

RECENT TRENDS IN GLOBALISATION OF R&D THE CASE OF INDIAN PHARMACEUTICAL INDUSTRY

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***T**HE world economy and competition becoming a global phenomenon, the only way to win is by using all the resources the world economy could offer. Multinationals from all over the world are accelerating the pace of their direct investments in overseas R&D and strategic alliances. Previously, companies expanded their R&D operations overseas primarily to support local manufacturing and marketing operations. But now, companies are making overseas investments to complement their domestic research, technology, and product portfolios. They are integrating their domestic and overseas R&D facilities into global R&D networks thereby achieving cost reductions and price advantages. These R&D facilities cover a wide range of industries, including computer hardware, computer software, consumer electronics, automobiles, pharmaceuticals, consumer products, and chemicals. Cross-border investments in R&D remain concentrated amongst the industrialized countries. However, of late, a number of newly industrializing/developing economies have emerged as important hosts to R&D investments by multinationals of industrialized countries origin. Looking at this, an exploratory study has been conducted to analyze the recent trends concerning globalization of R&D in the Indian pharmaceutical sector. The present paper brings out the preliminary results of this study.*

Introduction

Globalization of R&D has followed the globalization of markets, and is essential for customizing products to meet local demands as well as gaining new knowledge and effectively utilizing cultural differences (Behrman and Fischer, 1980). The important issue here is how to organize and conduct R&D in other countries in line with one's domestic R&D efforts. At present, many firms do recognize globalization of R&D as the number one item in their priority list. In fact, a recent survey of CEOs indicated that globalization is their number one challenge (Saji, 2003). The move from simple geographic expansion to integration is a new stage in the global management of R&D. The Industrial Research Institute and the Massachusetts Institute of Technology defines it as "the ability of the technology development organization to recognize and respond to technology and market signals from all strategically important locations" in a study in 1996. Globalization is both a core competence and a process (Florida, 1997). It is expected that this competence will be even more critical for this new stage.

The pharmaceutical industry is mainly driven by the growing expectations of the consumer and the rising cost of developing new products. All pharmaceutical companies want to reduce their R&D costs and are under extreme pressure to develop new drugs. To economize on R&D and to reduce the lead-time for new drug development many companies have sought alliance partners with bleeding-edge technologies and expertise in particular fields as a way to outsource R&D activities. The pharmaceutical industry is one of the most R&D intensive sectors and the R&D activities involve scientific research in emerging or unexplored fields. It comes along with a lot of risk as the research may or may not ultimately lead to a commercial product.

The drug firms prefer greater flexibility inherent in international alliances to the substantial investments required for mergers, since the drug development generally entails great risks and an alliance can allow partners to change strategies and even withdraw if necessary. The R&D function among the Indian pharma companies is

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at a very nascent stage. Even well established companies spend as low as 2.5% of their total turnover towards R&D expenses. Signing of the recent WTO agreement by India facilitates the recognition of product patents. To counter this regime, domestic players have initiated investment on research.

The Notion of Globalization

Faced with tough global competition, firms have recognized the need to internationalize their operations: a trend evidenced by a ten-fold expansion of foreign ventures during 1980s, and it got accelerated in the 1990s. Cross border mergers and acquisitions, strategic alliances and Greenfield investments are the latest trends in expanding the scope of global business. Motivators of this expansion include search for new markets in order to exploit unique assets in overseas markets and to achieve lower costs or higher quality inputs, and for large-scale economies and other efficiencies. As a result, there is increasing influence of multinational enterprises in economies of nations worldwide (Palich and Gomez-Mejia, 1999).

Industry is globalising more rapidly and through different modes than previously. New patterns of globalization are accelerating internationalization of industry and reshaping the industrial structures at global level. Firms earlier expanded geographically through foreign trade and investment. Now, international strategy for complete restructuring of their operations is being pursued. Cross border mergers and acquisitions (M&As) and strategic alliances are common paths to internationalizing operations, research and markets. A variety of factors are promoting the above cause. Regulatory reforms, liberalization of trade and investment coupled with decreasing computing, communications and transport costs have encouraged firms to adopt global strategies. Privatization and deregulation of vast sections of industry by governments have opened up cross border transactions. This has led to intense global competition. In order to survive in such an environment and enhance flexibility, firms have chosen the path of co-operation to growth. (Kang and Sakai, 2000).

