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The Indian Challenge: The Evolution of a Successful New Global Strategy in the Pharmaceutical Industry

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ABSTRACT *UK and European public policy has sought to encourage young biotechnology firms adopt American-inspired strategies. The venture-backed start-up associated with Silicon Valley and Route 128 in Boston, has been the preferred model. These policies have had limited success thus far. Indian companies are evolving indigenous business models that are achieving success within the pharmaceutical industry. Some Indian pharmaceutical firms, established initially as low cost suppliers, are investing in building innovative capabilities. This paper analyses the strategies and trajectories of a number of Indian pharmaceutical companies that are expanding successfully in Western markets. It assesses the local and international contextual factors that have underpinned the strategies and discusses relevant conceptual frameworks.*

Introduction

Prahalad¹ has recently discussed the difficulties in escaping from the ‘dominant logic’ of an industry, the lens shaped by past successes through which all emerging opportunities are seen. He argues that it prevents recognition of the significance of novel business models employed by new entrants to an industry. He questions the emphasis on benchmarking ‘best practice’, which leads to companies converging on the same model. Instead he advocates strategies developed through looking beyond the boundaries of industry and geography to identify ‘next practice’. In a similar vein Day and Schoemaker² have argued that the emerging trends can be identified through a greater focus on the periphery. Building on Prahalad’s analysis they have predicted that Western companies may be blindsided by competitors from India or China.

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In this paper we analyse key, shared, features of the strategic trajectories of a number of entrepreneurial Indian pharmaceutical companies that are demonstrably successful in Western markets and which are currently aggressively expanding their activities. These companies, at present mainly active in the generics sector, are still relatively small—the largest are Ranbaxy, market capitalisation US\$3.27 billion, and Dr Reddy's, market capitalisation US\$2.48 billion (18 August 2006, Bloomberg). However, they are highly profitable, fast-growing, and now developing drug discovery capabilities.

The success of these companies does not fit the pattern identified by Western researchers. Henderson *et al.*,³ in their analysis of the evolution of the pharmaceutical industry since the 1970s, have concluded that institutional factors within the USA and UK have been major factors in producing new biopharmaceutical companies. The factors they cite such as intellectual property (IP) protection regimes, venture capital, reimbursement systems, do not explain the current emergence of the Indian pharmaceutical industry as an increasingly important global competitor, with significant and growing revenues in the USA and Europe. Until recently the institutional environment in India was designed to exploit the innovation of other regimes through copying products—in 1970 the Indian Government passed the Indian Patent Act (1970) which prohibited pharmaceutical product patents and limited pharmaceutical process patents to seven years.⁴ This changed in 2005 when India implemented the WTO–GATT agreement. The Indian Government has invested to create a core of researchers with biotechnology expertise. However it has focused on agriculture rather than healthcare.⁵

In the following sections we explore the evolution of an alternative strategic model by the leaders of the Indian pharmaceutical industry that is allowing them to develop international competitiveness. Local and remote factors are analysed, which have allowed firms to exploit differences between institutional arrangements between India and the USA and Europe. The conceptual issues this raises for the process of devising successful new business models is considered. The paper is ordered as follows: the sample of companies is listed. Key characteristics, emerging strategies and targets achieved are briefly reported. More detailed case studies of the two leading firms are presented, which give indications of some of the resources that the firms are employing, and some clues as to how they have accessed them. Some of the contextual factors that they have exploited, including regulatory, economic and institutional changes and knowledge flows are then presented and their interactions analysed with respect to their role in the evolution of the set of capabilities the firms demonstrate today. We then consider conceptual frameworks that throw some light on the underlying processes. In the concluding section the apparent trajectory and future possibilities open to the firms are considered.

The Leading Indian Companies

The companies examined here have been selected on the following basis:

1. They have substantial levels of international business including products on sale in the highly regulated markets of the EU and/or the USA.
2. They have converged towards a similar strategic model.
3. They have attracted the interest of financial analysts in leading Western finance houses who regularly visit them and report on their progress (Morgan Stanley, Goldman Sachs,

Bank of America all cited in this paper), indicating potential to attract significant Western investment.

4. Their initial technical skills have been in chemistry. (There are a number of Indian firms whose initial core competence is in life science technologies, but they are not included in this analysis because they have not entered Western markets and there is not yet a basis for comparing them with Western firms.)

