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# Experimentation with strategy in the Indian Pharmaceutical Sector

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## Abstract

This paper studies the strategies employed by four established Indian pharmaceutical firms. In response to new economic opportunities generated by the Hutch Waxman Act (1984) in the US and the New Patent Act (1999) in India , these firms pursued different marketing, internationalisation and R&D strategies. Inter-organisational learning makes this variety akin to a natural experiment where firms learn about their own 'best' practices by observing what other firms do. Such experimentation is a necessary condition for the development of dynamic capbilities, but not sufficient.

Keywords: Internationalisation, R&D management, Indian pharmaceutical sector, corporate strategy.

# 1. Introduction

Resource based views of the firm place special emphasis on the roles of heterogeneous capabilities of firms in driving variety in strategy. However, in dynamic markets, the relative roles of capabilities, entrepreneurship and ad hoc problem solving remain entangled in the race to gain competitive market shares. This paper draws upon the experience of the Indian pharmaceutical sector in the 1990s, where a largely homogenous set of incumbent firms experimented with a variety of strategy mixes in order to tap into the new economic opportunities facing them.

The popular perception in the writing about the Indian Pharmaceutical industry is that the two (domestic) regulatory changes that offered new economic opportunities were the New Industrial Policy of 1991[1] and the adoption of the New Patent Act in 1999. However, we argue that the opportunity of far greater significance for the growth of Indian pharmaceutical firms was the passing of the Hutch Waxman Act in the US in 1984. Liberalisation facilitated the ability of Indian firms to exploit this opportunity to market generics drugs to the US and other Western economies. Furthermore, stronger patent protection under the new patent law of 1999 has shut down the avenues for exploitation of this opportunity, but promised large rewards to Indian firms that could transform their reverse engineering capabilities into drug discovery capabilities. Whether 15 years or more of experience in reverse engineering is sufficient to transform process innovators into product innovators remains to be seen and the jury is still out on the who will succeed and how.

Another element of the popular accounts of the growth of the Indian pharmaceutical sector is that all the leading firms are treated as behaving similarly. Whilst there is recognition of the managerial ingenuity employed by Indian firms in exploiting the generics opportunity (Madanmohan and Krishnan 2003, Bower and Sulej 2005) there is little appreciation of the variations in strategy-mix employed by the leading generics manufacturing firms in the industry nor the consequence of these variations for the evolution of firm strategies and the industry. Using a comparative case study method, our paper details the evolution of strategic change within the firm and emphasises the subtle differences in the strategy set pursued by firms exploiting broadly similar market opportunities. These differences in strategy by early firms

constituted a natural experiment by which all firms in the industry learned about what the pay-offs and constraints to the different strategies were. Later entrants seeking to exploit the generics market opportunity, pursued strategy sets more conditioned by such learning.

However, the value of our study also lies in the light that it can shed on the central issue of how developing country firms can acquire unique dynamic capabilities that allow them to become independent players in oligopolistic industries such as pharmaceuticals, without major technological assets of their own. Here we find that the market for firm acquisitions is a popular route to acquiring market share whilst also buying time and resources to access the complementary technological and regulatory capabilities required to compete with larger more integrated firms. This is interesting as hitherto discussions on technological capability have tended to concentrate far more on R&D investments, technology transfer and licensing issues, though capital market asymmetries have been acknowledged as playing an important role. Since 2000, leading Indian firms have used their strong capital market positions to fund acquisitions that will gain them market share and time to build their own technological, marketing and regulatory capability. In this respect, their behaviour is remarkably similar to that of some American pharmaceutical manufacturers in the early twentieth century when European firms held all the patents but antibiotics manufacture provided a great economic opportunity during the Great War. [2]

The remainder of the paper is organised in the following way. Section 2 briefly reviews the literature on resource based views of strategy formation. Section 3 provides a brief background to the Indian pharmaceutical industry, noting the main features of change in the policy environment and the opportunities and constraints that regulatory change threw up for established firms in the domestic sector. Section 4 presents the case studies of four established firms and describes the evolution of their strategies for international expansion and the long term positioning to be drug discoverers. Section 5 discusses the elements of similarity and difference in the strategies pursued by the four firms and discusses some of the implications of the comparative studies. In Section 6 we look at the overall performance of the four firms and the implications of strategic variety for the future evolution of the industry. Section 7 concludes.

## 2. Capabilities in changing markets

The literature on firm capabilities originated in the writings of Penrose (1959) who posited that the growth of firms was conditioned by their particular inherent resources and a desire to exploit these more fully. A rich tradition of literature on strategic management built on this perspective to predict what strategies firms would employ for growth (e.g. diversification as in Rumelt 1984) and the problems involved in growth strategies that stretched the core competencies of firms. The mechanisms by which new capabilities come into being have been stressed by behavioural and evolutionary views. Nelson and Winter (1982) argued that each firms' access to technological and organisational knowledge is different and conditioned upon its past learning. This kind of learning and the consequent stretching of profit possibilities in production is 'localised' within firms and so difficult to imitate by other firms- thus, this perspective emphasises the heterogeneity of firm capability as well as its stickiness. By implication firms have different strategies that suit their capability resources.

However, situations of change prompt a disturbance of these stable patterns. Exogenous events disrupt or add new value to the rents to existing capabilities and thus influence the competitive positions of firms. As Teece et al. (1997, p. 529) point out, 'competitive advantage is not just a function of how one plays the game; it is also a function of the assets that one has to play with and how these assets can be deployed and re-deployed in a changing market'. Teece (1998, p. 72) defines dynamic capabilities as 'the ability to sense and then seize new opportunities, and to reconfigure and protect knowledge assets, competencies, and complementary assets and technologies to achieve sustainable competitive advantage' and has argued that dynamic capabilities are the key to strategic changes. In fact, the dynamic capabilities framework outlined by Teece et al. (1997) proposes a triad of factors that influence the development of firms' competitive advantage: firms' internal processes (organisational and managerial); firms' (asset) positioning in the market; and the paths open to it consequent on the first two factors. Often the paths open to firms may be quite narrow making value-augmenting strategic change slow and incremental.

An important factor in rapidly changing markets is the possibility of leverage through deployment and re-deployment of existing capabilities. Which product market niche

or business model best utilises/ gives value to the internal and external assets of the firm? Teece (1998: 72-75) notes the importance of sensing and seizing such advantage in realising the best value for a firm's resources through entrepreneurial processes as well as intrepreneurial strategy within incumbent firms. It needs the ability to seize new opportunities, absorb and manage risks in much the same way as entrepreneurial firms that enter into markets for the first time.

Teece's framework has prompted much discussion and analysis of what constitute dynamic capabilities in the context of market changes. Eisenhardt and Martin (2000) note that dynamic capabilities are a set of identifiable processes such as product development, strategic decision making and alliancing which are idiosyncratic in their detail and path dependent in their emergence but nevertheless maybe common across firms. They also argue that in highly dynamic markets such dynamic capabilities may be quite simple experiential and fragile processes with great uncertainty surrounding final outcomes. In a further contribution to this debate, Winter (2003) has argued that 'the strategic substance of capabilities involves the patterning of activity, and that costly investments are typically required in sustaining such patterning'. Dynamic capabilities thus refer to a higher order capability, viz. routines to improve on the established routines of firms. However, firms can and do accomplish change without the reliance on higher order capability by adhoc problem solving.

In contrast to the role of new opportunities in redefining capabilities and developing new ones, a large literature on technology management has subscribed to a product cycle view of the industry and seen different types of capabilities as necessary in different stages of the industry life cycle. Thus, it is well recognised in this literature that different problem solving approaches generate strategic variety in the early stages of a technology/industry evolution (Utterback, 1996). However, once a dominant design is established there is lock-in and a convergence of firm strategies. Thus strategic variety defines the direction of evolution in an industry, since one of the experimental designs will become the dominant design in the industry. In this view, strategic variety is consistent with the emergence of a new economic/technological opportunity.

However, the product cycle view also sees the sequence of innovation in an industry as progressing from product innovation, establishment of a dominant design followed by process innovation along that dominant design. This is not usually the situation that faces a number of developing country firms seeking to enter new markets. As Hobday (1995) pointed out in his study of East Asian economies, leading firms in Taiwan and Korea moved backwards on the product cycle – they start from being process innovators and transit to becoming OBMs (Own Brand Manufacturers) and launch their own innovative products. Detailed case studies of successful transition, such as those of Hyundai, suggest that such firms needed to pay a lot more attention to design and marketing capability and the integration of these with technological capabilities in order to become successful at gaining product market share. Further these investments by firms often took place in an oligopolistic environment dominated by barriers to entry. [3]

The role of integrated knowledge bases and different strategies scoped by firms who may not possess technological advantages or assets is highlighted by Chandler's analysis of US pharmaceutical firm's strategies in the late nineteenth century. As other scholars (e.g. Liebenau 1981) have observed, American companies had become proficient in the manufacturing and marketing of biological medicines, but were behind their German competitors who innovated and patented extensively when the First World War broke out. As the market for antibiotics grew, even though European firms held all the major patents, their knowledge of marketing, distribution and production management enabled several over the counter (OTC) drug firms such as Smith Kline, Eli Lilly, and Abbot laboratories to successfully launch themselves into pharmaceutical markets by exploiting their knowledge of new dosage forms - itself a by-product of their knowledge of large batch manufacture of chemical compounds. However, Chandler (2005) also notes that the paths adopted by Squibb, Parke-Davis and American Home remedies to enter the pharmaceutical market differed considerably from that of the OTC firms. Thus, Squibb hired the services of a scientist who had formerly worked for Merck's US subsidiary, while Parke-Davis emulated the European leaders and internationalised production operations rapidly. However, American Home Remedies rose to the number one spot in sales based upon mergers and the diversification of business into product lines that could cross-subsidise each other. [4]

In the context of the debate on dynamic capabilities the case of early twentieth century US firms is illustrative. First, as noted by all the writers on dynamic capability ad hoc problem solving preceded the period before distinctive organisational and technological strengths emerged. Thus, strategic variety is probably necessary for dynamic capabilities to emerge. However, the dynamic capability that allowed US firms to dominate the Pharmaceutical industry is only evident in hindsight. Integrative capabilities were the distinguishing characteristic of American pharmaceutical firms that enabled them to scale up rapidly.

