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INNOVATIVE CAPABILITY DEVELOPMENT IN THE INDIAN PHARMACEUTICAL INDUSTRY

Dinar Kale

Development Policy and Practice

The Open University

Walton Hall,

Milton Keynes, MK7 6AA,

UK

Email: D.Kale@open.ac.uk

<http://dpp.open.ac.uk/people/Kale.html>

With increasing globalization, firms in emerging countries are facing turbulent business environment that is marked by liberalization of economic policies and regulatory changes. In such cases firms have to undertake dynamic learning to develop new capability. In developing countries the challenge for firms to develop new competencies is more complex due to political and economic complexities. This paper shows the key role of Diaspora scientists and collaborative models of R&D in development of innovative capabilities in the Indian industry. It also reveals that Indian firms transformed their business models as a response to changing external environment and raises questions regarding future development of the Industry.

Keywords: Innovation; capabilities; pharmaceutical industry.

1. Introduction

The transition to a new technology, market or regulatory regime is difficult for any public or private organization to manage. In the case of technological advances or fundamental regulatory reforms firms have to develop new competencies through dynamic learning (Tushman and O'Reilly, 1996). Dynamic learning normally involves a crisis and a strategy to turn the situation around, whereas cumulative or incremental learning is learning that can take place along a firm's current trajectory under normal circumstances (Tushman and O'Reilly, 1996; Teece et al., 1997; Kim, 1998). The example of the development of biotechnology capability by large pharmaceutical firms in response to advances in molecular biology represents one such example of dynamic learning (Henderson et al., 1999). In developing countries, particularly where the state plays an orchestral role in industrialization, changes in government policy or new regulations can impose a crisis in a particular industry. This creates a greater challenge for firms in developing countries to become more adaptable and respond to change more quickly which requires rapid and greater learning. Henderson and Clark, (1990) suggest that such change and adaptation involves not only learning new components of knowledge but also new linkages

between these and existing components and therefore requires reconfiguration of the existing systems of linkages. India's transition to strong regulatory environment due to Trade Related Intellectual Property Rights created crisis of existence for Indian pharmaceutical industry and their dynamic response forms focus of this paper.

In the last decade many researchers have concentrated on the process of technological learning within firms; processes by which firms build up, accumulate and sustain their technological capability (e.g., Kim, 1997, Leonard–Barton, 1995, Figueiredo, 2001; Nelson and Winter, 1982,).

In developing countries this technological learning is more difficult as it is shrouded in economic, political and social complexities. Previous research on developing countries focused mainly on building the minimum knowledge base essential for production and innovation activity (e.g. Kim, 1998; Bell and Pavitt, 1993). During the mid -1990s some researchers such as Kim, (1998) and Dutrénit, (2000) explored technological learning in firms from developing countries. These studies expanded Nonaka and Takeuchi (1995) concept of the conversion of individual knowledge to organizational knowledge to initiate a new generation of studies on firm level technology learning in developing countries. However, in the developing countries literature, there is a scarcity of analytical frameworks which examine the firm level processes involved in dynamic learning

This paper proposes a conceptual framework to explore the processes involved in dynamic learning focusing on firms in developing countries. The framework is used to explore the responses of Indian pharmaceutical firms to strengthening of patent laws due to the TRIPS agreement (Trade Related Intellectual Property Rights), a requirement of accession to the World Trade Organization (WTO). In some developing countries, particularly India and China, the presence of weak patent laws played a crucial role in the development of a domestic pharmaceutical industry and would now be severely affected by the TRIPS agreements. As a result of this regulatory change, firms from these countries will have to acquire new knowledge and combine that with accumulated knowledge to develop competencies in innovative R&D, as opposed to their current competencies in the replication and production of existing pharmaceuticals. This paper focuses on the Indian pharmaceutical industry.

The Indian pharmaceutical industry is a successful high technology based industry, which has witnessed consistent growth over the last three decades. The growth of Indian industry was very slow up until 1970. The Patent Act of 1972 and government investment in the drug industry infused life into the domestic pharmaceutical industry. The Act removed product patents for pharmaceuticals, food and agro-chemicals, allowing patents only for production processes. The statutory term was shortened to seven years for pharmaceutical patents and automatic licensing was put in place. It started the era of reverse engineering where firms developed new products by changing their production processes (Gehl Sampath, 2007).

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. In 2003, the top ten firms together covered around 34% of the total pharmaceutical market (an 8% increase in the concentration ratio from 1996). Six of those top ten firms were now of Indian origin and four were MNC subsidiaries (Ramani, 2002).

Regulatory challenge: Trade Related Intellectual Property Rights

In the beginning of 1990's the Indian pharmaceutical industry faced critical challenge from signing of the TRIPS agreement by the Indian government.