Sources of company data used in this analysis are company websites, Annual Reports, financial analysts' reports, press releases and press commentary. The companies' names and websites are listed below:

Ranbaxy	www.ranbaxy.com
Dr Reddy's	www.drreddys.com
Wockhardt	www.ockhardt.in
Zydus Cadila	www.zyduscadila.com
Nicholas Piramal	www.nicholaspiramal.com
Lupin	www.lupinworld.com
Dabur	www.dabur.com
Glenmark Pharmaceuticals	www.glenmarkindia.com
Cipla	www.cipla.com

Emerging Strategies

The companies discussed here have diverse roots. Some were founded many years ago, e.g. Dabur in 1884, Wockhardt in 1924, and some comparatively recently, e.g. Dr Reddy's in 1984. Founded as family firms, their initial entrepreneurial strategies have been characterised by substantial levels of improvisation and bricolage—making do with the means and resources at hand⁶—an approach which Baker *et al.*⁷ have found among knowledge-based firms in the USA. Most have gone on to acquire listings on Indian stock exchanges, and a few have more recently obtained listings on Western exchanges.

From an early stage all the companies listed here have had core competences in chemistry and low cost manufacturing. Until recently, all were deficient in biological/pharmacological skills but most are strengthening their capabilities in these areas and in the last 10–15 years have all converged towards a similar business model. They have announced similar strategies and have professionalised their top management, their management styles and practice (Maris *et al.*⁸—interviews with company representatives; Annual Reports of the companies; company websites).

The Convergent Strategy

Their core strategy has involved a sequence of three steps aimed at generating revenues and moving the company into development and marketing of proprietary therapeutics:

- (1) make generics to sell in India; then
- (2) obtain approval for and market generic drugs in the USA and Europe;
- (3) develop in-house capability in 'discovery'—inventing and developing new patented drugs including biopharmaceuticals.

During this progression they have steadily increased their cash generative capability and profitability before attempting to develop a 'discovery' capability. This contrasts with the strategies of Western biotechnology companies, which have started with some 'discovery' capability, attracted finance and complementary expertise through strategic alliances with pharmaceutical firms, venture capital and public equity finance, and have become profitable, if ever, after long periods of time.⁹

Milestones Achieved Thus Far

The Indian companies listed here have already demonstrated success in the first two of these steps. This has given them strong cash flows and many of the capabilities required within a pharmaceutical company. They are now establishing 'discovery' capabilities, which they are steadily enhancing. Thus far, Dr Reddy's has gone furthest towards achieving success in drug discovery. It initially licensed three proprietary candidate drugs for diabetic treatment to Novartis and Novo Nordisk, which they have not, however, taken forward, and it is currently negotiating licences for several other candidate drugs (Company Annual Reports).¹⁰ Thomas Ebeling, head of Novartis' pharmaceutical business on 4 March 2004 in a news conference reported by Reuters 3000 Xtra said that Novartis will continue to pitch for more collaborations with Indian firms. Previously Novartis had held these 'collaboration symposiums', which are part of its efforts to bolster the product pipeline, only in the USA and Japan.

Their success records testify to the competences that these companies have acquired, which have underpinned these levels of performance. Keller¹¹ in a recent review of the resource-based model of the firm, noted that researchers are increasingly focusing on the intangible resources of diverse knowledge bases and capabilities that differentiate firms and lead to superior performance. Firms' ability to innovate in a particular industrial and technological context requires highly specific competences on several levels,¹² including a range of skills, diverse types of knowledge, management systems and institutional values.

In the following section the evolution of two of the leading companies, Ranbaxy and Dr Reddy's Laboratories, is briefly traced with a focus on their progress towards success in Western pharmaceutical markets.

The Leading Indian Companies, Ranbaxy and Dr Reddy's

This section summarises the development of the leading companies, identifying some important milestones. These give some information about the knowledge resources they have acquired and the processes employed. Except where other sources are cited data in this section is taken from company websites.

The Board and senior management teams of both companies include individuals with relevant Western expertise and experience, and analysts' reports indicate that there has been some recruitment of Western-trained scientists into the R&D divisions, but the extent of this has not been documented.¹³

Both companies are members of the Organisation of Pharmaceutical Producers of India (OPPI¹⁴, a major trade association. The role of trade associations in promoting interchange of key business, technical and professional knowledge within the IT industry between US and Asian professionals is discussed in a later section of this paper.