Against this background of issues, the Indian pharmaceutical industry is an interesting case study for students of strategy and technology management. The leading firms in the industry were all engaged in similar production activities till the early 1990s. The passing of the Hutch Waxman Act in 1984, provided a great opportunity for Indian firms to gain value for their reverse engineering capability as well as develop new capabilities to differentiate themselves in the market. This set into motion a period of strategic experimentation in the industry.

## 3. The Indian pharmaceutical industry

The Patent Act of 1970 and government investment in the drug industry, it is widely acknowledged, infused life into the Indian pharmaceutical industry. The weakening of the patent law and the growth of the health sector led to the entry of a number of manufacturers who set up production units of different sizes. The availability of trained manpower, comparative ease of imitation and a strong chemistry base among Indian research institutes supported these manufacturers. Domestic firms slowly started dominating the domestic market and their share climbed from a mere 10% in 1970 to 70% by 1989. The small scale sector in pharmaceuticals was also actively encouraged.

By the mid 1980s most Indian pharmaceutical firms were producing bulk drugs for the domestic market though market leaders had begun to explore markets in Asia and Africa. In 1984, an important source of external demand opened up following changes due to the Hatch-Waxman Act in the US. Under this new law, manufacturers of generic drugs no longer had to go through a lengthy period of extensive clinical trials in order to market a generic drug - demonstration of bio-equivalence was

sufficient to acquire a patent on a generic drug. Procedures were established for the resolution of disputes between branded drug manufacturers and generic manufacturers.. Western markets were a lucrative business opportunity and the low cost advantage enjoyed by Indian firms on account of the cheap availability of scientific labour combined with the scale economies inherent in the manufacture of bulk chemicals made for big margins.

The 1990s saw a number of changes to the regulatory environment facing Indian Pharma firms. In 1991, the economy was liberalised and the pharmaceutical sector was de-licensed. In 1995, 50% of the drugs were also removed from price control and by 2004 only 76 drugs (26%) remained under price control.[5] Liberalisation of national and international financial transactions followed (in 1995). Hot on the heels on liberalisation, India announced its entry to the WTO and its intention to institute the intellectual property regulations required by TRIPS. In 1999, the Patent law of 1970 was repealed. The new Patent Act strengthened patent protection, by introducing the recognition of product patents for pharmaceuticals, food products, agro chemicals and micro organisms. It also significantly increased the life of a patent from seven years to twenty years.[6]

Though liberalisation had facilitated the entry of Indian generic producers in Western markets, the implication of the 1999 Patents Act was that these opportunities based on reverse engineering strengths would close by 2005. Indian firms needed interim strategies whereby they could reap the rewards from production of generics for markets in the US and Europe, but also prepare to cope with the loss of molecule supply through the building up of their 'discovery capabilities' so that these capabilities could be used to utilise the new market opportunities afforded by strong product patents post 2005.

Figure 1 below sketches the growth of revenues in the Indian pharmaceutical industry. The industry grew rapidly in the 1990s, with an average industry growth rate of about 15% for bulk drugs and 20% for formulations (OPPI, 2001). Figure 2 plots the R&D intensity of the industry which shows an overall declining trend even though in absolute amounts R&D investment in the Pharma sector has increased and this increase is often seen as a consequence of stronger patent law (Gehl Sampath, 2006).

**Figure 1: Turnover and export growth in Indian pharmaceutical industry (1980 – 2003) (Source: OPPI, 2001)**

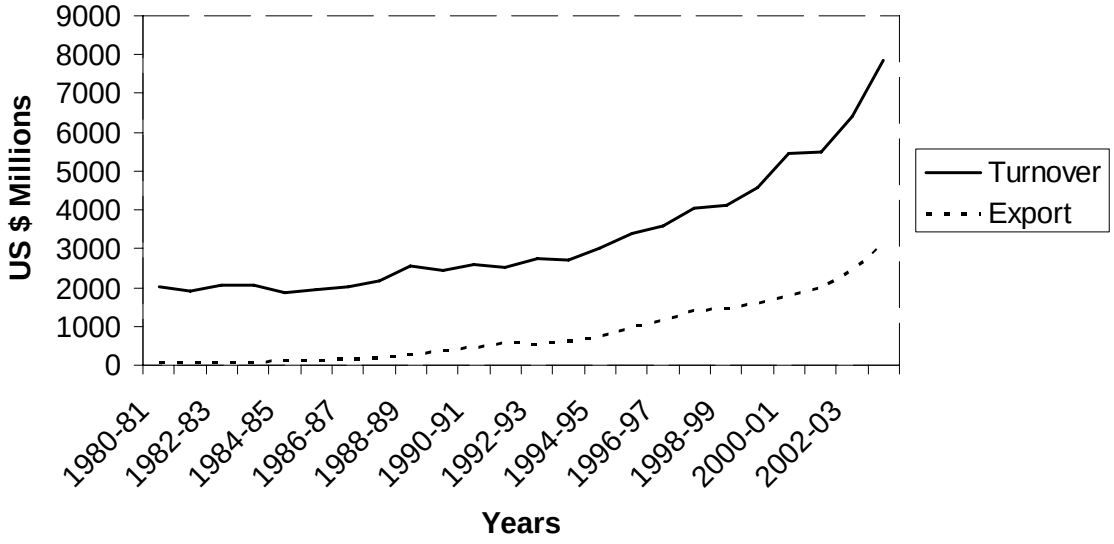



**Figure 2: R&D intensity of Indian pharmaceutical industry (Source: OPPI, 2001)**

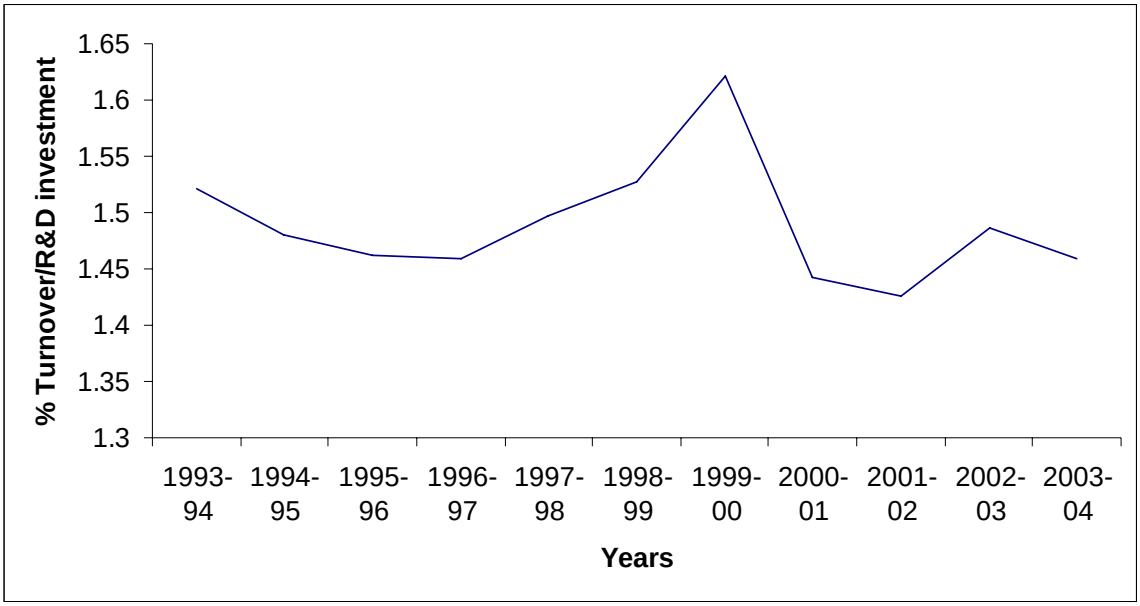


Table 1 below shows the top ten companies for selected years 1970, 1996 and 2003. Figures in parentheses indicate the market shares to each firm. The growing strengths of the domestic firms are reflected in the table. Thus, in 1970, the Indian market was clearly dominated by multinational firms (eight of the top ten firms were MNCs) that accounted for about 15% of the market. After two decades following the 1970 Patent Act, Indian Pharma was dominated by domestic firms. Only 4 of the top ten firms were now multinational and they accounted for 11 % of the market in 1996. However, between 1970 and 1996, the domestic firms that ranked in the top ten were also different to those that held leading shares in 1970 (except for Alembic).

In 2003, the top ten firms together covered around 34% of the total pharmaceutical market (an 8% increase in the concentration ratio from 1996). Six of those top ten firms were now of Indian origin and four were MNC subsidiaries. They accounted 13% and 22% of the market respectively. A point of interest is that the Indian firms that had an external market focus gained in market share and emerged in the top ten, even while the large MNCs operating in India were focussed on serving the Indian market alone.

**Table 1: Top ten pharmaceutical companies in India from 1970 to 2003**

| rank | 2003 Company (market share) | 1996 Company (Market Share) | 1970 Company (Market Share) |
|---|---|---|---|
| **1** | GlaxoSmithKline* (5.6) | Glaxo-Wellcome* (4.97) | Sarabhai (4.97) |
| **2** | Cipla (5.5) | Cipla (2.98) | Glaxo* (2.9) |
| **3** | Ranbaxy(4.7) | Ranbaxy (2.67) | Pfizer* (2.6) |
| **4** | Nicholas Piramal (3.4) | Hoechst-Roussel*(2.6) | Alembic (2.6) |
| **5** | Sun Pharma (3.1) | Knoll Pharma* (1.76) | Hoechst* (1.7) |
| **6** | Pfizer* (2.7) | Pfizer* (1.73) | Lederly* (1.7) |
| **7** | Dr. Reddy's (2.6) | Alembic (1.68) | Ciba* (1.6) |
| **8** | Zydus Cadila (2.5) | Torrent Pharma (1.60) | May & Baker* (1.6) |
| **9** | Abbott* (2.3) | Lupin Labs (1.56) | Parke Davis* (1.5) |
| **10** | Aventis – includes merger with Hoescht * (2.2) | Zydus-Cadila (1.51) | Abbott* (1.5) |

*** indicates a multinational firm**
**(Source, OPPI, 2000, 2003; Lanjouw, 1996)**

The national and international regulatory changes detailed above which opened new economic opportunities form the context for the experimentation with strategies by Indian pharmaceutical firms. We turn next to a consideration of changes in strategy in four leading firms.

# 4. Four case studies

We use the comparative case study method to study the evolution of strategy in four established Indian pharmaceutical firms, viz. Ranbaxy Laboratories, Dr. Reddy's Labs, Wockhardt and Nicholas Piramal. The primary data for the case studies was collected through a variety of sources: interviews with R&D presidents, senior scientists and IPR managers working in these firms, data in Annual reports, analysts' presentations and articles in the business press.

