Discontinuous learning as a response to disruptive regulatory change: The case of Indian pharmaceutical industry

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Abstract

Technological or institutional change has proven to be big cause for failure of established firms and history is full of such examples. The stregnhthening of patent laws as a result of TRIPs (Trade Related intellectual property rights) agreement represents such a institutional change for knowledge based industries from developing countries. This represents a radical break with the past in which developing countries typically had only weak levels of patent protection. In this context this research examined the learning processes involved in development of innovative capabilities in the Indian pharmaceutical firms as a response to strengthening of patent law.

This research shows that Indian pharmaceutical firms are responding to disruptive regularity change by developing competencies incrementally as well as radically. Indian firms are hiring the Indian scientists working overseas in multinational pharmaceutical R&D and collaborating with Indian and overseas research institutes and universities to build radical capabilities. This explorative and exploitative learning in Indian pharmaceutical firms have wider implications for firms from other developing countries facing TRIPS challenge.

Keywords: Innovation, capability, Pharmaceutical industry , R&D

Suggested track:
Knowledge creation and innovation, e.g., in R & D

1. Introduction

In the case of some events, such as fundamental regulatory reforms or radical technological advances, firms have to go through non–linear or discontinuous learning. Discontinuous learning normally involves a crisis and a strategy to turn the situation around whereas cumulative learning is learning that can take place along current trajectory under normal circumstances (Tushman and O'reilly, 1996; Kim, 1998). The example of large pharmaceutical firms' development of biotechnology capability as response to advances in molecular biology represents one such example

of discontinuous learning. In face of these disruptive challenges firms must learn not only new components of knowledge but also the new linkages between the various components of knowledge. Therefore such learning involves regeneration and development of organisational knowledge by combination of the accumulated knowledge with new knowledge. In developing countries, particularly where the state plays an orchestral role in industrialisation, the change in government policy or new regulation could impose a crisis in particular industry. With the advent of globalisation and resulting political and economical complexities, firms in developing countries are going through battles of survival and reinvention. Thus the challenge is more acute for firms in developing countries.

In the last decade a lot of researchers have concentrated on process of dynamic learning within firms, however this research has mainly focused on the firms from the advanced countries (e.g., Nonaka and Takeuchi, 1995; Leonard– Barton,1995, Kogut and Zander, 1992, Teece et al., 1997). In developing countries dynamic learning process is more difficult as it is shrouded in economic, political and social complexities. The previous research on developing countries mainly focused on building the minimum knowledge base essential for production and innovation activity (e.g. Kim, 1998; Bell and Pavitt, 1993). During mid -1990s some researchers like Kim, (1998), Dutŕenit, (2000) explored dynamic learning in firms from developing countries or newly industrialising countries. But in the developing countries literature, there is scarcity of research which examines the processes involved in discontinuous or dynamic learning.

This paper presents analysis of processes involved in dynamic learning from firms in developing countries by using Indian pharmaceutical firms' responses to disruptive regularity change. Due to WTO (World Trade Organisation) agreements for the first time in international law, all countries are now required to provide protection to both process and product inventions made in all fields of technology including pharmaceuticals and agro-chemicals products. In some developing countries like India and China the absence of product protection played a crucial role in the development of the domestic pharmaceutical industry and would be severely affected by it. As a result of this regulatory change, pharmaceutical firms in these countries will have to develop competencies in innovative R&D. Some Indian firms have made transformation towards innovative R&D albeit in small way and so used as case studies in this research. This dynamic and complex process of technological learning in the innovative Indian pharmaceutical firms was explored by developing a theoretical framework drawing on the strategic management literature and organizational theory literature focused on knowledge, learning and innovation. It explored the social

processes or mechanisms used for knowledge acquisition, transfer, assimilation and application. It also explored the relevance of prior knowledge base in a new environment and processes involved in building it.

The paper is organised as follows: Section 2 presents the research context which includes the effect of TRIPs on the pharmaceutical industries from developing countries along with the main characteristics of the Indian pharmaceutical industry. Section 3 reviews some of the literature on the capability accumulation process in developing countries and capability renewal in advance countries. Section 4 presents the theoretical framework, which guides the firm level research. Section 5 describes the methodology of the study and rationale behind using such a research design. Section 6 maps the technological paths adopted by Indian pharmaceutical firms as a response to change in patent law. It also discusses mechanisms adopted by Indian pharmaceutical firms to develop competencies in innovative R&D and covers the analysis of six innovative Indian firms. Conclusions are drawn in section 7.

