# DEVELOPING THE KNOWLEDGE CREATION CAPABILITY FOR INNOVATION – THE CASE OF THE INDIAN PHARMACEUTICAL INDUSTRY

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## Abstract

In the globalised era, the ability of firms to reconfigure existing competencies and create new knowledge for innovation has become a strategically important capability. In the emerging environment, firms will have to create knowledge for innovation by acquiring the necessary new knowledge and combining it with the existing knowledge base. This research explores the approaches used by Indian pharmaceutical firms to combine existing accumulated knowledge from imitative R&D with new knowledge in order to develop innovative R&D as a response to the World Trade Organisation agreement.

The analysis shows that personnel transfer plays a crucial role and is thus a primary mechanism for acquiring knowledge for innovative R&D. Complementary to this, is the network model of collaborative R&D, in augmenting innovative capabilities. This research provides insight into the processes involved in the reconfiguration of existing capabilities to develop new knowledge for innovation and which have wider implications for firms in other developing countries.

**Keywords:** Knowledge, organisational capabilities, pharmaceutical industry, India, developing countries.

# Developing the knowledge creation capability for innovation – The case of the Indian pharmaceutical industry

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## 1. Introduction

The drivers of globalisation are bringing in 'competency destroying changes' (Tushman and Anderson, 1986) for firms in some industries. As a result in the 'globalised' era, the ability of firms to reconfigure existing competencies and create new knowledge for innovation has become a strategically important capability. In the last decade a lot of researchers have concentrated on firms' capabilities of managing and creating knowledge, 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, D. et al., 1997). In developing countries this reconfiguration 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; Lall, 1992; Bell and Pavitt, 1993). This research explores the neglected area of rebuilding the capabilities and creation of knowledge for innovation by firms from developing countries as a response to a turbulent external environment.

The research mainly focuses on mechanisms used by Indian pharmaceutical firms for the acquisition of new knowledge and its combination with existing accumulated knowledge to create the knowledge required for innovation as a response to TRIPS (trade related intellectual property rights) agreement. It also provides insights into the process of technological capability accumulation which plays an important role in building absorptive capacity and forms the basis of the reconfiguration process. The analysis is done by using a theoretical framework based on the approaches used for the transformation of organisational competencies as a response to technological change.

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 characteristics of the Indian pharmaceutical industry. It further elaborates the area of research. Section 3 reviews some of the literature on the capability accumulation process in developing countries and capability renewal in advance countries. It also presents the theoretical framework, which guides the firm level research and explains the basis of using it. Section 4 describes the methodology of the study and rationale behind using such a research design. Section 5 explains the pharmaceutical R&D value chain in context of the Indian scenario and related of process of capability creation within the Indian pharmaceutical industry. Section 6 discusses Indian firms' approaches towards reconfiguring the

competencies in pharmaceutical R&D and covers the analysis of six innovative Indian firms. Conclusions are drawn in section 7.

## 2. The Research context

### 2.1 World Trade Organization Agreements – TRIPS

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 degree of patent protection given to pharmaceutical products in the past was clearly related to the development of the domestic pharmaceutical industry.

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.

Numbers of studies have been carried out on the effect of change in patent law on pharmaceutical firms. These include studies focusing on socio economic issues like the pricing of the drugs (see for instance, Lanjouw, 1996; Watal, 1996), technological development of the firms (e.g. Sequeria, 1998) and the resultant heterogeneity (D'Este, 2001) as well as strategic issues like adaptive strategies of firms as a response to change (Madanmohan et al., 2003; Halemane et al., 2003).

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 TRIPS (Watal And Mathai, 1995). The TRIPs agreement is a substantial and complex challenge for firms in developing countries. The distinction between the ability to produce a product by imitation and the

capability to generate it, have profound implications in pharmaceutical R&D. The difference in the scientific knowledge bases involved in reverse engineering R&D and innovative R&D adds to the complexities.

In the new environment, firms have to acquire new knowledge and combine that with accumulated knowledge to develop firm specific competencies in innovative R&D. To explore the transformation and reconfiguration of competencies for innovation, the Indian pharmaceutical industry is used as a case study.