Several industry analysts believe that the whole industry was fairly homogenous prior to the liberalisation of 1991 in the sense that all firms were pursuing very similar market strategies and had fairly similar technological competences. The following extracts from our interviews with industry insiders illustrate the areas of homogeneity

> *"Indian industry decided to move up the value chain from bulk drugs to finished formulations and that trend started in the early 90s when Indian companies started going for generic formulations. Today there are companies like Ranbaxy, DRL to some extent Sun, Wockhardt, Cipla; they are all suppliers of finished formulations in the USA. Many of these formulations also are first applicants if not the first approvals or at least one of the 3 approvals in the world".* (Author's interview with Dr. Himadri Sen, Vice President R&D, Lupin in 15th July, 2002)

> *"Process development forms the base of the model which Indian industry is following and till 1995 all efforts of Indian companies in R&D were focused on the process development"* (Author's interview with Mr. Dilip Shah, President of Indian Pharmaceutical Association in Mumbai on 20th December, 2002)

All the four firms we study were established in the pre-liberalisation period with Wockhardt being the oldest and Nicholas Piramal being the newest. Three of the four firms are among the top ten companies in the Indian Pharma markets (Table 1). Of the four firms, Ranbaxy and Dr. Reddy Laboratories were the early entrants to the generics market whilst Wockhardt and Nicholas Piramal made an entry only in the late 1990s.

**Table 2: The four case study firms**

| **Name of the firm** | **Year of establish-ment** | **Year of starting Innovative R&D** | **Business Areas** | **Market Segments (generic)** | **NCE Therapeutic class (no. of molecules)** |
|---|---|---|---|---|---|
| Ranbaxy Laboratories | 1962 | 1992 | Generics<br>NDDS<br>NCE | Anti-infectives, Anti-retrovials | Cholesterol and Tri glycerides Reducers (1)<br>Oral Antidiabetics (1)<br>Antirheumatic Non Steroidals (1) |
| Dr. Reddy's Laboratories Ltd | 1984 | 1994 | Speciality generics<br>NCE | Dermatology | Cholesterol and Tri glycerides Reducers (2)<br>Oral Antidiabetics (1) |
| Wockhardt | 1959 | 1997 | Biotech drugs<br>NCE | Hepatitis B, Human insulin | Antirheumatic Non Steroidals (1) |
| Nicholas Piramal (I) Ltd | 1988 | 1998 | Contract research<br>NCE | | |

Table 2 details some comparative data for the four firms studied in this paper. The firms have occupied different niches/market segments within the generics market. Thus, Ranbaxy specialised in antibiotics, Dr. Reddy's Laboratories in Cardiac and NSAIDs (non-steroidal anti-inflammatory drugs), Wockhardt in vaccines and Nicholas Piramal in respiratory drugs. The new chemical entities (NCE) research of three of the four firms is also targeted at the different market segments. All the segments chosen by Indian firms are within the largest ten therapeutic segments in the world.

**Table 3: Turnover and Employment (Source: Annual Reports, 2000-2005)**

| Firms | a. Turnover ($US Million) and export intensity (%) | | | |
|---|---|---|---|---|
| | **2000** | **2001** | **2002** | **2003** |
| **Ranbaxy** | 435.46 (50.8) | 584.04 (65.61) | 735.37 (70) | 793.48 (68) |
| **DRL** | 350.06 (61) | 360.87 (64) | 417.91 (64.4) | 427.55 (65.6) |
| **Wockhardt** | 156.75 | 167.90 (38) | 204.09 (57) | 275.43 (64) |
| **NPIL** | 123.17 (3.43) | 203.78 (3.15) | 200.67 (8.5) | 305.48 (12.4) |
| **Firms** | **b. Total number of employed** | | | |
| | **2000** | **2001** | **2002** | **2003** |
| **Ranbaxy** | 5784 | 6424 | 6297 | 6797 |
| **DRL** | 2100 | | 5500 | 5852 |
| **Wockhardt** | 2300 | 2700 | 2805 | 2928 |
| **NPIL** | 3600 | 3840 | 4036 | 5880 |
| **Firms** | **c. R&D Intensity (% of sales)** | | | |
| | **2000** | **2001** | **2002** | **2003** |
| **Ranbaxy** | 4.2 | 3.8 | 5.2 | 6.1 |
| **DRL** | 4.2 | 6.29 | 7.70 | 10 |
| **Wockhardt** | 7.20 | 6.20 | 6.20 | 7.90 |
| **NPIL** | 1.80 | 2.16 | 1.63 | 3.90 |

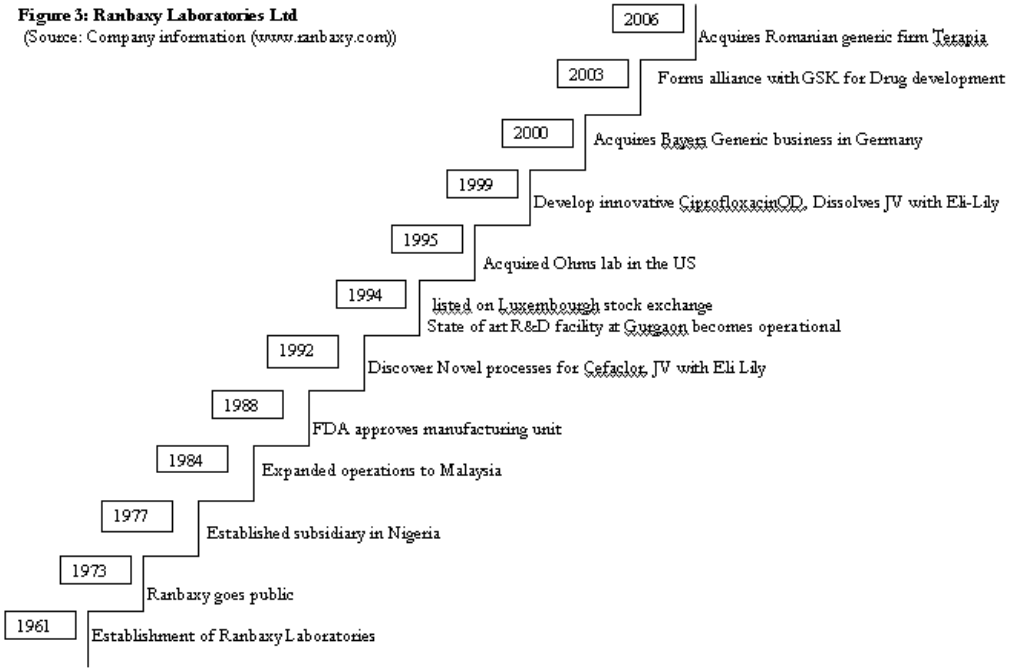
Table 3 presents the turnover, employment, and export and R&D intensity of the four firms studied. The two firms that entered the generics market earlier are also larger in terms of both turnover and employment. However, all four firms have re-invested the profits from their generics business into R&D and this is visible in both the R&D intensity and employment figures. Not only is this contrary to the industry trend of a declining R&D intensity (noted in the Figure 2), but the R&D intensity in all the four firms is catching up with that of leading international generics companies like Teva and Mylan.[7] Thus we may conclude that these are also firms with long-term strategies based on technological advantages.

In the remainder of this section we present brief case histories of the four firms detailing the evolution of different aspects of their strategy. The main milestones in the growth of each firm is summarised in the form of a flow chart that informs the narrative.

## 4.1 Ranbaxy Laboratories

Ranbaxy Laboratories Limited was established in 1961 and listed on the Bombay Stock Exchange in 1973. The main milestones in the company's history are summarised in Figure 3. Ranbaxy started as a manufacturer of active pharmaceutical ingredients (API) and soon began looking at international markets for securing these ingredients. In 1977, Ranbaxy established a subsidiary in Nigeria through a joint venture and in 1984 it expanded operations to Malaysia.

**Figure 3: Ranbaxy Laboratories Ltd**
(Source: Company information (www.ranbaxy.com))




R&D activity in Ranbaxy started in the late 1970s when a small R&D division that employed eight people was established. Early R&D efforts were focussed on formulating bulk drugs into dosage forms and on developing cheap processes to synthesise bulk drugs. Soon after Ranbaxy began to concentrate its R&D efforts towards developing a novel production process that would let it sidestep other company's process patents, with a view to entering the profitable generics market. In 1985 these efforts bore fruit and Ranbaxy found a novel way to manufacture the anti-ulcerant Ranitidine, the world's best selling drug and the generic version of Glaxo's Zantac. This marked the start of a strategy based on the manufacture of generic drugs. The Ranbaxy Research Foundation was also established in 1985.

The generics strategy received a great boost when one of Ranbaxy's API manufacturing plants was approved by the US Federal Drugs Authority (FDA) in 1988. However, the real breakthrough in process R&D and the generics strategy came with the development of an innovative novel process for Cefaclor. The molecule was owned by Eli Lily since 1979, and more than 70 patents were filed by Eli Lilly for process improvements to protect the drug from generic competition. Ranbaxy started work on developing a new seven stage process for the production of Cefaclor in 1988 despite internal doubts about committing R&D resources to a product that was difficult to manufacture and in addition would be too expensive for the Indian market.[8] After three years and spending nearly $2 million, Ranbaxy emerged with a non-infringing process for the manufacturer of Cefaclor and also managed to obtain higher yields from its process compared to Eli Lily's original production process.

It was mutually profitable for both companies to start a joint venture for the manufacture and supply of Cefaclor by Ranbaxy. Despite the commitment of large investments in Cefaclor production, Ranbaxy was not confident of successfully market the drug in the US on its own. Lilly-Ranbaxy LLC a joint venture was formed and headquartered in Indiana, with a five year, no-divorce clause. By 1995, within three years, Eli-Lilly wanted to call off the joint venture. Had Ranbaxy pursued the courts Eli-Lilly might have had to pay up to $25-30 million, but instead Ranbaxy bought the exclusive rights to eight Eli Lilly products that were over thirty years old and had combined sales of less than $5 million. All these were off-patent drugs but Eli-Lilly was their only producer and its letter to all its distributors notifying them of the sale achieved immediate brand recognition for Ranbaxy at little expense in what was a shrewd marketing move. [9] In 1998 Ranbaxy established a 100 percent subsidiary in the US and started marketing products under its brand name. Within just four years of starting its US operations, Ranbaxy touched the US $ 100 million mark for sales in the US.

