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Strategic integration of knowledge in Indian pharmaceutical firms: creating competencies for innovation

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Abstract: Trade liberalisation and changes in the Intellectual Property Rights (IPR) have fashioned new dynamics in the pharmaceutical industry across the globe. Firms are forced to bring changes to their research, innovation, technology and marketing practices by a reconfiguration of their competencies and resources. The most common strategic concern that Trade Related Aspects of Intellectual Property Rights (TRIPs) has raised for Indian firms is the perceived need for R&D and technological strength. For firms that have given little attention to research and innovation in the past, this transition is very difficult. Indian firms have responded to these changes in novel and complex ways. Employing firm-level case studies, this paper examines the contemporary strategic approaches adopted by Indian leaders for integrating new knowledge and capabilities in order to develop innovation competencies for tomorrow.

Using empirical evidence from firm-level investigations, this paper shows how Indian firms are evolving from reverse engineering outfits catering to domestic market to technologically advanced and sophisticated organisations capable of catering to diverse markets.

Keywords: knowledge; innovation competencies; Indian pharmaceutical firms; strategies.

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Biographical notes: Kalpana Chaturvedi has recently completed her PhD on Innovation and Knowledge Management in Pharmaceuticals. Her research interests and work include corporate strategy; knowledge-based competition; innovation, knowledge and learning in technology institutions and firms in developing countries; and strategic knowledge management and dynamic capabilities of firms. Some of her current research focuses on

the study of policy, knowledge and market influences in shaping up firm-level technological trajectories and changing innovation dynamics. In her professional work spanning research, industry and government experience, she has dealt with different facets of basic research, technology development, transfer and commercialisation, particularly in the pharmaceutical and biotechnology sectors.

Joanna Chataway's research focuses on biotechnology, science and technology capacity building, North-South Public Partnerships (PPPs), innovation and development. Chataway is part of the Senior Management Team for the ESRC Innogen Centre, which conducts research on the social and economic aspects of life science innovation. She is currently the Principal Investigator (PI) for two Innogen centre projects investigating technology and knowledge flows in biotechnology and genomics between North and South and PI for another project funded by the ESRC Science in Society Programme looking at capacities to manage risks of agricultural biotechnology in several African countries.

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1 Introduction

How and why do firms adapt and succeed in times of rapid change? Theoretically, there are a number of mechanisms through which firms can transform themselves in response to environmental challenges. Researchers have looked from very different angles at how environmental factors such as policy, knowledge and market dynamics can affect firm-level strategies. Schumpeter (1947), with his 'gales of creative destruction', gave a vivid description of the dynamism of innovation and its effects on industrial and world economy. Many authors further elaborated on this theory, notably Rosenberg (1969), Nelson and Winter (1977) and Freeman and Perez (1988). A very different and dominant paradigm that emerged in strategy during the 1980s was the competitive forces approach developed by Porter (1990), wherein he argued that industry structure strongly influences the competitive rules of the game as well as the strategies.

Another distinct class of approaches that link firm-specific capabilities and assets with its strategies, often referred to as the resource-based perspective, have their roots in the much older work of Penrose (1959) and Selznick (1957). Recently there has been a resurgence of interest in the role of firm's resources and capabilities as the foundation for firm strategy (Teece *et al.*, 1997). Modern literature on innovation management has identified knowledge as a critical resource, and research and innovation as firms' core competencies (Pavitt, 1990; Leonard-Barton, 1992; Malerba and Orsenigo, 2001). Keller (2004), in a recent review of the resource-based model of the firm, noted that researchers are increasingly focusing on the intangible resources of diverse knowledge bases and capabilities which differentiate firms and lead to superior performance. From this perspective, technology development ought to be considered as a knowledge-led process and knowledge-management as a strategic necessity for firms.

Evolutionary economists emphasise the cumulative and dependent nature of technical and organisational change within firms. The particularities of the way different firms incorporate new technology and new processes need to be understood in the context of their previous trajectories and their capacity to absorb new knowledge (Cohen and Levinthal, 1990).

A number of studies have recently looked at the impact of knowledge-related policy changes coupled with enhanced knowledge levels on the social, economic and technological development of developing countries. Lanjouw (1997), Kumar (2002) and Correa (2000) have studied the impact of stringent patent regimes on the social, technological and economic development of India. Halemane and Dongen (2003) investigated innovation management in the Indian pharmaceutical industry as a response to environmental changes based on the theories of strategic groups from industrial economics. But most of these studies have focused on the relationships between the actions that firms have taken and the outcomes (success and failures) and have paid less attention to the strategies underlying those actions.

In parallel to the academic literature, firms in developed and developing countries have increasingly seen knowledge capabilities and knowledge management as key resources. In part, this is driven by new policy developments in intellectual property protection and Trade Related Aspects of Intellectual Property Rights (TRIPs).

Picking up from where others have left off, this paper analyses the technology development, innovation and wealth creation approaches (strategies) being adopted by Indian pharmaceutical firms in the wake of a rapidly changing technology and policy environment. The terms 'innovation' and 'knowledge' in this paper are not restricted to technology alone, but encompass other business and management processes as well. In practice also, the R&D function in business firms has shifted focus to the strategic integration of the R&D effort with the overall business goal (Madanmohan and Krishnan, 2003; Sakakibara and Dodgson, 2003; Bower and Sulej, 2005). These shifts reflect the increasing complexity and maturity in which companies are tackling the management of their technology, products and markets. The paper analyses the key elements of the strategic trajectories of leading Indian pharmaceutical firms which have been demonstrably successful in the domestic as well as western markets in the past and are currently aggressively expanding their activities to build innovation competencies for tomorrow.

Structure of the paper

This research coincides with a period of rapid restructuring in the regulatory framework, patent laws and market dynamics across the globe. The principal objective of this paper is to look at the effects of TRIPs on the research and innovation strategies of Indian pharmaceutical firms. Section 2 presents the research context and the theoretical framework which guides the research. This section also describes the methodology of the study and rationale behind using such a research design. In order to understand Indian firms' response, it is crucial to look at them in the context of key historical factors. Section 3, as historical background, explains capacities and capabilities created within the Indian pharmaceutical industry in the process patent regime and shows how changes in policy regimes have influenced technological choices and trajectories of Indian firms over time. Section 4 looks at how firms are strategising for innovation-based post-TRIPs competition. Section 5, while discussing the key observations of this study, maps the

transformation of Indian firms as they move from process engineering (working at the lower end) to drug discovery (the higher end of pharmaceutical value chain). The paper concludes with a few final thoughts and a summary of firm-level strategies in Section 6.

2 Context, framework and methodology

2.1 The research context

It is well established in the literature (Kumar, 2002; Watal, 2000; Rasiah, 2002) that the technological advance achieved by the Indian pharmaceutical industry owes much to the 1970 Patents Act. In the 1970s, India introduced complex laws and policies to regulate the pharmaceutical industry, to counteract monopoly abuses by multinationals and to promote local industry. The reforms included changes to foreign exchange regulations, price controls, industrial licensing and most important of all, the non-recognition of pharmaceutical product patents that legalised reverse engineering of patented molecules. The reforms contributed to many tangible benefits such as the creation of manufacturing capacities, lower drug prices, and availability of modern drugs to the masses.

