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capability in the Indian Pharmaceutical Sector**

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Experimentation with strategy and the evolution of dynamic capability in the Indian Pharmaceutical Sector

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Abstract

This paper demonstrates that radical regulatory changes can be tantamount to technological revolutions by studying Indian pharmaceutical firms. It shows that radical regulatory changes such as the Indian Patent Act of 1970, the New Industrial Policy of 1991 and the signing of TRIPS (Trade Related Intellectual Property Rights System) in 1995 served to open up new economic opportunities and constraints in the wake of which the winners and losers were selected as a function of the dynamic firm capabilities most appropriate for the new market environment.

Key words: International marketing, R&D management, Indian pharmaceutical sector, corporate strategy.

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1. Introduction

Resource based views of the firm place special emphasis on the roles of heterogeneous capabilities of firms in driving variety in strategy. They are particularly pertinent for dynamic markets, where firm-specific deployment of capabilities, entrepreneurship and ad hoc problem solving skills determine the winners of the race for market shares, as new or untapped economic opportunities emerge. In the absence of natural, socio-economic or political upheavals, radical innovations and technological discontinuities are often considered necessary to provoke such market change and opportunities. In contrast, through an examination of the Indian pharmaceutical sector, the present paper demonstrates that radical regulatory changes can impact capability development similarly. It shows that radical regulatory changes such as the Indian Patent Act of 1970, the New Industrial Policy of 1991 and the signing of TRIPS (Trade Related Intellectual Property Rights System) in 1995 served to open up new global economic opportunities and constraints in the wake of which the winners and losers were selected as a function of the dynamic firm capabilities developed that were most appropriate for the new market environment.

The effect of new opportunities on firm strategy is a major concern of the literature on dynamic capabilities and market evolution and it is to this stream that our paper makes three types of contributions. First, it highlights how regulatory changes can serve to re-orient technological capabilities even in the absence of a radial technological discontinuity. Liberalisation of industrial policy and homogenization of intellectual property rights initiated “pull and push” forces on the R&D and innovation focus of Indian firms. The “push” factor was the ban on re-engineering of patented goods and the “pull” factor was the emergence of a consciousness of “opportunities presented by lucrative international

markets” for the exploitation of already-acquired technological skills and the development of new ones. Starting from a unique R&D focus for developing more cost-efficient or quality enhancing processes, market leaders now have a multi-focus incorporating a transition towards the development of technological capabilities required for new drug discovery. However, this re-orientation has had little impact on the industrial organization of the local market.

Second, the paper identifies the kinds of dynamic capabilities that can be developed as a response to radical regulatory changes through a study of four leading Indian pharmaceutical firms. They are of three kinds and significantly inter-related: diversification of knowledge and technological capabilities; internationalisation of production and distribution units; integration in the innovation creation process of Western country firms through providing services related to innovation creation.

Third, it affirms that radical regulatory change can provide a period of strategic transition when the portfolio of dynamic capabilities developed by firms varies significantly. Such transition strategies are a function of past firm specific technological trajectories, firm-specific managerial vision and inter-organisational learning through observation of strategies of other firms.

The remainder of the paper is organised as follows. Section 2 briefly reviews the literature on resource based views of strategy formation. Section 3 provides a background to the Indian pharmaceutical industry and examines the evolution of the R&D strategies of Indian firms before and after TRIPS to draw inferences and formulate hypotheses to be tested by the case studies. Section 4 details the evolution of strategy and capability with the help of case studies of four established firms. Section 5 discusses the findings of the case studies. Section 6 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 founded on behavioural and evolutionary hypotheses. 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 is difficult to imitate by other firms. Thus, this perspective emphasises the heterogeneity of firm capability as well as its stickiness implying that firms pursue different strategies that are optimal given their firm-specific capabilities.

Firm capabilities also evolve over time due to endogenous market changes and exogenous shocks and this change is referred to as a dynamic capability. Such evolution disrupts or adds new value to the rents to existing capabilities thereby influencing 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". Furthermore, 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 argues 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 entrepreneurial 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 with some common features across firms. They also argue that in rapidly changing markets such dynamic capabilities may be quite simple experimental 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. Put differently, it is the higher order capabilities that have the capacity to produce lasting new competitive advantage as a consequence of the change in market opportunities. However, firms can and do accomplish changes in strategy without the reliance on higher order capability by ad hoc 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 to succeed 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 greater convergence of firm strategies. Thus, strategic variety will always accompany the emergence of a new economic/technological opportunity and the variety of strategies generated will define the direction of evolution of the industry concerned, since one of the experimental designs will one day become the dominant design.

3. Salient Features of the Indian Pharmaceutical sector

3.1: Regulatory reform and industrial structure

It is often touted that the Indian Patent Act of 1970 infused life into the Indian pharmaceutical industry. By this time, the Indian government had invested in the creation of a network of universities and research institutions, which were generating large pools of qualified labour in the form of chemists, pharmacists, engineers and managers available to work in pharmaceutical firms. On the demand side, millions were without access to basic

drugs and national and international procurement agencies ensured certain demand. Thus, the change in regulation opened the market gates to entrants, which could develop the necessary dynamic capabilities to bring generics to the market through new, cost-efficient, process technologies and grab market shares through penetration pricing in quintessential Bertrand competition games.

Table 1 below shows the top ten companies for selected years 1970, 1996 and 2003, and they clearly reveal what a weaker patent system can do to spur competition. It allowed Indian firms to adopt 'duplicative imitation' and 'creative imitation' as strategies for technology capability development (Kale and Little, 2007). The growing strengths of the domestic firms are reflected in the table, in which the figures in parentheses indicate the market shares to each firm. Thus, in 1970, the Indian market was clearly dominated by multinational firms and eight of the top ten firms were MNCs. After two decades following the 1970 Patent Act, Indian pharma was dominated by domestic firms and only 4 of the top ten firms were now multinational. By the mid 1980s most Indian pharmaceutical firms were producing bulk drugs and formulations for the domestic market and the leading domestic firms (e.g. Ranbaxy) had begun to explore markets in Asia and Africa.

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 controlⁱ. Liberalisation of national and international financial transactions followed in 1995. Hot on the heels on liberalisation, India became a member of the WTO in 1995 and thereby agreed to change the regulatory framework in accordance with the TRIPS convention, a mandatory condition for WTO membership. Between 1994, when TRIPS was signed by India, and 2005 when it came into

effect in India, three amendments to the patent law of 1970 were passed in the Indian Parliament to make it TRIPS compliant. They were the 'Patent First Amendment Act' in 1999, 'Patent (Second Amendment) Bill' in 2002 and the 'Patents (Amendment) Bill' passed in 2005.

Production, exports and imports shot up after the adoption of economic reforms (see figure 1). 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). Currently, the Indian pharmaceuticals market ranks 4th in volume and 13th in value in the worldⁱⁱ. The value of its production is estimated to be approximately \$4.5 billionⁱⁱⁱ and it employs about 5 million workers directly and 24 million workers indirectly. The industry structure remains dualistic with about 90% of the 20,000 firms in the small scale sector.^{iv}

The decade preceding TRIPS was also marked by technological upheavals and radical regulatory reform in Western markets. Policy makers in Western countries also became more sensitive to the need for developing the market for generics drugs, in order to bring down the costs of providing health care and decrease social security payments to its citizens. Ironically, these concerns were quite similar to those which had provoked the Indian Patent Act of 1970.

The USA pioneered new policies designed to decrease spending on medical care and the Hatch-Waxman Act was passed in 1984 to stimulate the market for generics, lower prices and enable greater accessibility to healthcare for its citizens. Prior to this law, a generics producer could not apply for marketing approval until after patent expiration and had to submit the full experimental and clinical data as is required for a new drug to prove safety and efficacy. This delayed market entry by as much as 3 years after patent expiry. With the Hatch-Waxman Act, manufacturers of generic drugs no longer had to go through

a lengthy period of extensive clinical trials - demonstration of bio-equivalence was sufficient to acquire marketing approval for a generic drug. European countries followed suit but the situation remains confusing as its national laws remain different.