The firm also listed on the Luxembourg Stock exchange and raised money to establish a global presence in generic drugs manufacturing through a combination of foreign investments and foreign acquisitions. First, it acquired a FDA-approved US-manufacturer, Ohm Laboratories. In 1996, it started a joint venture with another US based firm Schein Pharmaceuticals for marketing Ranitidine in US. The firm also

began expanding its production facilities in Europe by setting up a subsidiary in the UK (1994) and establishing a manufacturing plant in Ireland (1995). These have proved instrumental in Ranbaxy's forays into other European markets. In 2004, it consolidated its position in this market further by acquiring the fifth largest generics company in France.

In order to protect its international investments, Ranbaxy also applied for patents all over the world for its innovative production processes. The experience gained also developed regulatory skills needed to obtain approvals for its products under Para 2 of the Abbreviated New Drug Applications (ANDAs) scheme in the US.

### *Transitioning to Drug Discovery*

From 1995, Ranbaxy stepped up its R&D expenditures from 2% of sales to 5% and established state-of-the-art multi-disciplinary R&D facilities at Gurgaon (near New Delhi). The company's new strategic intent was to ascend the research value chain and accordingly it began to establish capabilities in the areas of discovery research, delivery systems and clinical research. The strategy for doing so was to adopt a two stage approach, where the firm expected to use the development of capabilities in drug delivery as a stepping stone to development of drug discovery capabilities.

In 1999 Ranbaxy registered its first success with this strategy when it developed the once-a-day dosage for the Ciprofloxacin molecule. This improvement in dose administration promised greater patient-compliance compared to multiple dosages offered by the patent holder, Bayer and hence was a major step forward. Former R&D president explaining the Ciprofloxacin OD project noted the link with Cefaclor in terms of technological capabilities of the firm

> *"Actually origination [of the idea] was when we made Cefaclor, bulk drug for Eli Lily and that I think we licensed in 1991-92. ... That was essentially a chemistry outcome in manufacturing bulk drugs. We always used to debate that we should have something similar in formulation which can give us this quantum profit like in Cefaclor".* (Author's interview with Dr. J. M. Khanna, in New Delhi on 20th June, 2003)

The development of once-a-day formulation became Ranbaxy's first major innovative R&D product. Ranbaxy licensed the once-a–day technology to Bayer of Germany for US$10million, to develop further and market. In 2004, Bayer successfully launched the 500mg and 1gm once-a–day formulation in US, based on delivery technology platforms developed by Ranbaxy.

Understanding the impact of different dosages of chemicals upon the human body involves an intricate understanding of how the chemistry of the drug interacts with human biology. Since Ranbaxy had no prior experience drug discovery research it has concentrated on first building a strong, well focused inter disciplinary research team. Over the years Ranbaxy has recruited scientists from India as well overseas, from academia and industry.

The company has also internationalised its R&D efforts mainly to fortify the 'developmental' aspects of R&D. Thus, Ranbaxy's US R&D facility was expanded to focus on three areas: clinical research, regulatory affairs and to give commercial inputs on diseases, targets and compounds that can be profitably pursued.

Ranbaxy's new drug discovery R&D focus now includes urology, anti-infective, respiratory, anti-inflammatory and metabolic disorders segments. Ranbaxy's first NCE, for Benign Prostrate Hyperplasia (BPH), was licensed to Schwartz Pharma but after Phase II clinical trials in India, the molecule has been abandoned. Ranbaxy's other promising drug candidate, is an anti-asthma molecule, undergoing Phase II clinical trials. Besides these, the company has other molecules in its NCE pipeline, which are at different stages of clinical development. [10] In 2003, the chief scientific officer at Ranbaxy Dr. Brar who had overseen their generic strategy successes left the company to start an entrepreneurial venture. In 2006, Ranbaxy entered into an agreement with Glaxo-Smith Kline

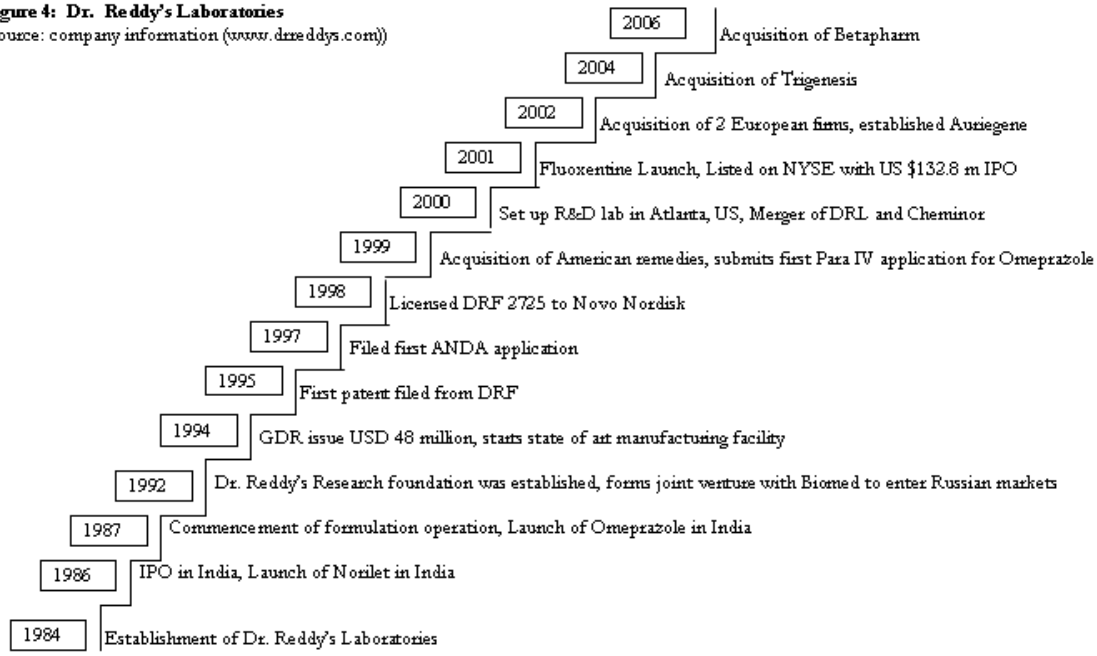
Ranbaxy presents the quintessential example of staged growth through integration of pharmaceutical production, R&D activities and internationalisation efforts. It showed great alertness and foresight in grasping the significance of the generics market opportunity much before liberalisation. In expanding its R&D capability the firm has paid attention to human resource recruitment as a means to building up skills, internationalising its R&D effort in order to stay close to regulatory market needs and

lastly managed risk in undertaking new R&D through targeted small outcomes in the drug delivery space that can help the company to build its technological profile further. However, recognising its limitations in the ability to test and market new drugs, Ranbaxy has also preferred to rely on licensing to multinationals for the direct marketing of its new dosages and molecules.

## 4.2 Dr. Reddy's Laboratories

Dr. Reddy's laboratories (DRL) was founded by Dr. Anji Reddy, who formerly worked in the public sector company Indian Drugs and Pharmaceuticals Ltd., in 1984, in 1986 it started operations on branded formulations. Within a year DRL had launched Norilet, DRL's first recognised brand in India. But big success came with launching of Omez, Omezaprozole which DRL managed to launch at 50% lower prices compared to other brands prevalent in Indian market at that time due to a superior process technology. Within a year of its inception, DRL also became the first Indian company to export active pharmaceutical ingredients to Europe.

**Figure 4: Dr. Reddy's Laboratories**
(Source: company information (www.drreddys.com))




The transition from a predominantly API focused firm to being a formulation company started in 1987 and in 1994, DRL started targeting the US generic market by building state of art manufacturing facility. In three years DRL filed its first ANDA in 1997 for Ranitidine 75mg tablets, and improving on that, in 1999 it submitted a Para IV application for Omeprazole- the drug it had so successfully marketed in India.

The big achievement of DRL's generic foray came in 2001 when DRL became the first Indian company to launch the generic drug, Fluoxentine (a generic version of Eli Lilly's Prozac) with 180 day market exclusivity in US. As a result of market exclusivity DRL's international sale of Fluoxentine 40mg, increased massively and its generic turnover touched $23.2 million for the third quarter of 2001, with Fluoxentine sales contributing 87% of these sales. This marketing success was followed by the launch of Ibuprofen tablets 400, 600 and 800 mg in the US under its own brand name, in January 2003. Direct marketing under the DRL brand name represented a significant step in the company's efforts to build a strong and sustainable US generic business. It was the first step in building DRL's fully fledged distribution network in the US market.

DRL's international marketing successes were built on a strong manufacturing base which itself was a result of inorganic growth through acquisition of international and national facilities. DRL merged Cheminor Drug Limited (CDL) with primary aim of supplying APIs (active pharmaceutical ingredient) to the technically demanding markets of North America and Europe. This merger also gave DRL entry into value added generics business in the regulated markets of APIs. DRL began its major international production by entering Russia through a joint venture with Biomed in 1992 and in 2002 DRL converted the joint venture into a fully owned subsidiary. It strengthened its Indian manufacturing operations by acquiring American Remedies limited in 1999 This acquisition made DRL the third largest pharmaceutical company in India, after Ranbaxy and Glaxo (I) Ltd., with a full spectrum of pharmaceutical products, which included bulk drugs, intermediates, finished dosages, chemical synthesis, diagnostics and biotechnology.

In 2001 DRL completed its US initial public offering of US$132.8 million ADS (American depository shares) issue and also listed on the New York Stock exchange. The funds collected from US IPO were diverted into the international expansion of production and acquisition of technology based companies. In 2002, DRL started its European operations by acquiring two pharmaceutical firms in UK. The acquisition of BMS Laboratories and its wholly owned subsidiary, Meridian UK allowed DRL to expand geographically and gave company an opportunity to enter the European market. DRL hopes to launch some molecules from its acquisition of the US-based Trigensis - a niche dermatology company. In 2003 DRL also invested US$. 5.25

million in equity capital of Bio Sciences ltd. In 2004 DRL acquired Trigenesis Therapeutics Inc; the US based private dermatology company. This acquisition gave DRL access to certain products and proprietary technologies in dermatology segment.