### 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 14$^{th}$ largest in the world accounting for a market of US$ 2.5 billion (Ramani, 2002) and 4$^{th}$ 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, 2001). 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 process of technological capability acquisition and accumulation in firms from developing countries has been widely discussed by different researchers (e.g. Lall, 1987; Bell and Pavitt,1995). Their research focused on the process of accumulation of basic minimum knowledge base required for production. The transformation of

South Korea and Taiwan into industrialised economies shifted the focus of research towards the acquisition of more complex knowledge base required for innovation. Nelson and Pack (1999) argued that at the macro economic level the absorption or assimilation of increasingly modern technology and change in industrial structure were critical components of the transformation. Song (2000) suggested that at firm level the experienced engineers who previously worked for technology leaders in advanced countries have provided basic knowledge to build the subsequent innovations locally in South Korean and Taiwanese firms. Continuing to focus on organisational issues Kim (1999) analysed the technological learning process in the South Korean automobile firm Hyundai, showed that internal organisational factors like 'deliberate crisis construction' by top management and collaboration with foreign technologically advanced firms played a crucial role in the technological capability acquisition process. But Dutrenit (2000) found that the transition from the 'early stage of accumulation of minimum knowledge levels of innovative capability to the management of knowledge as a strategic asset' is a very complex process specifically in the context of developing countries.

In the last few decades technologies and economies have undergone dramatic changes which have influenced the organisation of production and management. The strategy management literature based on firm level research from advanced countries points out that in an environment of increasing pressure and uncertainty accumulated distinctive competencies or capabilities gives firms the competitive advantage (Grant, 1991; Leonard – Barton, 1995). In a rapidly changing globalising world, the challenge for firms is to find new ways of doing things (Teece, 2002). In the management literature there is increasing evidence that knowledge allows the creation of the capability and that determines the ability to do things (Grant, 1991; Henderson and Cockburn, 1994; Leonard- Barton, 1995). The manner of knowing or learning is as important as what should be known (Spender and Grant, 1996). Leonard – Barton (1992) points out that the firm nurtures and creates knowledge through certain activities and these activities basically involve the sharing of knowledge within the organisation, and the transfer and integration of knowledge across organisational boundaries.

Teece, et al (1997) suggests that in order to adapt and shape the changing business environment, firms must develop 'dynamic capabilities'. Teece et al. (1997) define these as 'firms' ability to integrate, build and reconfigure internal and external competencies to address rapidly changing environments'. This perspective is based on continually developing new capabilities as well as exploiting old ones in the context of shifting environment.

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. Henderson and Clark (1990) investigated the failure of established firms in the face of subtle technological advances in the semiconductor industry and found the complexities involved in discontinuous learning. Technological advances destroy the architectural knowledge; that is knowledge about the ways in which the components are integrated and linked together in a coherent whole. These technological advances are triggered by changes in component knowledge which creates new interactions and new linkages with other components in established products. Therefore firms require the reconfiguration of established systems in order to link together existing components of knowledge in a new way. As a result, to prepare for the future, firms must learn not only new components but also the new linkages between the components, that is to say, the architecture of the product.

According to Henderson and Clark (1990) architectural knowledge is embedded in organisational structure, problem solving strategies and information processing procedures of the established firms. Architectural knowledge concepts also include the control systems and the culture of the organisation, giving it the same identity as 'collective knowledge' (Spender, 1996), 'combinative capabilities' (Kogut and Zander, 1992) or 'dynamic capabilities' (Teece et al, 1997).

With the advent of globalisation, firms in developing countries are going through battles of survival and reinvention. The institutional context is often rather different in developing or newly industrialised countries compared to advanced countries, but the basic process of learning and advancement as a response to change are applicable to them as well. In the case of the Indian pharmaceutical industry, innovative R&D will require new component knowledge bases. It will affect the architectural knowledge and so will require different ways of linkages to create the innovative product.

This research tries to explore processes involved in the creation of new knowledge for innovation, requiring the transformation of existing competencies and the integration of these competencies with the newly acquired external knowledge. According to Pavitt (2002), combining radically new technological competencies with existing competencies and organisational practices is the most difficult and challenging task before firms in their response to technological innovations. This research explores the neglected area of new competencies creation as a response to environmental change by using firms from the Indian pharmaceutical industry as case studies.

### 3.1 Theoretical Framework

Henderson and Cockburn (1994) suggest that two forms of architectural knowledge are important in pharmaceutical research: the ability to access knowledge from outside the boundaries of organisation; and the ability to integrate knowledge flexibly across disciplinary and therapeutic class boundaries within the organisation. The challenge to create new architectural knowledge implies the acquisition and integration of different types of component knowledge and new ways of linkages among them.