2. Research context

World trade agreements, especially TRIPS agreements, are instrumental in setting uniform standards in intellectual property rights (IPRs) all over the world. The strength of the patent regime plays an important role in knowledge intensive industries and especially in the pharmaceutical industry. The pharmaceutical industry is significantly different from other high tech industries in that the R&D process is stringently controlled by regulation making it very costly and risky. In the pharmaceutical industry, patents provide strong appropriation and profit maximisation by conferring limited monopoly rights to inventors. As a result the strength of an IPR regime is an important issue for pharmaceutical firms but sensitive for countries. The access to technology is also relatively difficult in this sector. The new product development in pharmaceutical industry involves highly professionalized and specialised technological R&D activities. The learning process involved in development of pharmaceutical manufacturing and R&D capabilities is much more complex. The large multinational firms that dominate this sector develop significant proportion of knowledge and through patent effectively control the diffusion of knowledge. These firms conduct most of their activities at home or in other developed countries and prefer direct investment to licensing when producing abroad. Therefore most of the developing countries have built domestic pharmaceutical industries by adopting weak patent laws which allowed these countries to overcome the patent barriers in acquisition of patented knowledge. The degree of patent protection given to pharmaceutical products in the past was clearly related to the

development of the domestic pharmaceutical industry. Now similar to Indian pharmaceutical industry the pharmaceutical industries from these countries will be severely affected by TRIPs agreement.

Now due to TRIPS agreements for the first time in international law, all countries are now required to provide protection to both process and product inventions made in all fields of technology, subject to classical parameters. In the case of pharmaceuticals and agro chemicals, patents will now be granted both for products and processes for the inventions in all fields of technology; 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. This broad regulatory framework will now guide and control the pharmaceutical industry in WTO member countries.

The research presented in thesis differed from previous studies of the patent system in developing countries. It employed capabilities approach to study response of industry and firms to strengthening of patent law. Most of the literature on patent system in developing countries has a. focused on socio economic issues like pricing of the drugs and welfare cost (Lanjouw, 1996; Watal, 1996), b. investigated the link between strengthening of patent system and its effect on the technological development (Sequeria, 1998) and c. analysed the effects of strong patent system in output and trade performance of the industry (D'Este, 2001). This research focused on the impact of the strengthening of patent law on learning processes involved in technological capability development and analysed mechanisms used by firms to transform their capabilities.

2.2 The Indian Pharmaceutical industry

The Indian pharmaceutical industry represents a successful high technology based industry, which has witnessed consistent growth over the last three decades. It is the 14th largest in the world accounting for a market of US$ 2.5 billion (Ramani, 2002) and 4th largest market by volume. The Indian pharmaceutical industry has developed enough capabilities to make the country self sufficient in health care needs and its export ability makes it a strategic trade sector in the Indian economy. The Indian pharmaceutical industry exports generic drugs to CIS (Commonwealth of Independent States) countries, Africa, and recently to the highly regulated US and European markets. The Indian pharmaceutical industry is characterised by a low degree of concentration; a large number of firms with similar market shares, a low level of R&D

intensity ratios with a high level of brand proliferation. The need and incentive for innovation was undermined by low purchasing capability of the domestic market along with the ease of imitation and horizontal product differentiation; features that are representative of an industry behind the technological frontier (D'Este; 2001).

The growth of the Indian industry was very slow till 1970. The Patent Act of 1972 and government investment in the drug industry infused life into the domestic pharmaceutical industry. The Act removed the product patents for pharmaceuticals, food and agro-chemicals, allowing patents only for production processes. The statutory term was shortened to seven years on pharmaceutical patents and automatic licensing put in place. It started the era of reverse engineering where firms developed new products by changing their production processes.

During the last three decades the large private Indian pharmaceutical firms focused their efforts on reverse engineering oriented process R&D, and activity was limited to applying known knowledge, or to making small adjustments in the contents (Wendt, 2000). A few public laboratories under the Council of Scientific and Industrial Research (CSIR) also operated in pharmaceutical R&D, specifically imitative process R&D. Production technologies were well mastered and the lag period between the launch of a new product in its first market and India was thus reduced, in some cases as low as two years (Lanjouw, 1996). The Indian pharmaceutical industry represents a successful case of indigenous self-reliant development. But the objective of indigenisation rather than innovation made R&D in Indian pharmaceutical firms more insular, with a knowledge base firmly rooted in imitative reverse engineering process R&D. As a result Indian pharmaceutical firms have accumulated extensive knowledge in process R&D (synthetic and organic chemistry) but severe weakness in other scientific disciplines like medicinal chemistry and biology. The ease of imitation in reverse engineering further resulted in intense competition among Indian firms for market share, hampering the development of a collaborative web of networks of research institutes, academia and industry (Ramani, 2002). The lack of trust resulting from the weak regulatory environment further prevented the development of research networks.