From an Indian perspective, the lack of Intellectual Property Rights (IPR) laid the foundation for a strong domestic industry. The recent signing of the TRIPS agreement, however, reverses the patent law followed since the 1970s. The firms that have developed knowledge and capabilities in reverse engineering-based R&D in the past are required to reorient themselves for R&D-based innovation to survive and compete in a regulated and open market. This has serious implications for the Indian pharmaceutical firms. Apart from upsetting their balance sheets and profits earned through exports of cheaper versions of patented drugs, access to new knowledge and technology is envisaged to be even more difficult in the stricter patent regime. Given this context, this paper examines the organisational processes employed to manage knowledge and innovation by Indian firms involved in a complex change process today.

2.2 Theoretical framework

The theoretical framework for this research is based upon the theories of co-evolution of policy and technology, and dynamic capabilities of firms and strategic knowledge management.

2.2.1 Policy analysis for research and innovation

This research proposes a novel application of the ‘content, context and process’ framework for policy analysis in the pharmaceutical sector. The research argues that much health policy wrongly focuses attention on the content of reform, and neglects the actors involved in policy reform (at the international, national, sub-national levels), the processes contingent on developing and implementing change, and the context within which policy is developed. Exclusive focus on policy content can divert attention from understanding the processes which explain why desired policy outcomes fail to emerge, for example, failure of strong IPRs in facilitating knowledge and technology transfer from developed to developing countries in the past. Focusing on the role of ‘firms’ in ‘making’ policy work, this research examines how policy analysis can be used not only to analyse the policy process, but also to better think about research, innovation and business strategies at the firm level.

2.2.2 *Strategic alliances for knowledge integration*

The fundamental question in the field of strategic management of R&D is how firms achieve and sustain competitive advantage in rapidly changing scenarios. Teece *et al.* (1997) confronted this question by developing the 'dynamic capabilities' approach. Stemming from fundamental firm-level efficiency advantage, the approach emphasises firm-specific capabilities and assets. The capabilities here do not represent technological capabilities alone but also management capabilities and difficult-to-imitate combinations of organisational, functional and technological skills. The dynamic capabilities framework directly addresses a firm's ability to strategically integrate, build and reconfigure internal and external competencies to address rapidly changing environments. Chiesa and Toletti (2004), in their recent study of the biotechnology sector, have also highlighted the role of strategic alliances in the development of R&D capability, the rate and quality of innovation, knowledge transfer, and organisational learning.

A review of firm-level case studies in other developing countries like China, Korea and Taiwan (Kim, 1997; Lee, 2000) suggests that the creative destruction of existing competencies and adoption of new practices is not an easy task and definitely not a one-step-straightforward process. The move has to be gradual and needs to be addressed strategically rather than purely technically. Within this framework, the present paper analyses the gradual reorientation of the Indian firms towards innovation-based R&D. Focusing at the firm level, the paper looks at research and innovation strategies that are being devised by the top Indian firms to attain leadership in the domestic market and carve a niche for themselves in the international market in the post-TRIPs regime.

2.3 *Research methodology*

Drug discovery and implementation of new product development processes are both contemporary phenomena as far as the Indian pharmaceutical industry is concerned. Both exert pressure on firms to strategically reconfigure their research and market activities. The success of firms operating under these pressures is determined by their propensity to innovate and commercialise innovations within the given space, time and opportunities. The data needed to investigate these issues require detailed information on the firm(s)' R&D base, technical capabilities and its own technology policy and strategy. In this study we also felt it essential to interact with the firms and conduct in-depth studies in order to understand how firms are dealing with the changing policy, knowledge and markets emerging in the post-2005 scenario. A multiple-case design was used and cases were chosen on the basis of degree of innovativeness and strategies to transform themselves.

The field work was conducted in two phases: preliminary and main investigations, the latter of which was to have detailed discussions on the issues identified in the preliminary phase and to provide an opportunity for us to make amendments. The preliminary phase mapped out major actors (individuals and institutions) and critical issues surrounding our research question through eight to ten pilot interviews which helped the final selection of cases and the research design for in-depth investigation in the second phase. A company dossier was made for each, combining the results of primary and secondary sources, including the analysis, observations and critique contributed by the researcher. The dossiers proved valuable in spotting commonalities and differences in the strategic content of the main research themes at the firm level and their overall approach to

innovation in the post-TRIPs regime. The multiple-case study method allowed replication logic, with each study confirming or disconfirming inferences from previous ones, thereby permitting induction of more reliable strategies.

Special use of existing literature was made to analyse the causes and effects of the legal and policy changes of the last five decades and to map the evolution of the Indian pharmaceutical industry in the pre-TRIPs era. Literature on the evolution of the Indian pharmaceutical industry was sourced from the annual reports of the Ministry of Science and Technology, the Ministry of Commerce and Industry, Parliamentary reports and reports published by individual organisations and authors (NCAER, 1984; Watal, 2000; Lall, 1984; Zaveri, 2002). In addition, industry journals trade journals, and industry associations' publications were also referred to.

3 History of Indian pharmaceutical industry

The story of the growth of the Indian pharmaceutical industry is a fascinating one. With approximately 5877 companies, the Indian pharmaceutical industry is currently one of the most fragmented in the world and provides an excellent case of Indian industry as a whole.

Before Independence, despite modest efforts on the part of the colonial government to spur local production, India was fully dependent on other nations for vital drug supplies. The independent government, in 1947, emphasised rapid industrialisation and invested heavily in pharmaceuticals (amongst other industries), yet did not discourage foreign companies from competing in India. As a result, even well after Independence, foreign-held patents ruled the Indian pharmaceutical industry and drug prices in India were among the highest in the world (Kefauver Senate Committee Report, 1962). The situation today is just the opposite. One of the important successes of economic and social development has been to make life-saving drugs available at affordable prices. This success is largely attributed to a combination of policy-led technological advances consciously followed since the late 1960s and the specific objective of providing affordable drugs for the masses.

The co-evolution of policy and technology that took place post-independence in India is clustered under four major policy time frames and is discussed in the sub-sections to follow.

3.1 Post-independence technology efforts (early years)

The government took its first concrete steps towards self-reliance in pharmaceuticals and healthcare in 1954 with the establishment of Hindustan Antibiotics Limited (HAL), followed by Indian Drugs and Pharmaceutical Ltd. (IDPL) in 1961. These two enterprises played an important role not only in starting domestic production of key bulk drugs but also in diffusing substantial spillovers in terms of technical know-how, technology transfer and the technology innovation process/system itself, and more importantly in generating entrepreneurs. One of the important observations of the fieldwork undertaken for this study has been that founders of many successful enterprises worked with these organisations initially, including the founder of the immensely successful Dr. Reddy's Laboratories.

