# Innovation patterns, limits to learning and the pathway of neoliberal globalisation: evidence from Indian pharmaceutical multinationals

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**Abstract:** The article assesses the pathway of neoliberal globalisation for its impact on firm-specific innovation patterns, the ties under formation for the acquisition of resources and assets and the emerging limits to learning for the Indian pharmaceutical multinationals. Evaluation indicates the persistence of sub-optimal conditions at home for product innovation due to insufficient augmentation of firm specific assets and lack of establishment of interactions and linkages by these firms within the national borders. Their acquisitions, alliances and collaborations were focused on gaining largely the access to complementary resources needed for marketing and production of off-patent generic pharmaceuticals. Linkages formed with foreign firms have failed to take-off as a significant external mechanism of technological learning. Path dependent systemic failures are observed to have impacted on the coevolving national system of innovation through the subcritical in-house product innovation capabilities, underdevelopment of local learning networks and lack of attention to domestic demand.

**Keywords:** India; pathway; neoliberal globalisation; outward foreign direct investment; OFDI; multinationals; pharmaceutical; learning; product innovation; national system of innovation; interactions and links; acquisitions; alliances; collaborations; location advantages.

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## 1 Introduction

Pharmaceutical innovation systems are in the early phase of making the transition from a process to product focus in respect of system building for innovation in India. Firms need to develop their own capabilities and interactions with the environment to make the transition from a process to product focus and from imitation to innovation. Today, the firms are operating in the environment of multiple sources of learning being still accessible at a cost to those who have the absorptive capacity. Learning processes are not constrained to intra-national interaction, but increasingly include international interaction. Firms can use foreign sources of knowledge comprising of foreign firms, universities, R&D laboratories, etc. Links with foreign sources of knowledge are under encouragement through the establishment of international acquisitions, alliances and collaborations. But to what extent the firms from emerging economies are in position to utilise these sources for accelerated technological learning needs investigations.

Though there is literature available which focuses largely on the emergence of interactions and links of the actors operating at the national level to build the systems of innovation, but there is little work on how the interactions of emerging market economies multinationals with the actors located abroad and at home are shaping up under the influence of external liberalisation and globalisation. During the period of last two

decades, there has occurred a major institutional change in the national ecosystems of learning and innovation. In most emerging economies, the pathway of neoliberal globalisation completely freed the domestic and foreign firms from the controls and obligations imposed on them by the national governments. This has allowed the domestic firms to realign in a number of industries their strategies for the acquisition of resources and assets with the incentives arising out of markets of advanced industrial countries.

During the beginning of '90s the Indian policy makers chose to implement in many industries the pathway of neo-liberal globalisation with a view to accelerate the pace and directions of technological learning. The policy makers had the belief that neither trade liberalisation nor stronger intellectual property requirements are likely to suppress the spread of research and innovation. Their important policy assumption was that disruptive product innovations would be realised by the domestic firms rapidly on account of the larger market and access that they will get to the sources of knowledge distributed across the world and spillovers as well as property rights protection. Although the Indian policy makers were compelled to delay the implementation of external liberalisation and strong intellectual property rights (IPRs) on account of the opposition from various quarters in the pharmaceutical sector, but they did go ahead in the beginning of 2000 to get the domestic pharmaceutical firms to aggressively pursue the foreign markets and sources of knowledge for the betterment of learning and innovation making.

There was an understanding that the innovation patterns in the case of pharmaceutical sector were imitative and not creative enough due to weak IPRs and closed economy environment, and that India would be able to use the opening up process for the creation of external learning mechanisms to develop new pharmaceutical products. Learning by doing in an environment of global competition is a self-sustaining process, and the new environment would therefore result in not only in accelerated export quality generic production in pharmaceuticals but in learning for product innovation making, for which incentives will build up rapidly on the sides of product demand and capabilities supply. Since even limited R&D and pharmaceutical production, as taking place now through the expansion of pharmaceutical production and sales in transition and emerging economies, is knowledge intensive and has some impact, the multi-layered impact of cooperation with foreign sources of knowledge will make it possible for the country to access foreign sources of learning. Among the Indian policy makers, there exists much excitement about achieving a lot for competence building and learning by using the reverse knowledge transfer through knowledge acquisition-related collaborations, alliances and networks in the pharmaceutical sector. Because the contribution of outward foreign direct investment (OFDI) for the emerging Indian pharmaceutical multinationals is also at the level of obtaining enhanced access to larger and more profitable markets it has been difficult for the policy makers to separate the facts from the irrational expectations associated with the learning connections of the OFDI linked acquisitions, alliances and collaborations.