Dr. Reddy's Para IV application strategy for generic business was however a risky one as it involved challenging existing patents. This strategy received a severe set back when DRL lost the patent challenge in case of Pfizer's drug Norvasc (amlodipine maleate). Amlodipine maleate, the generic version of Pfizer's Norvasc, is indicated for the treatment of hypertension and angina. The cost involved in patent litigation as well as the strategic reversal affected DRL's plans to start speciality business in the US generic markets.

### *Transitioning to Drug discovery*

DRL's transition path into new drug discovery involves targeting speciality generics products in western markets in order to transit to drug discovery capabilities. In the words of their Mr. Prasad, the CEO:

> *"Our key priority is to create an exciting and sustainable pipeline of specialty products and the commercial front end to take these products to market. The specialty business will be a vital link in our transition from a diversified generic pharmaceutical company to a discovery-led global pharmaceutical company".*

The reason development of speciality drugs can be an important link to the development of new chemical entities is that all the elements that are involved in a NCE effort, such as innovation in the laboratory, developing the compound sending the sales team to the market etc. are also stages in the development of a speciality drug, except that the scales are smaller and therefore more manageable. Uday Saxena, chief scientific officer at DRL is also quoted as saying, a speciality launch is like a dry run before an NCE launch.[11]

DRL have also invested heavily in building R&D labs and are the only Indian company to have significant R&D being undertaken overseas. Dr. Reddy's Research Foundation (DRF) was established more than a decade ago, in 1992 and dedicated

to research in area of new drug discovery. Initially, DRF's drug discovery research strategy revolved around analogue research but DRF changed its focus to work in discovery R&D with a hiring strategy that targeted fresh scientists especially Indian students studying abroad on doctoral and post doctoral courses. Though DRF wanted to introduce modern skills such as drug discovery based on genomics and proteomics, it struggled with this change. Therefore in 2000, DRF set up a lab in Atlanta, US, dedicated to discovery and design of novel therapeutics. The lab is called Reddy US Therapeutics Inc (RUSTI) and its primary aim is to conduct drug discovery using molecular genomics and proteomics approaches for next generation drugs. Research thrust at DRL is focused towards large niche areas in western markets, viz. anticancer, anti diabetes, cardiovascular and anti infective drugs.

In terms of new drug discovery achievements, DRF currently has 9 NCEs (new chemical entities) in various stages of development: five molecules are in clinical development and another four in preclinical stages. The clinical development of three molecules is being undertaken by DRL (on its own) while two other molecules are developed in collaboration; Balaglitazone (DRF 2593) with Rheoscience and DRF 1042 with Clintech international. Although DRF's progress in innovative R&D is remarkable, it also had a fair share of failures. For example in 1998 DRF signed the agreement with Novo Nordisk to develop and market pharmaceutical products of its first molecule, Ragaglitazar (DRF 4158). However in 2002 adverse effects appeared during clinical trials and Novo Nordisk abandoned research on the molecule and decided to work on another DRL molecule, (DRF 2725). However in 2003 Novo Nordisk terminated development of the molecule due to adverse effects. In 2002, DRL granted exclusive rights for the development and commercialisations of DRF 4158 to Novartis Pharma AG, however in 2003 Novartis opted to replace dual acting insulin sensitizer, with other follow up compound.

Since 2000, DRL is scoping other means to improve their chances of success in drug discovery efforts. Thus, Auriegene Discovery Technologies, a contract research company was established as a fully owned subsidiary of DRL in 2002, to gain experience of drug discovery through contract research for other Pharma companies. As mentioned above, it has acquired Trigenesis, a niche dermatological company with new molecules in its product portfolio and taken an equity stake in Bio Sciences. Lastly, DRL has entered into a venture investment type of agreement with the Indian

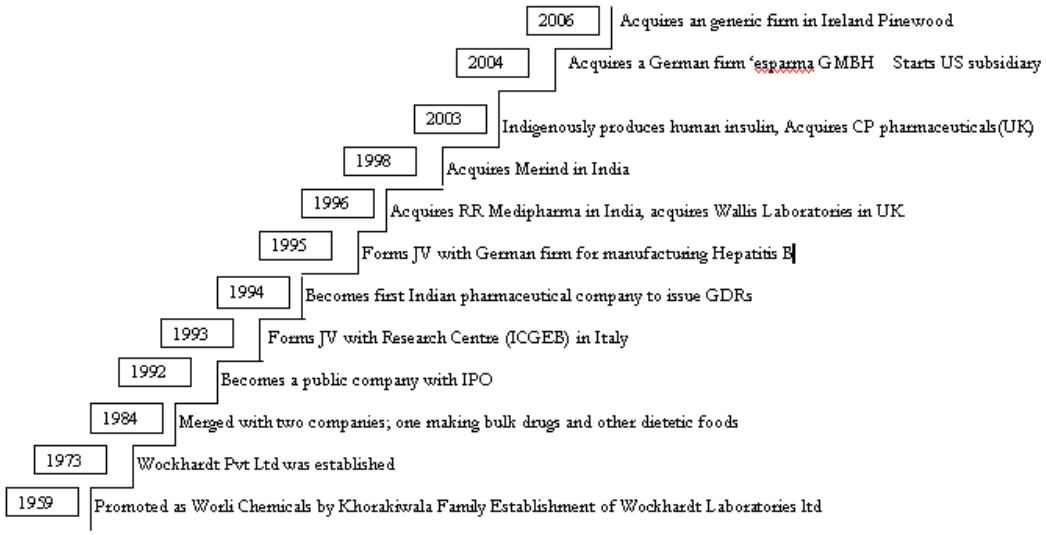
bank, ICICI. Under the terms of the agreement, ICICI Venture will fund the development, registration and legal costs related to the commercialization of ANDAs on a pre-determined basis. On commercialization of these products, Dr. Reddy's will pay ICICI Venture royalty on net sales for a period of 5 years.

DRL's successful growth into a fully integrated pharmaceutical company in less than a decade was founded on a successful and targeted program of inorganic growth and investments in process R&D. It chose a high risk-high gain strategy to growth by going into direct competition with existing patent holders. A major challenge for DRL is to find ways to de-risk its overall strategy. One way may lie in managing the cash flows from the 'safer' API and formulations businesses. Another way may be to seek out more experienced partners for the R&D business or use acquisitions to boost R&D resources and revenues. Evidence suggests that DRL is trying both.

## 4.3 Wockhardt Ltd [12]

Wockhardt was started by Khorakiwala family in 1959 as a small pharmaceutical distribution and selling entity. The company set up its first formulation plant in 1977 and soon established a bulk drug plant in 1983. In many ways it is a typical business house that has diversified into other businesses overtime. Currently, Wockhardt's product portfolio includes pharmaceuticals (bulk drugs and formulations), medical nutrition, Agri-sciences and also hospitals. This diversified portfolio of products also makes the position of Wockhardt quite different from that of the other firms we have studied. In particular, the existence of a thriving hospitals business makes it potentially possible for the company to be a fully integrated company, viz. undertake clinical trials and be a manufacturer of drugs.

**Figure 5: Wockhardt Laboratories Ltd**
(Source: Annual report, 2000-05); Company information (www.wockhardtin.com))




The company was privately held and listed on Mumbai stock exchange only in the year 1992 and followed that with listings in Luxemburg in 1994 and in the US in 2003. Despite this only 35% of its shares are publicly held and only 9% are held internationally.

Interviews with company officials indicate that the company had placed biotechnology at the heart of its strategy, and made it core to the development path of the company since the early 1990s. Thus, from the early 1990s the company has spent 20 -30% of its total research budget on biotech R&D. In 1993, the company initiated a joint venture with a Research Centre (ICGEB) in Trieste, Italy for joint research on recombinant products such as Hep-B vaccine, EPO and human insulin. Under the deal, the company would invest Rs. 50 million (what is the amount in 1993 dollars) over five years in return for the development of 3-4 products. However, the company called the deal off after 3-4 years and spending Rs.20million because of a lack of output. Subsequently, the company Wockhardt set up its R&D centre at Aurangabad in 1994 and in 1995, entered into a joint venture with Rhein Biotech, a German firm, for the development and manufacture of Recombinant Bio-pharmaceuticals. The venture was funded by equities on the Wockhardt side and resulted in the successful production of the hepatitis B vaccine, Biovac-B in 2001. However, due to a conflict of interest over the rights to this product the joint venture was dissolved and Wockhardt bought Rhein's shares and today controls 100% of the

subsidiary. This joint venture also helped company to develop manpower trained in biotechnology R&D and provided access to crucial know-how.

In 2001, Wockhardt indigenously produced a drug called erythropoietin (EPO) for severe anaemia. It was produced using genetic engineering methods. However, the most important milestone in biotech R&D came with development of human insulin. In 2003, Wockhardt launched Wosulin. The company is fourth in the world – first outside US and Europe – to develop, manufacture and market this life saving drug used in diabetes. In 2004 Wockhardt commissioned a state of the art production facility dedicated to the manufacture of biotech products. The company is also developing a generic version of the biopharmaceutical Interferon Alfa 2b, which is in the third phase of clinical trials.

From 2000, the company went through a major re-structuring. The company split the pharmaceutical business from the agro-chemical, I.V. Fluids and Hospital business to form two divisions: Wockhardt Life Sciences and Wockhardt Ltd. The aim of this restructuring was to allow Wockhardt Ltd to concentrate more on building skills and capabilities in the pharmaceutical business while Wockhard Life Sciences would focus on managing businesses related to agricultural sciences, parentals[13] and hospitals.

Wockhardt started targeting international markets only in the late 1990s when early entrants like Ranbaxy and DRL had already made exports of generic drugs from India credible. Furthermore, Wockhardt's internationalisation effort has not targeted the US generics market first. Instead interviews[14] revealed a strategy for globalisation based on the ease of procedural clearance in different countries. Thus, Wockhardt aimed to take products developed for the domestic market to other countries in South East Asia and Eastern Europe and Latin America. Subsequently they plan to target markets in countries where there was some regulation (like Hungary and Poland) where registration could take up to 2 years. Then target Europe and Canada. The US market was last on the list because of the costs and risks of expensive litigation.

