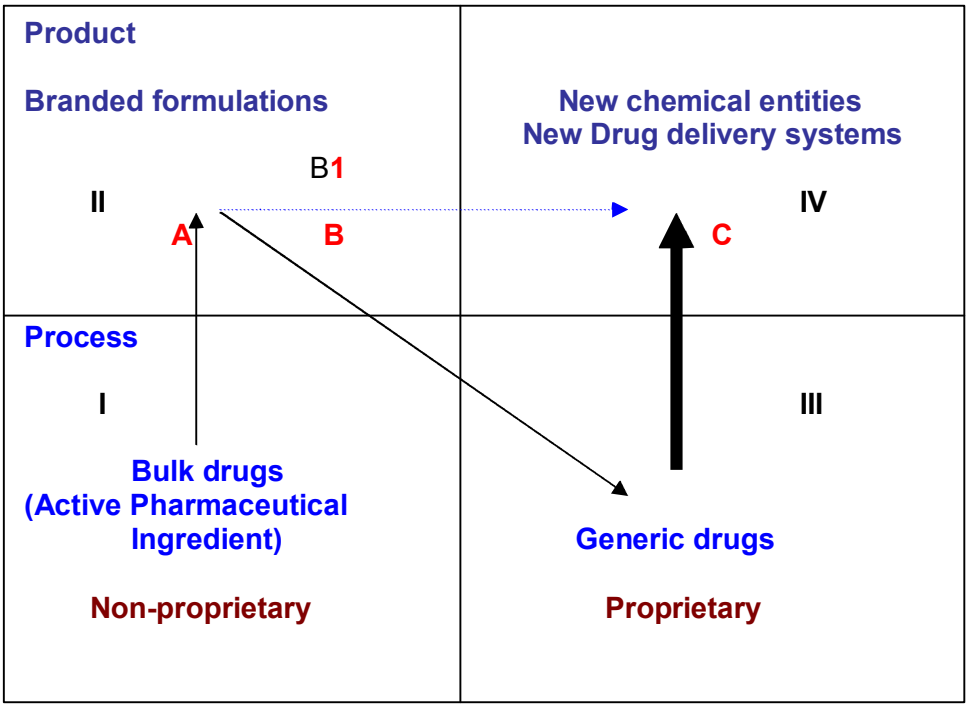
GAMMA initially started as a manufacturer of bulk actives and using process development skills it developed several bulk actives and finished dosages. Then it moved into generic products targeting the highly regulated but very profitable markets in advanced countries. From 1990s GAMMA started developing capabilities in innovative R&D under the leadership of core teams of experienced scientists, by hiring teams of fresh scientists to work with them, and expanding R&D overseas..

6 Technological paths of innovative Indian pharmaceutical firms

Our analysis of innovative Indian pharmaceutical firms' approaches to transform their R&D capabilities in response to strengthening of patent law suggests that these firms adopted a similar strategy of ambidextrous capability development but followed different technological paths.

The firms began by manufacturing bulk drugs and then followed it by developing capabilities to produce and market branded formulations for the domestic market (quadrant I and II). In terms of capability development this represents a move from the process-non proprietary quadrant to the product non-proprietary quadrant, represented by vector A in fig 3.

Fig 3 Proprietary- product –process grid



Generic product R&D, which occupies the process-proprietary quadrant (quadrant III), involves creating non infringing processes or in some cases invalidation of an existing patent. The non-infringing process gives the product a novel and innovative element and firms could apply for a patent for this new process. In innovative Indian pharmaceutical firms the development of innovative processes to create generic version of existing drugs forms the incremental capability development represented by vector B in fig. 3. The knowledge base underlying generic product R&D builds on organic and synthetic chemistry skills accumulated in reverse engineering but adds a patentable innovative element, providing value for the firm in comparison with its competitors. This represents the process-proprietary quadrant with examples like Alpha's process for preparing Cefaclor or Gamma's development of Fluoxentine 40 mg capsules and subsequent 180 day exclusivity in US generics market. This patentable innovative and novel process for known products created value for these firms over their competitors. Indian firms developed generic product R&D competencies by building on strong synthetic and organic chemistry skills and leveraging process R&D capabilities. Innovative process R&D not only helped these firms to build capabilities in different aspects of regulatory management such as strategic patenting of innovations and patent litigation but also developed the capabilities required to compete in the highly competitive generics market of the US

and Europe. Such movement towards innovative process R&D is exploitative in nature and represents incremental capability development.