## 2 Literature review

Many scholars have been engaged at home and abroad in the study of performance of the emerging Indian pharmaceutical multinationals using the perspective of resource-based theory. But they are yet to use the framework of national system of innovation to study the impact of neo-liberal pathway of globalisation using the OFDI connections for competence building, learning and innovation making. Take the research work which

sees the contribution of the emerging Indian pharmaceutical multinationals from an international asset seeking, resource-accumulation and catch up perspective. Bruche (2011) critiques this research work to be lacking in a global industry perspective, and states that a benchmark is needed for the assessment of their level of achievement of competitiveness; the 'strategic pathways' or 'trajectories' of leading Indian pharmaceutical companies, that are principally located in the strategic space of increasing internationalisation/risk, will not allow fully integrated companies to catch up with 'Big Pharma' in the medium term. And the Indian pharmaceutical companies need to follow:

1 adequate resource and capability building strategies

2 surmount industry-specific entry and mobility barriers

3 resist the voluntary sales of assets and hostile takeovers to deal with the developments in the market for corporate control

4 pursue a patient long-run strategy in which they may have to sacrifice short-term gains in favour of long-term rewards [Bruche, (2011), p.25].

But this assessment too begs an answer to the problem of what prevents today the emerging Indian pharmaceutical multinationals from forging adequate resource and capability building strategies. The neo-liberal pathway of globalisation had its important rationale in the advancement of the learning connections of OFDI, which is that the domestic pharmaceutical firms would be able to gain access to external knowledge, how come the emerging Indian pharmaceutical multinationals have not been able to help so far the country to overcome the limits in respect of product innovation. This question can be answered by studying the details of OFDI learning connections and of the sources of failures of the innovation systems in transition. Insights can be provided using the framework of innovation system into the subject of what type of access to external knowledge could be gained for the benefit of product innovation and for the building of innovative competences. It is not clear that under what kind of conditions it would be possible through the OFDI learning connections to achieve the relevant contribution of the relationships and linkages under establishment to the coevolving national system of innovation. Can the neo-liberal pathway deliver the conditions for reverse knowledge transfer? Can these economies create even the national systems of innovation and sustain them through the OFDI learning connections?

Literature review on the learning connections of OFDI suggests that the ex-ante management capabilities and culture can determine the ex-post level of achievement of global competitiveness in the case of emerging economies multinational companies. Huaichuan and Yip (2008) review the well-known cases of Lenovo and Huawei to suggest that how the capacity to integrate and combine Chinese culture with world class Western management systems has been a key to the success of their acquisitions. In particular they lay stress on the institutional support received for the upgrading of production operations by their managements from the government. In the literature, there emerges an important understanding regarding the role of national level absorptive capacity when the challenge of absorptive capacity being built across the sectors using the acquisitions, alliances and collaborations by the firms of emerging economies is analysed.

Amighini et al. (2010) points out that the innovative activities of firms trying to catch up depend on the technological regimes in their industries, regimes where innovation is

more predictable and frequent latecomers have had far more opportunities to catch up. They suggest that the factor of modularity of production in an increasing number of sectors, combined with the factor of weak national innovation systems (NISs) in developing countries, explain why the sourcing of strategic assets-including technology and innovation-from abroad through OFDI is becoming such an important channel for technological catch-up in the sectors with high-technology content where innovation is even far less predictable.

Nightingale (2004) specifies those necessary conditions which have to prevail as a rule in the relationships of public and private sector S&T infrastructure of a nation to make the process of innovation possible and predictable.[1] Predictability is not natural; it is a function of investment devoted to public science and technology infrastructure and to building of the close relations for the acquisition of generic knowledge and skills and trained manpower with the public science and technology infrastructure by the private sector firms. Both firms and nations need to invest in infrastructure to exploit research, innovate, import technology or access the international science system. Suggestion is to look into kind of connections and linkages that these firms have been able to build with the public science and technology infrastructure in order to exploit the economies of scale and scope of national level networks for research, innovation, import of technology and knowledge.

In the case of pharmaceuticals, there also exists much evidence of the system of knowledge production becoming more modular than before. Already the global pharmaceutical companies are using the channel of outsourcing in a big way to access the infrastructure and manpower available in China and India to lower the costs of drug innovation. Although the Indian scholars have not yet systematically looked into the question of how much the emerging Indian pharmaceutical multinationals could utilise the OFDI enabled connections of international acquisitions, alliances and collaborations for the development of absorptive capacity at the level of firm, industry and national level, but there have been optimistic claims from some of them on account of the general hype about the OFDI learning connections. Pradhan (2008) uses the perceptions of CEOs to analyse the motives of Indian pharmaceutical multinationals. It is claimed that when the emerging Indian pharmaceutical multinationals invest abroad for acquisitions and collaborate with foreign firms they are very much seeking to overcome their limited product development capabilities.[2] This conclusion has however not been reached on the basis of any systematic investigation in to the contribution of these firms to system building but on the basis of perceptions that the CEOs of these companies offered to the scholar.