Firms are now adopting newer business strategies. Core competence focus, downsizing, more specialization, and adopting leaner and flatter structures are the new set of business dynamics. Outsourcing functions such as R&D, computer system support and market analysis are in vogue. This is all in relation to the growing importance of intangible assets (Serapio et al, 2000). Corporations are defining their value in terms of intangibles and these assets are being re-organized on a global basis in search of efficiency gains. Globalization is placing more importance in pooling technology and know-how, rather than combining plant and equipment or building new facilities (Saji, 2002^a). This has led to the expansion of product lines by firms in specialized niche markets. The dematerialization of economic activity has fixed the new pattern of globalization.

Globalization of R&D

Multinationals from the United States, Europe, and Asia are accelerating the pace of their direct investments in overseas R&D (Bruner, 2000). The focus of these companies have shifted from using overseas R&D operations for supporting local manufacturing and marketing operations to complement their domestic research, technology and product strengths. Overseas R&D operations are thus becoming important sources of new science and technology for the entire global corporation (Saji, 2002^b). Companies like these do more than simply acquire science and technology. They are integrating their domestic and overseas R&D facilities into global R&D networks. The acceleration of industry investment in global R&D shows that firms believe they need a presence in foreign markets if they are to grow. To be effective in these markets, they also need to benchmark themselves against the best performers in the world. Globalization of R&D is an excellent way for firms to utilize the world's growing stock of resources and knowledge, and to support business growth. (Pury, 1994).

Emerging Technology Centers

Traditionally, R&D has stayed close to company headquarters, and cross-border investments in R&D remain concentrated among industrialized countries. However, a number of industrializing/developing economies have emerged as important hosts to R&D investments by multinationals from industrialized countries. China, Taiwan, and India are the three most successful emerging economies in attracting foreign R&D in recent times (Serapio et al, 2000). The following examples illustrates the same: Microsoft has R&D centers in India; ICI has labs in China; Technology centers like HITEC City at Hyderabad in India; Hsinchu Science Industrial Park of Taiwan.

The success of technology centers in emerging markets like India in attracting R&D and high-technology investments can be attributed to several factors, which include: availability of high-quality R&D personnel;

proximity to companies specializing in the manufacture, design and development of certain products (e.g., semiconductors in Taiwan); availability of world-class R&D infrastructure and presence of a vibrant research culture; and the Government incentives and protection extended to investing companies. In sum, these developments point to an emerging trend in the globalization of R&D, where expatriate R&D is assuming a more significant role in the generation of technology and innovation for the global corporations.

The Corporate Advantage

There are now corporations involved with many divisions, alliances and increasing numbers of subcontractors. R&D is moving in that same direction. Several advantages will accrue to the multinational corporation in global R&D. First, the cost of technical work in many parts of the world is substantially less than in Europe or the United States. But the cost of material, particularly high-tech equipment, is higher. Once that capital investment is in place and continually supported, however, the overriding expense in R&D – highly educated human labor – will be cheaply available.

Second, overseas-trained scientists will work with colleagues and associates in an environment that may be more congenial to their creativity by presenting fewer cultural and social barriers. On the other hand, the linkage to R&D headquarters will be just as firm and solid as if they were down the road. The availability of technologies like artificial intelligence in expert systems will allow the best of the technical talent to be cloned and made available throughout its laboratories. (Van den Bulte and Moenart, 1998).

The Challenges and Opportunities

Working across cultures will be the biggest challenge to R&D globalization. Training costs would plummet as the global network allows one to deliver technical material on an ad-hoc basis to the trainee (Helms, 1998). Internal communications documents and reports will all be available electronically throughout the corporate network quicker and in a much more responsive and interactive mode than paper permits. The pace of scientific literature production will get speeded up. In many situations, traditional publication will be archival, while the most rapid developments are disseminated through the electronic network both within corporations and between the corporation and the outside community.

Learning has emerged as a key element in the globalization of R&D. More and more companies are viewing direct investment in R&D as not only a vehicle for transferring a parent company's technology to the host country but, more importantly, as an opportunity to learn and develop externally-developed science and technology. Finally, the global network will make it easier for R&D managers to alert and drive home to researchers corporate goals and the potential practical consequences of the research that they are doing. (Coates and Wolff, 1994).

The Logic behind the Trend

The business logic behind the move towards globalization of R&D is often clear. Creativity, combined with technology, is undoubtedly an increasingly important determinant of competitiveness, and most companies are looking for more effective ways to respond to this changing market situation. Also, as a consequence of past downsizing of R&D groups, some companies are struggling to maintain a position in important development areas. Managed outsourcing is a way of maintaining this necessary critical mass.