In parallel to capability development in innovative process R&D, these Indian firms' invested in exploration of the risky and costly but highly profitable and innovative area of the new chemical entities represented by the product-proprietary grid quadrant (quadrant IV). However, innovative product R&D requires a different knowledge base and organisational capabilities compared to innovative process R&D. Such movement towards proprietary-product R&D (Vector B1 and Vector C) is exploratory in nature and represents the movement towards 'radical' capability development. Alpha followed the organic route of first entering in generics market and then investing in development of innovative product R&D capabilities. Beta focused on strengthening biotechnology capabilities and put effort into developing innovative R&D capabilities in only one therapeutic area. Gamma, on the other hand, employed the 'high risk high return' speciality generics model to exploit its existing process R&D capabilities and in parallel globalised its R&D set up to develop innovative R&D capabilities.

Thus the innovative Indian pharmaceutical firms responded to strengthening of patent laws by adopting what O'Reilly and Tushman, (2004) have called ambidextrous technology capability development paths. Generics product R&D is also creating economic resources for Indian firms to fund the investment in exploration of radical capabilities. It helped these firms to develop what Teece (1987) has termed complimentary assets such as competitive manufacturing, marketing and distribution networks and the ability to deal with regularity procedures involved in getting new products to the markets in advanced countries. Thus the exploitive use of process R&D has helped these firms to develop the complimentary capabilities required to compete in new product markets.

7 Conclusion and discussion

This paper has analysed issues related with patents and the impact the TRIPS agreement on the pharmaceutical industry especially in developing countries, using data from India. Changes in regulation as a result of the TRIPS agreement raise questions about survival and success of pharmaceutical firms in developing countries. This paper explored some of these questions by studying the impact of TRIPS on the learning processes in Indian pharmaceutical firms. The findings reveal that Indian firms responded with an ambidextrous capability development approach. Firms exploited existing process R&D capabilities to create 'complimentary assets'

while in parallel investing in developing capability for innovation. Entry into the generics markets of advanced countries helped Indian firms to overcome two extreme disadvantages: dislocation from frontiers of pharmaceutical research and innovation; and, distance from advanced markets. This approach enabled the Indian pharmaceutical industry to emerge as a net foreign exchange earner and chief exporter of cheap generic drugs to the USA, UK, CIS countries, Latin America, and Africa.

Analysis of the Indian pharmaceutical industry response to TRIPS suggests that these technological paths could be adopted by pharmaceutical firms in other countries. The forces of globalisation, such as WTO agreements, do impose restrictions on developing countries in terms of choice of policy selections and in firm level learning processes. However, as Westphal (2002) suggests, globalisation and changes in technology are also removing barriers to international trade and offering new opportunities for developing countries to pursue a strategy of export-led technological growth and development. The ambidextrous capability development model and licensing strategy in product R&D practised by Indian pharmaceutical firms is giving rise to a new pharmaceutical R&D business model which is characterised by a new division of labour and 'outsourcing' of pharmaceutical R&D functions.

This has implications, not only for reducing the cost of healthcare in advanced countries, but also for the development of domestic pharmaceutical industries in other industrialising countries. The pharmaceutical industry in some countries, such as Brazil and China, has also developed basic and intermediate capabilities in process R&D and manufacturing. Pharmaceutical firms in these countries could learn from the Indian model of ambidextrous capability development to move up the pharmaceutical R&D value chain. In this context, mechanisms adopted by the Indian pharmaceutical industry to develop more advanced levels of process and product capabilities, are applicable to further growth and development of pharmaceutical firms in other countries. Thus, ambidextrous capability development in the Indian pharmaceutical industry has important implications for pharmaceutical firms in other developing countries facing similar challenges from the TRIPS agreement.

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