Chittoor (2009) claims that the path of internationalisation undertaken associated with the OFDI operations of Indian pharmaceutical firms is particularly unique and distinct. The internationalisation of resources and product markets is itself seen by them as the most important component of organisational transformation for local firms. They even suggest that there has occurred the development of business groups capable of filling the institutional void and creating the distinct emerging economy market in India. There has occurred a jumping of the stages through overseas acquisitions linked accelerated development of capabilities. While Kumar and Singh (2008) have reported the finding of a negative relationship at mature stages of internationalisation and performance in the case of Indian pharmaceutical industry, but they limit themselves to claiming that researchers should pay attention to the dynamics of a specific industry and this will help

academics and business managers to better understand the performance impact of different degrees of internationalisation.

Rasiah et al. (2010) state that attention would have to be paid by the home governments to the motives and activities of their own TNCs rather than simply to the aggregate picture provided by global surveys. Augmentations to the prior frameworks of drivers and motives of OFDI are therefore necessary. It is also our understanding that we can arrive at such a conclusion only after finding out whether or not the necessary institutional changes have occurred for appropriate learning activity to emerge for the benefit of product innovation at the firm, industry and national level. Otherwise, it is quite premature to sustain the claim of either accelerated learning or of development of business groups capable of filling the institutional voids. Scholars need to pay attention to the motives and outcomes of relationships and networks being formed by these firms through the OFDI learning connections to contribute effectively to creation of the institutional conditions for accelerated learning for the benefit of product innovation at the national level.

## 3 Theoretical framework

Starting from the perspective of international business theory, as the sources of firms' ownership (O) advantages are a function of the ability of the national system to create the sources of internationalising firms' location advantages, the question of how will the firms realise the technology seeking motive without a clear basis for exchange needs an answer. Firms do not cooperate without a clear basis for exchange; mutual gains are essential for the reverse knowledge transfer to take place through the relationships being established through non-equity route in the form of collaborations, alliances and networks. Foreign firms will not be willing to transfer easily knowledge to latecomer firms. They are also seen by foreign firms as potential competitors; the costs of knowledge acquisition can be substantial.

Capability building needs time and long-horizon investment. There exists the possibility of failure of persistence of lack of capabilities. Diffusion of knowledge is not automatic even within the national system. The transactions involved for knowledge transfer are risky in the case of making of product innovation. The nature of risk can only reduce with the development of the system of competence building. The strategic intent to invest in capability building should exist. The strategic intent to invest is ultimately a function of firms being patient and the firm and nation being able to perform individually and collectively with regard to learning activity at the level of industry and nation. The emerging Indian pharmaceutical multinationals did not have as a lever access to domestic market to offer to foreign firms after external liberalisation. Technology-seeking motive is a desirable motive for the OFDI activities of the Emerging Economies Transnational Corporations. The extent of support these firms have from the home government for the prior capability upgrading was going to matter. The moot question is whether the domestic firms were sufficiently enabled to practice the strategic intent to invest for the creation of a basis for exchange under the influence of neo-liberal pathway of globalisation. Since the issue of firms' location advantage implies that the nation and industry should 'get right' the institution building for capability upgrading, then the emerging Indian pharmaceutical multinationals would need to practice assiduously the

behaviour of building of firm specific assets, development of industry networks and science industry links and influence appropriately the culture and management of learning and innovation making.

In this contribution, with a view to discover the manifestations in the innovation making and learning behaviour and relationships, we propose to evaluate the nature of motives and outcomes of technology seeking for the process and outcomes of the efforts being made by the emerging Indian pharmaceutical multinationals at the three inter-related levels namely:

a the micro-economic level, which provides elements like the quality of products and internal organisational competitiveness of the firm which concern and are dependent on the availability of firm specific competencies which are necessitated by the need to have the know-how, regulatory capabilities and marketing capacities needed for the introduction of new drugs in the domestic and foreign markets

b the meso-economic level, reflected in the stability of the relations between the innovating firms and their partners who could be working within the interlinked sectors supplying active pharmaceutical ingredients (APIs) and providing the innovating firms with all the complementary knowledge inputs of high quality needed with regard to the development of process innovations on a longer-term basis for the introduction of new drugs

c the macroeconomic level of national system of production and innovation, where interactions for the firms generate the forces which determine the structural competitiveness at the level of the national structure, beyond the meso-level structure of firms, on the one hand, by providing for impetus from the side of the state in the form of support required for the conduct of public infrastructure for research and development, education and training and intermediation (financial as well incubation) and on the other hand, by ensuring the maintenance of appropriate demand conditions and of strategic alignment of firms with the overall developmental direction.