Just as Indian patent law of 1970 had made the pharmaceutical market more competitive, the legislation to make entry into the generics market easier was also accompanied by new entrants who made the market more price-competitive. The firms leading the generics challenge internationally were Teva and Mylan from Israel and Ranbaxy and DRL from India.

3.2 Evolution of R&D strategies among Indian firms

The market opportunities opened by the Indian Patent Act of 1970, the constraints for expanding the manufacturing base under the license Raj and the endogenous evolution of the market together determined the capabilities of Indian firms in this period. Market leadership belonged to firms which had competence in chemical process technologies necessary for re-engineering targeted drugs and the ability to withstand technology races in process improvements through pursuing a diversified product portfolio. The common features of technological capabilities and strategy among all the leading firms included low R&D intensity, innovation focus on cost-efficient or quality enhancing processes, direct commercialization of innovation in countries where the product patent regime was not recognized and technology transactions with Western multinationals in the form of licensing and marketing agreements (which worked both ways).

The knowledge base of Indian pharmaceutical firms was firmly embedded in organic and synthetic chemistry and any R&D investment was specifically targeted to lower the costs of production of selected drugs identified as having good commercial prospects,

with the outlays just to the point needed to arrive at the objective (Ramani, 2002). In 1992, only about 47 companies out of 23,000 odd firms in the pharmaceutical sector) registered positive R&D expenditures, of which only 7 companies spent more than 1.5% of their sales revenue on R&D. Western multinationals contributed very little to innovation creation in India. Between 1970 and 1995 only two multinationals in India (Ciba-Geigy and Hoechst) had more than 2 patents list in the USPTO.

TRIPS introduced three main elements of change in the Indian patent system. It banned production and sales of re-engineered pharmaceutical products. It extended product patent protection applied to all branches of manufacturing, including drugs, the period of protection to 20 years. Finally, it forbids discrimination between imported and domestic products.

A study based on interviews just prior to TRIPS enforcement revealed that pharmaceutical firms were adopting one or more of three types of strategic positioning in response to TRIPS (Ramani and Maria, 2005). First, the target for R&D is the creation of drugs, vaccines and diagnostics that are off-patent or are soon to be off patent, especially in regulated Western markets. Second, Indian firms are vying to participate in the international division of labour for the creation of new drugs by Western multinationals by offering contract research and custom manufacturing services, bioinformatics services for genomics based drug research, and carrying out clinical trials. Third, and in a smaller measure, some Indian firms are investing in the creation of new drugs for global diseases such as diabetes. Gehl Sampath (2006) also notes that the objective of the leading firms is to find the right mix of competition and collaboration with the multinationals in order develop their dynamic capabilities.

The rationale behind these choices is of course quite clear. The comparative advantage of Indian companies is in reverse engineering and process improvements that lowers the price of generics. The US market is the largest single-nation market for generics in the world and along with other lucrative European markets they are even larger. Leveraging the rents to their reverse engineering capabilities by selling to these markets is a prime example of picking the low hanging fruit – and one that totally escaped prediction in the economics literature on the impact of TRIPS in India.

The other two strategic choices involved the development of new technological capabilities in new product and process innovations more linked to the different steps in the sequential process of bringing a new drug to the market. The launch of a new drug typically has to go through the stages of basic research, identifying the appropriate active pharmaceutical ingredients, combining these novel ingredients into a product, performing preclinical and clinical trials to test impact, identifying the right dosage and drug delivery system, seeking regulatory approval through completing a number of procedures, and finally marketing the new drug. From start to finish the commercialization of a new drug can take anything between 15 and 20 years. With the Patent Law of 1970 Indian firms developed skills in the middle stages and the marketing but not in new drug discovery research techniques or preclinical or clinical trial methods. For Western firms, which are proficient in all the above steps but need to speed up and cheapen the drug discovery process, the presence of Indian firms proficient in reverse engineering offers outsourcing opportunities. For Indian firms aspiring to become new drug manufacturers the task is rather more daunting. They have to develop absorptive capacity and technological capability in creating drugs, performing preclinical and clinical trials and seeking regulatory approval. Finally, they also have to build new capabilities to market new products through doctors in Western hospitals.

Thus, the second choice of strategy viz. becoming a cog in the wheel of an international division of labour and helping Western multinationals create their innovations is like the helping hand sought by a poor relative. Indian companies realise that they cannot match the deep pockets of Western multinationals as far as R&D budgets are concerned but want to avoid exclusion^v. By partnering with Western MNEs in latter's new drug discovery endeavours, they hope to build new dynamic capabilities. .

The third choice for innovation creation through new drug development, involves head-on competition with existing pharma majors and is clearly the road least travelled by Indian pharmaceutical firms for two reasons. First, high innovation rents can be reaped in Western markets for generics with more certainty. Another more important reason is the lack of significant complementary competencies required to create a new drug. The drug development process starts with preclinical tests on animals on the basis of which a firm applies for an INDA or an Investigational New Drug Application. At this stage the drug development process enters into a series of clinical testing phases, at the end of which an NDA or a New Drug Application is made with the regulatory authority^{vi}. Then in order to enter the market some additional information and technical support may need to be provided to the regulatory authority and such requirements vary from country to country^{vii}. Under the process patent regime, Indian firms largely skipped the INDA, phase I, phase II and phase III of clinical trials and went straight to the regulatory authorities for an NDA to prove bio-equivalence of the generic form of the drug and to satisfy the additional requirements to market the generic in India. Sometimes, even patents were not necessary. Thus, lack of competencies in the initial and final phases of new drug development are the Achilles heel of Indian firms.

Aggregate data however confirm the intentions of Indian firms to upgrade their technological ability. By 2005, about 109 pharmaceutical companies had positive R&D expenditures; out of which 81 had an R&D intensity of 1.2% and 28 firms had an R&D intensity of 8.79% (Chaudhuri, 2007). Yet, even by 2005 no Indian company had come up with a significant innovation in the form of a new drug based on indigenous R&D. Pradhan (2007) confirms that small firms spend either 0% or less than 1% of sales revenue on R&D.

The above discussion leads us to the following two hypotheses on strategy and the evolution of dynamic capabilities of Indian pharmaceutical firms after liberalisation that we examine in the next section through case studies.

Hypothesis 1: The combined effect of the Hatch-Waxmann Act, economic liberalisation and TRIPS has been to provide new incentives to exploit existing opportunities, which were hitherto not given much attention, such as the international generics market, technology collaborations with Western firms and transition towards new drug discovery.

Hypothesis 2: The growth of the Indian innovator firms depends on their capacity to identify and develop the optimal dynamic capabilities to exploit opportunities associated with the different stages of the sequential process of bringing a new drug to the market.

4. Strategy and the evolution of dynamic capability: Four Case Studies

To explore the above hypotheses, we now present very brief case studies of the R&D and innovation related strategies of four of the leading pharmaceutical firms in India viz. Ranbaxy Laboratories, Dr. Reddy's Labs, Wockhardt and Nicholas Piramal focussing on the period after TRIPS, i.e. 1995^{viii}. 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. The firms occupy different niches/market segments within the generics market. Thus, Ranbaxy is 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. However, all the segments chosen by Indian firms are within the largest ten therapeutic segments in the world. Comparative data for the four firms are given in tables 2 and 3.

Our reasons for focussing on these four firms alone are two-fold. First, there is a very strong correlation between size and R&D intensity in the Indian pharmaceutical sector (Pradhan, 2007; Ramani and Putz, 2001). Therefore, major innovations in terms of process and product are likely to emerge only from the top 30 firms. As of now, no 'NCE' or 'New Chemical Entity' has been commercialized by an Indian firm, though some are in the clinical trials phase. Clearly, if any Indian firm at all is going to commercialize an NCE, and that too an NCE that can lead to the creation of a major drug, it is likely to be one of the top 10 firms. Three of the four case study firms are also among the top 10 firms in the Indian pharmaceutical sector. Second, all the four firms we study were established in the pre-liberalisation period with Wockhardt being the oldest and Nicholas Piramal being the newest. This allows us to examine the transitioning strategies between the old and new regimes more clearly

4.1 Ranbaxy Laboratories

Ranbaxy Laboratories Limited was established in 1961 and listed on the Bombay Stock Exchange in 1973. 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. The main milestones in the company's history are summarised in Figure 2.