In 1991, the economy was liberalized and the pharmaceutical sector was de-licensed. Hot on the heels of liberalization, India announced its entry to the WTO and its intention to institute the intellectual property regulations required by TRIPS. In 1999, the Patent law of 1970 was repealed. The new Patent Act strengthened patent protection, by introducing the recognition of product patents for pharmaceuticals, food products, agro chemicals and micro organisms. It also significantly increased the life of a patent from seven years to twenty years.

With the signing of WTO agreements, specifically TRIPS in 1994, Indian industry and market structure is poised to change. In a product patent regime, Indian firms will have to look for new future sources of growth and the biggest source will be productive R&D, which can deliver patentable innovations. The TRIPS agreement with its requirement of strong patent laws is triggering change in the pharmaceutical industries of developing countries like India, which have grown on the basis of weak patent laws.

A number of Indian firms have made this transformation towards innovative R&D, albeit in a small way and these provide the case studies for this research. Five innovative Indian firms were studied to explore the processes involved in dynamic learning by using theoretical framework proposed in this research. The framework applied to these studies is based on absorptive capacity concept and focuses on the social processes involved in knowledge generation. This paper points out the importance of Diaspora scientists working in advance countries in innovative R&D capability development. It shows that Indian firms transformed their R&D business models as a response to changing external environment.

Significantly this paper shows that transformation of Indian firms followed similar trajectory as large MNC firms' response to biotechnology revolution. Indian firms transformed in-house R&D model to collaborative R&D model similar to large MNC firms and hired Indian scientists working in advance countries.

Advances in biological science and the advent of biotechnology made several biology based of the core competencies of existing pharmaceutical firms' obsolete (Henderson et al., 1999). As a response to these challenges, large global pharmaceutical firms acquired biotech capability by hiring star scientists, accessing new external sources of knowledge and investing in internal biotech R&D. These firms collaborated with biotech firms and in some cases acquired them and changed the in-house nature of their R&D to a collaborative model of the R&D.

Section 2 reviews the literature focused on technological capability development in developing countries while Section 3 concentrates on various concepts from organizational knowledge creation, organizational learning, and innovation management literature, showing the role of knowledge in developing capabilities for innovation. Section 4 describes the processes involved in dynamic learning in large pharmaceutical firms as a response to the biotechnological revolution. Section 5 presents the theoretical framework proposed for exploring the dynamic learning in firms from developing countries. Section 6 discusses methodology used in the research and Section 7 analyses the Indian pharmaceutical firms' responses to change in patent law using the theoretical framework. Section 8 concludes the paper.

2. Innovative capabilities in firms from developing countries

Technological capability consists of stocks of resources needed to generate and manage technical change including skills, knowledge, experience and institutional structures and linkages (Bell and Pavit, 1993). Research on developing countries is

mainly focused on the issue of the long term process of technological capability accumulation in industry. Technological learning involves processes by which firms build up, accumulate and sustain their technological capability and a number of studies have addressed technological learning in late industrializing countries such as South Korea, Taiwan and Latin America (Katz, 1987; Hobday, 1995; Kim, 1997). It is sometimes suggested that firms in developing countries have accumulated technological capabilities in particular sequences, moving through definable stages (Dhalman, et al., 1987). However, rigid ideas about sequences and stages may be misleading, especially at the firm level (Kale D, 2009).

Developing country literature emphasizes that 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, 1992). However the increasing specialization 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 a given technology and the kinds of knowledge required to create, generate or change technology, has reduced the possibility of acquiring the latter largely by experience in the former (Bell and Pavitt, 1993).

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 the developed world and its environment. Availability and access to technical knowledge for firms from developing countries is an important issue. Literature on developing countries is mostly focused on the technical knowledge dimension of the build-up of technological capabilities (Bell and Pavitt, 1993) and much less on the specialization of knowledge bases and other firm level issues for example coordination and integration of knowledge across organizational boundaries (Dutrenit, 2000). The process of knowledge specialization and the need to integrate knowledge across organizational boundaries refer to different aspects of the firm's activities. Due to this conflict Pavitt (2003) suggests that it is necessary for firms to strategically manage integration of different specialized knowledge across the organizational boundaries of the firm as a crucial process in building capabilities for innovation.

3. Managing knowledge within the organization

The knowledge based view argues that firms exist because they provide the ideal platform for the creation, transfer and application of knowledge (Spender, 1996; Tsoukas, 1996). There is an increasing understanding that knowledge allows the creation of capability and that this determines the ability to do things (Leonard-Barton, 1995) and so the manner of knowing or learning is as important as what should be known (Spender and Grant, 1996). According to Tsoukas and Mylonopoulos (2004) the knowledge based perspective on organization links two traditionally different domains: the skills that sustain organizational learning and a firm's competitive advantage through its idiosyncratic capabilities.