Similarly, there are a number of technological driving forces behind this trend, viz. the convergence of markets and technologies; the high cost of technology leadership across a widening spectrum; increasing ease of access to new technology; the implications of the technological revolution (IT revolution is intensifying the R&D process by breaking time and space barriers); the importance of tapping regionally concentrated science bases; and customer demand for superior and low priced products.

Managing the Difficulties

Most R&D organizations acknowledge that they will have to respond to tomorrow's world, where customers' lifestyles and behaviors require the delivery of new products, processes and services that will necessitate a change in the way R&D is carried out. However, in accepting the need for globalization of R&D, even if only applied selectively, there are still many questions to which companies need to find the answers if the approach is to be adopted successfully.

To be able to globalize R&D, a company needs to demonstrate ability in five areas, viz. A global understanding of technologies and their relevance; Assessment of relative competences; A cultural shift to an open sourcing policy - companies must be able to develop the right contacts, and be able to make objective partner assessment - considerations such as cultural affinity and communications need to be addressed; Negotiation of partnership agreements on mutually beneficial terms (The technology ownership must be sorted from the start, and managing the tension between the retention of technological ownership and building trust requires constant effort. Similarly, effective exploitation is part of the virtual R&D culture, and how commercialization is to be achieved needs to be detailed at the outset of any collaboration); and a technology management process, which must include the integration of business and technology thinking, and use multidisciplinary team working. These five aspects also have to be translated into an R&D structure. Overall, for most companies this all adds up to a totally different cultural way of thinking about R&D management.

Globalization of R&D in India

Generally, technology flows from developed to developing countries (Saji and Jain, 2004). Liberalization, privatization, and globalization have all changed the business context of all the developing countries. If a country has a reasonable level of factor endowments including technological competence, global firms are likely to exploit it. In high technology areas, four major changes have been observed in India, namely:

- Many global companies have started R&D centers in India to access the research skills there, especially since 1997.
- Technology has started flowing from India through alliances, especially in the pharmaceutical sector, and most of these are entrepreneurial firms.
- Entrepreneurial firms have started appearing in the biotechnology segment, after economic liberalization mostly supported by venture funds.
- Global companies have also increased contract research and contract manufacturing in India. (Bowonder and Richardson, 2000).

The Case of Indian Pharmaceutical Industry

The global pharmaceutical industry is a knowledge-based industry, and is presently undergoing a series of changes induced by competition, evolution of biotechnology-based drugs, harmonization of intellectual property rights, value chain disintegration, changing demographic profile, and most importantly the globalization of R&D. Due to globalization of R&D, India is fast emerging as a destination for funding creative ideas in the pharmaceutical sector.

The world's best R&D Pharma industries not only wanting to set up their own laboratories in India, but also desire to cooperate with the Indian research. Even Indian pharma firms are treading on the big boy's turf. There are various reasons for this. Studies indicate that drug discovery in India can be 80-90% cheaper than in developed markets (Carvalho, 2002). Indian pharma companies have built competence in chemistry, by copying drug processes of multinationals. The chemistry capabilities are cheap and world-class in India. Post 2005, once the product patents come into force and Indian companies can no longer copy drugs made by Big Pharma – which in turn will be more eager to launch more of its newer drugs to launch more of its newer drugs domestically – much of the domestic industry runs the risk of losing out on growth avenues.

Besides this, India offers some other unique advantages. It has a 53 year old democracy. It has an educated work force and English is commonly used. It has a solid legal framework and strong financial markets. Professional services are easily available. There is already an established international industry and business community. It has a good network of world-class educational institutions and established strengths in Information Technology. The country is now committed to a free market economy and globalization. Above all, it has a 70 million middle class market, which is continuously growing. Some of the pharmaceuticals MNCs who have set up their bases in India recently include: Eli Lilly & Company, Astra Zeneca, Pfizer, and Novartis AG.

The top Indian pharma majors who have the scale of investing 5-6 per cent of their sales in research are also opting for the discovery gambit in a big way. The pioneer in Indian R&D, *Dr Reddy's* – which began the process

when it was a Rs.150 crore company 12 years ago – has increased its budget on R&D from 3.3% to 8% of turnover this year. It is betting most of its chips on discovering new molecules in the areas of diabetes, cancer cures, non-steroidal anti-inflammatory drugs, and anti-infectives. *Ranbaxy Labs* has at least five molecules in the pipeline that have reached phase-I of clinical trials. *Wockhardt* has three NCE (new chemical entities) in the works. The *Daburs* have filed 41 NCEs in the area of oncology and *Torrent pharma* has concluded pre-clinical trials on three cardio-vascular compounds. But all this implies, that Indian companies will have to continue growing at double-digit growth rates, for allocating substantial portion of their turnover to sustain their growth rates.