Wockhardt's expansion of international production into Europe and the US is based largely on acquisitions of plants that had FDA approval. Thus, it entered UK market

by acquiring Wallis Laboratory, in 1998 and CP pharmaceuticals in 2003. In 2004 Wockhardt streamlined its European operation by selling Wallis's manufacturing plant to Bristol Laboratories and shifting some of the manufacturing operations of Wallis to CP Pharmaceutical's plant in UK and rest to the company's Indian plant. Wockhardt is also investing £1 million for up-gradation of the CP pharmaceutical plant to make it company's largest overseas manufacturing base and it main base for European operations. In 2004 Wockhardt acquired the German pharmaceutical company 'Esparma', GmbH to enter Germany, the largest generic drug market in Europe. Esparma has a portfolio of 135 marketing authorisations, of which 67 are in Germany. The company also has nine international patents and 94 trademarks. This acquisition has given Wockhardt increased depth in product portfolio and helped company to strengthen its presence in the European business.

Wockhardt launched its US operation by starting Wockhardt Americas Ltd and now has its own marketing and regulatory teams based in US. In 2004 key officials handling corporate scientific affairs and intellectual property management were relocated from Mumbai to the newly established subsidiary in the US. Wockhardt's US strategy is based on launching formulation products through ANDA route (rather than file DMFs) and till 2003 it has filed 17 ANDA applications with USFDA (see Table 7). It doesn't intend to sell API in US and European markets, and currently sells four products in the US – ranitidine, enalapril, bethanecol chloride and captopril.

### *Transitioning to drug discovery*

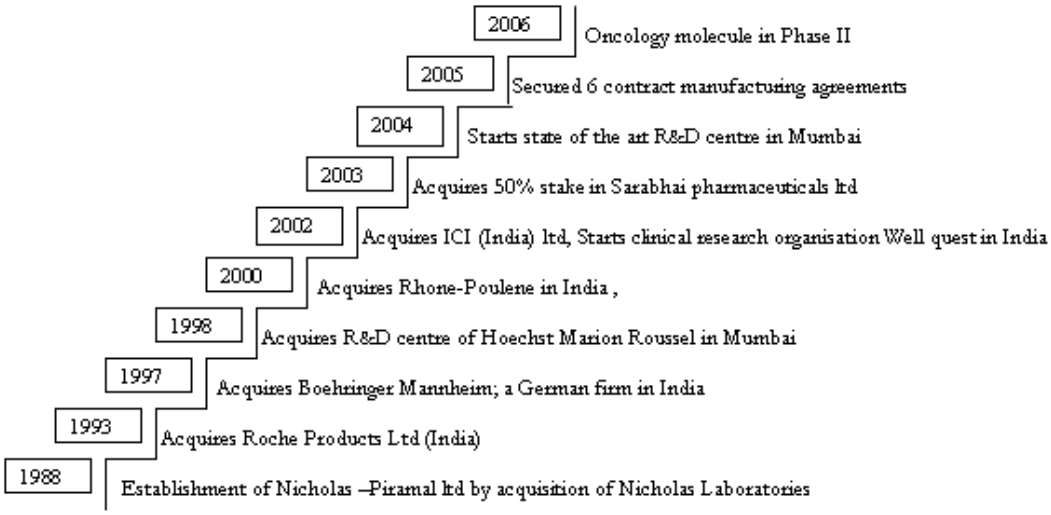
Wockhardt's R&D centre at Aurangabad entered the field of new drug discovery research in 1997. Wockhardt has decided to focus its efforts on the anti-infective therapeutic segment, as the main thrust area in new drug discovery R&D, in order to build depth in its research capability. It has concentrated on the biotechnology route to drug discovery and targeted the anti-infective segment for new products However, in order to gain experience in biotechnology it has selectively concentrated on the bio-generics market in its generic market strategy. Building on these biotechnology capabilities Wockhardt is aiming to develop competencies in genomics and proteomics to support its ambitious new drug discovery programme. In future it expects to use globally available libraries of proteins for novel drug discovery research.

The drug discovery programme has yielded a few lead molecules, one of which, WCK-771, a broad spectrum antibacterial, has completed Phase I clinical trials and is entering the next phase of trials. The other chemical entities WCK -1152 and WCK-1457 are under stages of pre-clinical trials.

## 4.4 Nicholas Piramal India Ltd (NPIL)

NPIL is part of the Piramal Enterprises, one of the India's largest diversified business groups with interest in retailing, textiles, auto components and engineering. In 2000, the group consisted of 26 companies (including joint ventures), with aggregate revenues of about US$500 million, however in the last ten years their pharmaceutical business has emerged as the fastest growing and most profitable of the lot. The Piramal enterprise was founded in 1933 and until 1987 most of the group's revenues had come from textile business. Increasing uncertainties in textile sector prompted the group to diversify and in 1984 it acquired a small glass company, Gujarat Glass which supplied bottles and vials for the pharmaceutical industry. In 1988 the group went ahead and acquired Nicholas Laboratories, an Indian subsidiary of a UK based pharmaceutical firm, renamed it Nicholas Piramal India limited (NPIL) and made it profitable in 4 years.

**Figure 6: Nicholas Piramal Ltd**
(Source: Company information (www.nicholaspiramal.com))




The success of this acquisition possibly spurred Piramal group to use acquisitions as a strategy of growth. The company acquired Roche products (India) Ltd in 1993, Sumitra pharmaceuticals and Chemicals in 1995, and Boehringer Mannheim India

Ltd in 1997. In April 1997 these three companies merged with Nicholas Piramal and a new management team was set up to manage it. This initial acquisition spree was followed by two more acquisitions – Rhone Poulenc (India) in 2000 and ICI (India) pharmaceuticals in 2002. In Dec, 2003 NPIL bought the 50% stake in Sarabhai pharmaceuticals ltd. Since most of the sellers were MNC pharmaceutical firms who wanted to quit the Indian market, NPIL acquired these firms at attractive prices and quickly synergised skills resulting in large benefits. The Managing Director of NPIL explained the business strategy in using acquisition as a route to growth,

> *"We knew that with TRIPS rules being introduced sometime in future, we should need to access new products. Also size matters – we needed critical mass to leverage on marketing and distribution as well as to increase the utilisation of Pithampur manufacturing plant*" (Annual Report, 2003).

These acquisitions also helped NPIL create strong linkages with MNC pharmaceutical firms and consequently NPIL has developed an impressive record in managing business partnerships (JVs and alliances) with a number of multinational firms like Roche, Boehringer, Allergan, Boots, Aventis, and Novartis. As a result NPIL has established itself as a partner of choice for any MNC looking at the Indian market.

Thus, NPIL (like Wockhardt) has decided not to target US markets with generics products. Instead NPIL aims to generate the same financial resources through alliance with overseas pharmaceutical companies and therefore its main focus areas are custom synthesis and contract manufacturing instead of generic markets in advanced countries.

Table 4 below details the contracts won by NPIL in recent years. The bulk of contracts won span a range of manufacturing and only two contracts have been for R&D services. But contract manufacturing is a competitive marketplace. Among Indian vendors NPIL faces competition from companies like Cadila Healthcare, Hikal limited, Dushman Pharma and Shasun Chemicals, all of whom hold contract manufacturing contracts with multinational firms.

**Table 4: Contracts obtained by Nicholas Piramal**

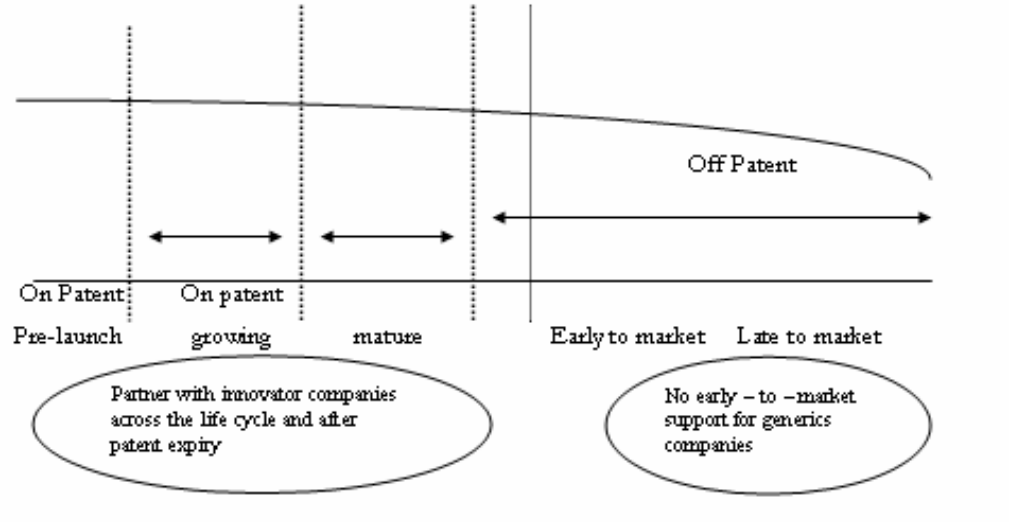
| Year | International partner | Nature of contract | Purpose |
|---|---|---|---|
| 2005 | Pfizer | R&D | 7 year agreement relating R&D services |
| 2005 | Allergan | Manufacturing | APIs for Levobunolol and Brimonidine |
| 2005 | Global hospital products comoany | Manufacturing | manufacture and supply select hospital care products |
| 2005 | Astra-Zeneca | R&D | to develop processes for manufacturing of API |
| 2003 | Advanced Medical Optics Inc | Manufacturing | Manufacturing of neutralising tables and sterile FFS packs |

**Source: Collated from KPMG (2006), NPIL annual reports and PharmaBiz website (www.pharmabiz.com on 01/09/06 last downloaded) and Business Line newspaper (www.hindubusinessline.com last downloaded 01/09/06)**

### *Transitioning to new drug discovery*

NPIL has developed a two pronged approach for developing NCE that builds on their good relationships with multinational firms. The first prong is inward co-licensing deals with foreign firms, custom synthesis and contract manufacturing for MNC pharmaceutical firms while the second prong is to undertake contract research for the development of the product patented molecules to make pharmaceutical drugs. This is described in Figure 7 below.

**Fig. 7: NPIL partnership strategy (Source: Annual Report, 2005)**




The first prong of the NPIL strategy involves partnering with innovator companies worldwide across different segments of the pharmaceutical value chain (see Fig. 7). It has developed the ability to provide end to end solutions in a range of activities, viz. chemical synthesis of APIs, intermediates and also dosage formulations. NPIL therefore is open to seeking partnerships with small research companies, MNC pharmaceutical firms, and generic companies in areas of manufacturing active pharmaceutical ingredient, development cheap production processes and new formulations. However, NPIL will not provide support to 'early to market' generic product development or contract with generics companies for such work. The 'early to market' generics involves challenges to existing patent and so patent litigation with patent holding firm whereas in case 'late to market' generics, patent is already expired and therefore involves no patent litigations. This way NPIL is able to avoid the generic patent challenge game and maintain good relationships with MNC pharmaceutical firms. In 2003 NPIL has set up a subsidiary in the US, NPIL Pharmaceutical Inc., for moving the custom manufacturing business development nearer to prospective customers. Recently NPIL signed its first custom manufacturing contract with a US firm for manufacturing select eye care products for their global markets – including US, Japan and Europe.