Central to the emergence of knowledge as a key resource is Michael Polanyi's distinction between tacit and explicit knowledge. Tacit knowledge is subjective and experimental and hard to formalize. Belief, perspective, mental models, ideas and ideals are examples of tacit knowledge. Explicit knowledge is objective rational knowledge and can be expressed in forms such as data, scientific formulas, specific actions and manuals. This distinction between different types of knowledge is often cited as the reason for distinguishing knowledge from other resources.

One of the key contributions towards the emergence of this focus on knowledge and its strategic role are the studies of organizational knowledge creation in Japan by

Nonaka and Takeuchi. Building on the distinction between tacit and explicit knowledge proposed by Polanyi (1966) and linking the resource and capability view of the firm with organizational learning literature, Nonaka and Takeuchi (1995) developed the model of the various ways in which organizations create knowledge. Organizational knowledge creation is seen as a capability of the organization. They postulate that the organization creates new knowledge through interactions between tacit and explicit knowledge, and through the dynamic conversion of knowledge between these two dimensions. Through this 'social conversion' process tacit and explicit knowledge expands in terms of both quality and quantity. Knowledge is transferred from individuals to the larger group in a spiraling process. This follows from the proposition that, although tacit knowledge is initially locked up in the heads of the individuals, shared experiences allows individuals to project themselves into each other's thinking processes. This 'SECI' (socialization, externalization, combination, and internalization) spiral represents the dynamic process, starting at the individual level and expanding as it moves through communities of interaction that transcend sectional, departmental, divisional and even organizational boundaries. Cook and Brown (1999) present a different model for organizational knowledge creation albeit based on a different view of the types of knowledge. They argue that tacit and explicit knowledge are two different forms of knowledge which complement each other but cannot convert into each other. They propose that individuals and groups can each possess explicit knowledge and tacit knowledge, giving four different categories of knowledge. However all four knowledge types can be mutually enabling in the pursuit of purposeful activity or 'active process of knowing'. New knowledge is generated as different knowledge types 'dance' together in the course of doing something.

These perspectives all propose that organizations have different types of knowledge and that identifying and examining these will lead to more effective means of generating, sharing and managing knowledge in organizations. However, Tsoukas (1996) characterized such perspectives as 'taxonomic' and argues that typologies of knowledge are marked by 'formistic' type of thinking as typologies are based on the assumption that observable systematic similarities and differences exist between objects of study. He further explains that as tacit and explicit knowledge are mutually constituted – they should not be viewed as separate types of knowledge. Tacit knowledge is a necessary component of all knowledge; it is not made up of discrete means which may be grounded, lost or reconstituted – tacit and explicit knowledge are inseparably related. According to Tsoukas (2001:976) organizational knowledge is the capability that members of an organization have developed to draw distinctions in the process of carrying out their work, in particular in concrete contexts, by enacting sets of generalizations whose applications depends on historically evolved collective understandings. Based on this perspective, Tsoukas (2001) suggests a 'constructivist' view of organizational knowledge emphasizing that the content of organizational activities or the social processes and practices surrounding these activities construct and create organizational knowledge. This supports Leonard-Barton's (1995) observation that firms nurture and create knowledge through certain activities which basically involve sharing of knowledge within the organization and the transfer and integration of knowledge across organizational boundaries.

Learning is a key process by which firms accumulate knowledge in order to compete; the process through which firms create knowledge and develop technological capabilities. Cohen and Levinthal's (1990) concept of absorptive capability can be seen as a measure of organizational learning, considering it is a set of collective

abilities developed through learning activities. As they point out these activities collectively constitute what we call a firm's "absorptive capacity". Spender (1996) points out that learning at collective level is the outcome of the interplay between conscious and automatic types of knowledge, and between individual and collective types of knowledge as they interact through collective social processes such as teamwork. Therefore organizational learning is a social process that creates organizational knowledge through various activities involving interactions between different knowledge bases, and it is not a sum of individual knowledge bases. Cohen and Levinthal (1990) argue that organizational learning is a function of an organization's absorptive capacity and its internal mechanisms within the firm that influence its absorptive capacity or ability to learn.

4 Transforming the identity of large pharmaceutical firms: the biotechnological turn

Advances in genetic and genetic engineering popularly known as biotechnology have profoundly affected the scientific and technological basis of the pharmaceutical industry and represent a dramatic shift in the '*scientific*' knowledge base of this industry (Henderson et al., 1999). Zucker and Darby (1997) referred to such advances as 'archetypical example of externally generated, incumbent skill obsoleting, discontinuous innovation' which can potentially replace incumbents (pharmaceutical firms) by entrants (new biotechnology firms). However, incumbent firms responded successfully to the technological challenge by transforming existing capabilities and developing new competencies.

The drug discovery pharmaceutical industry offers a case in which numerous firms have pursued a strategy of adopting a new technological trajectory by transforming existing technological identity and capabilities. According to Henderson et al., (1999) the molecular biology revolution and the response from firms reveals the detailed mechanisms of industrial transformation at firm and industry levels, with the co-evolution of scientific knowledge on one side and organizational capabilities, industry structure and institutional context on the other side.