The modest growth rates achieved jointly by the public and private initiatives, though useful and timely, were not enough to jumpstart local production. The pharmaceutical industry policies for the 20 years after independence continued to emphasise national health and self-reliance rather than indigenous production and allowed Multinational Corporations (MNCs) to exploit the Indian market. By 1970, the industry had a huge MNC presence, most of which maintained minimal physical operations in India (Smith, 2000). Thus, MNCs had the benefit of operating in a free market with exclusive privileges for 16 years (under the Patents and Design Act, 1911) without having to contribute anything to the local industry. The combination of these provisions had a negative impact on the industry.

3.2 Post-1970 technological progress

Before 1970, patent protection served to encourage foreign inventors and foreign R&D. MNCs patented their inventions in India, but did not produce locally, using the patents to establish a protected foreign market in the country (Justice Ayyangar, 1959, p.12). This not only denied the spillovers of technologies developed by MNCs to the local innovation system, but also did not help develop local technological capabilities. The need for a system that encouraged technology acquisition, transfer, development, diffusion and incremental innovation was obvious. Patent Law was used as a tool to establish this system in India. It was The Indian Patents Act, 1970, that laid the foundation of the local industry.

In the 1970s, India introduced complex laws and policies to regulate the pharmaceutical industry, to counteract monopoly abuses by multinationals and to promote local industry. The reforms included changes to foreign exchange regulations, price controls, industrial licensing and, most important of all, the non-recognition of pharmaceutical product patents. The Patents Act, 1970, which came into effect in 1972, represented a significant change in the legal and technological regime and had an enormous impact on the technological evolution of the pharmaceutical industry in India. It started the era of reverse engineering, where firms developed new products by simply changing a few steps in their production processes. Beginning in the late 1970s and early 1980s, legal reverse engineering made new technologies and new drugs available easily and at an affordable price. These reforms not only enabled the emergence of a competitive domestic industry but also set the foundation for generic drug production.

3.3 Technological progress in the liberalised economy

Before liberalisation began, protection of domestic production and local technological efforts enabled India to build up a diverse and fairly sophisticated base in the pharmaceutical sector. However, technological backwardness and lack of genuinely innovative products were evident. The fresh lease of reforms in 1991 (liberalisation) set the pace for technological advancement. Once the Indian market was opened up to foreign firms and the import of goods, demand for improved manufacturing processes and new products drove the need for new technology and innovative products at par with international products.

Indian firms responded to liberalisation in many different ways. Much new technology was imported, but our case studies show that particular firms started investing more in in-house R&D as a move to build a proprietary technological base. Some firms

like Ranbaxy, Dr. Reddy's and Sun increasingly started focusing on Novel Drug Delivery Systems (NDDS), thereby adding their own value to the existing products. "There were even more successful attempts to produce products better tailored than MNC drugs for the Indian market" (Smith, 2000, p.14).

Pharmaceutical firms like Cipla, Alembic, Cadila, Zydus and Lupin improved their manufacturing efficiency and established large production facilities. Some firms like Sun, Torrent, Dabur, Cadila, Ranbaxy and Wockhardt restructured and shifted their technology focus, product basket and market focus. Special emphasis was given to strengthening marketing and distribution networks after liberalisation. Indian firms increased their in-house R&D investments and implemented new approaches to drug/product development. Most technological changes during this era were driven by competition via liberalisation. However, the changes were not entirely due to this reason. Some ambitious and visionary firms started taking technological initiatives even before liberalisation. Nonetheless, liberalisation did set the pace.

The firms studied have restructured and changed in some combination of the above responses and the changes are cumulative. Even without strong patent protection, Indian firms matured during the 1990s. In particular, large firms have grown less reliant on reverse engineering and have developed capabilities for NDDS. Our evidence indicates that the combined effect of policy and market shifts has facilitated a 'research tradition' in the Indian pharmaceutical firms to a very large extent.

3.4 The new patent regime (TRIPs) and challenges ahead

The growth of the Indian pharmaceutical industry over the last four decades owes a lot to the 1970 Patent Act, which allowed the domestic manufacturing and marketing of patented products without a licence. During the process patent regime, Indian firms developed competence in applied research for developing production-process technologies, particularly for synthetic bulk drugs. However, the drugs and pharmaceutical industry in India today faces many challenges stemming from liberalisation of the Indian economy, globalisation of the world economy and new obligations undertaken by India under TRIPs. The 1970 Patents Act that facilitated the extraordinary growth of the domestic industry has been totally reversed with the signing of the TRIPs agreement in 1991. TRIPs marked the turning point of India's policy regime towards the world.

At the national level, these challenges require a change in emphasis in the current pharmaceutical policy and the need for new initiatives beyond those enumerated in the Drug Policy 1985, and modified in 1994, so that policy inputs are directed more towards promoting accelerated growth of the pharmaceutical industry and towards making it more internationally competitive. The Drug Policy 2002 has been framed against this backdrop.

Similarly, changes are required at the firm level, with more emphasis and focus on technology and innovation. In the process patent regime, the emphasis has been on reverse engineering and production of generics, and the R&D focus of firms during this era clearly reflects this. Firms need to improve their R&D efforts to produce quality drugs, whether generics or new, not only to compete with MNCs in the liberalised market but also to enhance exports to the developed world. A shift to a product patent regime would demand capability development for indigenous research to enable the industry to achieve sustainable growth. The large players have already started upgrading their R&D

capabilities and various approaches are being adopted to cut time and cost factors and add quality and innovation in drug development, which are discussed in the next section. Interestingly, not all firms are pursuing identical strategies. The following section discusses firm R&D strategy in more detail.

4 Firm strategies in the post-TRIPs regime

As is evident from the discussion in the previous sections, Indian firms developed their knowledge and capabilities in reverse engineering-based R&D in the pre-TRIPs era. The new patent regime that does not allow reverse engineering of known molecules, together with the pressure exerted by liberalisation and globalisation, is forcing firms to transform their R&D activities and realign their competencies. Firms like Ranbaxy, Dr. Reddy's, Dabur, Sun, Wockhardt, and Torrent are seriously pursuing new drug discovery programmes now. This study suggests that these are the firms, generally, that have invested more in the R content of R&D and have gradually moved away from reverse engineering. Other firms like Cipla, Lupin, Cadila and NPIL have invested more in the D content and have strengthened their infrastructure and financial position through process efficiencies, economies of scale and large product baskets rather than research. These firms are of the opinion that technology needs to be fostered gradually and hence they take a slightly different route to drug discovery. Within these two very broad categories there is further differentiation.

Firms have different views on how to ensure success in this new environment and hence have different strategies. As evolutionary economists suggest, competencies created in the past vary from one firm to another and each firm has therefore devised a different strategy for itself. Nonetheless, R&D does seem to be judged as essential in the long term by all firms. State-of-the-art R&D facilities, equipped with sophisticated instruments, equipment and skills, are considered an absolutely essential part of corporate strategy and, accordingly, investments are being made (company interviews and visits to research parks).