The second constituent of post 2005 strategy is development of product patented molecule and licensing them to MNC pharmaceutical firms. To this end, the company has focussed on four therapeutic areas: Oncology, Diabetes, Anti Fungal and Rheumatology. In 1998 NPIL acquired the research centre of Hoechst Marion Russell located in Mumbai, India which since its establishment in 1972, was focused on new drug discovery research and herbal research. In 2002 NPIL also established clinical research organisation (CRO) to strengthen its clinical trial capabilities. Aligned with NPIL's core philosophy of partnership, the aim of CRO is to serve the generic pharmaceutical industry by conducting clinical pharmacokinetic studies and subsequently, leveraging its skills by partnering with Indian as well as MNC pharmaceutical companies.

# 5. Variety in firm strategies

## 5.1. Strategies employed to tap the generics market

As the detailed case studies make clear, all four firms aimed to make profits from the opening up of the generics markets in western economies and all firms registered increases in their share of exports (Table 3). However, they pursued different strategy-mixes in order to tap this economic opportunity.

Ranbaxy pioneered the exploration of the generics market and had started preparations to enter it well before liberalisation and the announcement of WTO accession. It built its presence in the generics market first by utilising its organic chemistry skills and investing in own process R&D to develop non-infringing process patents. The impetus for this appears to have come in the 1970s, from Dr. Parvinder Singh, son of the founder Bhai Mohan Singh, who had studied in the US, as the following quotes reveal:

> *'Even in the United States, I could see that Parvinder would one day change Ranbaxy, which was at that time a me-too company. Though I didn't know that he would one day take over the reins of the company, but I was certain he would change the destiny of the company. ..He would say how backward we were in our thinking, oriented towards licensing and copying.'* (Arun Bharat Ram

speaking on the death of his friend in 1997 as quoted in Bhandari 2005, page 51.)

*'To become a research based international pharmaceutical company with one billion dollar in sales by 2003'* (Dr. Singh's vision for the company, annual report 1993)

However, despite this vision Dr. Singh had to contend with the conservative mentality and the domestic market orientation of the existing Board of Directors led by his father. This conflict assumed threatening proportions in 1990 when the Ranbaxy board was on the verge of a split following differences between father and son. Perhaps this pushed Ranbaxy into a more gradualist approach towards the tapping of the new research based opportunities. It used the steady but low return Para III approach of ANDA fillings, where the generic manufacturer enters the market only after expiry of the product patent. Dr. Singh's efforts paid off and Ranbaxy was able to secure a generics patent in a very rapidly growing antibiotics market. Having established its reputation Ranbaxy began internationalising its operations with a view to building a global brand.

Dr. Reddy Labs was another early entrant to the generics market, though they turned their attention to the generics market only after the successes of Ranbaxy in the early 1990s. Industry insiders attribute much to the pioneering vision of Dr. Reddy, the founder of the firm.

*'Two decades ago Hyderabad was full of bulk drug companies, all spawned by IDPL (Indian Drug and Pharmaceuticals ltd.). But DRL stood out among all of them. While others were trying to make a fortune, Dr. Reddy was trying to make a name. Fortune he knew would follow. He built a company on the back of his research skills.'* (Tony Joseph in Editors Note, Business World, August 16, 2004).

*'Ranbaxy's Parminder Singh, he had phenomenal vision, and the same is true with Dr. Reddy who is himself a researcher, a hard core researcher. Maybe that gives the edge at times. They can*

> *foresee, having been there, so they know what it means. I cannot categorically say that somebody who is not a researcher can't have the vision, but in general, I think they had vision in this, we must accept that.'* (Author's interview with Bansi Lall, R&D president Nicholas Piramal on 17th July, 2003 in Mumbai).

Despite the similarity in vision, the route DRL took to enter it contrasted strongly with the Ranbaxy approach. DRL adopted the more aggressive strategy of Para IV filings, which involves invalidating existing patents or producing non-infringing process through a costly process of litigation. It is a high risk-high return strategy due to the litigation costs involved and the 180-day market exclusivity that the firm wins on a successful challenge. Though DRL got six-month exclusivity for selling Fluoxentine 40mg capsules in US, it also received a severe set back when it lost the AmVaz case to Pfizer.

Defending their high-risk strategy of trying to play the patents game, G.V. Prasad the CEO of DRL has said:

> *'If we had just stuck to bulk and branded formulations, which was the case till two or three years ago, we would be highly profitable. But those are declining businesses. Bulk will be commoditised and branded is gone. So if you stay there, it is much more risky. The whole value of the company comes down. By taking this risk (in innovation), we have actually ensured the future of the company'.* (As reported in Mukerjea 2004).

In contrast to Ranbaxy and DRL, Wockhardt and Nicholas Piramal (both older firms and business houses) were relatively late entrants into the generics market, when the economic opportunity it represented well understood and the success of Ranbaxy and DRL had already established a reputation for the cost competitiveness of Indian manufacturers of generics. It could be argued that Wockhardt and Nicholas Piramal too showed a role for managerial vision in taking their gambles on the future of bio-generics and contract research respectively. Nevertheless these decisions were far more circumscribed by the actions of competitors and informed by the successful strategies of firms in other sectors (e.g. biotechnology, software). Perhaps it was

newness of the opportunity that Ranbaxy and DRL tried to exploit which makes industry insiders ascribe a role for managerial vision. For when there is no other firm to emulate, managerial inventiveness is the only guide.

The internationalisation efforts of both Ranbaxy and DRL started well before the formal liberalisation of the economy in 1991. Ranbaxy internationalised by establishing green-field subsidiaries in Nigeria and Malaysia while DRL internationalised first through exports of ingredients to Europe and then by internationalising of their R&D before internationalising their production.[15] Both firms targeted the US market for generics, set up their own distribution and marketing networks in the US and tried to achieve brand recognition for their generic products, before expanding into the European generics markets. In contrast, Wockhardt has preferred to target the European markets earlier because of the higher (litigation) costs of entering the US market. Their preferred route to building an international generics market share has also been different – relying more on acquisitions of generic plants that are already FDA approved in US and Europe. This strategy of internationalisation by acquisition has also permitted them to enter the generics market with low process R&D expenditures and target their R&D efforts exclusively on building capabilities in molecule discovery and the development of new chemical entities. Since 2000, the older firms (Ranbaxy and DRL) too have adopted this strategy. Table 5 on the recent history of acquisitions by the four firms shows this quite clearly.

**Table 5: Acquisition history of the four firms**

| **1. Ranbaxy Laboratories Ltd** | | | | |
|---|---|---|---|---|
| **No.** | **Year** | **Acquired firm** | **Purpose of acquisition** | **Value** |
| 1 | 1995 | Ohm Laboratories (USA) | FDA approved state of art manufacturing facility in the US | |
| 2 | 2000 | Basics (Germany) Bayer's generic business | Entry into European generic market | |
| 3 | 2004 | RPG Aventis (France) | Entry into European generic market | US$84 million |
| 4 | 2005 | generic products of Efarmes S.A. (Spain) | Entry into European generic market | US$18 million |
| 5 | 2005 | Veratide from Procter & Gamble (Germany) | Expansion into European generics market | US$5 million |
| 6 | 2006 | Unbranded generic business of GSK in Italy and Spain | Expansion into European generics market | |
| 7 | 2006 | Terapia (Romania) | Expansion into European generics market | US$324 million |
| 8 | 2006 | Mundogen; a GSK subsidiary in Spain | Expansion into European generics market | |
| 9 | 2006 | Belgian company Ethimed NV | Expansion into European generics market | |
| **2. Dr. Reddy's Laboratories** | | | | |
| **No.** | **Year** | **Acquired firm** | **Purpose of acquisition** | **Value** |
| 1 | 1988 | Benzex Laboratories (India) | to expand Bulk active business | |
| 2 | 1999 | American Remedies Ltd (India) | Expansion into Indian domestic market | |
| 3 | 2002 | BMS laboratories and Meridian labs (US) | Enter into UK generics market | US $16 million |
| 4 | 2004 | Tregenesis (US) | Speciality products – access to drug delivery platforms in the dermatology segment | US$11 million |
| 5 | 2005 | Roche's Generic Business (Mexico) | Expansion into US generics market | US $ 59 million |
| 6 | 2006 | Betapharm (Germany) | Entry into European Generic market | |
| **3. Nicholas Piramal Ltd** | | | | |
| **No.** | **Year** | **Acquired firm** | **Purpose of acquisition** | **Value** |
| 1 | 1993 | Roche Products (I) ltd (India) | Entry into Indian domestic market | |
| 2 | 1996 | Boehringer Mannheim (I) Ltd (India) | Expansion into Indian domestic market | |

| | | | | |
|---|---|---|---|---|
| 3 | 1998 | Hoechst Marrion Russel (I) Ltd (India) | R&D | |
| 4 | 2000 | Rohne-Poulene (I) Ltd (India) | Expansion into Indian domestic market | |
| 5 | 2002 | ICI (I) Ltd (India) | Expansion into Indian domestic market | |
| 6 | 2004 | Rhodia's International business (UK) | Entry into European generics market | US $ 40 million |
| 7 | 2005 | Avecia Pharma (UK) | Expansion into European generics market | US $ 16.9 million |
| 8 | 2005 | Biosyntech (Canada) | R&D capability | US $6 million |
| **4. Wockhardt Laboratories Ltd** | | | | |
| **No.** | **Year** | **Acquired firm** | **Purpose of acquisition** | **Value** |
| 1 | 2002 | Wallis Laboratories | Entry into UK generics market | |
| 2 | 2003 | CP Pharma (UK) | Expansion into UK generics market | US$20 million |
| 3 | 2004 | Esparma (Germany) | Entry into German generics market | |
| 4 | 2006 | Dumex India Pvt Ltd | Speciality products (Nutrients) | |

**(Source: Company information; Annual Reports, 2000-2005; Pharmabiz magazine (www.pharmabiz.com), last downloaded 01/09/06)**

However, Nicholas Piramal has chosen the strategy of partnering with MNC and generic pharmaceutical firms for contract manufacturing and custom synthesis. Their business model appears to be strongly similar to the outsourcing model used by software companies and is driven by the desire to avoid any direct competition with Big Pharma companies in favour of piggybacking on their marketing and R&D expertise.