The 1972 Patent Act therefore changed the pattern of competition towards volume / price led competition rather than traditional pharmaceutical competition based on the development of new medical treatments (Wendt, 2000). From 1970 onwards Indian pharmaceutical firms slowly started dominating the domestic market reducing the market share and influence of Western companies. Today the market share of domestic firms is around 60-70% compared to 10% in 1970 (Ramani, 2002). With the signing of WTO agreements, specifically TRIPS in 1994, the Indian industry and market

structure is poised to change. In a product patent regime, Indian firms will have to look for new sources of growth in the future and the biggest source will be productive R&D, which can deliver patentable innovations. The extensive literature that deals with the pharmaceutical industry is focused on the technological frontier firms in the developed world. But not enough attention is paid to the capability acquisition process by pharmaceutical firms from developing countries and to the changed patent law whose impact represents change in the scientific knowledge base for firms.

The following section briefly reviews the literature on capability accumulation in developing countries and then present theories related to knowledge creation capability in advanced countries.

3. Literature Review

The technological capability building is an issue that has been widely discussed in the last 20 years by different theoretical research traditions. Technological capability consists of stocks of resources needed to generate and manage technical change including skills, knowledge and experience and institutional structures and linkages (Bell and Pavitt, 1993). The research on developing countries mainly focused on the issue of long term process of technological capabilities accumulation in industries. This literature to larger extent discussed the capability development in developing countries referring to importance and difficulties associated various formal and non formal mechanisms of knowledge transfer. It pointed out that the firms in developing countries compete on the basis of production capabilities, largely acquired from elsewhere and reinforced by basic to intermediate technological capabilities related to a simple knowledge base (Lall, 1987; Bell and Pavitt, 1995)

However the increasing specialisation of knowledge is limiting the existing modes of formal and non formal technology transfer. The widening gap between kinds of knowledge and skill required to imitate or operate given technology and the kinds of knowledge required to create, generate or change technology has reduced the possibilities of acquiring the latter largely by experience in the former (Bell and Pavitt, 1993). In addition to that the fast pace of change in markets, technology and competition are making existing firm and industrial level capabilities redundant. Therefore in this new era the ability of firm to create new knowledge for innovation has become strategically important capability. The area of rebuilding or reconfiguring of capabilities has been addressed by strategic management literature (SML), however by focusing on innovative firms competing at technological frontiers in advanced countries. This research studied learning and capability building concerned with sustaining,

deepening and renewing of the existing innovative capabilities by focusing on most innovative firms competing at the technological frontier in advanced countries (Leonard – Barton, 1995; Prahlad and Hamel, 1990; Teece, et al., 1997, Nonaka and Takeuishi, 1995). Therefore there is a flourishing literature available on the firm specific factors that affect the success and failure of innovation in advanced countries, but there is no literature of equivalent scope and depth for developing countries (Bell and Pavitt, 1995).

The main difference is in the object of analysis, the firm in a developing country and its external environment as opposed to a firm in developed world and its environment. In case of firms from developing countries economic, political and social complexities makes the transformation of capabilities a challenging and difficult process. The availability and access to technical knowledge for firms from developing countries is an important issue and so literature on the developing countries is mostly focused on technical knowledge dimension of the building up of technological capabilities. However, Bell and Pavitt (1993) points out that the technical as well as organizational dimension of managing knowledge is crucial in building capabilities for innovation. The research on developing countries has to larger extent focused on the accumulation of stocks of technological knowledge, and much less on the specialization of knowledge bases and other firm level issues like coordination and integration of knowledge across organizational boundaries. Thus research focused on capability development in developing countries the interaction between organizational and technical dimensions of knowledge; a key issue in development of technological capabilities needs more attention.

Some of the researchers like Kim (1997), Dutŕenit (2000) and Figueirdo (2003) focused on the organizational and managerial issues involved in the development of innovative capabilities. These researchers mostly focused on firm level learning processes involved in establishing a base of technological knowledge that did not previously exist as opposed to renewing accumulated knowledge base or using that knowledge base in a different way. The change generating capabilities have become increasingly more complex and specialised as they have differentiated from the capabilities required to use them (Bell and Pavitt, 1993).

This research mainly investigated these change generating capabilities by focusing on learning processes used by Indian pharmaceutical firms to transform existing capabilities and develop innovative R&D competencies as a response to strengthening of patent law. Thus this research contributes to this neglected area of research in

developing countries literature by investigating transformation of capabilities and development of new capabilities in firms from developing country.

4. Theoretical Framework

The experience of today's developed and developing countries shows that the differentiated and path dependent processes of learning are the basis for changing of capabilities as they develop and so both historical and contemporary analysis is needs to be undertaken in order to understand the dynamics of these processes fully (Bell and Pavitt, 1993). Therefore theoretical framework focuses on both historical and contemporary analysis of processes involved in learning and change in Indian pharmaceutical firm.