Ranbaxy

Ranbaxy, India's largest pharmaceutical company had global sales of US\$11.2 billion in 2005, including US\$328 million in the USA. It was incorporated in 1961 and obtained a quotation on one of the Indian stock exchanges in 1973. In the same year it set up a chemical plant for the manufacture of active pharmaceutical intermediates (APIs). In 1983 it began to manufacture finished drugs. In 1988 one of its API manufacturing plants was approved by the US Federal Drugs Authority (FDA). In 1990 it was granted its first US patent for the manufacture of a generic, Doxycycline. In 1992 Ranbaxy entered a joint venture with Eli Lilly to market some Lilly products in India.

A year later (1993) it had announced that its mission was to become 'a research-based international pharmaceutical company'. It obtained a listing on the Luxemburg stock exchange in 1994, and in 1995 acquired an FDA-approved US manufacturer, Ohm Laboratories Inc. In 1998 it entered the US market with generics branded with its own name. It filed its first Investigational New Drug (IND) application in India in 1999 for permission to conduct Phase 1 trials on a proprietary molecule. Currently Ranbaxy has 118 FDA-approved products listed in the FDA's Orange Book, the official US list of approved drugs, based on 34 different chemical entities (see www.fda.gov/cder/ob/default.htm). This emphasises the importance of alliances, partnerships and acquisitions in its strategy.

In 2003 Ranbaxy and GlaxoSmithKline plc announced a global alliance for drug discovery and development (also announced by Glaxo in *Process Engineering*).¹⁵ As at 2006 its products are manufactured in eight countries and are sold in over 125 countries. It is a member of the OPPI, the major Indian Pharmaceutical Industry association (www.indiaoppi.com).

It aims to have a significant business in proprietary prescription products by 2012. It has established state-of-the-art multi-disciplinary R&D facilities near New Delhi. In 2006 it employed 1100 scientists and spent 7% of sales on R&D. It has 10 new drug development programmes including one anti-malarial programme in phase II clinical trials. Its first candidate drug RBx 2258, for Benign Prostate Hyperplasia, was initially licensed to Schwarz Pharma of Germany, but they have decided not to develop it. Microbia, a start-up firm in Cambridge, MA, has signed contracts with Ranbaxy to improve bioprocess manufacturing.¹⁶

In an interview with Maris *et al.*,¹⁷ Ranbaxy's Vice-President Business Development, Chuck Caprariello, stated that part of their success is speed of getting product to market. He claimed this was due not just to low costs—they have a greater sense of urgency than US competitors. He commented on the indigenous science/medicine strength in India—a significant pool of talent on which the company was able to draw. The Board and senior management team also include individuals with relevant Western expertise and experience, including periods in Beechams, Glaxo, Proctor and Gamble, Franklin Templeton, Bank of America and others. Analysts' reports indicate that there has been some recruitment of Western-trained scientists into the R&D Division.

Dr Reddy's

Dr Reddy's had sales of US\$438 million in 2005. It currently manufactures in more than 100 countries. It was incorporated in 1984 and obtained a public listing on an Indian stock exchange in 1986. In 1987 it received its first approval for an API from the FDA. In 1993 it initiated its own drug discovery programme. In 1997 it licensed its first proprietary molecule

to Novo Nordisk and also filed its first abbreviated new drug application (ANDA) with the FDA for its generic Ranitidine.

Dr Reddy's was the first Indian company to list on the New York Stock Exchange in 2001. By this time a dozen of its generics had been approved for sale in the USA. According to the FDA's Orange Book Dr Reddy has products marketed in the USA based on 15 chemical entities (www.fda.gov/cder/ob/default.htm). In 2002 it conducted its first overseas acquisitions—BMS Laboratories and Meridian Healthcare in Britain. In 2003 it launched its first own brand generic in the USA. In 2004 it made its first, and successful, challenge to a pharmaceutical patent in the US courts. Dr Reddy's strategy for drug discovery is to balance internal development, in-licensing and out-licensing, focusing on unmet clinical needs. It regards alliances and partnerships as a means to growth. It is building a comprehensive R&D capability and in 2006 employed more than 950 scientists. It recruits on campuses across India for both scientific and business skills. The Board and senior management team also included individuals with relevant Western expertise and experience, and analysts' reports indicate that there has been some recruitment of Western-trained scientists into the R&D Division. It is a member of the OPPI, the major Indian pharmaceutical industry association.