Large pharmaceutical firms' responses to biotechnological challenge illustrate the specific characteristics of reconfiguration of architectural knowledge. The biotechnological challenge shifted the scientific knowledge base underlying drug discovery process from chemistry dominated to biology dominated. Thus, advances in molecular biology provided significant innovation for large pharmaceutical firms, representing a shift in the scientific knowledge base of an industry (Henderson et al., 1999). Large pharmaceutical firms responded to technological advances by acquiring the component knowledge bases and reconfiguring the linkages between them.

The revolution in life sciences changed the organisational and managerial aspects of drug research; it changed the internal structure of R&D with 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 the existing structure. They promoted collaboration and joint ventures with university scientists and new biotechnology firms to augment internal expertise (Zucker and Darby, 1997). Nicholls- Nixon (1993) presented the absorptive capacity model to explain the use of internal R&D and technology sourcing linkages in the development of capabilities required in a new technological paradigm. The process of transforming the 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 outs 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 to complement internal capabilities in biotechnology as mechanisms of knowledge transfer. He

identified four types of linkages like 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. These 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.

The case of the molecular biology revolution and the response from firms provides the detailed mechanisms of industrial transformation at the firm and industry level, and of the interactions and coevolution of scientific knowledge on one side and organisational capabilities, institutional context on the other side (Henderson et al., 1999). Some large global pharmaceutical firms acquired biotech capability by hiring a star scientist, restructuring their research teams, accessing new external sources of knowledge and building the absorptive capacity by investing in internal R&D. These firms changed the in-house nature of their R&D to the network model of the R&D.

These mechanisms direct the theoretical framework (Fig.1) which constitutes the core features of reconfiguration process. These features are mechanisms used for knowledge acquisition and assimilation, knowledge transfer, intra firm and inter-firm networks, along with absorptive capacity.

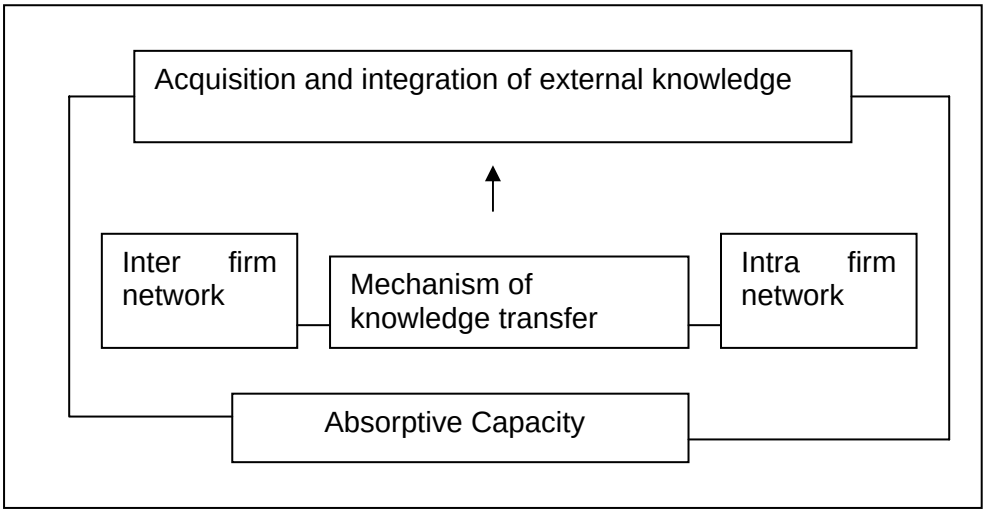


Fig .1 Theoretical Framework

**4. Methodology**

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 certainly helps to capture the richness and

complexities of the issues at hand. As Spender (1996) points out, interpretative research focuses on the ways by which we attach meaning to experiences.

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 have 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.

| Firms | No. of patents filed for | | Licensed to MNC pharmaceutical firms |
|---|---|---|---|
| | New Drug delivery systems | New chemical entities (IND) | |
| DRL | | 9 | 3 |
| Ranbaxy | 3 | 4 | 1 |
| Wockhardt | 2 | 2 | |
| Torrent | | 4 | 1 |
| Lupin | 1 | | 1 |
| Glenmark | | 2 | |

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

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 was 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 knowledge processes in the organisation identified in the literature but mainly focusing on activities involved in learning communicating and remembering. The questionnaire also referred to the measures of organisation's architectural knowledge in pharmaceutical R&D used by the Henderson and Cockburn (1994). These measures include changes in the importance given to publication by the firm, the involvement of the firm in joint research projects with one or more research universities, and the resource allocation process.