The third macroeconomic level is particularly important for the achievement of technological autonomy in the case of latecomer firms. Ties of interdependence must also appear between national economic entities through the activities under perusal by the firms to allow the national system of innovation to emerge in the long run.

Assessment can be carried out in terms of the required capabilities and interactions using appropriate benchmarks. Interactions, linkages and capability acquisition can be measured in terms of the scale of development, stages of development and development of content of innovative competences to find out about the development of culture and institutions of learning. Achievements and limitations of the outcomes of learning being undertaken and of the institutional processes under evolution should be suitably related to the strategies under perusal at the level of the firm, industry and nation by measuring their effectiveness against the benchmarks. An evaluation is necessary to examine whether the system of innovation is evolving in an accelerated way.

Analytically speaking, the learning trajectories under formation at the level of the firm-specific assets can show either the ability to change rapidly the capabilities or there still exists a significant amount of inertia and rigidities exists leading to the underdevelopment of capabilities. The possibilities are that either the learning trajectories under formation at the level of industry networks are evolving in a path dependent,

collective, cumulative and co-evolutionary way mainly for the benefit of global generics or have also started to work for the benefit of development of new drugs that can meet all the different types of priority needs in a coherent way. As the learning trajectories of pharmaceutical industry get determined by the ties of interdependence, whether the OFDI learning connections under the influence of neo-liberal pathway are capable of generating at the level of national system of innovation the variety and diversity at the level of scale, scope and content of capability building in a way which is either balanced or myopic?

Our proposed understanding for examination is that due to the perusal of the OFDI learning connections under the impact of the neo-liberal pathway of globalisation the emerging Indian pharmaceutical multinationals have failed to get the institution building right for the benefit of development of the national system of product innovation. This path dependent failure has occurred because they were operating under the influence of the conditions of neo-liberal globalisation where they had complete freedom to align themselves with the incentives coming from the global markets and there was absence of domestic market linked obligations and incentives. Given the historical positions, paths and processes of the firm specific acquisition of in-house capabilities and resources and the relations of firms with the system of public sector science in the past for the leading pharmaceutical firms in India, it was important for these firms to get right the strategic balance in:

a the acquisition of complementary resources for marketing and production for generics

b the building of assets for firm specific learning

c the strengthening of complementarities and linkages for learning at home to make the internal dynamics of innovation making self-sustaining for product innovation.

The impact of neo-liberal pathway of globalisation can be expected to reflect in a myopic way in the limits to learning to the detriment of product innovation as a self-sustaining process in the future for the pharmaceutical industry as a whole in India. In the learning and innovation making behaviour and relationships manifestations of this myopic behaviour would be seen in the case of a large majority of firms in the form of excessive focus on the acquisition of complementary resources for marketing and production of generics and relative neglect of the processes of firm-specific capability building and system and network building at home for product innovation through the balanced use of foreign and domestic sources of knowledge. But this understanding has to be verified in empirical terms at the level of evaluation undertaken against the benchmarks to be specified.

## 4 Benchmarking of post-TRIPS institution building for capability upgrading

In India, the historical requirements of post-TRIPS period included the building of institutions for the development of in-house research culture and talent upgrading mechanisms for generic and product specific research, public sector science, science-industry links, clinicians and researchers having links, etc. From the mid ‘80s

onwards several committees have pointed out that the country needed institutional changes to achieve the following outcomes:

1 the establishment of a balanced blend of domestic and foreign sources of knowledge

2 the creation of appropriate interactions and linkages for product innovation.[3]

While the policy makers were committed during the pre-TRIPS period to undertaking steps in the pharmaceutical sector for the implementation of the process of decolonising and gaining technological autonomy, still the emphasis of system building was limited to the development of capabilities for process innovation and occurred in distinct policy driven steps.

In India, firm specific in-house R&D capabilities began to grow for process innovations and analogues development in the pharmaceutical sector only from the late '80s onwards. In the past, their in-house capabilities evolved mainly as a part of the domestic market. As an industry that had to rely mainly on the stimulation of demand provided arising out of the out of pocket expenditure of a small section of retail consumers and national health programmes export markets were important. During the first phase of development, the emerging Indian pharmaceutical multinationals depended on the public sector science system for the development of process innovations.[4] See Table 1 for the details of the pattern of process technologies contributed by the laboratories of Council of Scientific and Industrial Research (CSIR) for the manufacture of compounds needed to treat all types of diseases. It is quite clear that the process innovation activity was being undertaken during this period for mostly Type I diseases, largely the diseases for which consumers could pay from their own pockets for medicines were available in India.