Sceptics, however, assert that Indian firms are not large enough to discover and develop their own drugs. Also, Indian firms lack the experience of MNCs that have spent the better part of the 20th century honing their R&D skills (Smith, 2000). In spite of all these odds, the firms have ambitious plans to launch their own New Chemical Entities (NCEs) and new drugs and have charted R&D strategies to build and fuel their drug discovery pipeline, albeit with a different time frame (short, medium and long). These strategies are discussed firm by firm.

4.1 Ranbaxy Laboratories Limited

Ranbaxy positions itself as aspiring to become a research-based international pharmaceutical company. In pursuit of such an objective and in the changing environment, Ranbaxy has responded by taking three initiatives: new drug discovery, domestic strengthening, and globalisation. Initially, Ranbaxy catered to the domestic market by manufacturing branded generics, pharmaceuticals, bulk actives and intermediates and spent little on R&D. In the last few years, however, the company has taken major initiatives and made investments to create infrastructure and state-of-the-art

dedicated R&D facilities at its R&D centre and to enhance its capabilities in the area of New Drug Discovery Research (NDDR). According to the President of R&D, Ranbaxy's overall R&D spending of around 5% of sales continues to be the highest, in value terms, in the Indian pharmaceutical sector.

The company's foray into Novel Drug Delivery Systems (NDDS) has paid rich dividends in the form of unique proprietary-control release-platform technologies. The development of a unique once-a-day formulation of Ciprofloxacin, which has been licensed to Bayer AG, originator of this molecule, has been a breakthrough success for the company (Annual Report 2002). Driven by therapeutic choice, the company's NDDR activity has made significant strides in areas like anti-infectives, respiratory, and urology. Responding to the status of NCEs, the R&D President gave information about the five NCEs in its pipeline at various stages of development (Table 1).

Table 1 Ranbaxy's pipeline of new chemical entities

<i>Compound</i>	<i>Therapeutic area</i>	<i>Development status</i>
RBx 6198	Urology	Discovery phase
RBx 8444	Urology	Discovery Phase
RBx 2258	Urology	Phase II (licensed to Schwarz Pharma)
RBx 7796	Respiratory	Phase II, IND* Filed
RBx 7644	Anti-bacterial	Phase II, IND* Filed

Note: * Investigational New Drug

Source: Company Interview and Annual Report 2002–2003

The company has decided to conduct clinical trials by itself in India, unlike Dr. Reddy's, who has opted to license out its molecules to MNCs for advanced clinical trials. The strategy is expected to save money in the short term and offer investors a large share of revenues from the new drugs, but on the other side it may also deny timely access to lucrative western markets.

Unlike NDDR, NDDS products are launched with strategic tie-ups with other leading pharmaceutical companies employing the company's proprietary technologies. Pharmaceutical research continues to strengthen the company's international presence through its focus on technology-intensive, difficult-to-make 'niche' products. In biotechnology, the current focus is to identify new biological targets (genomics, proteomics and bioinformatics) and develop DNA-based biopharmaceuticals and vaccines. In the phytomedicines (herbal drug research), the strategic focus is to develop high-quality nutraceuticals and ethical products and subsequently move into isolation and characterisation of active principals, either as NCEs or as potential lead molecules for drug discovery. According to the President of R&D, Dr. Khanna, "while most of the products in these areas will be developed in-house, the company is evaluating strategic tie-ups with other partners to speed up the licensing and development process".

In line with its strategy and focus, Ranbaxy is seeking licensing for NCEs at advanced preclinical stages or in early clinical phase trials from international companies for further development. Overall, this strategy reflects the company's intent in moving up the value chain and in becoming a research-based company.

4.2 Dr. Reddy's Laboratories (DRL)

Unlike Ranbaxy, which initially started with reverse-engineered products and gradually moved up the high-value end, Dr. Reddy's Laboratories (DRL) opted for a much riskier path (new drug discovery), even during its formative years. DRL was the first Indian pharmaceutical company to conduct research and begin a drug discovery programme as early as 1993 focused on the speedy translation of scientific discoveries into innovative products. Drug discovery efforts at DRL focus on early phase discovery and preclinical studies of newly synthesised compounds for the treatment of cancer, diabetes, dyslipidemia, inflammation and infections. DRL's current R&D investment at 8% of its sales turnover continues to be the highest among the Indian pharmaceutical firms. DRL is further increasing its investment in drug discovery and research activities to about 10% of the total revenue, a sharp jump from 8% in 2002–2003 (company interview).

Having identified bio-generics as a significant market area, the company's strategy to enter this market is to have a portfolio of bio-generics in key therapeutic segments by leveraging core competencies and focusing on efficiencies along the value chain (from development to marketing). According to company sources, initially the technology platforms will be utilised to develop capabilities in manufacturing products that are already in the world markets, but the ultimate aim is to build up capabilities in basic research in biotechnology. The company has a pipeline comprising several recombinant proteins in various phases of development for the treatment of cancer, diabetes and cardiovascular diseases (Table 2).

Table 2 Dr. Reddy's R&D pipeline

<i>Compound</i>	<i>Therapeutic area</i>	<i>Development status</i>
DRF 2593	Diabetes	Phase II (licensed to Novo Nordisk)
DRF 2725	Diabetes and dyslipidemia	Phase III (licensed to Novo Nordisk)
DRF 4158	Metabolic disorders	Preclinical done (licensed to Novartis)
DRF 4832	Metabolic disorders	Late preclinical
DRF 1042	Cancer	Phase I completed
DRF 1644	Cancer	Preclinical completed
DRF 11057	Bacterial infections	Preclinical
DRF 10945	Metabolic disorders/dyslipidemia	Preclinical

Source: Annual Report 2002–2003 and company interview

Review of the company literature and subsequent interviews suggest that in initially focusing on bulk actives (APIs), DRL in the past has used innovation in process development and finished dosage to build a profitable and strong business. In 1992 DRL started building up its base for the US generics business (Annual Report 2003). But the ultimate pharmaceutical challenge – drug discovery research – is being pursued intensively to compete in the post-2005 era. So far, DRL has out-licensed three molecules – DRF 2725, DRF 2593 in diabetes and DRF 4158 in cancer – to MNCs for development. The key strategy to move up the value chain incrementally and manage risks is to out-license new molecules to larger pharmaceuticals with resources to take it to the market faster. According to the Vice President–Formulations, “this strategic integrated

discovery approach is envisaged to meld talent and skills throughout the organisation. DRL's global presence gives the advantage of providing a cost-effective combination of critical skills and scale".

4.3 Chemical industrial and pharmaceutical laboratories (Cipla)

Unlike DRL, which entered the market in the mid-1980s with a research focus, Cipla, one of the oldest firms (1935), is better known for its reverse-engineering skills. With its reverse-engineering strengths facilitated by the Patents Act of 1970, Cipla has made rapid progress during the last three decades. Both Dr. Reddy's and Cipla command a leadership position in the domestic market today, albeit with different research strategy strokes.

Despite the risk of being termed a 'patent-buster', Cipla opted for an aggressive product development (reverse-engineered) strategy that catapulted it to the top league. According to Dr. Hamied, the Chairman and Managing Director of Cipla, much of Cipla's progress is attributed to the company's strategy and focus on "from inception-to-R&D-to-commercialisation and its thrust in making available the very latest in modern drugs and advanced delivery systems in a wide range of areas".