In the case of some events, such as fundamental regulatory reforms or radical technological advances, firms have to go through revolutionary change or discontinuous learning to develop new competencies to adapt and change. This ability of the firm to learn, change and develop new competence is termed by Teece et al., (1997) as dynamic capability. According to Teece et al., (1997) dynamic capability of the firm refers to the capacity of firm to renew competencies so as to achieve congruence with changing business environments. It refers to firm's ability to make effective use of knowledge in efforts to assimilate, use, adapt and change existing technologies. Therefore it enables firms to create new technologies and to develop new products and processes in response to changing economic environment.

The review of strategic management literature suggests that the capability of the firm to renew or reconfigure technological capabilities is based on the ability of the firm to develop new competencies by acquiring new knowledge and integrating or combining it with existing knowledge bases (Kogut and Zander, 1992, Teece, et al., 1997; Cohen and Levinthal, 1990; Pavitt, 2002). In similar vein Henderson and Clark, (1990) show that in order to adapt and change as a response to such challenges, firms must learn not only new components of knowledge but also the new linkages between the components and so requires the reconfiguration of existing system of managing and creating knowledge in new way. In case of pharmaceutical R&D, the biotechnological change required new competencies in both research and process development, and subsequently it altered the relationship between different components of knowledge involved in pharmaceutical R&D. Therefore as a response to biotechnological change, large pharmaceutical firms not only developed new

competencies through discontinuous learning but also reconfigured existing system of managing and creating knowledge in new way.

The firm's ability to develop new competencies depends upon firm's learning capacity, that is, on firm's ability to acquire, create and disseminate new knowledge. Cohen and Levinthal (1990) refer to this organisational capacity to generate new knowledge as absorptive capacity and define it as a ability of firm to identify, assimilate and apply external knowledge. However they suggest that absorptive capacity tends to be cumulative and path dependent as it builds on prior knowledge base and experience which is firm specific. The prior knowledge base is an essential component in firm's learning ability or absorptive capacity as existing knowledge increases ability to make sense of, assimilate and apply new knowledge. Firms tend to move along particular trajectories in which past learning (by doing and by other mechanisms) contributes to particular directions of technical change, and in which the experience derived from those paths of change reinforces the existing stock of knowledge and expertise (Bell and Pavitt, 1993). The stock of past capabilities, routines provides the base on which firms develop the capabilities to cope with new technological change or new external environment: change is certainly possible, but it is conditioned by past. Patel and Pavitt (2000) shows that firms are, in fact heavily constrained by their prior competencies in the extent to which they are capable of accumulating competencies in new emerging fields.

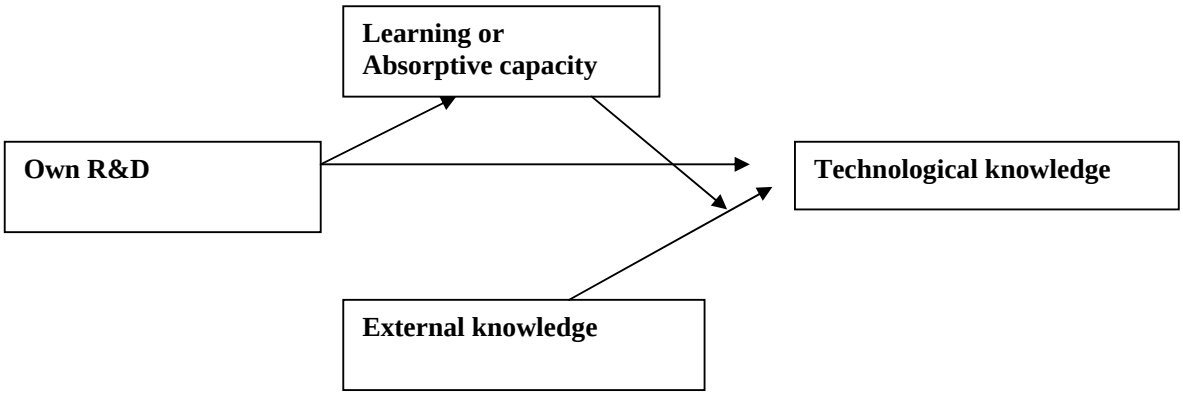

Fig.1: Model of sources of firm's technological knowledge (Source: Cohen and Levinthal, 1990)

Absorptive capacity also refers to the organisation's ability to exploit externally acquired or assimilated knowledge. Therefore an organisation's absorptive capacity does not simply depend on the organisation's direct interface with the external

environment but it also depends on the transfers of knowledge across and within subunits that may be quite removed from original point of entry. The structure of communication between the external environment and organisation as well as among sub units of the organisation is an important determinant of absorptive capacity (Cohen and Levinthal, 1990:132).