The interview transcripts were analysed by locating series of narratives around the transformation issues in each firm and from these, replicating patterns of acquisition and reconfiguration processes were identified. These patterns were supplemented by secondary data which was collected from industry journals, industry association publications and annual reports of firms. The observed patterns in Indian pharmaceutical firms are then compared with the theoretical patterns identified from the framework to find the similarities and differences between them.

The next section will describe the pharmaceutical R&D, followed by the capability creation process within Indian pharmaceutical R&D.

## 5. The process of accumulation of knowledge - building the absorptive capability

### 5.1 Pharmaceutical R&D value chain

Traditionally, pharmaceutical R&D has two distinct phases; product research and later, process development for production. Process development occurs in parallel with the product development and is responsible for producing the compound in relatively large quantities, in extremely pure form, at an economically feasible cost and by following all the regulatory requirements. Product development research has two distinct components; discovery and development. In the discovery stage, drug molecules are obtained, screened and promising lead compounds are selected for development. The development stage involves a series of tests to determine safety, efficacy and proper dosage strength and form. The discovery stage represents the innovative phase in the pharmaceutical product R&D.

In the pharmaceutical R&D value chain (Fig.2) technological level from intermediate and bulk substance stage till OTC (over the counter drugs) and new drug delivery systems stage, depend mainly on skills in the process R&D. But as the technological complexities increases at each level, so it requires an increased input of original

knowledge. Products from new drug delivery systems research and branded generics research are patentable innovations and require higher skills and capabilities in process R&D.

In terms of scientific capabilities new drug discovery research can be classified as analogue research and new chemical entity research. Analogue research involves working on already validated/known targets where the structure and activity of the molecule is well known. Many drugs coming out of large pharmaceutical firms' R&D in developed markets are the products of analogue research. Analogue is defined as superior modifications of original molecules. It also represents drug discovery research. Original new chemical entity research represents a entirely new area of investigation in terms of either targets or leads that could result in breakthrough drugs.