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 generic molecule of an original drug developed by Glaxo and sold under the brand name of Zantac. This marked the start of a strategy based on the manufacture of generic drugs, accompanied with the opening of the Ranbaxy Research Foundation in 1985.

The generics strategy received a great boost through several developments: One of Ranbaxy's API manufacturing plants was approved by the US Federal Drugs Authority (FDA) in 1988. 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. 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 as compared to Eli Lilly's original production process.

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 systems as a stepping stone to the development of drug discovery capabilities.

In 1999 Ranbaxy registered its first major success, 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. Ranbaxy licensed the once-a-day technology to Bayer of Germany for US\$10 million, for further development. In 2004, Bayer successfully launched the 500mg and 1gm once-a-day formulation in US, based on delivery technology platforms developed by Ranbaxy^{ix}.

Ranbaxy had no prior experience drug discovery research, and therefore it first concentrated on building a strong, well focused inter disciplinary research team. Thereafter, it initiated an open policy of recruitment including 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, based in their US subsidiary 'Ranbaxy Pharmaceuticals Inc', does not carry out any laboratory work but focuses on clinical research, regulatory affairs and 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 was 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.^x

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 long before liberalisation and TRIPs made entry into Western markets for generics easier. 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 in 1984 by Dr. Anji Reddy, who formerly worked in the public sector company Indian Drugs and Pharmaceuticals Ltd. In 1987, DRL launched Norilet, DRL's first recognised brand in India. Major success came with the launching of Omez, the brand name under which the generic Omezaprozole was sold. A superior process technology, allowed DRL to launch it at a price 50% lower than that of the other brands selling in Indian market. Within a year of its inception, DRL also began to export active pharmaceutical ingredients to Europe.

In 1994, DRL opened a state of art manufacturing facility in Hyderabad, India, in order to increase its production capacity in generics. Three years later DRL filed its first ANDA (Para III application) 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- and Rantidine. It got approval before patent expiry and without litigation for Ranitidine but for Omeprazole, it only won a tentative approval but lost out in subsequent court battles. In 2001, DRL became the first Indian company to launch Fluoxetine (a generic version of Eli Lilly's Prozac) with a 180 day market exclusivity in US. 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 building DRL's fully fledged distribution network in the US market.

Dr. Reddy's Para IV application strategy for generic business aimed at gaining market exclusivity was a risky and expensive strategy as it involved challenging existing patents. This strategy received a severe set back when DRL lost the patent challenge in the case of Pfizer's drug Norvasc in February 2004. Furthermore, Big Pharma companies have found a loophole in the Hatch-Waxman Act have started pre-emptively launching their own version of the generics drug which wipes out the six month exclusivity.^{xi}

DRL's transition path towards new drug discovery involves targeting speciality generics products in western markets in order to transit to drug discovery capabilities (see Fig. 3). The reason that 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. DRL have also invested heavily in building R&D labs and remain 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 is dedicated to new drug discovery.

Initially, DRF's drug discovery research strategy revolved around analogue research but DRF changed its focus to work in rational drug design with a hiring strategy that targeted fresh scientists especially Indian students studying abroad on doctoral and post doctoral courses^{xii}. Though DRF wanted to introduce modern skills such as drug discovery based on genomics and proteomics, it struggled with this change as it could not find scientists in India equipped enough in these areas of research. 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 7 NCEs (new chemical entities) in various stages of development: five molecules are in clinical development and another two 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 (Denmark) and DRF 1042 with Clintech international (Germany). 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). Furthermore, in 2003, Novo Nordisk terminated development of the molecule also due to adverse effects. In 2002, DRL granted exclusive rights for the development and commercialisations of DRF 4158 to Novartis Pharma AG. But in 2003 Novartis opted to replace dual acting insulin sensitizer with another follow up compound.

The most important lesson that DRL has learnt from such failures is that new drug discovery is a risky business and it is necessary to formulate and implement a strategy for risk management, both in terms of collaborative ventures and financial support, in order to move on. Therefore, DRL is scoping other means to improve their chances of success in drug discovery efforts. Aurigene Discovery Technologies, a contract research company was established as a fully owned subsidiary of DRL in 2002, in Bangalore, India, to gain experience of drug discovery through contract research for other Pharma companies. As mentioned above, it has acquired Trigenesis (US), 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 still trying out various de-risking strategies. DRL has entered into out of court settlements where a Para IV strategy appears likely to succeed. Thus, DRL has made a private settlement with Novartis to delay its launch of the generic rival to Exelon- its drug for Alzheimer's. In 2007, the new drug discovery units of DRL were de-merged from the rest of the business- a trend that was followed by Ranbaxy and several other leading firms.

4.3 Wockhardt Ltd

Wockhardt was started by Khorakiwala family in 1959 as a small pharmaceutical distribution and selling entity. 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 (see fig. 4). Thus, from the early 1990s the company has spent 20 -30% of its total research budget on biotech R&D. Wockhardt's R&D centre at Aurangabad initiated programs in the field of new drug discovery research in 1997, a clear break from the past when the focus had been uniquely on biogenerics. Wockhardt has decided to concentrate its efforts on the anti-infective therapeutic segment, as the main thrust area in new drug discovery R&D. Moreover, it has chosen to explore the biotechnology route to drug discovery and in order to gain experience in biotechnology it has concentrated on the bio-generics segment in its generic market strategy. As of now, 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. The other chemical entities WCK -1152 and WCK- 1457 are under pre-clinical trials.

In 2001, Wockhardt indigenously produced a drug called erythropoietin (EPO) for severe anaemia 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 onwards, 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 remain focused on managing businesses related to agricultural sciences, parentals^{xiii} 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. Wockhardt's expansion into Europe and the US is based largely on acquisitions of plants that have FDA approval. Thus, it entered UK market by acquiring Wallis Laboratory, in 1998 and CP pharmaceuticals in 2003. In 2004 Wockhardt acquired the German pharmaceutical company, Esparma GmbH, to enter Germany, the largest generic drug market in Europe. This acquisition has given Wockhardt increased depth in product portfolio and helped company to strengthen its presence in the European business. In

2007 it acquired Negma laboratories, the fourth largest independent, integrated pharmaceutical group in France.

Wockhardt launched its US operation in 2003 by starting Wockhardt Americas Ltd and now has its own marketing and regulatory teams based in US. Wockhardt's US strategy is based on launching formulation products through ANDA route and as of 2003, it had filed 17 ANDA applications with USFDA.

4.4 Nicholas Piramal India Ltd (NPIL)

NPIL is a part of the Piramal Enterprises, one of India's largest diversified business groups with interests 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. In the last ten years their pharmaceutical business has emerged as the fastest growing and most profitable of the lot (see Figure 5).

For the Piramal group acquisitions have been an instrument for 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 through attaining critical mass to leverage on marketing and distribution.

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 for distribution of foreign products and contract manufacturing.

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.

One part of the NPIL strategy involves partnering with innovator companies worldwide across different segments of the pharmaceutical value chain. 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 does not provide support to 'early to market' generic product development or contract with generics companies for such work. The 'early to market' generics involve challenging the existing patent and instigating litigation with the original innovator, whereas in 'late to market' generics, the patent is already expired and therefore patent litigation is avoided. In 2003, NPIL set up a subsidiary in the US, NPIL Pharmaceutical Inc., for moving the custom manufacturing business development nearer to prospective customers. In 2003, NPIL signed its first

custom manufacturing contract with the US firm Advanced Medical Optics, Inc. for manufacturing select eye care products for their global markets – including US, Japan and Europe.

The second constituent of its strategy is development of product patented molecules for licensing to MNC pharmaceutical firms. 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 a 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. Discussion of the results of case studies

The findings of the case studies clearly support hypothesis 1 and hypothesis 2 of section 4. In addition, they refine hypothesis 2 by identifying the strategy-mix and capabilities required to exploit the opportunities thrown up by the regulatory changes viz. (i) entry into the generic markets of developed countries, (ii) collaboration with Western multinationals on different segments of the sequential process of new drug commercialization; and (iii) acquisition of skills for new drug discovery and commercialization. The case study evidence is summarised in Tables 4a-4c.