**Table 1** Process technologies developed & licensed to industry by CSIR

| *Type of disease* | *Year* | | | *Total* |
|---|---|---|---|---|
| | *1965–1980* | *1981–1994* | *1995–2005* | |
| Type I | 39 | 21 | 7 | 67 |
| Type II | 5 | 2 | 3 | 10 |
| Type III | 6 | 4 | 2 | 12 |
| Others (not targeted to any type of disease) | 1 | 1 | 3 | 5 |
| Grand total | 51 | 28 | 15 | 94 |

*Source:* Based on the Audit Report on Drug Development CDRI, Lucknow, December (2007)

During the decade of '80s, the state intervention was embedded in a different kind of public policy package favouring far more the development of in-house production capabilities. Public sector science, sectoral reservation, import regulations, patent act, price regulation and supply of talent developed within the public sector units and publicly funded R&D supplying process know-how were used in tandem by the state to play a major role in the emergence and consolidation of the system of process innovation in India (Abrol, 2004). In-house production capability building of the industry was built step by step through the implementation of the drug policy of 1978. An effective public policy package of FDI regulation and price control was in place for the benefit of the system building and domestic pharmaceutical firms.[5]

During this phase, the process of capability building was explicitly targeted and supported in the Drug policy of 1978 by encouraging the production from basic stage; the national system of learning was put in place. Through state support a sound industry wide knowledge base for the development of formulation, bulk drug and fine chemical business was developed by encouraging 'Technopreneur' of 'non-big business' variety of capitalists who responded to the incentives provided and built effectively the links with the public sector science system for process innovations. Talent for the development of process innovations and entrepreneurial leaders came to the private sector through the route of establishment of public sector manufacturing facilities in bulk drugs and the spillovers in knowledge and technology being obtained by the private sector through their links with the laboratories of CSIR.

Although the CSIR laboratories have been active for the development of both, products and processes within the system of public sector science for quite a while, but the success has remained limited to the making of process innovations due to the early stage of industrial development and lack of system building. Central Drug Research Institute (CDRI) was one of the few laboratories that developed not only process innovations but also some new drugs. These drugs did work in the domestic market for a while. Some of these drugs were used in the national disease control programmes. Until the early '90s, the emerging Indian pharmaceutical multinationals existed still in the nature of medium scale firms which did not have the capabilities to invest in the development of product development capability. They lacked resources for the development of product development capability. There was only a weak link between the CSIR laboratories and the emerging domestic firms for the development of product innovations with the public sector science undertaking the major responsibility of development of innovative competence.

As far as the process of beginning of internationalisation is concerned, in the first phase they only chose to export to the markets of developing world and Russia. These exports did not require OFDI. This process was dependent on the building of exports being undertaken on the basis of the strengths available in the domestic manufacturing facilities. Even when the regulated markets of USA and Europe became available for the export of generics the capability building and innovation making efforts of the private sector was a bit late and depended still to a large extent on the system of CSIR laboratories for know-how development.[6] The drug policy of 1978 was gradually abandoned. During the '90s, the domestic industry was lucky to enjoy the conditions of internal liberalisation and delayed implementation of product patent and permitted them to build the in-house capabilities for process innovation in an accelerated manner. The emerging Indian pharmaceutical multinationals could get time to build the initial capabilities required for new processes, formulations, dosages, new salts, derivatives, isomers, polymorphs and other such 'less radical' products to gain entry into the regulated markets of USA and Europe.

Looking at the prevailing factor conditions and the distance to be covered with regard to the scale of capabilities needed to be achieved for the discovery and development of new drugs, the scale of the capabilities under development for product innovation remained subcritical even then. Even by the beginning of last decade in the country, the capabilities of public sector science system were largely limited to basic biomedical research. Public sector science system capabilities for drug discovery and development were quite small in terms of scale and limited to few disease conditions. When the Indian

policy makers chose to undertake external liberalisation, links between industry and science were only beginning to be established for product innovation. Inward and OFDI was liberalised. There was a deregulation of the industry. Whatever controls the earlier 1978 drug policy framework had at the level of the objectives of production and innovation were abandoned and the industry was given complete freedom. The behavioural conditions for rivalry and competition underwent a change. Foreign firms were free to enter into generic business in all markets. FDI for acquisition of the domestic firms was possible. The structure of industry began to change; domestic firms were free to reconfigure their business models and the location of technological infrastructure.