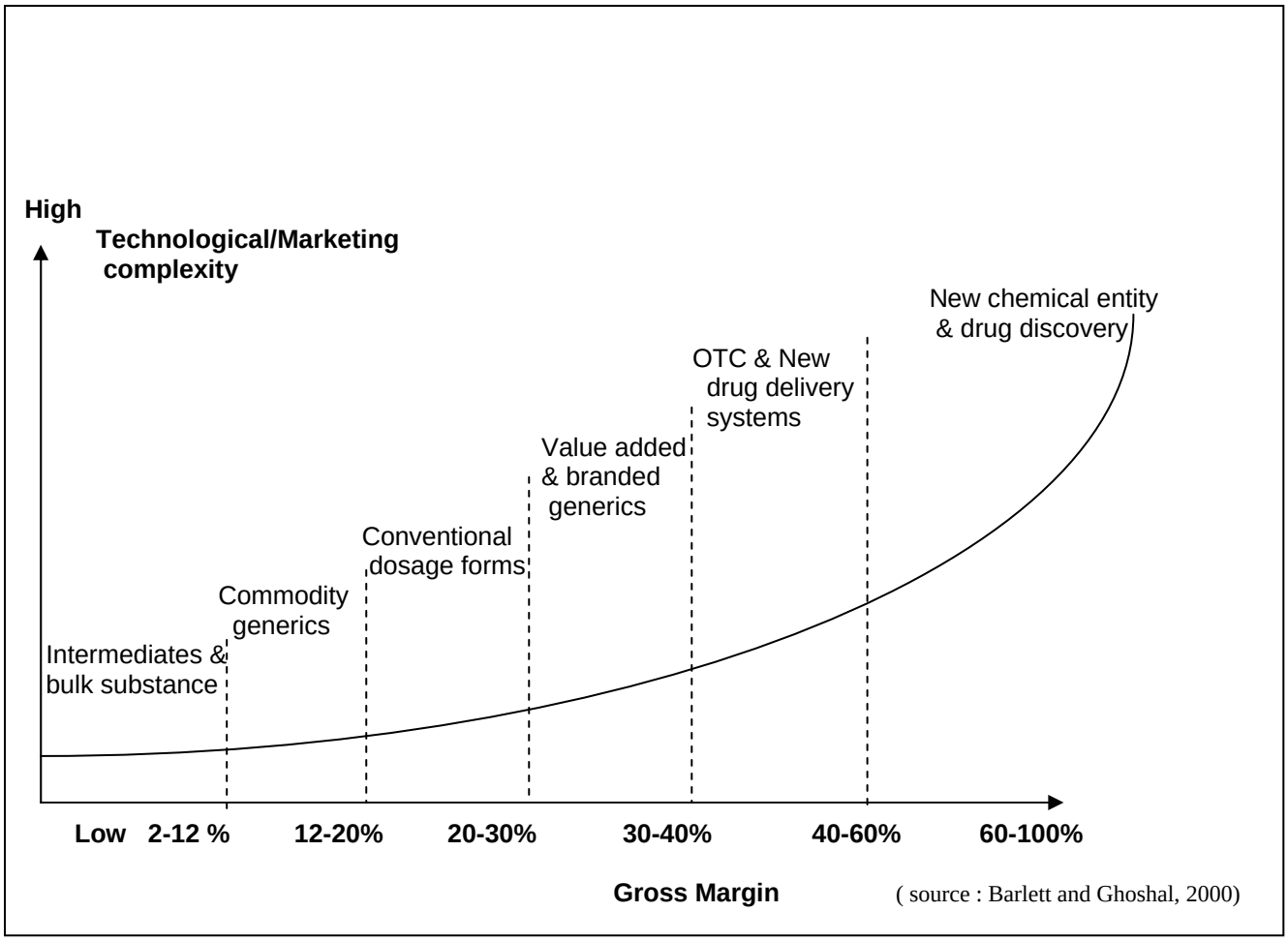


Fig. 2. Pharmaceutical R&D value curve

**5.2 Hierarchy of scientific capabilities in context of Indian pharmaceutical firms**

The growth of the Indian pharmaceutical industry reflects the rise of the industry up the value chain of activities involved in pharmaceutical R&D. The process of

capability accumulation is closely aligned with the rise of the Indian pharmaceutical industry. The next section aims to explain this through the capability creation model (Fig.3.).

In the context of Indian pharmaceutical firms' R&D value chain, reverse engineering activities represent the stage of duplicative imitation, whereas generic R&D research represents the 'creative imitation stage'. In terms of the capability creation model (Fig. 3) analogue research and new drug delivery systems represent 'intermediate capability' Original new chemical entity research represents the 'mature capabilities' as it is a very complicated process and involves the culmination and application of different complex knowledge bases.

**5.3 The capability accumulation process**

The capability creation model (Fig.3) represents the gradual movement of the Indian pharmaceutical industry from acquisition of basic minimum knowledge base (process development) towards the creation of new competence for innovation (NCE research). The Indian pharmaceutical industry has come a long way from importing bulk drugs to exporting formulations to highly regulated markets in the developed world.