However, there are a few companies like *Ranbaxy*, *Sun Pharma*, and *Lupin Labs* that are following a more middle-of-the road game plan. In the shorter term, they are focussing on the US market for drugs going off patent. In the medium term, they are chasing novel drug delivery system (NDDS), which is a modification of an existing molecule, which can be patented. And there are others like *Dabur* and *Glenmark*, who are targeting the generics market, as they feel that new drug discovery is a longer process and more expensive.

Pharmaceutical companies are also utilizing substantially the services of Contract Research Organizations (CROs). Indian Pharmaceutical Industry, with its rich scientific talents, provides cost-effective clinical trial research. It has an excellent record of development of improved, cost-beneficial chemical syntheses for various drug molecules. Some MNCs are already sourcing these services from their Indian affiliates. For example:

- Advanced Biochemical Limited (ABL), a Thane based 1 billion biotech major has tied up with Pacific Corporation, South Korea, the largest drug manufacturer in South Asia.
- Wockhardt has tied up with German based Rhein Biotech, the biggest producer of enzymes in Asian region.
- Cipla has invested about Rs.100 million in its biotech ventures with smaller companies overseas.
- East India Pharmaceuticals has tied up with US based Cleveland Clinic Foundation for research in biotechnology and molecular biology.
- Zydus Cadila has plans to invest 7.5% of its turnover on R&D and tie up with other R&D institutions internationally.
- In Ranbaxy, the R&D process development facilities exist to transfer technology from lab to pilot plant to manufacturing locations worldwide.
- DRL has struck a deal with Novo Nordisk, the world leader in diabetic care, under which the Danish company would conduct clinical trials and develop the drug further.

Clearly, the opportunities for Indian pharma firms are virtually limitless. The strategy pharma majors are following is to bring in the formula from generics, and pump it into innovation and drug discovery. Other shorter-term avenues include sourcing bulk drugs to generic manufacturers (*Sun pharma*) and targeting export markets in a big way (*Ranbaxy*, which today makes more money in the US than in India).

But, the emerging scenario of globalization of R&D brings challenges also to the Indian pharmaceutical industry. Compared to their Big Pharma counterparts, Indian drug companies still have a long way to go, with just a handful progressing to clinical trials. The Indian companies – other than *Dr Reddy's* – have yet to deal with failure, which in the long run means a proportionate increase in discovery costs. Indian Pharma is still miniscule compared to Big Pharma, so investments will always be a constraint. Licensing out discoveries for development and marketing to international majors is inevitable, which in turn means sharing the spoils. Indian skills are no doubt world-class, but the skill-sets are limited and restricted to a few therapeutic areas. Indian companies will have to continue growing at double-digit growth rates post 2005 to sustain their research thrust. In generics, more than research what matters is investments in litigation, which can be as much as US\$18 million per drug (*Carvalho*, 2002).

Today, the drug development costs are soaring and the failure rate is not coming down either. Developing a drug today costs about US\$800 million, and the average revenue per drug is only US\$265 million in its lifetime. More than two-thirds do not get a return on investment. Another important factor is by 2005, 53 of the top 100 drugs will go off patent. So the pharmaceutical industry has to increase its R&D productivity. The pharmaceutical industry has several options, but all of them have to finally try for getting the probability of success increased.

Conclusion

Going by the industry trends, post 2005, Indian companies would be research outfits for MNCs or powerful players in niche segments with unmatched price competitiveness. With just few months to go before product patent bill implementation in India, only two discovery research projects of Indian origin have moved to phase I/II, and even they are an improvement on existing targets. Not surprisingly, only five Indian companies have undertaken serious R&D investments, and even they are necessarily meagre, given the limited profitability and the low value of the rupee. Much of the research efforts are still focused on analog research, as that is not only financially affordable, but also what the current skill levels would allow. No doubt, the effort in the last one decade has been quite encouraging, and the outlook is very bright indeed, given the very talented and highly educated workforce and increasingly global resource base of the selected companies. There is only one problem; there is very few experience of drug discovery in India. Once this experience gets build up, India could hope to become a hot destination for drug discovery as it has realised in the IT services sector by now.

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