5.1: Tapping the international generics market

Entry into the global generics market could be achieved through exporting activity and /or through the setting up of production and manufacturing facilities for generics in particular countries. Exports of generics could be targeted to the higher value but tightly regulated Western markets or to other developing country (DC) markets. Similarly, setting up of manufacturing facilities in third countries could also take one of three forms: Greenfield investments, acquisitions or joint ventures. Table 4a gives some indicators to measure the extent to which each mode was employed by the four companies we studied suggesting learning through observation of compatriot competitors and revealing subtle differences in firm strategy.

Early bird gets the worm of international generics? Ranbaxy was the first company to spot the opportunity offered by the US generics market and started preparations to enter it long before liberalisation and TRIPS. Indeed their first success was announced through the development of a non-infringing patent in 1991. DRL was possibly spurred by Ranbaxy success - prior to 1994 they were content to sell API to worldwide markets. Ranbaxy was the first to use the ANDA filing route to enter the US generics market directly. It used the steady but low return Para 1 to Para III approach of ANDA filings, where the generic manufacturer enters the market only after expiry of the product patent and securing a niche in the US antibiotics segment. On the other hand, DRL adopted the 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 Fluoxetine 40mg capsules in US, it also received a severe set back when it lost the AmVaz case to Pfizer.

Thus, the two early entrants differed quite markedly in their propensity to take risks. The two later entrants have followed the example set by Ranbaxy and DRL but the low-risk strategy of Para 1-3 applications is more popular among them.

Internationalisation through subsidiaries and joint ventures: 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. 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 started from developing country markets in Asia and Latin America like Ranbaxy but thereafter preferred to target the European markets earlier. NPIL has established subsidiaries in advanced markets such as Europe and US primarily to target contract research and manufacturing opportunities.

Internationalisation through acquisitions: Starting with the acquisition of Ohm laboratories in the USA in 1995 by Ranbaxy, other firms have followed with a string of acquisitions of generic plants that are already FDA approved in US and Europe. This strategy of internationalisation by acquisition permits the entry into developed country market and incorporates more cost efficient processes. Though Ranbaxy and DRL pioneered this approach, it has been imitated by all the four case study firms and increasingly adopted by other leading Indian firms as well.

Geographic coverage: Table 4a reveals that all the four firms we studied are committed to expanding their presence in the global generics market whether measured through their exporting activity or through their foreign investment activity. Ranbaxy and Dr. Reddy have concentrated on both the US and the European markets though Wockhardt has preferred to penetrate the European rather than the US market. All firms have listed on international stock exchanges and since 2000 have embarked on an acquisition spree in order to gain market shares in foreign markets. Technological capability can be measured through the number of 'Abbreviated New Drug Applications' (ANDA) and 'Drug Master Files' (DMF) filed by the four firms. Again NPIL comes out as the firm with lower competencies when measured this way.

Extending brand image through acquiring skills to deal with regulation: In terms of the drug cycle the foray into international generics required Indian firms to develop their international marketing capability, acquire a capacity to deal with food and drug regulation in Western markets and also have the capacity and deep pockets for patent related litigation. In keeping with their greater focus on the US and UK markets we find evidence of marketing with own brand development in Ranbaxy and DRL. Wockhardt has also developed this ability in the UK market. Similarly, all the four case study firms show evidence of regulatory capability through their ANDA filings though Ranbaxy clearly leads in terms of total numbers. However, only Ranbaxy and DRL show the ability to manage the more difficult Para IV filings.

5.2: Integrating in the global division of innovative labour

Cross-licensing of process improvements to foreign pharmaceutical firms and manufacturing the improved product was part of the strategy of the more technologically competent firms even before liberalisation and TRIPS. In addition, the case studies reveal new forms of collaboration such as licensing out of molecules discovered by Indian firms, joint R&D contracts and outsourced clinical trials. All of our four case study firms have participated in the international division of labour and Table 4b presents evidence on the nature and form by which these firms have positioned themselves. The interesting aspect of Table 4b is that all four firms are quite different in their strategies for participation in the international division of labour.

Licensing out and contract R&D in upstream stages of drug discovery: The type of activity chosen is clearly dependent on the level of technological competence of the company. Consistent with their higher technological competence as revealed by the rows on ANDAs filed and DMF s filed in Table 4a, both Ranabaxy and DRL have tried to use joint R&D agreements and licensing-out to access the complementary capabilities in the drug cycle that they need (viz. screening of appropriate molecules and testing in order to bring to market). However, DRL has set up a separate unit in order to undertake R&D services presumably giving the signal that doing R&D for other firms will not leak their secrets to the generics arm of their business.

Contract services in downstream stages of drug commercialization: In contrast, Wockhardt and NPIL have tried to use the international division of labour in a targeted way to develop their absorptive capacity in areas of the drug cycle where they perceive own capabilities are lacking but still sense future advantages - e.g. clinical trials. NPIL exploited their process development skills to undertake contract research (in clinical research trials and process

development) for multinational firms. On the other hand, 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 and is also more spread out than Wockhardt having activities involving contract manufacturing, R&D collaboration and clinical trials. Neither of the two firms is involved in licensing-out.

5.3 Acquiring skills for new drug discovery

The value chain in pharmaceuticals, from least knowledge/value added intensive to most knowledge intensive/value added product is as follows:

- (i) bulk drugs;
- (ii) generics;
- (iii) bio-generics;
- (iv) dosage formulation;
- (v) drug delivery system;
- (vi) New Chemical Entity
- (vii) Niche segment drug
- (viii) Broad therapeutic segment blockbuster.

No Indian pharmaceutical firm has come up with a major innovation in (v) - (viii). At the moment Ranbaxy, the forerunner is also at the head of the pack with its innovation on dosage formulation. Among our case study firms both Ranbaxy and Dr. Reddy's have greater strengths in generics rather than bio-generics, which is the forte of Wockhardt. All

four firms we have studied are strong in (i). These gaps in performance are closely linked to missing capabilities along the the different phases of the sequential process of new product development for each of the above categories.

Table 4c lists the main indicators of rising technological ability in new drug discovery and also the strategies pursued to gain these capabilities. It can be seen that despite a large number of patents from 1991-2005, both Ranbaxy and DRL show a very small number of molecules in clinical trials. Wockhardt has a smaller number of overall patents but similar number of molecules in clinical trials. NPIL is once again different in that it has registered very few patents and has no drugs in pre-clinical trials.

Investment in R&D at home and abroad: Strategies to improve technological abilities have included increasing the level of own R&D spending. 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. All four firms have internationalised their R&D by setting up R&D units in US. However, 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. This is also reflected in the patents drawn from overseas labs: DRL draws more patents from RUSTI than do Ranbaxy and Wockhardt from their international R&D subsidiaries.

Developing interdisciplinary communication: Another aspect of R&D management is hiring the right sort of people for R&D and making inter-disciplinarity a way of research thinking in the organisation. To this end, 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. Of all the Indian firms only Wockhardt has explicitly targeted biotechnology processes as a means to achieve generic market successes. Ranbaxy gave up its initial attempts and DRL has been patenting a number of proteins but these patents cannot unambiguously be called biotech patents.

Internal R&D vs. collaborative R&D: Two key strategic choices in building up own technological capacities are: how much to keep in-house and how much to collaborate with foreign firms? How much to integrate within the different steps of the sequential process of new drug discovery and commercialization? The uneven use of foreign sources of knowledge revealed in table 4c is testimony to the question marks that surround this issue. Some of the challenge is related to managing human resources that emerge in different contexts but there may also be fears of how much to share of the firms own knowledge base. The commercial success of Nicholas Piramal and other contract manufacturing firms like Lupin, Dishman Chemicals, Shasun chemicals and the high risk and long gestation involved in the new drug cycle have cast some doubt on the value of integrative capabilities. Proof of this is to be found in the recent attempts of DRL to set up a contract research facility which it has also de-merged from its main generics business- thus resembling more a disintegrated specialist supplier.