Thus an organisation's absorptive capacity or capability to learn depends on: prior knowledge base, that is, the sum of the abilities of all the individuals in organisation to recognise what they know and the way(s) in which they know; and mechanisms of knowledge transfer; the effectiveness with which information or knowledge is transferred externally between firm and external source as well as internally from one unit to another.

Absorptive capacity is thus a function of two separate but interrelated dimensions: a. the firm's ability to acquire the knowledge relevant to the new technological paradigm, and b. firm's ability to integrate external knowledge into existing capabilities.

Theoretical framework broadly focuses on practices or mechanisms associated with these two dimensions of absorptive capacity. So its focus is on the transformation of what happens in 'practise' as a response to change in external environment. It covers accumulation mechanisms which govern the content and location of stocks of knowledge in the firm; the transfer mechanisms which govern the balance between, internal and external sources of knowledge; it includes assimilation mechanisms which governs the way in which firms internalizes the newly accessed knowledge and is also focuses on application or deployment mechanisms like coordination and integration practices which govern the ways in which the stocks of knowledge or specialized knowledge bases are brought to bear within decision making.

The other approaches or frameworks focusing on the firm level studies in developing countries mostly concentrated on the differences in tacit and explicit knowledge or between individual, group and organizational knowledge and conversion of different knowledge types knowledge to create organisational knowledge (see for instance Kim, 1998; Dutŕenit, 2000). However varieties of innovation studies have shown limitation of such approach as categorisation of knowledge for innovation reflects a fair degree of overlap. The knowledge used in innovation does not come in watertight boxes but is mutable and multidimensional, precisely because of complex social processes by which it is generated and utilised (Faulkner, 1994). The review of organisational knowledge creation literature also suggests that the social processes that facilitate interactions among distributed knowledge systems within as well as across firms enable the creation of knowledge (Tsoukas, 1996). Therefore the focus

of theoretical framework is practices or processes involved in managing and creating knowledge in contrast to other approaches used for exploring firm based learning processes in developing countries.

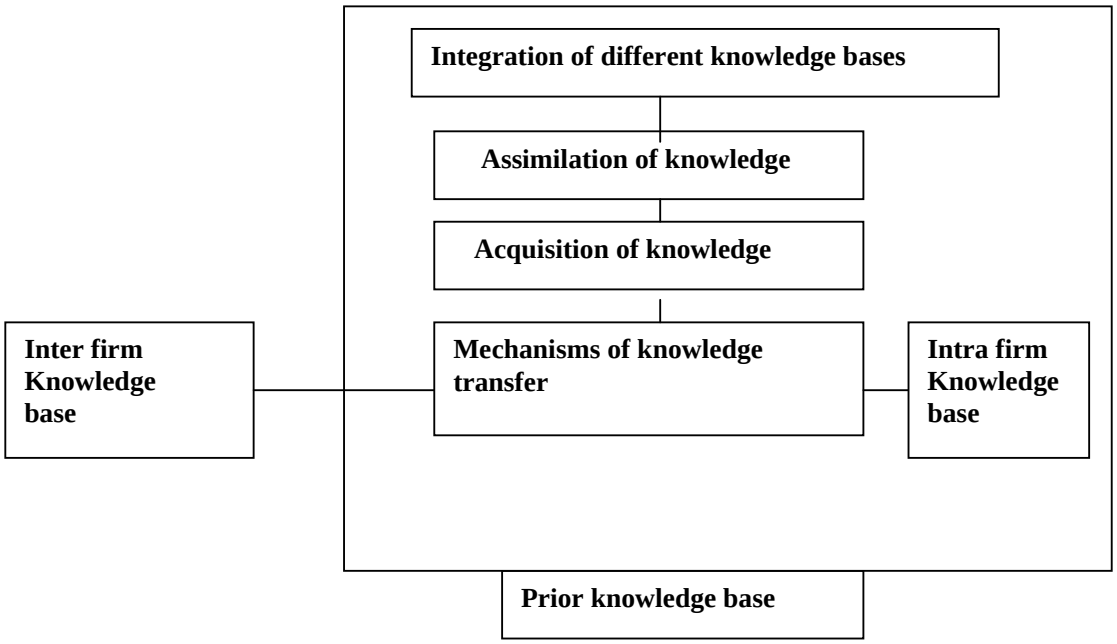

Fig. 2: Theoretical Framework

To summarise theoretical framework (Fig.2) focuses on the social processes or mechanisms used for knowledge acquisition, transfer, assimilation, and application. It also explores the relevance of prior knowledge base in terms of its usefulness in new environment and how firms have built it.