In many therapeutic categories, such as anti-asthmatics, Cipla offers the widest range of possible products. Focusing on process research, Cipla has made substantial progress in NDDS and chiral synthesis. Cipla has already developed its first chirally resolved molecule, salbutamol, which is an anti-asthma drug. Two of Cipla's anti-asthmatic devices, namely Rotahaler and Zerostat spacer, are patented internationally. The company commits significant resources to R&D, which currently is close to 5% of the company turnover and is expected to go up (company interview). The R&D work focuses on New Improved Chemical Entities (NICE), NDDS and development of patent-free processes for known molecules.

Cipla has a strong pipeline of products and is expected to come out with innovative drugs through NDDS and chiral synthesis. Given the public knowledge that Cipla is working on improved chemical entities and drug delivery systems, the research pipeline of Cipla could be moving on a similar trajectory to Ranbaxy's. Discussions with the company's Director suggested that it is possible for Cipla to get into joint development partnerships with present patent holders of blockbuster molecules to develop improved versions by using chiral chemistry.

Cipla's top management strongly believes that the key to success in the current environment is not basic research but technological innovation. Consequently, Cipla is aiming for continuous innovation and complements this by achieving operational and marketing excellence. The company has consistently come out with modern drugs that multinationals introduce, far more cheaply in the domestic market. The strategy has been effective in a price-sensitive market.

4.4 Nicholas Piramal India Limited (NPIL)

Quite unlike Ranbaxy, DRL and Cipla, which had focused on pharmaceutical interests, Piramal Enterprises was initially in the textiles business. Visualising the opportunities in the fast-growing pharmaceutical sector, the Piramal group acquired Nicholas Laboratories, a formulations company, from Sara Lee in 1988. After its first acquisition in 1988, in the last 15 years NPIL grew to its leadership position through a series of acquisitions, mergers and alliances.

According to Dr. Sikka, the Senior President, “NPIL aims to be an integrated pharmaceutical company with a commitment to discovery, development, manufacture and marketing of indigenous pharmaceutical products”. NPIL’s R&D focus is designed to maximise opportunities throughout the research value chain. Its R&D programme is divided into four strategic business units, each focusing on different aspects of and opportunities in pharmaceutical research: basic research – on new drug discovery; natural products; clinical research – on providing quality clinical and bio-analytical support to facilitate the international introduction of generic products to support research on NDDS and clinical development of new chemical entities; and genomics research – translating cutting-edge research into innovative applications. R&D investment is quite low compared to other domestic pharmaceutical firms, at 2% of sales. However, recognising the importance of basic research in this knowledge-based industry, NPIL has made strategic investments in its research centres.

NCE research is currently concentrating on three lead molecules in the diabetes, oncology and anti-infective fields. All three molecules are in the preclinical stage. According to Dr. Sikka, “the goal of the NDDS division is to develop novel formulations of already approved drugs and gradually develop an innovative technology platform”. Capex, a new R&D facility, is being created at Goregaon, Mumbai, to house the expanded R&D team. This new facility will be utilised to pursue rheumatology and cancer research, in addition to the ongoing diabetes and anti-infectives projects, as Dr. Sikka informed the researcher during the interview. The research strategy in NPIL appears to be driven by ‘research services’. Accordingly, NPIL is creating infrastructure and investing on skills development for clinical research and contract manufacturing.

4.5 Sun Pharmaceuticals Limited

Following the same path as NPIL, growth through mergers and acquisitions, Sun Pharmaceuticals has taken major strides quickly. Sun manufactures and markets specialty medicines and APIs for chronic therapy areas such as cardiology, psychiatry, neurology and gastroenterology. According to one of its senior managers, Sun was one of the earliest among Indian companies to invest in research. Serious resources were committed to research in 1993 when it was a much smaller company. Ever since, 4% of an increasing turnover has been invested every year on time-bound projects at the company’s research centre, Sun Pharma Advanced Research Centre (SPARC).

SPARC works on process synthesis, dosage forms, NCEs and NDDS. The research strategy has been phased in three stages. In the first phase, which has been accomplished, the emphasis was on reverse engineering and on high-yield processes for specialty bulk drugs. The processes developed for specialty bulk actives at SPARC enabled the company to commercialise more than 60 specialty bulk actives in just seven years (1993–2000), several of which are based on novel and non-infringing processes. In the second phase, the focus is on innovative drug delivery systems and alternative patentable routes. The output of the first and second phase coupled with increasing investments in the infrastructure and resources (financial as well as technical) equips the company for drug design in the long term, which is the third phase.

Based upon my discussions with managers, Sun Pharma's research approach appears to be incremental: from simpler dosage forms to NDSS and complex bulk actives. The research focuses on new chemical entities and NDSS. From about 30% of the current research budget allocated to innovation-based projects, the company expects to increase it to 70% over the next three years (interview).

4.6 *Lupin India Limited*

Lupin, a global leader in the anti-TB segment, is the world's largest manufacturer of Ethambutol and Rifampicin (through the complex fermentation process). Its Rifampicin plant is one of only three plants in the world approved by the US Food and Drug Administration (USFDA). Most of its products are placed in the top three positions under different categories of anti-TB segments (OPPI, 2003). Being the world's largest integrated manufacturer of cephalosporins, Lupin has a strong presence in this segment. Other principal therapeutic areas are cardiovasculars and Non-Steroidal Anti-Inflammatory Drugs (NSAIDs). According to Dr. Sen, President of R&D and Regulatory Affairs:

"Lupin spends more than 5% of its sales on research activities. The company's R&D Park in Pune city near Mumbai, conducts leading-edge research in generics, new chemical entities (NCEs), Novel Drug Delivery Systems (NDDS), Oral Controlled Release Systems (OCRS) and phytomedicines."

The company has devised twin strategies for the short and long term. The short-term goals are driven by market rather than research. Building upon its existing R&D competencies in the anti-TB sector, Lupin is augmenting its product portfolio and broadening its market and distribution network. The strategy is to identify and implement profitable operations without new drug discovery in the short term. The short-term strategy is devised on the market opportunities that exist today and Lupin's core competencies in exploiting them. To fully utilise its backward integration expertise, Lupin has entered into the business of fixed dosage formulations and is exploiting synergy by entering those therapeutic formulations which require APIs where Lupin is already present, like cephalosporins and ACE inhibitors.

The long-term research focus is on developing NDDS, herbal products and NCEs. Herbal research is accorded a high priority. Realising the fact that formulation business for conventional-TB disease in the near future is not promising (as most of the demand comes from Third-World countries, low profit margins and strong national health services), Lupin appears to be steering a shift in its product mix in the coming years.

4.7 *Cadila Pharmaceuticals Limited (CPL)*

Positioned as a research-based, technology savvy firm, Cadila Pharmaceuticals Limited (CPL) has current focus on areas like branded formulations (human and veterinary), NCEs, NDDS, APIs, bulk drugs, vaccines and immunoglobulins (Company Interviews and Annual Reports, 2000–2004). Ongoing investment is made for basic and applied research in phytochemistry, biotechnology, plant tissue culture, toxicology, analytical research and genetic engineering (interview). There are three separate research units, namely Chemical, Biotechnology and Generics.