It has several R&D laboratories including one set up in 1999 in Atlanta, Georgia, and another set up by a subsidiary, Aurigene Discovery Technologies, in Boston, Massachusetts.

In recent years Dr Reddy's generics became increasingly off-patent drugs rather than generic copies of drugs still under patent and Reddy lobbied the Indian Government to adopt and enforce an international IPR regime.

The publicly available evidence summarised above about Ranbaxy and Dr Reddy indicates that both are using all the mechanisms that have been identified in the research literature to steadily increase their stock of internal and externally-accessed knowledge resources, both in the area of technical knowledge and *business/regulatory knowledge*. This importance of business and regulatory knowledge and of integrating it effectively with the varied technical knowledge required in the pharmaceutical industry is discussed further in the final section.

Global Opportunities and the Indian Pharmaceutical Industry

Maris *et al.*¹⁸ list some of the cost factors which are favourable. In India a chemist with a PhD costs US\$15,000 p.a. compared with US\$100,000 in the USA. Huge volumes give efficiency in pharmaceutical manufacturing. The FDA has now approved more manufacturing plants in India than in any country other than the USA—their costs are one-tenth of the developed world's for plant. PhDs are a quarter of the price of those in the developed world.¹⁹

Most expenditure (R&D, clinicals, marketing) by the Indian companies is being funded from their strong, cash generating business (written submission by Dr Reddy's to Maris *et al.*²⁰; company Annual Reports). Many lucrative drugs are going off patent in the next few years, giving the opportunity to continue to strengthen their cash flows. This underpins companies' plans to move develop proprietary drugs.

The Growing Generics Market in the US and Europe

The fast growing generic sector has been crucial for the success of the Indian firms listed here in gaining access to the US and EU markets (Company Annual Reports).²¹ US sales

of generics were US\$22.3 billion in 2005 growing by 13% in 2006.²² In 2005 generics held 56% by volume of the prescription drug market in the USA, up from 22% in 1985 (company reports). Similar trends have been noted by the same sources in Northern Europe.

Generics are on average one third of the price of branded drugs.²³ Generic substitution has been supported by US (and other) governments driven by growing national expenditure on drugs. The US Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch–Waxman) was the first US move to encourage generic substitution. Before this generics had to undergo extensive clinical trials before they could be sold in the USA. The generics approval process now takes about 20 months and thanks to continuing legislative efforts this is expected to fall to seventeen months or less. Hatch–Waxman also established other advantages for generics.

The opening of the generics market in the USA and Europe has been an important contextual factor for the Indian firms. Most of the Indian firms established themselves strongly in the generics market at an early stage in their development. Generics margins are relatively low, although some of the Indian firms have very high profitability, with Dr Reddy reporting gross margins of 52% in its 2002 Annual Report. Indian generic companies have a 20–30% cost advantage over European and US manufacturers in API, which constitute approximately 50% of the cost of the drug. This has allowed them to compete aggressively in this sector while retaining high profitability.

Their ability to do so has given Indian companies strong cash positions and growth prospects, which now underpin their strategy to move into drug discovery and development. It has also allowed them to build up their legal and marketing knowledge in the USA and the EU.

The main technical strength of the Indian companies which commentators note and which the level of success in producing generics confirms is world class is in chemistry. Most have some bio-generics capability which indicates that they have life science-based skills and bio-processing skills. However it is not clear from the evidence available how well-developed these skills are. However, Pisano²⁴ has pointed out that biotechnology process development does not have as rich a theoretical and empirical knowledge base as traditional chemistry-based pharmaceutical process development has. Even the most experienced bioprocess firms have a limited knowledge base to draw on. Hence the Indian firms which are now in the stages of bioprocess development for bio-generics may not have much catching up to do. If they are successful this would widen even further the areas in which they could mount a competitive threat.

Theoretical Models

The firms discussed here have demonstrated through their performance that they have acquired the capabilities to compete successfully with the leaders of the Western pharmaceutical industry in many of their areas of expertise. There is some evidence that they may be developing drug discovery capability. The case histories reported above raise the question of what precisely the knowledge resources are that have underpinned the current levels of success of the Indian pharmaceutical firms, where and how have they accessed them, and where do they now reside? Are they, for example, embedded within the organisation, within individuals or groups, or are they external to the firms?