The OFDI connections of learning grew rapidly when the policy makers decided to globalise the Indian pharmaceutical industry. With the shift to product patent recognition being only a few years away the domestic firms were free to follow the incentives coming from the OFDI connections. In the benchmarking exercise, the type of path corrections needed were required to be strictly guided by the prevalence of weak in-house capabilities and interactions and linkages between the public sector science and domestic industry for product innovation making activities. Conditions for prior capability building were missing. The emerging Indian multinationals had a major challenge at hand; their relationships with the foreign companies and public sector science were required to emerge now under the influence of the motives of learning activity bearing OFDI for generic entry in the markets of USA and Europe bearing stringent regulatory requirements. Enhancing technological autonomy, leveraging available product development capabilities for analogues, undertaking capability building for new domestic market via priority diseases investing in the exploitation of technological opportunities for domestic markets to increase their own leveraging power vis-à-vis foreign pharmaceutical firms, all of these were the historical requirements of capability building and innovation making processes in India.

During the post-TRIPS period firm strategies needed to establish distinct competence development routines which would allow the emerging Indian pharmaceutical multinationals not only to achieve generic entry in regulated markets but also to realise technology autonomy for the development of first mover advantage in the domestic markets for new products via building the focus on priority diseases. Till recently where the private sector industry was completely dependent on the system of public sector science for not just manpower needed for drug discovery and development but also for capabilities and facilities required for the introduction of process innovations the challenge of innovation and learning system upgrading in terms of arrangements to be created for the building of new institutions was unique. Drug discovery and development activities that were earlier neglected by the industry as well as the public sector science were required to be simultaneously stimulated at home through the development of appropriate research collaborations and learning networks.

Suitable relationships were required to be established simultaneously via the common programmes within and across national borders for the benefit of network learning to involve public sector science and industry. Policies and schemes were required to be established for the purpose of knowledge diffusion and system upgrading by using the connections under establishment with the foreign companies and R&D organisations through appropriate licensing agreements, strategic alliances and research collaborations. The emerging Indian pharmaceutical multinationals were required to establish the business and revenue models in a way which would give autonomy and free them from dependence. It was necessary to upgrade and leverage the firms' location advantage. The

historically determined conditions demanded taking recourse to the building of national system of product innovation on a big scale. Whether the emerging Indian pharmaceuticals could respond when some of these initiatives were put in place by the government is also an important issue for the benchmarking of the coevolving NIS under the influence of OFDI connections.

## 5 Methodology

In this study, our own investigations extend to studying mainly the overall conduct of the group of top Indian pharmaceutical firms in respect of development of firm specific competences, science-industry links, industry networks and system building for the benefit of product innovation. Benchmarking is undertaken of the capabilities and links under evolution between science and industry, of the type of industry networks and of the system development for pharmaceutical product innovation. We have evaluated the overall conduct of the selected group of 14 leading firms in respect of the achievement of the scale of required efforts for obtaining (adequacy of skills and the ability to change rapidly capabilities), the breadth and depth of efforts being carried out for the relevant stage of innovation development (discovery work, drug development, research services) and the content of efforts under perusal (disease orientation) and the extent of formation of ties of interdependence for the relevant purposes with the domestic and foreign actors operating in the spheres of science as well as industry.

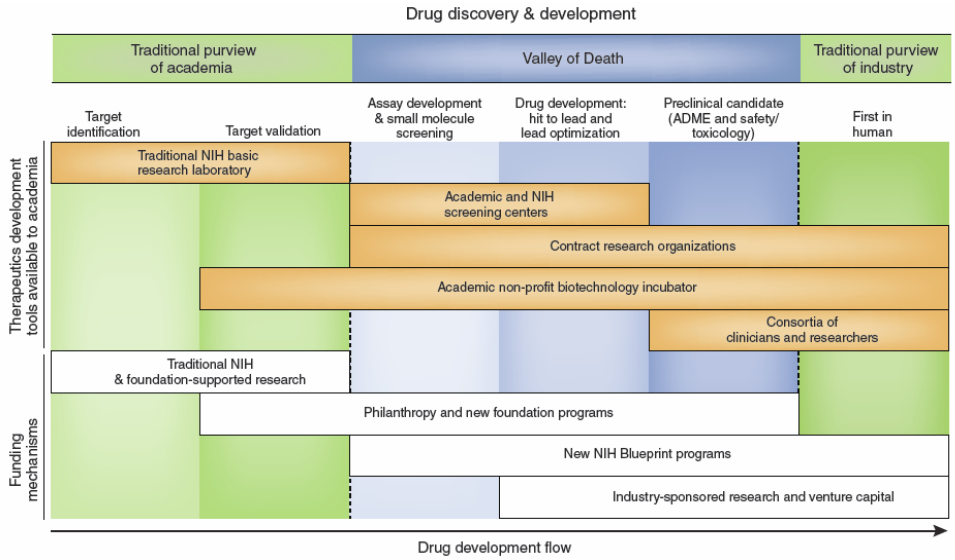
Our sample consists of the top 14 large domestic integrated pharmaceutical firms which have their foreign sales as a percentage of their total sales turnover as more than 25%. Firm specific competences are assessed on the basis of evaluation of the magnitude and composition of inventive output as reflected in the number and type of patents received by these firms from USPTO during the period of 1990 to 2007, the new chemical entities (NCEs) under clinical development and the type of compounds commercialised as generics. Information on the alliances, collaborations and acquisitions entered into during the period of 1999 to 2011 has been gathered from the company websites, annual reports, trade journals and CMIE Prowess database. Investigations focus on the contribution of the top group of 14 domestic pharmaceutical firms at the relevant levels of the development of firm specific competencies, industrial networks and national system for drug innovation during the post-Trade Related Intellectual Property Rights (TRIPs) Agreement period in India.