The revolution in the life sciences changed the organizational and managerial aspects of drug research; it changed the internal structure of R&D by increasing emphasis on collaboration, publication and willingness to exploit external sources of technology (Cockburn, 2004). Large pharmaceutical firms focused on internal R&D transformation primarily by hiring new personnel, embracing new technology and incorporating these into existing structures. They promoted collaboration and joint ventures with university scientists and new biotechnology firms to augment internal expertise (Zucker and Darby, 1997). Nicholls-Nixon (1993) presents the absorptive capacity model to explain the use of internal R&D and technology sourcing linkages to develop the capabilities required in a new technological paradigm. The process of transforming an existing knowledge base is dependent upon a firm's absorptive capacity. This capacity has two important elements: a prior knowledge base and mechanisms for knowledge transfer. Nicholls-Nixon (1993) points out that large pharmaceutical firms developed new capabilities by investing in biotechnology related R&D activities and by accessing new external technological linkages. According to Galambos et al., (1998) some pharmaceutical firms used an incremental approach of working with biotech companies to develop in-house biotechnology capability, while other firms used the acquisition route. Supporting this observation Gamberdella (1995) explained that large pharmaceutical firms used different forms of linkages with universities and research institutes as mechanisms of knowledge

transfer to complement internal capabilities in biotechnology. He identified four types of linkages: research and/or joint development agreements with other firms, research agreements with universities, investments in the capital stock of biotechnology firms and acquisitions of biotech firms. Such changes led to the transformation of new drug discovery and development in large pharmaceutical firms from a totally in-house activity to a networked activity.

5. A conceptual framework for analyzing the firm level processes involved in development of competency for innovation

The current experience of both developed and developing countries shows that differentiated and path dependent processes of learning are the basis for changing capabilities as they develop. Both historical and contemporary analysis is needed to fully understand the dynamics of learning processes (Bell and Pavitt, 1993). Therefore the theoretical framework described here focuses on both historical and contemporary analyses of the processes involved in learning and change in Indian pharmaceutical firms.

In the face of events such as fundamental regulatory reforms or radical technological advances firms have to adapt and change by developing new competencies through dynamic learning. This ability of firms to learn, change and develop new competences is termed *dynamic capability* by Teece et al., (1997). According to Teece et al., (1997) the dynamic capability of a firm refers to its capacity to renew competencies so as to achieve congruence with changing business environments. It refers to a 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 develop new processes in response to a changing economic environment.

A review of strategic management literature suggests that the capability of a firm to renew or reconfigure technological capabilities is based on the ability of that firm to develop new competencies by acquiring new knowledge and integrating or combining it with existing knowledge bases (Teece, et al., 1997; Cohen and Levinthal, 1990). In a similar vein Henderson and Clark, (1990) show that in order to adapt and change in response to competency destroying challenges, firms must learn not only new components of knowledge but also new linkages between components and so reconfigure existing systems to manage and create knowledge in new ways. In the case of pharmaceutical R&D, the biotechnological turn required new competencies in both research and process development which consequently altered the relationship between the different components of knowledge involved in pharmaceutical R&D. Therefore as a response to the biotechnological turn, large pharmaceutical firms not only developed new competencies through dynamic learning but also reconfigured an existing system of managing and creating knowledge in a new way.

Cohen and Levinthal (1990) present a simple model depicting sources of technological knowledge generation in a firm (fig.1); its own R&D and external knowledge generated outside of a firm. A firm's ability to develop new knowledge through these sources depends upon its learning capacity, that is, on its ability to acquire, create and disseminate new knowledge. Cohen and Levinthal (1990) refer to this organizational capacity to generate new knowledge as *absorptive capacity* and define it as the ability of a 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 a prior knowledge base and on experience which is firm specific. This prior knowledge base is an essential component of a firm's learning ability or absorptive capacity as existing knowledge increases the 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 and routines provides the base on which firms develop new capabilities to cope with change in technology or external environment: change is certainly possible, but it is conditioned by the past. Patel and Pavitt (2000) point out 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.

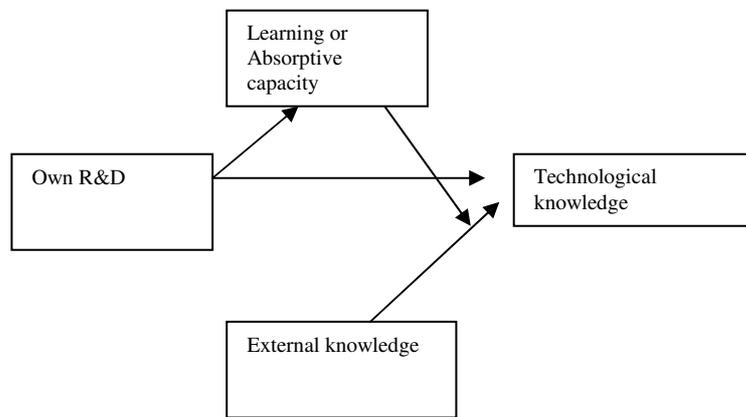


Fig.1: Sources of firm's technological knowledge (Source: Cohen and Levinthal, 1990)