Maris *et al.*²⁵ note that Indian pharmaceutical executives estimate that 15% of drug company and academic life scientists in the USA are Indian, and some are returning to jobs in India. Companies in our list name senior executives who have relevant Western experience. However, Kale, Wiend and Chataway have reported that Ranbaxy and Dr Reddy's have both experienced difficulties in absorbing the knowledge of returnees and in retaining them.²⁶ They found that mismatch in skills, and also cultural problems were barriers to knowledge diffusion.

In the case of external resources, what structures and processes are enabling the firm to use them? The public records show that they are engaged in alliances with public and private partners, including Western pharmaceutical companies. Are these contributing in a similar way as they have for Western biotechnology firms (see, e.g. Gambardella)?²⁷ Most have acquired Western firms and created direct Western subsidiaries. What role has this played in the knowledge building strategy?

Although the sources drawn on here give a considerable amount of information about the companies' strategic evolution they give limited insights into the processes by the firms have advanced so rapidly in this competitive global industry. However they provide a great deal of circumstantial evidence. Several theoretical approaches are now discussed, which are helpful for analysis of the developments in the Indian industry.

Absorptive Capacity

Cohen and Levinthal²⁸ proposed that firms' ability to exploit new technology/knowledge is dependent on their 'absorptive capacity'—their capacity to absorb the information surrounding the innovation, which in turn is dependent on them having made prior investments in similar knowledge which allows them to recognise the significance of the knowledge, integrate and deploy it.

The performance of the Indian firms testifies to considerable absorptive capacity, both of business and technical skills. Their current business skills are demonstrated by their proven ability to handle the legal, regulatory and market challenges of entering the US and EU markets, although they have yet to take a new chemical entity through clinical trials to the market. This in turn carries implications about the strength and scope of the endogenous organisational competences they had previously built up. Their technical skills have expanded to cover a wide range of biomedical skills and now are increasingly embracing the molecular and bioinformatic techniques of drug discovery.

The type of investments made by firms in order to build absorptive capacity may include investments in social capital.

Social Capital

Social capital theory focuses on the investment in social relations with expected returns in the market place.²⁹ It looks at the embedded resources in social networks and proposes that four elements give social capital its effectiveness and ability to control—its ability to give access to information, influence, social credentials and reinforcement. It finds that social links can by their nature facilitate information flow, exert influence on the agents who make critical decisions, give credentials, and give social support. The location of particular social ties may carry particular powers and resources.

Social capital and the exchange of human capital in economic globalisation.

Investment in social capital has been shown to be a major factor in the growth of the Chinese IT industry. The social relationships that link foreign professionals to their native land have facilitated the development of links and institutions that specifically underpin the transfer of human capital, i.e. knowledge and skills embedded in individuals. A number of studies have documented the flows of highly skilled personnel between China, Taiwan and Silicon Valley in the IT industry and the institutional supports which facilitate them. Hsu and Saxenian³⁰ have analysed the dense social and professional networks which underpin two way flows of technology, capital, know-how and information between Taiwan and the USA. Ethnic Chinese associations in the Silicon Valley area serve as a conduit for knowledge and people between the USA, China and other Chinese communities.³¹ Leng³² in a detailed study of the movement of IT workers between China, Taiwan and the USA, has reported the willingness of Chinese professionals to leave jobs in US companies and return to China for half their US salary. He presents Chinese government statistics that show a rapid increase in the numbers of overseas students returning to China, while noting that most will not return until they have permanent residence or citizenship status in foreign nations as insurance against adverse political change. He discusses the complementarity of the skills of Taiwanese managers in marketing, finance and legal services with the abundant engineering skills of mainland China, which lacks relevant business skills. Ethnic Chinese professional associations that help to promote this interchange include the Chinese American Semiconductor Professional Association (CASPA, www.caspa.com).

The Indian companies are involved in similar interactions, according to the reports discussed at the beginning of this section.

Strategic Alliances and Joint Ventures

Another theoretical approach, which may elucidate the development of Indian pharmaceutical firms, is that relating to the establishment of strategic alliances, joint ventures and other forms of collaborations. These organisational forms can be linked to several of the areas already highlighted, e.g. the development of social capital, the potential contribution to the development of R&D capability, increasing the rate and quality of innovation, knowledge transfer and organisational learning.³³

Alliances have also been argued to be a key factor in developing therapeutic approaches as well as providing small biotechnology firms with access to marketing and distribution expertise through partnering with larger firms.³⁴ The authors of this paper are currently analysing the public announcements of 15 major pharmaceutical companies in India including companies such as Dr Reddy's, Biocon, Ranbaxy and Wockhardt. These releases indicate that over 30% of their strategic activities in terms of mergers, acquisitions, strategic alliances and subsidiaries was specifically related to the formation and management of joint ventures and strategic alliances.