5.4: Capabilities, Strategy and Dynamic Capabilities

The preceding section makes it amply clear that there are clear relationships between existing capabilities, changed capabilities in response to new opportunities and target capabilities identified as being likely to capture competitive advantages. While existing technological competence played an important role as did the firm's historical trajectory, two other factors namely, 'firm specific managerial vision', and 'inter-organisational learning through observation of compatriot leader firms' also had important roles to play in defining the strategy-mixes adopted by Indian innovators.

The vision of Parminder Singh that Ranbaxy could be a big player in the generics market that was opening up in the US was both audacious and unforeseen. Anji Reddy's ambition to show Indian firms could overturn patents and win guided DRL's forays was viewed in the same light. However, later entrants learnt from both these experiments. DRL's high risk Para IV strategy has not been imitated, but its successful experiments with acquisitions and inorganic growth to rapidly expand generics capacity has been.

In transitioning to new drug discovery we find that three of the four firms chose different transitioning paths to new drug capabilities — Ranbaxy through improving dosage forms, DRL through speciality chemicals and Wockhardt through pursuing the bio-generics route, yet the strategies that they have used to achieve these transitions have borrowed from each other. Outlicensing, first initiated by DRL was imitated by Ranbaxy and Wockhardt. De-risking drug discovery through de-merger and venture finance of those R&D subsidiaries was initiated by DRL but is now proving to be popular among other large drug manufacturers. It seems that inter-organisational learning through observation of other firms' successful strategies has significantly influenced the strategies pursued by the firms and may be as important as own firm learning. In this sense the variations in

strategy initiated by particular firms have constitute a natural experiment for the whole industry.

Another finding is that while existing capabilities do constrain the strategies firms adopt in the face of new opportunities, 'new' capabilities developed by firms co-evolve with the particular strategy chosen. This is most clearly illustrated by comparing the different experiences of NPIL and Ranbaxy. Starting with strengths in process engineering, Ranbaxy chose to go down the route of becoming an integrated producer of new drugs. This meant that it would have to acquire 'new' capabilities along the whole of the drug cycle and as we have shown many of its strategic efforts are also geared towards such an outcome. However, NPIL has decided instead that in the new situation, it will play on its strengths and become a specialist supplier favoured by Western drug producers. In choosing to operate as a disintegrated specialist supplier, NPIL will not need to develop the integrative capabilities that Ranbaxy is developing. Instead its strengths may lie in becoming a reliable and trustworthy partner in an innovative division of labour.

6. Conclusion

The central objective of this paper was to examine, if regulatory changes could be a catalyst for the creation of dynamic capabilities in firms even in the absence of the introduction of radical innovations, through the case study of the Indian pharmaceutical industry. Our analysis clearly confirmed this hypothesis. It also demonstrated that dynamic capabilities can co-evolve with firm strategy in order to exploit new opportunities thrown up by regulatory changes through three main results.

First, regulatory changes such as adoption of a liberalisation policy, changes in the Indian patent laws and changes in laws concerning entry of generics in the US, created

three kinds of opportunities for Indian firms. These included possibilities for the exploitation of the international generics market, especially lucrative developed country markets, new forms of collaboration with Western multinationals and a transition towards new drug discovery.

Second, in initiating a variety of strategies to exploit these new opportunities, the firms concerned also triggered an evolution of their capabilities all along the value chain of commercialization, starting from upstream expansion of knowledge base and re-orientation of R&D to downstream enhancement of marketing capabilities in new markets. Three kinds of dynamic capability building patterns have been identified: “safe integrated capability building” such as by Ranbaxy, which consists of building competencies in the maximum number of phases of new drug development; “safe niche capacity building” typified by NPIL as a specialist supplier; and the “risky capacity building” through challenging Western incumbent firms on their own turf as exemplified by Dr.Reddy’s. It is likely that the winning configuration of dynamic capabilities would involve a combination of these three models. The larger the scope targeted, the greater the integrative capabilities across the value chain needed; the narrower the scope chosen, the higher the capability in scale up process engineering and production required. Thus, dynamic capabilities co-evolve with firm strategy and observations of strategies of other firms.

Third, the co-evolution of firm strategy and capability are determined by three main factors: the historical trajectory of the firm and existing capabilities, firm-specific managerial vision and learning by observing the successes and failures of other compatriot firms.

Where does this leave us on our discussion of dynamic capabilities as ‘second order’ capabilities- or those capabilities that have the potential to provide lasting

competitive advantage in the future in the context of Indian pharmaceuticals? At present, it is not possible to identify the winning strategy or winning dynamic capability as the “transition phase” in response to the sweeping regulatory changes is not yet over and there is no sign of an evolutionary trajectory emerging through selection. In particular it is not yet clear if the integrated model of drug production will lose out to a more disintegrated model of drug discovery. This indicates that firms are still uncertain about the payoffs of the game being played and must discover these through a tatonnement proces involving experimentation, which in turn is a necessary condition for the development of dynamic capabilities.

Figures and Tables

Figure 1: Turnover and export growth in Indian pharmaceutical Industry (Source: OPPI, 2004)

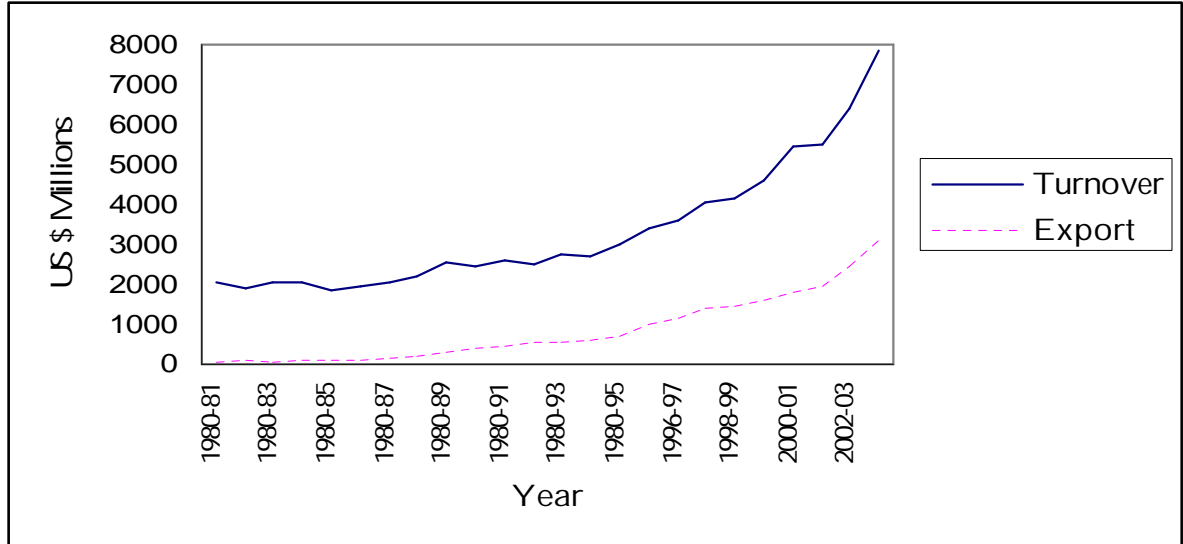


Figure 2: Ranbaxy Laboratories Ltd
(Source: Company information (www.ranbaxy.com))