Cadila Pharmaceuticals is revitalising its research and business through a mix of conventional and modern approaches. According to Dr. P.K. Ghosh, Head – Biotechnology:

“Innovation in products and processes may be achieved by the firms faster based on a systematic technology breakdown and mapping of each technological trajectory with possible application areas, already experimented and exploited in the research institutions rather than reinventing the wheel in-house. The collaboration and cooperation method enables one to direct joint efforts on the most prominent research topics.”

Based on this philosophy, the firm has established a strong R&D base in biotechnology and developed working relations with key R&D institutes in the country for outsourcing of research and development. Interactions with Cadila suggest that as of today, Cadila does not invest much in basic R&D and does only developmental work. The company rather buys or collaborates with research institutes and picks up lab-proven technologies to upgrade and commercialise. Through collaborations and networking CPL intends to source complementary assets and expertise from external sources while simultaneously building their in-house capabilities to assimilate, absorb and innovate upon.

Cadila’s current R&D strategy is to transform itself from a chemical formulation outfit to a true life sciences company. However, the expertise and core technological strengths developed over the years in chemical formulations are being exploited by implementing innovative manufacturing and marketing strategies. Thus, on one hand the company has captured the high-volume market by developing generics and on the other the company is investing seriously in life sciences in order to capitalise on the future opportunities.

5 Key observations and analysis

5.1 Enhanced R&D investments

Under the process patent regime, Indian firms effectively used reverse engineering to make patented products and emerged as major generic manufacturers. Competitive pressures induced through liberalisation in 1991 constrained the benefits from imitation and hence restricted its use. Later, changes in patent law under the TRIPs obligation, preventing the reverse engineering of patented molecules, forced Indian firms to enhance their R&D efforts and investments. The total R&D expenditure, which was only Rs. 3 crores in 1965–1966, reached an impressive Rs. 140 crores in 1995, a significant year, when the WTO and IPR protection came into being. With the increasing realisation that copying will no longer be permissible after 2005, R&D investments have gained serious momentum since 2000. From a paltry sum of Rs. 140 crores in 1995, it went up to Rs. 200 crores in 2002 and was expected to exceed Rs. 1000 crores in 2004 (IDMA, various bulletins).

Firms have cited different reasons for low R&D investment. According to some, the process patent regime coupled with a protected market prevented Indian firms from investing more on R&D. My analysis of firms’ views suggests that initially there was a large, ready domestic market for cheap generic drugs available to Indian firms. As the domestic market became saturated, other developing countries and Russia served as the primary markets for finished formulations. Thus neither market-pull nor policy-push was there to encourage research and innovation. Consequently, research was limited to better production processes which required minimal research and hence low investment.

Lately, with the change in patent laws and policy scenario, large pharmaceutical firms have begun to invest in R&D. The case studies suggest that from about 2% of total sales around three to four years ago, the average R&D expenditures of the leading research-based domestic firms has gone up to around 5%–6% in 2003–2004 (Table 3). Among these companies Ranbaxy, Dr. Reddy's, Cipla, Wockhardt, Torrent, Sun, Lupin, NPIL and Aurbindo are prominent. Dr. Reddy's R&D expenditure increased from 7% in 2002–2003 to 10% in 2003–2004 and is slated to increase further in future.

Table 3 R&D investments in selected Indian pharmaceutical firms

<i>Company</i>	<i>R&D spending as percentage of sales</i>					
	<i>1999–2000</i>	<i>2000–2001</i>	<i>2001–2002</i>	<i>2002–2003</i>	<i>2003–2004</i>	<i>2004–2005*</i>
Ranbaxy	3.6	4.2	4.0	5.0–5.5	6.3	7.0–8.0
Dr. Reddy's	2.7	3.5	4.0–4.5	6.8	9.9	12.9
Cipla	3.5	3.5	4.0–4.5	4.5–4.8	4.8–5.0	5.0–5.5
NPIL	2.0	2.0	2.0	2.0	4.0	5.0
Sun	4.0	4.0	4.0	7.0	10.0	10.0–12.0
Lupin	1.7	2.0	2.0	3.0	3.0–3.5	8.0
Dabur	–	–	–	–	8.0–9.0	8.0–9.0
Cadila Pharma	1.0–2.0	1.0–2.0	1.0–2.0	2.0	2.0–3.0	3.0–4.0

Note: * represents projected investments

Source: Compiled by the author from various sources (company interviews, annual reports, journal articles and press releases)

NPIL has doubled its R&D spending from 2% (in 2002–2003) to 4% (in 2003–2004). Torrent Pharma's R&D expenditure increased from around 5% (in 2001–2002) to 9% (in 2003–2004) and is expected to go to 10%–11% (in 2004–2005).

5.2 *Enhanced patent filings*

The number of patents filed and granted in a particular sector indicates the level of inventive activity and R&D capabilities of a country in that sector. Two Indian entities, Council of Scientific and Industrial Research (CSIR) and Ranbaxy, find mention in the 2002 top ten list of the World Intellectual Property Organization (WIPO). Patent applications by industry during 1995–2000 indicate that pharmaceuticals rank highest with 396 applications (Journal of Intellectual Property Rights, various issues).

Indian firms have been filing Abbreviated New Drug Applications (ANDAs) and Drug Master Files (DMFs) internationally primarily to gain entry into regulated markets. India filed more than 112 ANDAs in 2003 and 392 in 2002. India's share of ANDA filings has been rising consistently and was around 23% in 2003. Indian firms accounted for over 30% of the DMFs filed in the USA in 2003. It remained in first position with 126 DMFs in 2003 alone (India Folio, 2004). This indicates not only the present level of patenting activity in Indian pharmas but commitment (pipeline) for the future as well. Firms have realised the need for beginning serious R&D for new drugs and patenting them. Top companies such as Ranbaxy, Dr. Reddy's, Sun, Cipla, Lupin and many others have enhanced their patent filings. Table 4 briefly summarises patenting activity in Indian firms.