Another area of potential importance in the Indian context especially in relation to the development of R&D capability is that of public-private sector partnerships such as those taking place through research foundations and their interactions with a wide range of institutions.³⁵ Overall then the use of alliances, joint ventures, public-private sector partnerships and other forms of collaboration can be argued to be potent strategic weapons in developing a successful global strategy for the Indian pharmaceutical industry and worthy of detailed exploration.

Discussion

Social Capital and the Growth of Absorptive Capacity

For complementary knowledge to flow there must be links of the right quality and with the right partners and networks. There must also be sufficient absorptive capacity within the firm to exploit the knowledge. How well-connected to the international industry and the international research community are the Indian firms? Returnees from abroad may be playing a role, in spite of Kale *et al.*'s findings that there are difficulties in absorbing them.³⁶ The publications cited here show that while the firms are mainly staffed by Indian-trained personnel (many to PhD level, whose equivalence to Western qualifications we are unable to estimate) all have some staff with US or European qualifications and significant US or EU experience in some of the relevant areas, technical, business and other industry-specific expertise, e.g. regulatory. The leading Indian companies have also acquired a number of smaller Western pharmaceutical companies, mainly generics companies with marketing capability, which has also given marketing and distribution capability in the West. These capabilities then complement and, to an unknown extent, transfer to, the acquirer (see Annual Reports and brokers' reports cited above). This goes some way towards accounting for the firms' demonstrable range and depth of internal knowledge/expertise.

Strategic alliances and partnerships can provide complementary capabilities that remain external to the firm. They can also, however, serve as channels for knowledge flows into the firm, thus increasing its internal capabilities. These possibilities are not mutually exclusive and may both be of significance for the Indian firms. For example, it has been argued³⁷ that access for firms to external networks is a key factor in the development of technology capacity. Internal benefits may be derived through key individuals, especially those who span boundaries within firms and in the case of alliances, between partner firms. In addition, the ability of firms to promote or develop such personal social capital into firm level social capital can also be argued to be of potential importance in providing successful alliance outcomes for Indian based firms.³⁸ Another factor is the degree of interdependence between the partner firms and the individuals involved that may be important in determining the ability of the firm to form effective partnerships. Interdependence may also be related to the nature of the market as well as the flow of people, learning, knowledge and products/technologies.³⁹ Other influences in relation to interdependence are the levels of organisation involved and the complexity of arrangements both within and between partner firms.⁴⁰ The existence of high levels of social capital may also serve to lower costs. Other issues influencing the effectiveness of the formation of social capital in alliances, especially in an international context, include the degree of decision making autonomy as well as organisational and cultural differences. Other influences may also be derived from the stage of research and development that the partners are at, especially in R&D alliances. McCutchen *et al.*,⁴¹ have argued that the level of success in terms of the alliance outcomes in the biopharmaceutical industry is very much dependent on whether the R&D is in the early or late stages of development—with the risk of failure in terms of abandonment being highest in the early stages of development. The relative importance of these various factors is now a focus of ongoing research.

Institutions

Yet another connection is through formal institutions that enable the dissemination of knowledge of all the relevant types between firms, including the Indian subsidiaries of

US and European pharmaceutical companies. The industry association, the Organisation of Pharmaceutical Producers (OPPI) is frequently referred to by the companies and by its constitution is well-designed to play an important role in facilitating knowledge flows. The Organisation of Pharmaceutical Producers of India (OPPI) www.indiaoppi.com has a membership which includes subsidiaries of all the major US and EU pharmaceutical companies and also local companies. It has a large number of committees in which knowledge about regulation, GMP, ethics and all other areas of pharmaceutical expertise is exchanged. The relative importance of this organisation as a knowledge channel for the Indian firms is under investigation.