The extent of development of firm specific competencies and the nature of involvement of these firms with domestic and foreign industry and the public sector research and development facilities available at home and abroad for the development of new drugs are evaluated by analysing the data compiled on patenting activity, drug discovery and clinical R&D projects and compounds launched and commercialised. Assessment is made of the impact in respect of the contribution of these companies to the establishment of complementarities and linkages for the purpose of development of competencies relevant for drug discovery and development work. Assessment covers the co-evolving ties of interdependence within the national system of innovation under development. Evaluation is in terms of the co-evolving involvement with the public sector science and industry networks through the formation of alliances, collaborations, public-private partnerships and acquisitions and system development at the national level for different types of activities by stage of development of drug and diseases.

## 6 Emerging Indian pharmaceutical companies, firm specific innovative competences and product innovation

At the start of the presentation of the results of evaluation, we would like to recognise that the process of globalisation of innovation is occurring in different parts of the world on the basis of institutional model of product innovation developed in the USA. But there are many good reasons that the latecomer countries do not slavishly imitate the US model. See Figure 1 for the changing system of drug discovery and development in the case of the USA. However, since it is true that the network forms of organisation have come to stay in many countries, we assume that the system of drug discovery and development that India needs would certainly have a role for the industry networks as well as the public sector system of science. Be the structures or the network relationships they would have to be carefully evolved between the public sector science and industry networks. Favourable conditions for talent development, management and application of intellectual property, funding mechanisms, etc. had to be created in a manner that there is also a proper network coordination and alignment of the system building with the national priorities.

**Figure 1** System of drug discovery and development (see online version for colours)




*Source:* Finkveiner (2010)

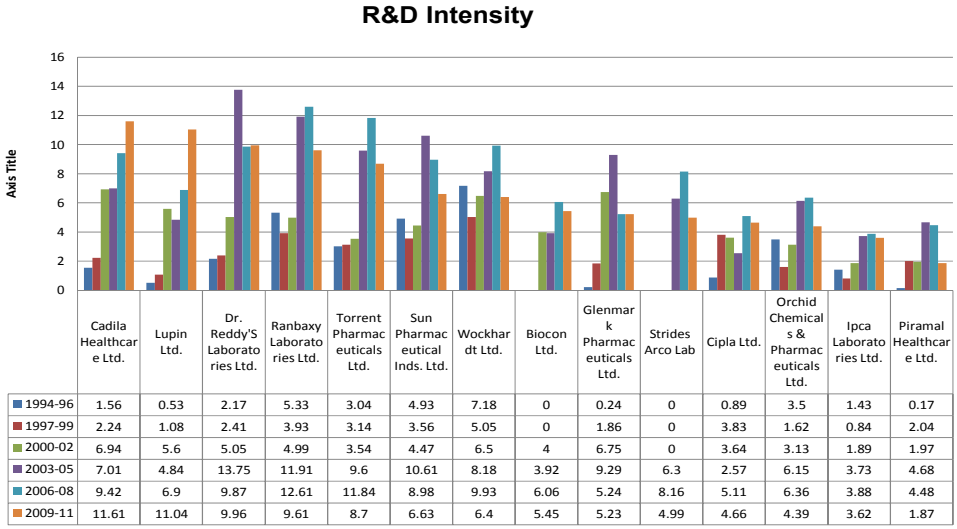
## 7 Firm-specific competencies

Academics have differed in their degree of optimism in respect of the positive effects of global integration and stronger patents on the development of firm specific innovative competences needed by the latecomer firms for product development (Abrol et al., 2011). Small size of domestic market and firm size not being large enough to take the risk of investing in the development of capabilities for product development have been

understood as raising barriers to entry for the latecomer firms. But scholars have also suggested that since the talent needed for R&D on new product development is less costly it is possible that the entry of latecomers is a matter of time. Their participation can grow sooner than predicted.