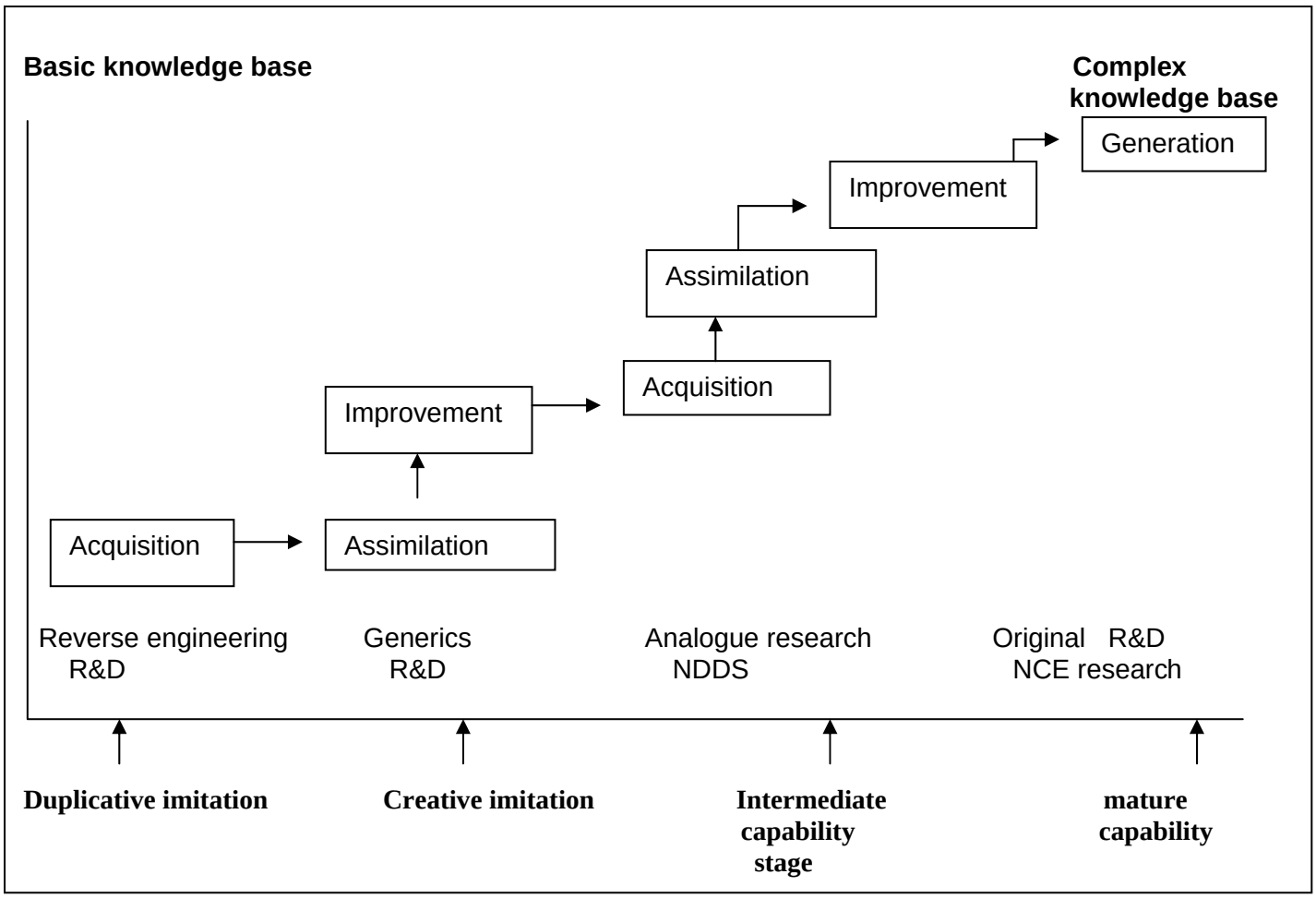

Fig.3. Capability creation model

The origin of the domestic Indian pharmaceutical industry goes back to 1954, when the Indian government set up a public sector firm called Hindustan Antibiotics, followed, in 1961, by Indian Drugs and Pharmaceuticals Limited. These companies created awareness about opportunities in the pharmaceutical sector and developed the basic knowledge base required for the industry. Managers working in these public sector units sensed the opportunities that emerged after 1970 and started creating their own firms on the basis of knowledge in reverse engineering. Until 1990, Indian firms used duplicative imitation to build the minimum knowledge base needed in process development; they simply followed the patent and reverse engineered the process, albeit with some minor modifications. Profits in the market were directly related to efficient production processes used by the firms. This resulted in the rapid assimilation of reverse engineering expertise across all the firms.

After the liberalisation of the economy in 1990, some of the Indian pharmaceutical firms started looking towards export markets. They started creating products with non-infringement processes which can be converted in the IPR. This allowed these firms access to global markets and slowly, entry into the generic markets of the developed world. Thus these firms gradually created the capability for generic R&D by assimilating and improving process research. 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.

After 1995, these firms started moving further up the value chain (Fig.2) in innovative R&D by concentrating on analogue research and new drug delivery systems, as the products resulting from this research can give leverage to firms in global markets. This upward movement of Indian firms represents the transformation from a creative imitation stage to a mature capability stage. The innovative Indian pharmaceutical firms are building on 'creative research traditions' to develop intermediate capability first; that is the capability to do research in new drug delivery systems and analogue research and then finally towards the mature capability stage. But that transformation is very challenging as the knowledge accumulated in creative imitation stage is not directly relevant to the discovery stage of the innovative R&D. It only acts as a base, and will contribute only in the development stage of innovative R&D. But managerial experience in process R&D has given Indian firms some understanding of the complexities involved in innovative research.