Table 4 Patents filings by Indian pharmaceutical firms

Company	Patents	ANDAs				DMFs			Comments
		Filed	Para IV	First to file	Target	Filed	Target	Target	
Ranbaxy	260 (India) 103 (USA) 126 (PCT)	127 (92*)	22	12	15–20	48 (2003)	15–20	An international generics player. Switchover from process to patent products. Para IV filing is accorded highest priority as a strategy to enter regulated markets and gain leadership. Licensing out molecules to MNCs	
DRL	67 (India) 74 (USA) 72 (PCT)	42 (12*)	24	9	15–18	100 (56 in 2003)	20	Already a research-driven and product-oriented firm. DRL has its NCEs at the most advanced stages. Para IV filing is accorded highest priority as a strategy to enter regulated markets and gain leadership. Licensing out molecules to MNCs	
CIPLA	NA	15 (35**)	15	5	15–20	53 (in 2003 alone)	30–35	A major generics manufacturer, opting for New Improved Chemical Entities (NICE) instead of NCEs. DMFs are considered to be the better, cheaper and faster route to international markets	
SUN	132 in all	13 (2*)	0	0	8–10	22	8–10	Major generics manufacturer. Quick switchover to research from reverse engg. ANDAs and DMFs are given equal weightings. Focus on specialty products (niche areas)	
Lupin	162 in all	13 (5*)	0	0	12–16	82 (21 in 2003)	20–25	A major generics manufacturer in anti-TB segment. DMFs is the favoured route as it is cheaper and faster and less complicated	

Notes: * Represents approved patents

** Represents patents to be filed in 2004–2005

Source: Compiled by the author from various sources (company interviews and annual reports, journal articles and press releases)

Firms have used multiple approaches to create intellectual property, such as filing for Indian patents, international patents, ANDAs and DMFs. Firms like Dr. Reddy's and Ranbaxy have made use of first-to-file and Para IV filings as well. However, other firms like Cipla, Cadila, Lupin, Sun and Zydus have opted for DMFs to gain cheaper and faster entry to regulated markets. The increase in the number of patent filings in the recent past and ambitious targets set up for the future strongly suggest that TRIPs has stimulated both R&D activity and filing of patents in the Indian pharmaceutical industry.

5.3 Enhanced research, licensing and outsourcing partnerships

Partnerships, collaborations and alliances have become increasingly common in the pharmaceutical industry not only in India but worldwide. Discussions with Indian firms suggested strongly that partnerships have become the most important and integral part of the overall corporate strategy since the mid-1990s. Indian firms have collaborated with premium technology and research institutions to change their market image (research driven); have acquired and merged to elevate their market position (size, brands) or to have access to certain technologies or markets; and have formed alliances to shift their market focus (from developing to developed); or have moved up the higher value chain by acquiring or collaborating for gaining new knowledge and skills from external sources. Ranbaxy, Cipla, Lupin, Cadila Pharmaceuticals, Dabur, Zydus, Wockhardt, Sun and Torrent are all involved in such alliances.

Various forms of strategic partnerships such as collaborative research, contract research, co-production agreements, co-marketing arrangements, cross-distribution arrangements, technology licensing and Mergers and Acquisitions (M&As) are increasingly being utilised for capacity additions, brand acquisitions, marketing channel integration, and R&D integration, depending upon the focus of a firm. Ranbaxy, Sun and DRL have acquired assets or formed alliances with the firms based in other countries to expand their international presence, on one hand, and have collaborated with other firms and premium technology institutes to strengthen their technology base. Sun Pharma's acquisition of Knoll's bulk laboratory, for instance, was motivated by the firm's technological strengthening strategy. Similarly repeated M&As with the leaders have provided NPIL with competitive edge over other firms in terms of innovative product line and a well-defined marketing and distribution network. Acquiring firms with existing innovative product lines or products in the advanced stage of development appears to be a feasible and favourable option for Indian firms. In addition, Indian firms have also acquired generic drug companies abroad or even set up manufacturing joint ventures in order to seize the international generics opportunity. For instance, Ranbaxy has expanded its presence internationally by acquiring Rima Pharmaceuticals in Ireland and Ohm Laboratories in the USA. Dr. Reddy's has an agreement with Pharmaceutical Resources Inc., USA to supply bulk drugs and intermediates.

These trends suggest that M&As are likely to be a continuing feature in the pharmaceutical landscape as firms seek to grow and consolidate market positions while still capitalising on new research opportunities. There is an increasing recognition in Indian pharmaceutical firms that one company's peripheral technologies are another's core activities, and that it makes sense to source such technologies externally rather than to incur the risks, costs and most importantly of all, time scale associated with the

in-house development, especially in NDD. Coordinating and redeploying internal and external sources appears to be the key strategy adopted by the firm to address the rapidly changing technology and business environments.

Subcontracting of research is a recent phenomenon in the pharmaceutical industry. Earlier, subcontracting in pharmaceuticals was mainly restricted to intermediate or API suppliers. Now, as the firms are moving up the higher value chain and competing to launch new drugs, subcontracting for research, advanced clinical trials, custom synthesis, marketing and sales support are gaining popularity. Indian firms (Ranbaxy, Cipla, Dr. Reddy's, NPIL) realise that it will be difficult for them to commercialise their discoveries on an international basis on their own and hence they are getting into licensing deals and strategic alliances with international companies. The cases under study suggest a change in the traditional technology development and commercialisation practices (where most of the innovations have emerged from in-house R&D efforts) to more open and participative approaches.

5.4 New motives: strategic integration of knowledge and technology

The literature review, together with case studies in this paper, suggests that the focus of collaborations in 1990s was on integrating brands, manufacturing capacities, and marketing and distribution networks. Vertical integration achieved new heights during this period. Ranbaxy, NPIL, Sun, Lupin and Cipla all expanded their manufacturing operations, marketing and distribution networks, product portfolios and brands through backward and forward integration. Ranbaxy bought a 30% stake in Vorin Laboratories in order to gain control over a key raw material and an intermediate supplier for its famous product Ciprofloxacin. This backward integration gave many benefits to the company. Sun Pharma has also utilised acquisitions for its organic and inorganic growth. Its acquisition of MJ Pharma and Gujarat Lyka was a part of its multimedia strategy, while integrating TDPL is an entry strategy into specialty areas like oncology, gynaecology and pain management.

Brand acquisition in India was initiated by Dr. Reddy's, who acquired Riflux and Clamp from Sol Pharma to supplement its existing anti-ulcer products range. The trend was feverishly followed by other firms. Ranbaxy acquired Mox, a top brand of the Amoxicillin drug, in addition to integrating an entire range of antibiotics and dermatological brands of Gufic Laboratories. The Piramal Group acquired Analgin/Aspirin fame from Nicholas. Later it took over Roche products like Valium to add to its product basket. These collaborations were particularly driven by market liberalisation in the 1990s.

However, with the signing of TRIPs in 1995 and changes in the patent laws, the focus of collaborations has shifted to R&D. The emphasis is on knowledge and technology integration rather than the critical mass and economies of scale. Many top Indian firms have pursued collaborations with international drug companies to access technology and knowledge vigorously in the last five years or so, for example, Ranbaxy with Eli Lilly and Gist Brocades, Dr. Reddy's with Novartis and Novo Nordisk, Lupin with Merck Generics and Wyeth Lederle, Torrent Pharmaceuticals with Novo Nordisk of Denmark and Sanofi of France and Cadila Pharmaceuticals with M.M. Schwabe, USA. These trends suggest a change in the mindset of Indian entrepreneurs and a change in the motives behind strategic alliances pursued by the Indian firms.