5 Research design

The main strategy used for the research is a case study method. This is because the nature of the research question requires a qualitative oriented research methodology. The research looks at firm level processes and so qualitative methodology like case study design is ideally suited for the exploration of such phenomenon (Yin, 1989). The interpretative methodology focuses on the ways by which we attach meaning to experiences and certainly helps to capture the richness and complexities of the issues at hand (Spender, 1996).

The multiple case study design was used and the cases were chosen on the basis of degree of innovativeness and strategies to transform themselves.

The realisation that the new patent regime will restrict, not end reverse engineering means that only a handful of pharmaceutical firms in India has started moving towards innovative activity, as the others do not yet perceive a need for innovative R&D in the immediate future. This has restricted the number and nature of firms chosen for the study. A number of firms (10 to 12) have invested in innovative R&D and have products in advanced stages, but for the purposes of analysis only those firms have been selected for the study which has filed patents in USA and India for new drug delivery systems or new chemical entities. Some of them have out licensed their molecule to the multinational pharmaceutical firms thereby demonstrating the capability in innovative research. The patent data was taken as the indicator of a firm's ability in innovative R&D (Table.1). However this data also has some limitations, as publication and patents were not a priority area until 1995, due to lack of trust in the case of the former, and lack of value in the case of the latter.

Table 1: Patent and licensing data on innovative firms (Source: Annual reports, 2003)

Firms	**No. of patents filed for**	
	New Drug delivery systems	**New chemical entities**
A		**9**
B	**3**	**4**
C	**2**	**2**
D	**5**	
E	**1**	
F		**2**

The qualitative data collection was carried out in two phases. In the first phase, interviews with academics, consultants and patent experts were conducted. The second phase involved interviews with R&D presidents and pharmaceutical scientists

from six innovative firms. In the end, a total of 33 interviews were conducted, and out of that 10 were conducted in the first phase, and 23 in the second phase.

The questionnaire used for the first phase was mainly focused on macro- economic issues such as the effect of changes in patent law on industry structure, market structure and emerging challenges. The firm level research was carried out in the second phase and the questionnaire was based on the different learning processes in the organisation as categorised by theoretical framework. The analysis of the empirical evidence was carried out by using various analytical techniques like pattern matching (Yin, 1994) and by building of analytical tables (Miles and Huberman, 1984). The interview transcripts were analysed by locating series of narratives around the transformation issues in each firm and from these, replicating patterns of learning processes were identified. These patterns were supplemented by secondary data which was collected from industry journals, industry association publications and annual reports of firms.

6. Technological paths of innovative Indian pharmaceutical firms

This section reflects on the paths taken by innovative Indian pharmaceutical firms' to transform their R&D capabilities in response to a strengthening of patent law.

The product/process and proprietary gird (Fig. 8.2) developed by Forbes and Wield (2002) is used for analysing the technology paths taken by Indian pharmaceutical firms in response to emerging TRIPS regime. The grid is divided into four quadrants based on product – process – proprietary dimensions and provides a framework to track the movement of firms from imitative R&D to innovative process and product R&D. 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 firm: patents, trademarks, designs, copyright.

In 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 patent 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 represents process – proprietary grid and 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. The new chemical entity 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 the diseased site in a novel way.

The innovative Indian pharmaceutical 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 process-non proprietary quadrant to product non-proprietary quadrant, represented by vector A in fig 3.

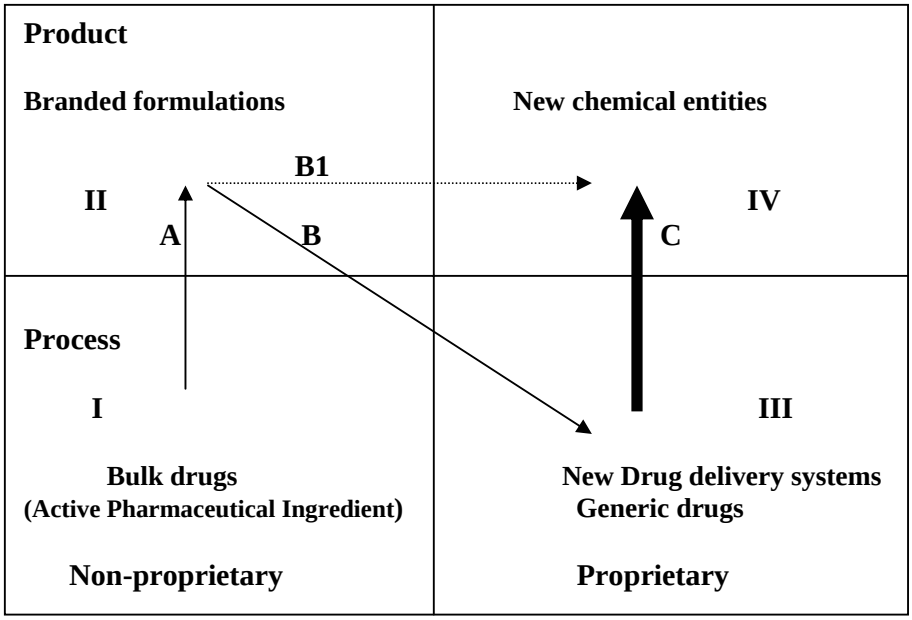

Fig.3 Proprietary- product –process grid (Ref: Forbes and Wield, 2002)