The next section covers the detailed discussion about the transformation and reconfiguration processes within the R&D practices of six innovative Indian pharmaceutical firms. These six firms are at the forefront of the Indian

pharmaceutical industry and are undergoing transition from the creative imitation stage to the mature capability stage.

**6. Reconfiguration process**

The TRIPS challenge demands innovative R&D which means that firms will have to create an environment that will motivate 'out of the box' thinking from the scientist and competence in regulatory management. In the beginning, Indian firms faced major constraints like financial and infrastructure resources, an insular knowledge base and a lack of scientists trained in innovative R&D.

To cover the financial cost required in drug discovery and development, these firms chose the strategy of collaborative research involving milestone payment and limited marketing rights. One consultant describes the early efforts of these firms,

"These companies saw the writing on the wall and worked towards developing the expertise in new areas of drug discovery and development research, considering the low resources available to them in comparison to those of MNCs, they have adopted a strategy of collaborative research through a licensing route, by gaining up-front milestone and royalty payments for the molecules licensed by them to MNCs for further clinical development".

In the interviews with the executive, he suggests that firms have realised that the time has come for the industry to move forward and graduate from copying to creating, which he acknowledges is a reflection of 'changing mindsets' within Indian firms.

These firms started building innovative capabilities by hiring scientists who have worked in laboratories of multinational companies and who have experience in innovative R&D. In India only a handful of scientists had experience in innovative R&D and these scientists became the 'guides' for the transformation. Most of these scientists had roots in Hoechst and Ciba-Geigy R&D centres in India, as during their existence these centres were dedicated to new drug discovery and development.

According to one R&D manager, 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. Research project teams for innovative R&D are built by focusing on fresh research talent rather than hiring those scientists experienced in reverse engineering. 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. Actually for 90% of workforce in the R&D, it was their first job, we were able to introduce scientific programme, induct people, mould them and could bring that culture into organisations. It is something nice to start with the clean slate rather than something that is there and erase it and then put it, it’s a sort of double job.”

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.

| Firms | No. of scientist working in innovative R&D | Total no. of R&D personnel |
|---|---|---|
| DRL | 260 | 550 |
| Ranbaxy | 400 | 700 |
| Wockhardt | 90 | 220 |
| Torrent | 160 | 290 |
| Lupin | 60 | 250 |
| Glenmark | 40 | 100 |

Table.2. Number of scientist working in innovative R&D (source: annual reports, 02)

Attracting good research talent wasn’t very easy and firms had to convince scientists of their commitment by investing in the infrastructure required for innovative R&D. 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 started using ‘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.

The 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. As the ability of firms to make use of outside knowledge depends upon their installed knowledge base (Cohen and Levinthal, 1990), without the investment in creation of knowledge in particular areas, it would be difficult for a firm to build capabilities to acquire, absorb and apply external knowledge.

| Firms | No. of R&D labs | R&D intensity (R&D spend % of sales) | | |
|---|---|---|---|---|
| | | 2000 | 2001 | 2002 |
| DRL | 5 | 3.3 | 4.4 | 6.3 |
| Ranbaxy | 3 | 4.2 | 3.8 | 5.5 |
| Wockhardt | 2 | 7.2 | 6.2 | 7 |
| Torrent | 1 | 5.0 | 4.6 | 5.4 |
| Lupin | 2 | 2.7 | 4.9 | 5.6 |
| Glenmark | 2 | 1.15 | 3.00 | 4.42 |

Table. 3. R&D intensity of innovative Indian firms (source: annual reports)

The R&D intensity of Indian firms is 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 and as one R&D director suggests,

"I think India has human resource cost advantage. By rough math 1/10$^{th}$ at MS level, at PhD level it could be 1/5$^{th}$ and at upper level the difference could be 1/3$^{rd}$".

The significant aspect is the increase in R&D expenditure actually spent on innovative R&D grew from 20% in 1995 to 50% in 2002, but there is wider consensus about potential to increase R&D investment. One R&D vice president defends the gradual increase of R&D investment saying that 'every company needs to develop its own comfort zone of risk' and links the issue to the mindset problem. He accepts the difficulty of convincing people to make a commitment of huge investment without any foreseeable returns for 8-10 years, and cite this as a reason for the gradual increase in R&D investment.