NPIL has identified leaders to partner with in order to gain technology, knowledge and expertise in its area of choice. The combined scientific teams of Hoechst R&D Centre, acquired recently by NPIL, and its earlier acquisitions of Boehringer Mannheim and Roche, provide it with an instant and unmatched knowledge base (more than DRL and Ranbaxy). Sun Pharma is another exemplary case of gaining access to technology and knowledge through acquisition strategy. Its acquisition of USFDA-approved Caraco Pharma Labs and UKMCA-approved MJ Pharmaceuticals provided Sun with a quick access to the proprietary knowledge created by these firms.

Accessing new knowledge from external sources has become extremely strategic in nature in the recent past. The straightforward sale and purchase of contemporary technologies is no longer a feasible option. Therefore, new modes are constantly emerging to acquire and access knowledge from external sources and internalise it. Acquiring or collaborating with firms with existing knowledge base, innovative product lines or products in the advanced stage of development appears to be a feasible and favourable option for Indian firms. Table 5 summarises the knowledge diffusion level associated with different kinds of collaborations and the use of these mechanisms in Indian firms.

Table 5 Forms of collaboration and knowledge diffusion

<i>Type of collaboration</i>	<i>Typical duration</i>	<i>Advantages (rationale)</i>	<i>Disadvantages (transaction costs)</i>	<i>Examples of Indian firms</i>	<i>Diffusion</i>
Subcontract	Short term	Cost and risk reduction, reduced lead time	Search costs, product performance and quality	Ranbaxy, DRL, NPIL	Low
Cross-licensing	Fixed term	Technology acquisition	Contract cost and constraints	Cipla, NPIL	High
Consortia	Medium term	Expertise, standards, share funding	Knowledge leakage and subsequent differentiation	Dabur, Cadila, HAL	High
Strategic alliance	Flexible	Low commitment, market access	Potential lock-in and knowledge leakage	Zydus, Sun, Lupin, Ranbaxy	Medium
Joint venture	Long term	Complementary know-how, dedicated management	Strategic drift and cultural mismatch	NPIL, Ranbaxy, Cadila	Medium
Network	Long term	Dynamic, learning potential	Static inefficiencies	Ranbaxy, DRL, Dabur, Cadila	High

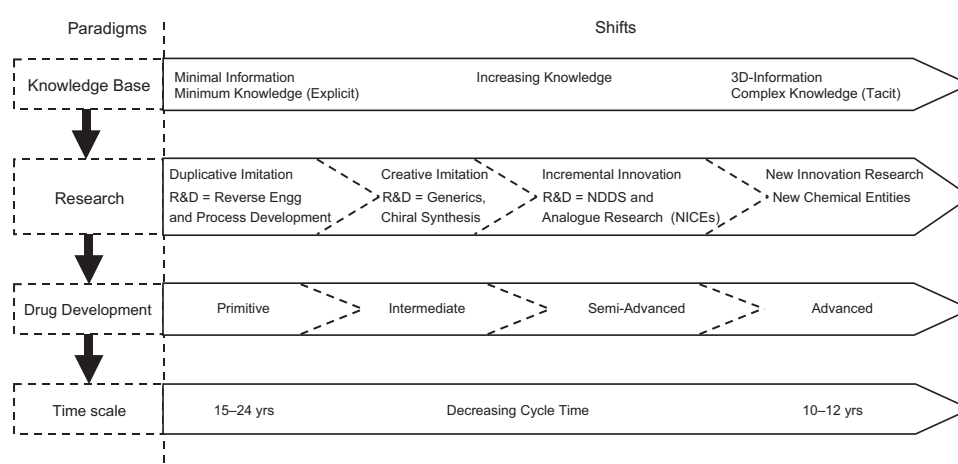
Source: Fieldwork data from India

5.5 *India's capability creation and value chain progression*

Previously, Indian firms began reverse engineering somewhere from the middle of the chain, that is, the process development, totally omitting the discovery and basic research part. Through backward and forward integration the firms advanced gradually from the stage of duplicate imitation to the creative imitation stage, that is, the generics and chiral synthesis. Though most of the medium- and small-scale firms got locked here, larger firms moved to the next stage of development, that is, the NDDS. Most of the companies are now involved in analogue research, which is one step behind the NCE research

(Figure 1). Moving up the value chain, firms have created core competencies in the middle part of the chain. The level of expertise achieved is so high that most of the firms appear to be well prepared for providing services to multinationals, and in turn the missing links in the drug discovery and innovation chain are strategically organised from external sources for in-house research. This indicates that Indian firms have indeed progressed and upgraded their status from mere ‘followers to partners’.

Figure 1 Progressive drug discovery paradigm of Indian firms



Collective analysis of selected cases implies that firms are adapting to the changing environments by making midway strategic corrections and are continuously integrating new parallel streams in the mainstream of corporate strategy. R&D is recognised as the ‘survival kit’ in the post-2005 scenario and building the science base for innovations is deemed necessary for long-term growth by Indian leaders. However, firms do recognise the risk involved in discovering and competing in open markets on the basis of drug discovery (path) alone. Hence, contingency plans are being made along with developing drug discovery capabilities. Most firms have reconfigured their research on short-, medium- and long-term bases. Firms have strategised to maintain a steady cash flow, tapping the large US generics market in the short term. In the medium term, they intend to move up the value chain through NDDS, which can be patented, and finally in the long term to launch their own molecules.

6 Conclusion

Combining ‘drug discovery and generics strategies’ is the model practised by the Indian firms. However, as an evolutionary perspective would suggest, each firm has its own distinctive approach. The accumulation of skills, technical know-how and expertise, whether at the level of firms or countries, takes time and is a process pertinent to long-run economic development. Our case studies in this paper suggest that technology and innovation is not something which firms buy-in from outside. On the contrary, it is rooted in a specific set of change-generating resources (context) or absorptive and innovative

capability firmly rooted within the structure of technology-oriented firms. The particular profile of each firm's approach needs to be understood in light of its own history. Each firm under investigation in this research has a rich mix of resources and has accordingly chalked out a strategy for itself. Although there are many commonalities, there are quite a few differences in approach and implementation of broad strategies. Ranbaxy's combo-strategy is to plough back profits from its generics business in the USA into new drug research in India. In research, also, Ranbaxy has alleviated its risk by focusing on NDDS instead of a sole thrust on NCEs. Although DRL has its major focus on NCEs, the firm is integrating NDDS and generics in its overall business strategy. Firms like Cipla, NPIL and Sun are intensifying their research and market activities but on new improved and value-added products rather than new drugs, based on their capabilities and expertise created in the past. Other firms that have now combined their traditional strategies with research are Dabur, Lupin, Wockhardt, Torrent, Cadila Alembic, and NPIL.

Firms are formulating future research and business strategies in different combinations and permutations of NCEs, NDDS, generics, contract manufacturing, conducting of clinical trials, and in-and out-licensing agreements. Aligning 'service-based business strategies' alongside the 'drug discovery', which are being vigorously pursued by the top-level firms is basically a strategic combination of imitative and innovative capabilities. Ranbaxy, DRL and Cipla are judiciously exploiting combo-strategies to combat the competitive pressures faced by the generic industry as well as to capture research-based high-end markets. Although the outcome of these contemporary strategies is yet to be seen, they provide a road map worth considering to new entrants.

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