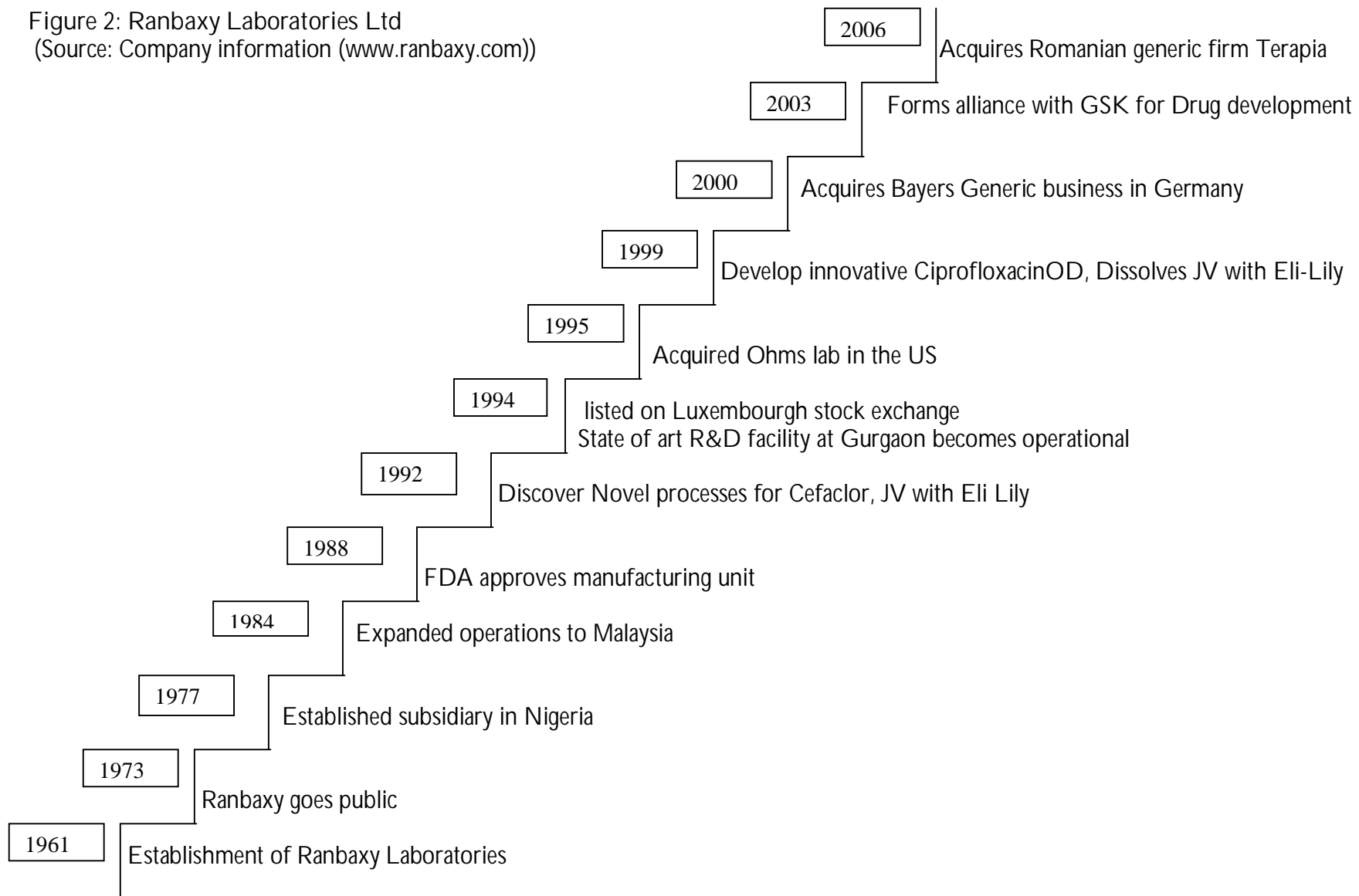


Figure 3: Dr. Reddy's Laboratories
(Source: company information (www.drreddys.com))

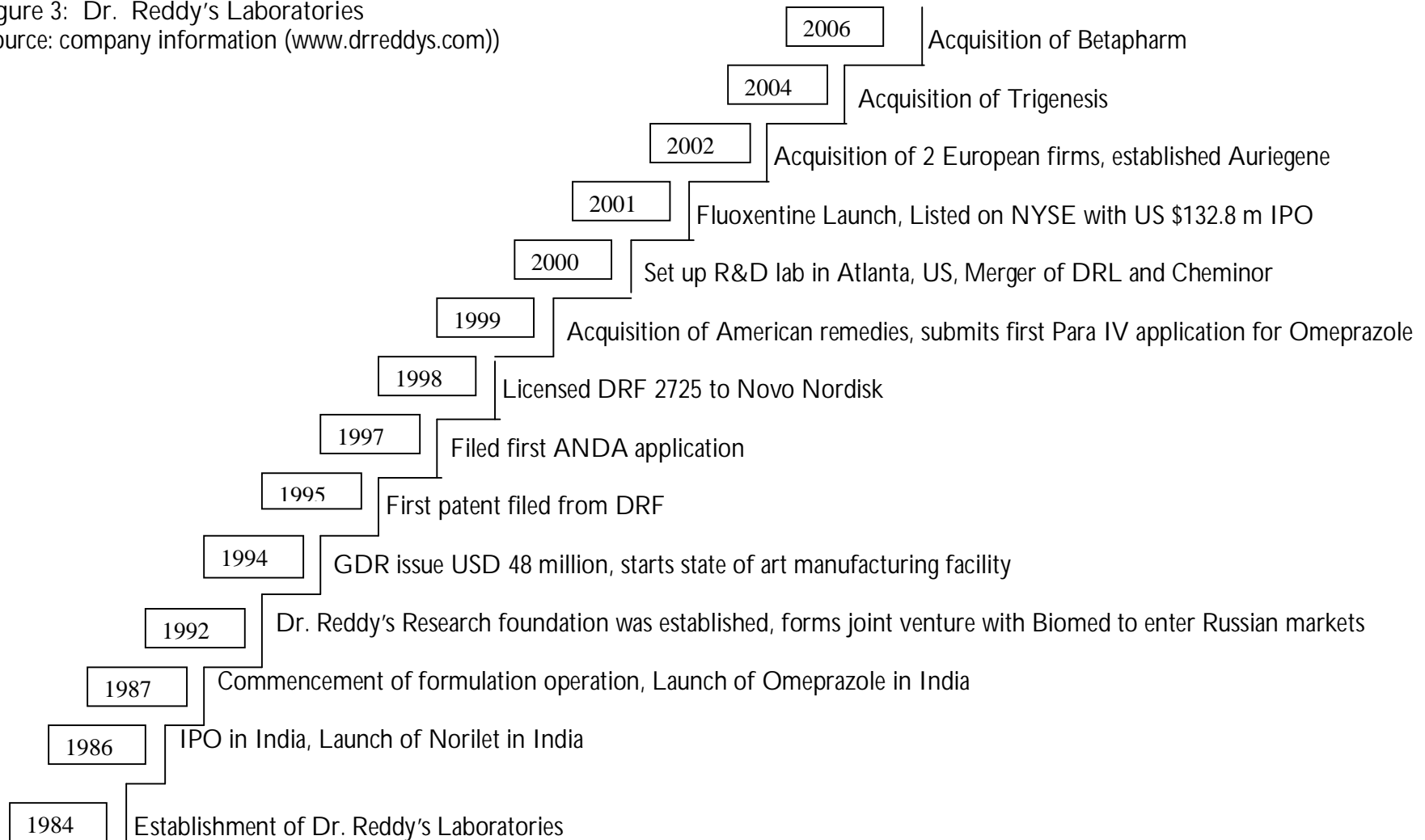


Figure 4: Wockhardt Laboratories Ltd

(Source: Annual report, 2000-05); Company information (www.wockhardt.in.com)