Absorptive capacity also refers to the organization's ability to exploit externally acquired or assimilated knowledge. Therefore an organization's absorptive capacity does not simply depend on the organization's direct interface with the external environment but it also depends on the transfer of knowledge across and within sub-units that may be quite removed from the original point of entry. The structure of communication between the external environment and organization as well as among sub units of the organization is an important determinant of absorptive capacity (Cohen and Levinthal, 1990:132).

Thus an organization's absorptive capacity or capability to learn depends on its prior knowledge base, that is, the sum of the abilities of all the individuals in the organization to recognize what they know and the way(s) in which they know; and on mechanisms of knowledge transfer; the effectiveness with which information or knowledge is transferred 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. the firm’s ability to integrate external knowledge into existing capabilities.

The conceptual framework broadly focuses on practices or mechanisms associated with these two dimensions of absorptive capacity. Its focus is on the transformation of what happens in ‘practice’ as a response to change in the 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 internalize newly accessed knowledge and it 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.

Other approaches or frameworks focusing on firm level studies in developing countries have mostly concentrated on the differences in tacit and explicit knowledge or between individual, group and organizational knowledge and the conversion of different knowledge types knowledge to create organizational knowledge (see for instance Kim, 1998; Dutrenit, 2000). However various studies of innovation have shown the limitation of such approaches. Categorization 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 utilized (Tsoukas, 1996). The review of organizational knowledge creation literature suggests that the social processes that facilitate interactions among distributed knowledge systems within as well as across firms enable the creation of knowledge and this research explores these social processes. Therefore the focus of the theoretical framework is on the practices or processes involved in managing and creating knowledge in contrast to the other approaches used for exploring firm based learning processes in developing countries.

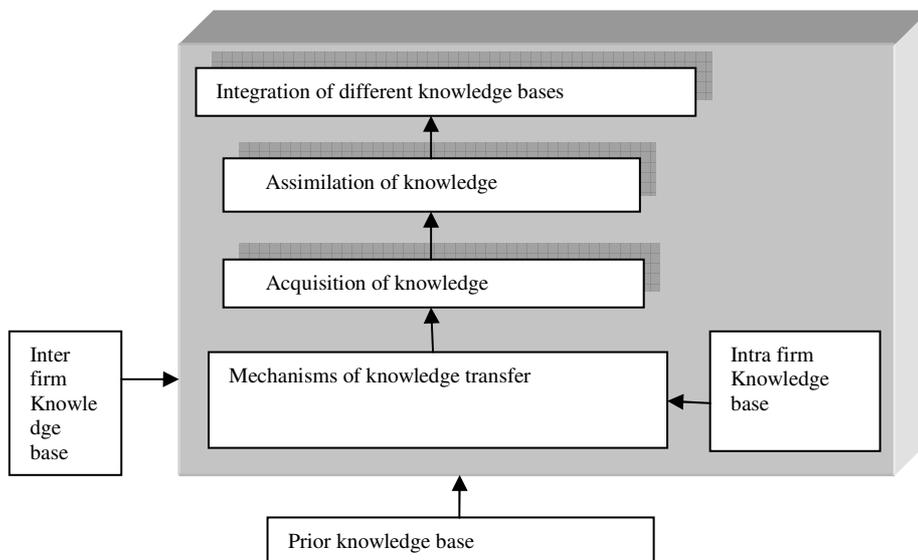


Fig. 2 Conceptual Framework

6. Research design

This research is focused on the social processes adopted by Indian pharmaceutical firms to develop competencies in innovative R&D as a response to change in patent law. In this ‘context’ based on the nature of the research question, a case study methodology is used to find answers for questions raised in this research (Eisenhardt, 1989; Yin, 1994).

Firms which have filed ‘New Drug Application (s)’ (NDA) in both USA and India have been selected as case studies. Five firms from Table 1 are leading Indian firms who have setup dedicated innovative R&D facilities and have shown evidence of R&D capabilities transformation. Some of them have out-licensed their molecule (new chemical entity) to multinational pharmaceutical firms’ thereby demonstrating capability in innovative research although none of the products have completed the development stage. These firms also provided detailed access to R&D staff for data collection. Thus due to evidence of superior innovative R&D capabilities and access to R&D staff for data collection these five firms therefore were chosen as case studies in this research (Table 1).