But firms which are run by leaders who are scientists have been able to balance this paradox well. According to the respondents, that plays a crucial role in directing a firm's efforts in innovative R&D. As one R&D president comments,

"People require good support from the management and that's what is important. Fortunately we have a leader who is a technocrat and then he is not a typical business man. That makes the big difference because he understands if somebody says chemistry is not working; he understands that, because he is himself a scientist".

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. 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. We have to really shake hands with the people who have got knowledge in this area, bring them as partner or bring them as a contract research for you, pay finite amount of money required for it and learn in the process”.

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.

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. One R&D president focuses on this aspect as most crucial for success in new drug discovery,

“We made it such a way that both chemistry and biology become seamless departments and the interactions are very informal; as informal as meeting people on the corridors of the labs’, finding out what is going on or telling people what exactly they should be looking into. These were a few fundamental things responsible and were really motivating factors, in addition to senior people like us; we are all telling them what they should doing. I would say that was one of the successful approaches”.

These firms are also using review meetings for increasing cross disciplinary understanding, as one 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 there difficulties are and vice versa’.

These review meetings are held quite often where each scientist presents his work which is critiqued, peer reviewed and further action plans are formulated.

To increase the quality of the interactions, 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 suggest 'all of which generates valuable feedback and built the confidence of researchers'.

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 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. If our people have gone and made presentations in a conference, then it's a validation of our science, showcasing of our science and also learning from others, all this adds to scientist stature as well company's reputation. "

However, all the respondents shared the viewpoint that patenting is the priority for all firms and lack of trust is still preventing full-fledged publication from firms.

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.

Knowledge upgrading in terms of management of regulatory compliance is a necessary requirement for a strong patent regime. Regulatory competence is closely associated with information management and here firms' investments in information technology played an important role. In early years filling the patents in different regions which requires the same amount of data as regulators from the developed world but have different ways of implementation helped these firms in acquiring the minimum regulatory expertise. This proved to be an effective mechanism for gathering the knowledge required for the successful filing of patents in US and Europe. The experience was further strengthened by successful filing of the patent application for generics (ANDA) in the US.

These observations suggest the similarity between the Indian firms' efforts to develop competence in innovative R&D with large pharmaceutical firms' responses to biotechnological advances but firms from developing countries have to confront crucial financial as well as infrastructural challenges which make process quite different and more complex.

This research also shows capability accumulation process within the Indian pharmaceutical industry through the capability creation model, specifically the importance of 'creating a research tradition' for the development of competence required in innovative R&D. This has implications for pharmaceutical firms in other

developing countries. Finally, at present innovative R&D is still in its infancy and this research has tried to capture the beginning of that journey.

## 6. Conclusion

The TRIPS agreement represents an enormous challenge for pharmaceutical firms in developing countries. But in the case of some Indian pharmaceutical firms it has provided a catalyst, accelerating their movement towards innovative R&D. This movement has also been positively influenced by changing socio- economic factors in India. Spender (1996) points out that the firm is an active participant in the social transformation process and so its knowledge creation process is affected by it. Indian success in the information technology sector has diffused confidence among other sectors and the pharmaceutical industry is the most striking example of this. The follies of the past decade like socialisms and import substitutions are today turning into the sources of strength, as they produced entrepreneurs who prepared products with their own resources. This self reliance is helping India now; as in last two years six companies have won prestigious Deming quality awards, triggering a surge in export orders (Business Week, 2003). In the new era Indian knowledge workers are making their way up the value scale, mastering tasks that require analysis and creativity. Business Week (2003), in acknowledging India's strength in brainpower suggests, "if India turns fast growth economy then it will be the first developing nation that used its brainpower, not natural resources or raw muscle of factory labour as the catalyst". Such socio economic transformation has played a significant role in creating an environment required for 'out of the box' thinking and has helped in changing the mindset of the organisation.

The 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 increasing R&D investment, by hiring new scientists embodying knowledge about innovative R&D. These scientists carried the crucial tacit knowledge with them. These firms reconfigured the architectural linkages by changing organisational structures along mechanisms of knowledge transfer and integration.

Indian firms are also embracing the network model of R&D by collaborating with research institutes, universities and other firms. Their networking is helping these firms to augment and leverage organisational capabilities in innovative R&D.

This research has wider implications for firms in other developing countries in terms of mechanisms for developing the innovative R&D capability by reconfiguring the existing competencies. Although in saying this, it should also be noted that India has some unique characteristics, and this puts limitations on the application of these approaches by other developing countries

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