## 5.2. Strategies to build basic R&D capability

As we noted in previous sections, the long term growth of all four companies depended upon the successful transitioning from being process innovators to becoming product innovators and producers of new chemical entities and molecules. The four companies adopted very different paths to this transition. Thus, Ranbaxy attempted to acquire knowledge of what was involved in new drug discovery by targeting new drug dosages, while DRL saw the speciality drugs business as the stepping stone. Ranbaxy's transitioning strategy is quite similar to those described

by Chandler (2006) as characterising the successful transition of the US OTC drug manufacturers into prescription drugs.

In contrast to this integrated R&D and product development strategy of the early entrants, Wockhardt and NPIL tried to develop more specialised technological skills which extended their existing strengths. Thus, Wockhardt extended their process development skills in the biotechnology domain and NPIL exploited their process development skills to undertake contract research (in clinical research trials and process development) for multinational firms. However, while Wockhardt has relied on an integrated strategy (including clinical trials) in developing its R&D capabilities, NPIL has preferred to act as like a specialist supplier- not dissimilar to auto-component or semi-conductor manufacturers in Taiwan or South Korea.

These differences in the extent of integration are reflected in the larger magnitude of R&D investments is among the earlier entrants. Ranbaxy and DRL have set up many more R&D units than Wockhardt and NPIL. In terms of R&D employment too, Ranbaxy, Wockhardt and DRL have larger proportions of their employees in R&D when compared to NPIL. A more integrated strategy has also allowed DRL, Ranbaxy and Wockhardt to develop more depth in their technological capability. This is evidenced by Table 6 below which shows the innovative R&D performance of the four firms under study. Innovative R&D performance may be measured by a number of indicators shown below. The complexity of technological activities increases as we move rightwards. Thus filing for a NCE involves a greater depth of technological knowledge when compared with the filing of DMFs. These activities also map onto the higher margin products in the manner shown in the lowest row of the table.

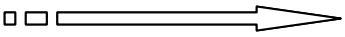
Table 6 shows that three of the four firms show innovative performance across the whole range of activities- culminating in NCEs. Despite their larger R&D investments the earlier firms appear to have struggled to succeed in new drug discovery. As we noted both Ranbaxy and DRL developed new molecules which have been abandoned after clinical trials. Both firms have also shown signs that they are considering other options such as partnering with MNC firms for molecule development and in the case of DRL also buying equity stakes in promising start-ups. To some extent this casts doubt on the usefulness of process research capabilities for success in new drug discovery. However, NPIL has leapfrogged into the NCE

stage directly through its strategy of partnering with multinational firms. Wockhardt too has been able to achieve the NCE status with fewer filings of ANDA and DMFs. Yet, as we saw their transitioning strategies have been quite different from that of the older firms.

**Table 6: R&D performance of the four case-study firms**

| No. | Firms | DMF (Drug Master File) | ANDA (Abbreviated New Drug application) | NDDS patents | NCE patents |
|---|---|---|---|---|---|
| 1 | Ranbaxy | 44 | 127 | 4 | 6 |
| 2 | DRL | 56 | 35 | | 8 |
| 3 | Wockhardt | 17 | 32 | 1 | 3 |
| 4 | NPIL | | | | 1 |

| Production segments | Bulk and contract manufacturing | Generics and Bio-generics | New Drug Delivery Systems | New Chemical Entities |
|---|---|---|---|---|

Knowledge intensity: LOW  HIGH

**(Source: Company information; Annual reports, 2005)**

There are also subtle differences in modes of technology acquisition. While DRL depended more heavily on in-house R&D (in international labs) and the acquisition of technology based firms as a route to knowledge acquisition, Ranbaxy relied on national and international licensing and international joint ventures as modes of technology acquisition. Later entrants show a greater propensity for the acquisition of whole labs/R&D units. Thus, NPIL has recently built its own research facility but started its innovative R&D research by acquiring the R&D facilities of Hoechst Indian research centre in 1998.[16] Wockhardt also invested in an existing R&D facility and upgraded it to cater requirements of biotechnology and new drug discovery research.

The transition to drug discovery needs R&D management of a different kind and the building of new competences. As Krishnan (2006) points out unlike in generics where the economic opportunity lay in only part of the value chain, new drug

discovery requires more distributed competencies in a large number of different areas of the value chain such as identifying the gene/chemical entity, screening thousands of chemicals, researching their biological efficacy, testing and finally launching them on the market. Among other things this requires a judicious mixture of biological and chemical skills and these in turn need to combine with regulatory understanding in Western markets in order to launch new drugs.

Firms are trying to address the synthesis of biology, chemistry and regulatory knowledge in the R&D labs in various ways. Internationalising R&D is a clear part of the solution and all four firms have set up R&D units in US, but the nature of activities they carry out in their overseas labs differs. Thus, Ranbaxy and Wockhardt carry out regulatory work in their US labs. DRL's R&D unit in the US is involved in conducting biological research on new targets, while NPIL's R&D operation is focused on targeting contract research and manufacturing work.

Another aspect of R&D management is hiring the right sort of people for R&D. Ranbaxy is aggressively hiring senior scientists from overseas as well as other Indian companies with emphasis on hiring senior scientists working in MNC labs. DRL we noted targeted Indian doctoral and post-doctoral students in the US, while Wockhardt mainly recruits scientists working in Indian academia and research institutes who are conversant with Indian medical problems. In our interviews, we came across many scientists who had worked in Hoechst or in Ranbaxy prior to joining R&D departments of Wockhardt, DRL and NPIL. This transfer of personnel has undoubtedly helped to transfer technical and managerial knowledge between organisations and resembles the strategies used by Merck to catch-up with its rivals.

There is evidence of inter- organisational learning through observation of other firms' strategies, especially among Wockhardt and NPIL. This includes learning from the actions of firms within the Pharma sector as well as imitating successful strategies of firms in other sectors such as software. Thus, DRL's high risk strategy has not been imitated, but its successful experiments with acquisitions to expand generics capacity has been. Location of R&D labs in the US and Europe also been important mechanisms of learning from the activities of foreign firms.

More surprising has been the influence of software experiences in informing strategies of Pharma firms. The service model of outsourcing developed in software is clearly quite similar to NPIL's business model. DRL tried to mimic a practice followed by software firms like WIPRO, in which marketing in the US was managed by US-based professionals. But this soon had to be abandoned as the human resource situations were different. Thus, G.V.Prasad, CEO DRL noted:

> *'To have a generics head in the US to worry about the operations in India meant both businesses were under managed. If I had a Vivek Paul managing my generics, may be it could have been the right thing. But the situation is where do you find a Vivek Paul?'* (Mukerjea,2004).[17]

# 6. Conclusion

This paper described how a largely homogenous set of imcumbent firms responded to the generic market opportunity opened up by the Hutch-Waxman Act and the new chemcial entitities market opened up by the New Patent Act of 1999, with the pursuit of different marketing and R&D strategies. Thus, the paper highlights the role of new economic opportunities in inducing experimentation in strategy among Indian pharmaceutical firms. While managerial vision appears to direct strategy when there is uncertainty about which strategy best targets the economic oportunity, imitation is rapid when uncertainties disappear. The paper shows that incumbent firms drew upon firms' own strengths, vision and managed risk in different ways. They also showed considerable intreprenuerial behaviour in pursuing new opportunities. This finding resonates with a new literature is now emerging that emphasises the role of entreprenuerial experimentation in industrial development (Hausman and Rodrick, 2002). Despite this variety however, there is no sign of a evolutionary trajectory through selection.

Inter-organisational learning from the mistakes and successes of other firms is at least as important to the formulation of firms' strategy as its own learning and history. What was surprising was that firms searched for strategies not only in their own sector but also in other successful sectors such as software. Another interesting result to emerge from our anlaysis is the similarity in the behaviours of strategic behaviours of Indian firms trying to survive international comeptition with

the strategies of US firms in the inter-war period. Though it is beyond the scope of our present anlysis to develop this comaprison further, nonetheless further analysis of the reasons behind such a similarity is needed to understand how devloping country firms can successfully carve out market shares in technology based industrial sectors, where they do not hold technological assets themsleves.

On the issue of the new dyanmic capabilities developed among firms, we find that the only significant capability that the four firms have developed thus far which has been helpful in garnering international market shares is the capacity to integrate technologies acquired from diverse technological sources and operate on reasonably large scales. Later firms have found less costly modes of technology acquisition than the earlier entrants in the market for firm acqusitions. However, these large scale production capabilities seem of limited use to Indian firms in the discovery space.

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[1] The policy statement which announced the full economic liberalisation of the Indian economy.

[2] Chandler (2005, 2006).
[3] See the case study detailed in Hyun, Young-suk (1995).
[4] See Chandler (2005), Chapters 7 and 8 in Section 3.
[5] Figures from OPPI (2005).
[6] Products that were patented before 1995 and already in the Indian market also remained free of patent protection till 2005.
[7] In 2004, the R&D intensity of Teva and Mylan was 7.05% and 7.35% respectively.
[8] The number of steps involved in synthesis of product, their potential for hazardousness and associated cost made the product too expensive for the Indian market. See Bhandari (2005).
[9] Bhandari (2005: 124-128
[10] These are two anti-bacterial molecules and one anti-malarial molecule. See Kale (2000: page 147) for more details.
[11] Cited in Mukerjea ( 2004: page 4).
[12] We are indebted to Shyama Ramani for allowing us to read and use notes from her interview with Shri V. Gopalakrishnan conducted on 15th May 2002 in writing this section.
[13] Parentals are injectible drugs and medicines like IV fluids which are administered directly into the human body.
[14] Shyama Ramani’s interview with V.Gopalakrishnan on 15th May 2002 in Mumbai.
[15] This is somewhat reminiscent of the Parke-Davis model described by Chandler (2006).
[16]The Hoechst research centre had started operations in 1978 and throughout the period of existence focussed on drug discovery research.
[17] Vivek Paul was the US-based Vice Chairman of Wipro Technologies,(one of the top 3 Indian IT firms) from 1999-2005. He was head hunted and hired from GE Medical. Under his leadership Wipro grew its revenue ten-fold, from $150 million to $1.4 billion.