Table 1 Firms Under study (Annual Reports, 2008; Kale, D 2007)

Firm	Year established	Total Sales (Rs. Million, 2008))	Total no. of employees (2008)	New chemical Entities in pipeline (phase I)	International acquisitions from 1990s	% from Overseas markets
Ranbaxy	1962	44814	12174	2	11	82
DRL	1984	69440	11281	4	4	67
Woc	1959	15454	6000	~ 2	8	73
PIH*	1988	32811	8157	6	5	~ 40
Glenmark	1977	21160	4100	6	5	~ 60

* Piramal Healthcare formerly known as Nicholas Piramal (I) Ltd

A phased based methodology approach with each piece building on the findings of the earlier phase was adopted. The first phase helped in improving knowledge about the real impact of change in patent law on the Indian pharmaceutical industry and different strategic approaches adopted by Indian firms. The second phase specifically focused on development of innovative R&D competencies in Indian firms. In the end, a total of 33 interviews were conducted, of which 10 were conducted in the first phase, and 23 in the second phase.

Two different interview question banks were used for the first and second phases respectively. In the first phase questions focused on TRIPS, the Indian regulatory set up, emerging strategies and existing capabilities of Indian pharmaceutical industry. In the second phase the question bank covered issues such as different learning processes in the organization as categorized by the theoretical framework.

The analysis of the empirical evidence was carried out by using various analytical techniques like pattern matching (Yin, 1994) and by the building of analytical tables (Miles and Huberman, 1984). In this research, a strategy of pattern coding is used to identify the processes involved in transformation of capabilities within and across the firms (Eisenhardt, 1989). In the analysis first level coding is used as a device for summarizing segments of data while pattern coding is carried out by grouping those codes into a smaller number of overarching themes or constructs. The transcripts were

analyzed by coding the different internal organizational processes around the transformation issues within each firm. The theoretical framework provided broad categories for classification of the data and various pattern codes are classified under those broad categories. Along with that mechanisms adopted by large pharmaceutical firms to acquire biotechnology capability are also used in identifying different themes in data analysis. Thus the replicating patterns of internal organization processes representing the learning mechanisms adapted by firms' to facilitate the development of innovative R&D were identified. These patterns were supplemented by secondary data which were collected from industry journals, industry association publications and annual reports of firms.

The differences in firms' learning processes were analyzed by comparing each firm on the basis of presence or absence of different learning process and the manner in which the firm had organized and implemented a particular learning process.

7. Transformation of identity at Indian pharmaceutical firms: the regulation turn

Indian firms responded to regulatory challenge by adopting different combination of strategies such as entering generic markets of advance countries by using process innovations, offering services to MNC firms and new drug discovery. While process innovations and service models were based on existing competencies while new drug discovery required new competencies. Over the years Indian pharmaceutical firms have developed 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 have severe weaknesses in other scientific disciplines such as medicinal chemistry and biology. This created important knowledge gaps for Indian firms to enter innovative R&D such as new drug discovery and new drug delivery systems. Indian firms developed new innovative capabilities by transforming in-house R&D model to collaborative R&D and hiring product R&D experienced scientists.

7.1 Dynamic firm level learning processes Indian pharmaceutical industry

7.1.1. Prior knowledge base:

Indian firms supported innovative R&D investment by exploiting process R&D capabilities and applying licensing model in R&D (Kale and Wield, 2008). On the basis of strong process R&D capabilities Indian firms entered generic markets of advanced regions and Custom Research and Manufacturing markets (CRAMS).

From 1990 onwards these innovative Indian firms targeted the generic market in advanced countries. In an intellectual property regime based on process rather than product protection, this involved developing equivalent products with non-infringing processes. This exposed these Indian firms to global markets, creating an awareness of future regulatory changes and giving a creative orientation to their imitative research. It also created a 'research tradition' in these firms.

The contract research and manufacturing services (CRAM) market has emerged as huge opportunity for the Indian pharmaceutical industry. According to Frost and Sullivan (2005), the global outsourcing market is worth \$37 billion and growing at almost 11%; 50% of the contract manufacturing market is in North America, 40% in Europe and just 10% in Asia and the rest of the world. Indian firms possess requisite capabilities to cater for the requirements of outsourcing markets, still India accounts for barely 1.5% of the global CRAM industry. Indian firms are targeting this market on the

basis of superior process R&D skills and cheap manufacturing trying to increase their share in the outsourcing market by moving closer to the market.

From 1995 these firms began increasing their R&D investment, momentum was gained in 2000 (table 2), with the building of the knowledge bases required for innovative R&D.

Table 2 R&D intensity of innovative Indian firms (source: annual reports, 2000-2008)

Firms	No. of R&D labs	R&D intensity (R&D spend as % of sales)									
		2000	2001	2002	2003	2004	2005	2006	2007	2008	
Ran	3	4.2	3.8	5.2	6.1	9.1	13.7	9.5	9.8	9.2	
DRL	2	4.22	6.29	7.7	10	14.6	8.2	6.4	7.0	6.0	
Woc	2	7.2	6.2	6.2	7.9		4.1	2.9	1.3	0.8	
PIH	2	1.80	2.16	1.63	3.9	3.7	5.7	4.3	1.22	2.0	
Glenmark	2	1.45	3.50	4.41	6.52	6.07	4.5	2.1	3.7	4.1	

The R&D intensity of Indian firms has grown consistently from 2000 although it is still low compared with the R&D intensity of large multinational pharmaceutical firms. However, according to some respondents, the cost of development of a drug in India can be a tenth of the international cost.