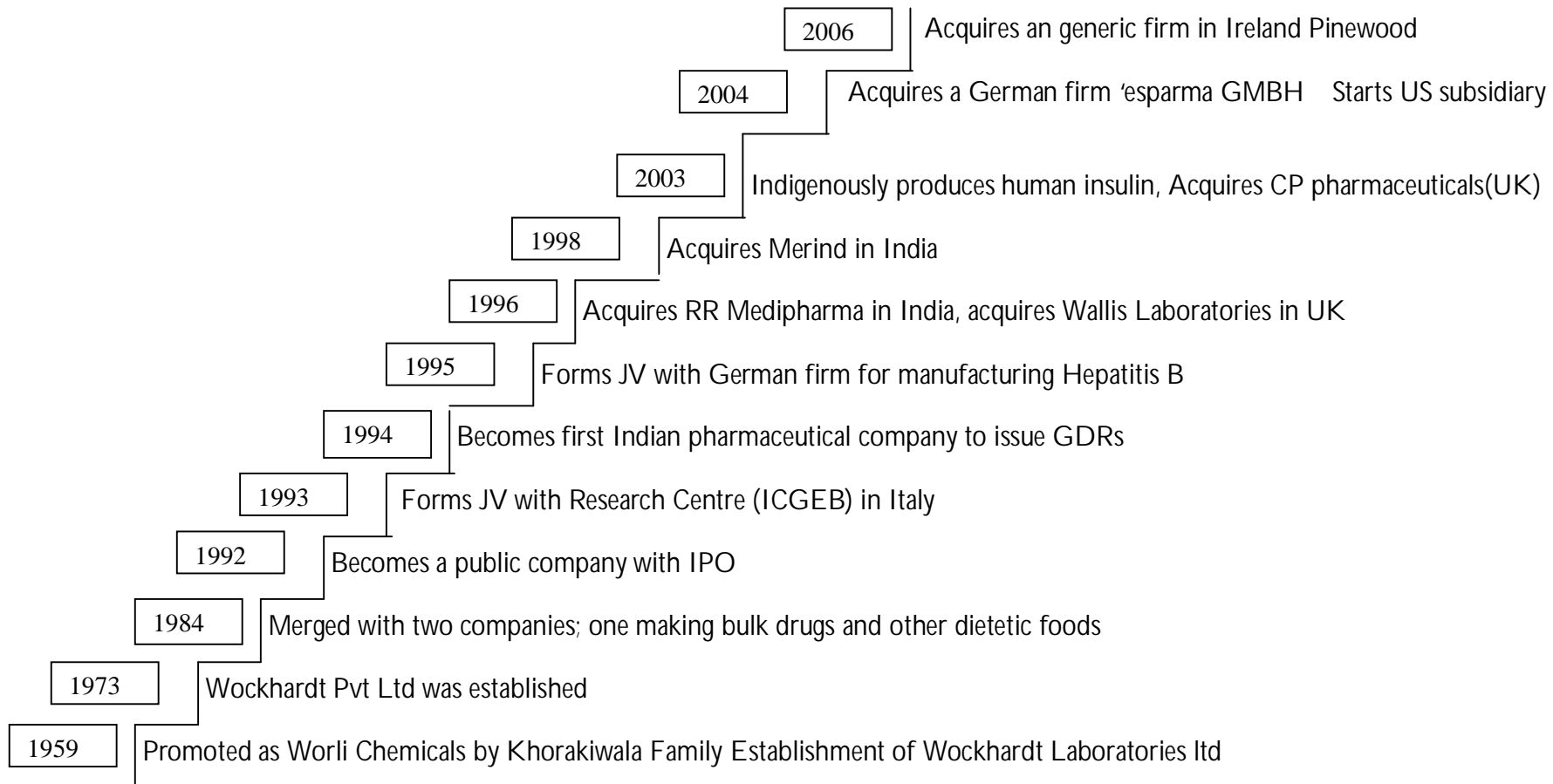


Figure 5: Nicholas Piramal Ltd
(Source: Company information (www.nicholaspiramal.com))

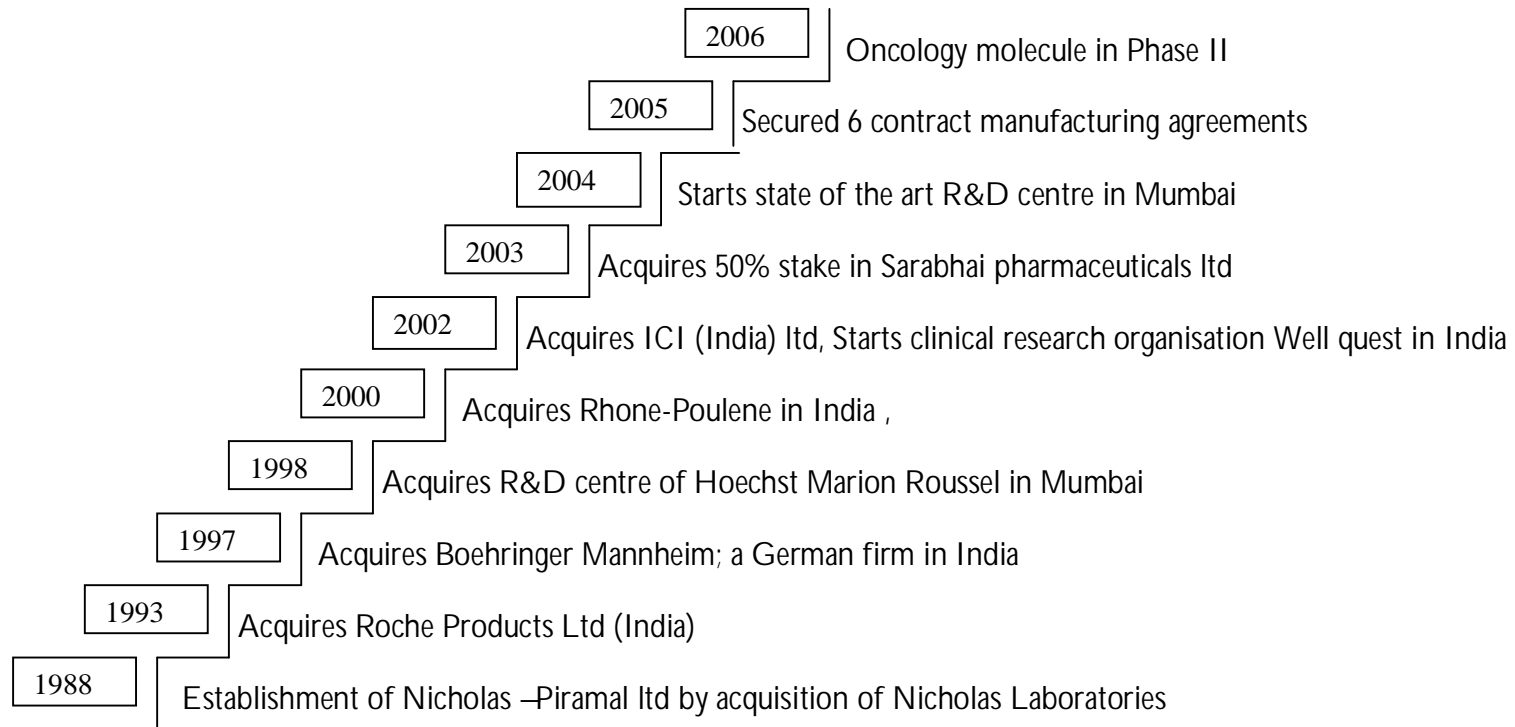


Table 1: Top ten pharmaceutical companies in India from 1970 to 2003

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

* indicates a multinational firm

(Source, OPPI, 2000, 2003; Lanjouw, 1996)

Table 2: The four case study firms

Name of the firm	Year established	Year Starting of Innovative R&D	Business Areas	Market Segments (generic)
Ranbaxy Laboratories	1962	1992	Generics NDDS NCE	Anti-infectives, Anti- retrovials
Dr. Reddy's Laboratories Ltd	1984	1994	Speciality generics NCE	Dermatology
Wockhardt	1959	1997	Biotech drugs NCE	Hepatitis B, Human insulin
Nicholas Piramal (I) Ltd	1988	1998	Contract research NCE	

Table 3: Turnover and Employment (Source: Annual Reports, 2000-2006)

Firms	a. Turnover (\$US Million) and export intensity (%)						
	2000	2001	2002	2003	2004	2005	2006
Ranbaxy	435.46 (50.8)	584.04 (65.61)	735.37 (70)	793.48 (68)	1170 (76)	1178 (76)	1339 (79)
DRL	350.06 (61)	360.87 (64)	417.91 (64.4)	427.55 (65.6)	463 (65)	546 (66)	1510 (86)
Wockhardt	156.75 (UC)	167.90 (38)	204.09 (57)	275.43 (64)	285 (UC)	324 (63)	390.8 (65)
NPIL	123.17 (3.43)	203.78 (3.15)	200.67 (8.5)	305.48 (12.4)	287.5 (31.8)	364 (21.4)	538.30 (43.1)
Firms	b. Total number of employed						
	2000	2001	2002	2003	2004	2005	2006
Ranbaxy	5784	6424	6297	6797	9224	9648	11343
DRL	2100	UC	5500	5852	6000	7525	9100
Wockhardt	2300	2700	2805	2928	3600	4000	4800
NPIL	3600	3840	4036	5880	5989	6931	7451

UC or unconfirmed indicates that the information available or provided could not be confirmed by a second source or by an expert.