Conclusions

The Indian firms have followed an alternative strategy for entering the international pharmaceutical industry. At present a number of them have lucrative generics businesses in the USA and Europe and aim to focus increasingly on discovering and developing proprietary therapeutics. This paper has discussed some of the key factors that have been essential to this strategy. They are:

1. The absence of IP protection has encouraged the firms to become highly competitive manufacturers of generic drugs.
2. Changes in US (and EU) regulation of generics have greatly increased the size of Western markets for high quality generics.
3. Indian firms' growing revenues have been invested to develop regulatory and marketing expertise in Western markets, often through acquisitions and alliances, and also through hiring skilled returnees.
4. Their knowledge and expertise has been enhanced through a range of knowledge transfer processes mediated by industry associations, skilled returnees and internationally based subsidiaries and acquisitions.

Factors 1 and 2 have been significant contextual factors that have shaped the possibilities for entering Western markets. Within the parameters they set, firms have progressively extended their competencies through building their absorptive capacity and knowledge capabilities as outlined in factors 3 and 4 above.

However, in spite of the strengths they have built, there are still significant barriers to becoming major pharmaceutical companies developing proprietary products. Their discovery capabilities are still in question—major pharmaceutical companies have not yet shown sustained interest in their proprietary molecules. The Indian companies are still relatively small and, without big pharmaceutical partners, lack development skills and finance on the scale required to bring products to market. In addition, the US and EU regulatory requirements are so stringent that even the biggest pharmaceutical companies struggle to maintain a flow of new products to market.

The Diversity of Knowledge Resources

It is interesting to note that knowledge resources which have been developed and employed have included business/legal/regulatory skills and knowledge as well as varied technical skills. Researchers have identified the importance of the combinative capabilities of the

firm in other industries.⁴² However, this has not attracted as much attention in research on the biotechnology industry. Many researchers have attempted to analyse the development of knowledge assets in Western biotechnology firms, but the process of acquiring and integrating the complex array of business-related skills with the technical skills required to carry a biotechnology company through to successful product approval, marketing and profitability is still poorly understood.

Social capital theory offers a helpful framework for understanding some of the detailed aspects of this process of acquiring new competences. In the same way that the flows of knowledge, people and financial resources among the mainland Chinese, Taiwanese and Silicon Valley Chinese communities, and the emergence of supportive institutions such as industry associations, have facilitated the growth of the Chinese IT industry comparable flows involving Indians appear to have helped to underpin the development of the Indian pharmaceutical industry, although with some difficulties.

However, there are clearly other factors that have not been analysed here, such as, for example, the initial entrepreneurial flair and general business skills, which allowed the founders of these companies to respond in their early days to the opportunities offered by the four factors listed above and progressively to integrate them into the present coherent and effective business model.

Trajectory of the Indian Firms

It is not clear yet whether Indian firms will have the skills to develop successful novel biopharmaceuticals in-house. Large Western pharmaceutical companies had great difficulty in adopting biotechnology and were dependent on alliances with small firms. Leonard-Barton has concluded from this case that competencies for a very different sort of knowledge development can become barriers to performance in exploiting novel knowledge. Will Indian firms experience integrate that expertise effectively into their 'discovery' programmes?

There is also the question of whether the acquisition of 'discovery' capabilities by will be sufficient to enable them to generate enough valuable products. All major pharmaceutical companies have run into problems of discovering enough sufficiently attractive candidate drugs and there is no reason for the Indian companies to have less difficulty in this respect. Like Western companies they could use their financial resources to license in and develop candidate drugs invented elsewhere, probably by small biotechnology companies in the West. If this is the case it offers some very interesting possibilities to small Western companies in areas such as stem cell research and other novel technologies for which the costs and risks of development in the West are expected to be very substantial.

One important question that the whole pharmaceutical industry faces is whether it will be possible to make chemical analogues of the active sites of proteins, rather than using the proteins as therapeutics, which are expensive and difficult to deliver. It is interesting to speculate that, with their skills in chemistry, the Indian companies may be able to make this step and gain a competitive edge. If so, this might offer a very lucrative direction for their future developments.

The 'Next Practice' for Western Biotechnology Firms

Whatever lies in the future, the current achievements of the Indian firms offer a striking contrast to the rather disappointing progress of European biotechnology industry. They set a question mark against European efforts to copy the US models of 10 years ago.

It is not proposed here that the Indian model is any more appropriate than the US model for EU firms. However, a possibility that might become attractive is for Western biotechnology firms to partner with cash- and skill-rich Indian firms. Bringing together the low costs of development in India, the skills of the Indian companies and the inventiveness of Western biotechnology companies is one strategic route that may emerge over the next few years.

Notes and References

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