7.1.2. Processes involved in acquisition of new knowledge

Innovative Indian firms started building innovative capabilities by hiring scientists who were experienced in innovative R&D and were working overseas in the laboratories of multinational companies. In India only a handful of scientists had experience in innovative R&D and these scientists became the 'guides' for the transformation. These scientists carried the crucial tacit knowledge with them.

Table 3. Percentage of R&D staff to total staff (Source: Annual Reports, 2000-03)

Firms	Percentage of R&D staff / Total staff			
	2000	2001	2002	2003
Ranbaxy	8.85	9.02	11.11	13.52
DRL		9.09	12.39	
Woc	9.57	11.11	12.47	13.66
PIH	2.66	3.38	4.53	4.33
Glenmark		5.55	6.00	10

According to one R&D manager, the innovative firms focused on R&D scientists and started investing in them. 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 (Table 3). One 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.”

Post 2000 Indian firms adopted overseas acquisitions as a key strategy to acquire knowledge regarding advance markets, technology and regulatory skills. The value of the Indian pharmaceutical industry’s overseas acquisition has grown from just US \$8 million in 1997 to \$116 million in 2004 (Bloomberg, 2005). Geographically the overseas acquisition by Indian pharmaceutical firms continues to be directed at developed countries specifically the US and Europe. The major acquisitions are in the area of marketing although some companies are investing in building manufacturing and R&D capacities in developed markets. Indian companies have already established manufacturing plants in the US, Europe, Brazil, Russia and China. The major Indian companies such as Ranbaxy, Dr. Reddy’s Laboratories, Wockhardt and others have established their own brand image in the international market and are taking steps to consolidate their activities. Indian firms are compensating for the spiraling cost of selling and marketing in advance countries by setting wholly owned subsidiaries or acquiring local firm. Thus reinforcing the argument that Indian firms internationalization through acquisition is directed towards acquiring new knowledge in different areas such as R&D capabilities, regulatory skills and distribution networks.

7.1.3. Processes involved in assimilation of new knowledge

To create an environment for creative research, firms changed their approach towards publication and have started to understand its importance for the growth of R&D. In these Indian firms’ scientists’ participation and publication in conferences is now valued and encouraged more. As one senior R&D scientist 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 and are allowing them to pursue their academic ambitions while working in the organizations. These firms have manufacturing and marketing centers all over the world including the US and Europe and as a result, they can make the best research facilities accessible to their scientists. This allows scientists from these firms to pursue their academic interests and develop new skills in innovative R&D.

These firms set up separate R&D centers with ‘state of the art’ analytical instruments, totally dedicated to innovative R&D. They changed their R&D structures, starting new divisions to manage intellectual property rights (IPR), as well as establishing new disciplinary divisions and in initiating a ‘matrix’ style of project management. Some firms even opened laboratories in developed countries to make use of the knowledge spillover and to attract research talent which was reluctant to shift to India. These firms concentrated on providing more experience to their scientists by providing opportunities to design research projects, as well as freedom to work on their chosen therapeutic areas.

To increase the quality of the interactions with international scientists, these firms have set up scientific advisory boards (SAB) to review their research. The SAB contains well known scientists from overseas as well as Indian academia and meet on a quarter or half yearly basis. This forum provides an opportunity to scientists from these firms to have closer interactions with external experts, and as one of the research scientist suggest,

“all of which generates valuable feedback and built the confidence of researchers”.

7.1.4. Mechanisms of knowledge transfer

Innovative Indian firms are building research networks by collaborating with Indian as well as overseas research institutes, and research companies (Table 4). Networking has emerged as one of key mechanisms for knowledge acquisition for Indian pharmaceutical firms. One R&D scientist explains the rationale behind the networking,

“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.”

These firms have set up different departments to scout for opportunities for collaboration. During collaboration, these firms send their scientists to work in the collaborators’ R&D divisions. This has changed the nature of R&D in these firms; from insular in-house R&D, to a collaborative network model.