Generic product R&D which occupies process-proprietary quadrant (quadrant III) involves creating non infringing processes or in some cases invalidation of an existing patent. The non-infringing process provide the product a novel and innovative element and firms could apply for a patent for this new process. In case of 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 2. 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 process – proprietary quadrant and shown by examples like Ranbaxy's process for preparing Cefaclor or DRL's development of Fluoxentine 40 mg capsules and subsequent 180 day exclusivity for in US generic market. Both were the patentable innovative and novel processes for known products and created the 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. This 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 highly competitive generics market of the US and Europe. Therefore movement towards innovative process R&D is exploitative in nature and represents incremental capability development.

In parallel to the capability development in innovative process R&D, these Indian firms' invested in an exploration of risky and costly but highly profitable and innovative area of the new chemical entities represented by a product – proprietary quadrant in the grid (quadrant IV). However, innovative product R&D requires a different knowledge base and organisational capabilities compared to innovative process R&D. This movement towards proprietary product R&D (Vector B1 and Vector C) is explorative in nature and represents the movement towards 'radical' capability development.

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, (987) have called 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.

6.1 Process involved in dynamic learning to develop competencies in innovative R&D in Indian pharmaceutical firms

6.1a. Prior knowledge base:

Innovative Indian firms gradually created the capability for generic R&D by assimilating and improving on process R&D capabilities. The exposure to global markets, realisation of future regulatory changes and creative orientation to imitative research, all facilitated the development of the 'research tradition' in these firms. The influence of accumulated knowledge and strong chemistry skill is reflected in the R&D strategies employed by all innovative Indian pharmaceutical firms in product R&D. All these firms choose analogue research to venture in new drug discovery as this research strategy involves chemistry base in terms of modifying the molecular structure to produce the drug with more efficacy or less side effects.

Table 2: R&D intensity of innovative Indian firms (source: Annual Reports)

Firms	No. of R&D labs	R&D intensity (R&D spend % of sales)			
		2000	2001	2002	2003
A	5	4.22	6.29	7.7	10
B	3	4.2	3.8	5.2	6.1
C	2	7.2	6.2	6.2	7.9
D	3	1.80	2.16	1.63	3.9
E	1		2.41	2.30	3.09
F	2	1.45	3.50	4.41	6.52

At the same time these firms began increasing their investment in R&D from 1995 but this gained momentum in 2000, which resulted in building the absorptive capacity required in understanding the advances happening at the technological front.

The R&D intensity of Indian firms is consistently growing from 2000 although it is still much less compared to the R&D intensity of large pharmaceutical firms. But according

to some respondents, the cost of development of a drug in India could be a tenth of the international cost.

6.1b. Processes involved in acquisition of new knowledge

Innovative Indian firms started building innovative capabilities by hiring Indian scientists working overseas on innovative R&D in laboratories of multinational pharmaceutical firms. In India only a handful of scientists had experience in innovative R&D and these scientists became the 'guides' for the transformation.

According to the pharmaceutical consultant, these firms focused on R&D scientists and started investing in them (Fig.5.). The main constraint was lack of scientists trained in areas of medicinal chemistry and biology. To over-come this constraint, firms targeted returning post graduates and post doctorates from overseas universities. Currently around 20% of scientists working on innovative research projects have either trained at overseas universities, or have working experience abroad in MNC laboratories. Firm A's R&D president explains "Our target was returning post grads who have gone abroad to do either PhD or post docs, they were returning and were very good."

Table 3: Percentage of R&D staff to total staff (Source: Annual Reports)

Firms	Percentage of R&D staff / Total staff			
	2000	2001	2002	2003
A		9.09	12.39	
B	8.85	9.02	11.11	13.52
C	9.57	11.11	12.47	13.66
D	2.66	3.38	4.53	4.33
E			5.45	6.11
F		5.55	6	10

Collaborative R&D has emerged as one of key mechanisms for knowledge acquisition for Indian pharmaceutical firms. These firms didn't have the skills, infrastructure or

resources in-house to carry out certain functions and activities in innovative product R&D. In such cases these firms collaborated and interacted with the Indian as well as overseas research institutes, universities and got work done. Firm A's R&D president explains the rationale behind the collaboration with research institutes and universities,

"Drug discovery is very complicated and you may not have everything in house, we can't and we don't have everything in house so you have to. It's a sort of collaborative approach, a collaborative process."