Table 4a: Entry into international generics market: Exports and foreign investment

	<i>Ranbaxy</i>	<i>Dr.Reddy's</i>	<i>Wockhardt</i>	<i>Nicholas Piramal</i>
<i>Exports in 2007 (%of sales) & Geographic distribution</i>	Exports: North America –31.3% Europe (includes Russia and CIS) –32.3% ROW –15.4%	Exports: North America –44% Europe –23% Russia and CIS –8% Others –11%	Exports: USA –10% Europe - 47% ROW –8%	Exports 43.1% UC
<i>International investments (project approvals data till 1999)</i>	Greenfield: 4 JV/Equity share:13 Acquisition: 9	Greenfield: 2 JV/Equity share: 3 Acquisition: 4	GF: 4 JV/Equity share:2 Acquisition: 3	GF:1 JV/Equity share:1 Acquisition:3
<i>Associated Capabilities</i>				
<i>Marketing in Western Country under own brand</i>	<i>USA(1998), UK</i>	<i>Ibuprofen in USA under own brand name</i>	<i>UK</i>	---
<i>Technological capability:</i> <i>ANDAs filed</i> <i>DMFs filed</i>	ANDA: 127 DMF: 44	ANDA: 35 DMF: 56	ANDA: 32 DMF: 17	ANDA: none DMF: none
<i>Regulatory approvals:</i> <i>ANDA (I, II, III paragraph applications)</i>	<i>Cefactor in 1997, Ranitidine in 1998</i>	<i>Ranitidine in 1997</i>	<i>Ceftriaxone injectible in 2004</i>	---
<i>Patent litigation</i> <i>ANDA (Paragraph IV with litigation application)</i>	<i>Cefuroxime Axetil applied in and won in 2005</i> <i>Lipitor (Atorvastatin) applied in 2005 and won in 2006 (patent 995)</i>	<i>Omprazole applied in 1999 and lost in 2001</i> <i>Fluxentine won in 2001</i>	<i>Allegra applied in 2007 for Para IV and after litigation and out of court settlement with Aventis changed to Para III</i>	---

UC or unconfirmed indicates that the information available or provided could not be confirmed by a second source or by an expert.

Table 4b: Integration into international division of labour for MNE firms

	<i>Ranbaxy</i>	<i>Dr.Reddy's</i>	<i>Wockhardt</i>	<i>Nicholas Piramal</i>
<i>Contract Manufacturing agreements</i>	UC	UC	UC	Medical optics, USA Global Hospital Products Company, USA Allergan Inc., USA
<i>Clinical Trials</i>	UC	UC	Established chain of hospitals through a subsidiary Wockhardt Hospitals in India to conduct clinical trials	Established Wellquest; an independent clinical research organisation in 2000
<i>R&D agreements</i>	Medicines for Malaria Venture, Geneva Glaxo Smith Kline, UK	Established Aurigene Discovery Technologies based in Bangalore, to undertake contract research	---	Pfizer (2005) R&D related services, Astra- Zeneca (2005) to develop processes for manufacturing of API
<i>Out-Licensing molecules</i>	RBx 2258 benign prostatic hyperplasia (BPH) molecule to Schwartz Pharma (later abandoned) RBx 10558 to Pharmaceutical Product Development Inc. (CRO) for further development	DRF 4158 to NovoNordisk, DRF 2725 to NovoNordisk DRF 4158 to Novartis DRF 2593 to Rheoscience DRF 1042 to Clin Tech	---	---

UC or unconfirmed indicates that the information available or provided could not be confirmed by a second source or by an expert.

Table 4c: New drug discovery

	<i>Ranbaxy</i>	<i>Dr.Reddy's</i>	<i>Wockhardt</i>	<i>Nicholas Piramal</i>
<i>New drug dosage</i>	Once a day dosage for Ciprofloxacin	Fluxentine 40mg tablets	UC	UC
<i>New drug delivery system</i>	Yes, Oral controlled release	<i>Collaboration with SkyePharma for Utilizing Two of SkyePharma's Proprietary Drug Delivery Systems (2008)</i>	In-licensing with Crawford Healthcare, UK (2007)	In-licensing
<i>NCE in preclinical trials</i>	2	2	2	1
<i>NCE in Phase I, Phase II trials</i>	2	4	1	3
<i>NCE in Phase III trials</i>	UC	1(DRF 2593)	Alfa 2b	---
<i>Strategies/ created capabilities</i>				
<i>R&D expenditure as % sales, 2003/ research capability</i>	13.28%	9%	7.9%	5.1%
<i>Multidisciplinary teams in India/ understanding interdisciplinary research approaches</i>	Yes, Gurgaon	Yes, where in India (Hyderabad)	Yes, Aurangabad	Yes, New Mumbai
<i>Investment in biotech</i>	UC	No specific investment targeted to biotech	20% to 30% of R&D expense on biotech	Collaboration with Centre for Biochemical Technology (CBT) for conducting basic research in genomics
<i>R&D labs abroad</i> <i>US Patents drawn from overseas labs</i>	---	RUSTI (USA, 2000) 12	Wockhardt International and Wockhardt Europe	----

UC or unconfirmed indicates that the information available or provided could not be confirmed by a second source or by an expert.

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Notes:

ⁱ Figures from OPPI (2004).

ⁱⁱ According to Organization of the Pharmaceutical Producers of India (OPPI, 2004).

ⁱⁱⁱ <http://www.pharmaceutical-drug-manufacturers.com/pharmaceutical-industry/>.

^{iv} Comprehensive surveys of the Indian pharmaceutical sector giving further details can be found in Greene (2007) and Gehl Sampath, (2006).

^v Chaudhuri (2007), pp. 6 notes that the sum of the R&D expenditure of the top 11 companies in India million in 2005-2006 was \$379, while that of Pfizer was almost 20 times more at \$7440 million.

^{vi} Phase I trials consist of tests on a small group (20-80 volunteers) of healthy human subjects. Phase II trials are performed on larger groups (20-300 subjects) and are designed to assess how well the drug works, as well as to continue Phase I safety assessments. Any potential drug that passes these two phases successfully enters into Phase III studies, which are randomized controlled multicenter trials on large patient groups (300–3,000 or more depending upon the disease/medical condition studied).

^{vii} In India the regulatory authority for the pharmaceutical sector is the Central Drugs Standard Control Organization.

^{viii} Full case studies can be obtained from the authors on request.

^{ix} Ranbaxy has focussed on developing oral controlled drug delivery systems and in case of Ciprofloxacin Ranbaxy has developed once a day formulation which can be taken orally. In the oral New Drug Delivery System space, Ranbaxy has already developed four platform technologies namely Gastro Retentive, Modified Matrix, Multiparticulate and AeroGel.

^x These are two anti-bacterial molecules and one anti-malarial molecule. See Kale (2005: page 147) for more details.

^{xi} See 'The bitterest pill', *The Economist*, 26 January 2008, page 72-73.

^{xii} Analogue research involves working on predetermined targets for specific diseases to develop molecules that alter the target's mechanism in the diseased person. Since existing molecules are taken and their molecular structures are altered to lock into predetermined target, the level of innovation is comparatively less in analogue research. In contrast, rational or structure based drug design involves the determination of a disease causing protein's three-dimensional structure. Once the structure is known, novel chemical entities are designed to 'lock-in' to the protein with the aim of reversing or arresting a disease's progression.

^{xiii} Parentals are injectible drugs and medicines like IV fluids which are administered directly into the human body.

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