Table 4 R&D collaborations (Annual Reports, 2000- 2008)

N o.	Firm	Collaborators
1	Ran	Delhi University/ Ana University/ Merck/ GSK/ ICEGB*
2	DRL	BITS, Pilani/ GSK /Merck/
3	Wock	University of Mumbai
4	PIH	University of Mumbai/CCMB/ Eli Lilly/Napo pharmaceuticals/
5	Glenmark	University of Mumbai/Forrest Labs/Tejin Pharama/ Eli Lilly/ Dyax Corp/Merck

ICEGB: International Centre for Genetic Engineering and Biotechnology, India

CCMB: Centre for Cellular and Molecular Biology

Due to financial constrains and lack of capabilities Indian firms started out-licensing their molecules after completion of pre-clinical stage or phase I to MNC firms in return of milestone payments. In 1997 DRL out-licensed anti-diabetic molecule to Novo-Nordisk while in 1999 Ranbaxy achieved first significant international success by licensing its once-a-day Ciprofloxacin formulation on a worldwide basis to Bayer. It provided both firms significant revenues and also set up a roadmap for other Indian firms. Significant examples include DRL deal with Novartis, Torrent deal with Novartis and Ranbaxy deal with Bayer however none of these deals could reach successful conclusion. Although some deals such as out-licensing of drug candidate for Dyslipidemia RBx 10558, to Pharmaceutical Product Development Inc. (PPD) by Ranbaxy, DRL’s co-development and commercialization deal for Balaglitazone with Rheoscience and Glenmark licensing of its molecule are progressing well. Glenmark Pharmaceuticals Ltd. signed a landmark USD 190 million deal with Forest Laboratories in 2004 for developing and marketing Oglemilast, Glenmark’s lead molecule for Asthma/ COPD, for the North American region. In February 2008, Glenmark further received a milestone of USD 15 Million from Forest Labs. Glenmark signed a similar deal with Teijin Pharma Ltd. for the Japanese territory for USD 53 million a few months later. Glenmark has retained the marketing rights for the rest of the world and is presently in discussions with potential partners in Europe. With Eli Lilly, Glenmark has signed a licensing deal for developing and marketing GRC 6211, Glenmark’s lead molecule for treatment of pain conditions, for North America, Europe and Japan which will generate revenues of close to USD 350 mn. GPL has completed

one outlicensing deal each from 2004 to 2007 with a cumulative payment of US \$117 mn.

These deals proved beneficial for Indian firms as it provided opportunities to collaborate and interact with product R&D experienced scientists working with MNC firms.

7.1.5. Processes involved in integration of different knowledge bases

It was not enough to just hire the scientist or build new R&D centers, 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 specialized knowledge groups by building cross-disciplinary teams of scientists from different disciplines like biology, pharmacology, medicinal chemistry, intellectual property rights.

These firms also use internal review meetings for increasing cross disciplinary understanding, as one senior scientist 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 their difficulties are and vice versa”.

To sum up the firm level analysis of learning processes shows that Indian pharmaceutical firms are developing capability in innovative R&D by acquiring new components of knowledge and reconfiguring the architectural linkages between these components. New components of knowledge have been acquired by increasing R&D investment, by hiring new scientists embodying knowledge of innovative R&D and collaborating with Indian as well as overseas research institutes and universities. However, in India the necessary infrastructure required for implementation of patent regulations is severely under developed, raising the questions about the effectiveness of the new patent law in preventing reverse engineering. This is also affecting the R&D investments of Indian firms in innovative areas of pharmaceutical research. Thus in developing countries economic, social and political complexities make firm-level knowledge generation a challenging and difficult process.

8. Conclusion

This paper discusses dynamic learning processes used by Indian firms as a response to change in the regulatory environment. From 1990 Indian pharmaceutical industry has emerged as a leading supplier in generic market world-wide and innovator in process R&D. Faced with change in regulation Indian firms moved in the area of innovative product R&D and transformed into global market focused industry.

This paper comprehensively covers a neglected area in developing countries literature; dynamic learning processes to innovative R&D capability as a response to regulatory environment. It shows the key role of Diaspora scientists and emergence of networked model of R&D in Indian firms. It also reveals that Indian firms used resources from generic market to fund innovative R&D and used internationalization strategy to access markets in advanced regions such as Europe and USA (Pradhan, 2006). Further this paper points out similarities of Indian firms' transformation with the approaches of large pharmaceutical firms to the transformation of technological capabilities in response to the challenge of biotechnology. However it is important to note that one of the top firms in the study Ranbaxy was acquired by Daiichi Sankyo in 2008 showing difficulties of transformation and may point towards the next phase of development for the Indian industry. Similarly the other firm Wockhardt is struggling

to manage its operation in post-TRIPs era and selling parts of its business to survive (Economic Times, 2009). It clearly emphasizes that transition to innovative capability development is not a straightforward and linear process. It requires managerial vision and sustained investments in firm level learning processes.

Further this paper proposes a conceptual framework based on the concept of absorptive capacity to explore the processes involved in dynamic learning in firms from developing countries. The result shows that the theoretical framework is a comprehensive and useful tool for exploring the firm level learning processes involved in knowledge generation. However it is clearly evident that a broader analysis of firm-level learning in developing countries should also include an exploration of the institutional environment as this plays an important but varied role in creating the environment for firm-based learning.

9. References

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