6.1c Processes involved in assimilation of new knowledge

To create an environment for creative research, firms are changing their approach towards publication and have started to understand its importance for the growth of R&D. Scientists' publication in conferences is now valued and encouraged more. As one senior R&D scientist from firm D suggests, "publication is certainly an incentive to the scientist, there is no doubt about that and we also need to showcase our science, it stimulates scientists to think."

These firms are encouraging scientists to take training in new scientific tools or allowing them to pursue their academic ambitions while working in organisations. These firms have manufacturing and marketing centres all over the world including US and Europe and as a result, they could make the best research facilities accessible to their scientists. This allows scientists from these firms to pursue their academic interests and this are also encouraged by firms.

These firms set up separate R&D centres with 'state of the art' analytical instruments, totally dedicated to innovative R&D. These firms changed R&D structures, started new divisions to manage IPR, as well as established new disciplinary divisions and adopted 'matrix' style of project management in R&D. Some firms even opened laboratories in developed countries to make use of the knowledge spillover and attract research talent which was reluctant to shift to India. These firms concentrated on providing more experience to these scientists by giving them opportunities to design research projects, as well as freedom to work on chosen therapeutic areas.

To increase the quality of the interactions with international scientists, these firms have set up scientific advisory boards (SAB) which meet every quarter or half yearly to review the research. The SAB contains well known scientists from overseas as well as Indian academia. This forum provides an opportunity to scientists from these firms to

have closer interactions with these experts, and as one of the research scientist from firm A suggest 'all of which generates valuable feedback and built the confidence of researchers'.

6.1d. Mechanisms of knowledge transfer

Innovative Indian firms are building research networks by involving themselves in lot of joint projects with Indian as well as overseas research institutes, and research companies. These firms have set up different departments to scout opportunities for collaboration. During collaboration, these firms are sending their scientists to work in collaborators' R&D. This has changed the nature of the R&D in these firms; from insular in-house R&D, to the collaborative network model. The analysis of innovative Indian pharmaceutical firms' knowledge transfer mechanisms suggest that the collaboration with research institutes and universities formed an important constituent in innovative Indian pharmaceutical efforts to develop innovative capabilities.

6.1e Processes involved in integration of different knowledge bases

It was not enough to just hire the scientist or build new R&D centres, the difficult part was to increase the cross disciplinary understanding of the scientists. To achieve that these firms focused on increasing the interactions and communications between different specialised knowledge groups by building cross-disciplinary teams of scientists from different disciplines like biology, pharmacology, medicinal chemistry, intellectual property rights.

These firms are also using review meetings for increasing cross disciplinary understanding, as senior scientist from firm B suggests, 'when chemistry is being discussed, a biologist will be present, when biology is discussed, a chemist would be present and so a chemist will learn some biology, at least will appreciate what there difficulties are and vice versa'.

This firm level analysis of R&D in Indian pharmaceutical firms shows that Indian firms are developing the capability in innovative R&D by acquiring new components of knowledge and reconfiguring the architectural linkages between these components in a new way. The new components of knowledge were acquired by hiring new product R&D experienced scientists, adopting network model of collaborative R&D and increasing R&D investments.

7. Conclusion

The results shows that innovative Indian pharmaceutical firms have developed basic level of process R&D capabilities through imitative R&D and as a response to change in patent law these firms are moving towards the development of advance level process and product R&D capabilities. It emerges that Indian pharmaceutical firms are responding to disruptive regularity change by developing competencies incrementally as well as radically. Indian firms are moving incrementally by developing innovative processes for patent expiring drugs and targeting the generic markets in advanced countries. This allows Indian firms to exploit its process R&D capabilities which they have created in reverse engineering era and helps firms in building regularity and marketing capabilities in advanced markets. In terms of radical competence development, Indian firms are investing in exploration of risky and costly but highly profitable and innovative areas of pharmaceutical business; new chemical entities and new drug delivery systems. The exploitative use of process R&D capabilities is creating economic resources for Indian firms to fund the investment in exploration of radical capabilities.

This research also points out that Indian firms acquired capabilities in innovative R&D by hiring the Indian scientists working overseas in multinational pharmaceutical R&D and collaborating with Indian and overseas research institutes and universities. The Indian pharmaceutical firms' response provides an interesting insights and which have important managerial and policy implications for firms and industries in other developing countries which are facing TRIPs challenge.

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