See Figure 2 for the details of the observed pattern of increase in R&D intensity over the period for all the 14 firms. This figure shows that there is certainly some progress in respect of the size of R&D in the pharmaceutical sector.

**Figure 2** Indian pharmaceutical companies and their R&D intensity 1994–1996 to 2009– (see online version for colours)




| | Cadila Healthcare Ltd. | Lupin Ltd. | Dr. Reddy'S Laboratories Ltd. | Ranbaxy Laboratories Ltd. | Torrent Pharmaceuticals Ltd. | Sun Pharmaceutical Inds. Ltd. | Wockhardt Ltd. | Biocon Ltd. | Glenmark Pharmaceuticals Ltd. | Strides Arco Lab | Cipla Ltd. | Orchid Chemicals & Pharmaceuticals Ltd. | Ipca Laboratories Ltd. | Piramal Healthcare Ltd. |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1994-96 | 1.56 | 0.53 | 2.17 | 5.33 | 3.04 | 4.93 | 7.18 | 0 | 0.24 | 0 | 0.89 | 3.5 | 1.43 | 0.17 |
| 1997-99 | 2.24 | 1.08 | 2.41 | 3.93 | 3.14 | 3.56 | 5.05 | 0 | 1.86 | 0 | 3.83 | 1.62 | 0.84 | 2.04 |
| 2000-02 | 6.94 | 5.6 | 5.05 | 4.99 | 3.54 | 4.47 | 6.5 | 4 | 6.75 | 0 | 3.64 | 3.13 | 1.89 | 1.97 |
| 2003-05 | 7.01 | 4.84 | 13.75 | 11.91 | 9.6 | 10.61 | 8.18 | 3.92 | 9.29 | 6.3 | 2.57 | 6.15 | 3.73 | 4.68 |
| 2006-08 | 9.42 | 6.9 | 9.87 | 12.61 | 11.84 | 8.98 | 9.93 | 6.06 | 5.24 | 8.16 | 5.11 | 6.36 | 3.88 | 4.48 |
| 2009-11 | 11.61 | 11.04 | 9.96 | 9.61 | 8.7 | 6.63 | 6.4 | 5.45 | 5.23 | 4.99 | 4.66 | 4.39 | 3.62 | 1.87 |

**Table 2** Average R&D intensity for top 14 leading companies

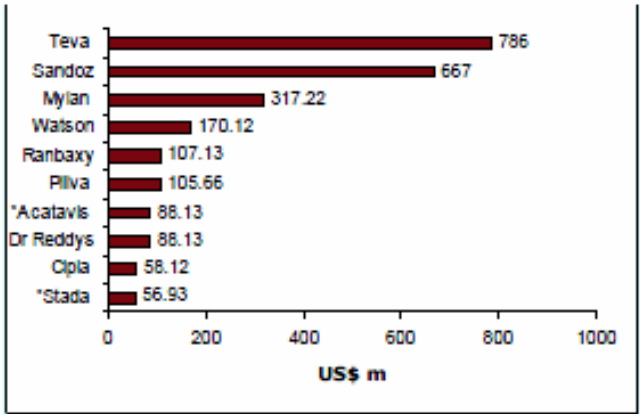
| *RDI (%)* | *Numbers of companies* | | |
|---|---|---|---|
| | *1991–1993* | *2000–2002* | *2009–2011* |
| < 0.5 | 2 | 1 | 0 |
| 0.5–1 | 3 | 0 | 0 |
| 1–2 | 2 | 2 | 1 |
| 2–4 | 1 | 4 | 1 |
| 4–8 | 0 | 7 | 7 |
| 8–12 | 0 | 0 | 5 |
| 12–16 | 1 | 0 | 0 |

Notes: # Top 14 leading Indian Pharmaceutical Industries are: *Ranbaxy Laboratories, Cipla Ltd., Dr. Reddy's Laboratories, Cadilla healthcare, Biocon Ltd., Sun pharmaceuticals, Lupin Ltd., *Piramal healthcare, Glenmark pharmaceuticals, Torrent pharmaceuticals, Strides arcolab, *Wockhardt Ltd., IPCA laboratories, *Orchid pharmaceuticals.

*Source:* Prowess database, CMIE (2011)

While a greater momentum for fund allocation during the period of last one decade (2000 to 2011) is reflected in the enhanced R&D intensity, however when we assess the pattern of average R&D intensity achieved the picture is different. It is clear that only six firms have been able to increase their R&D investments in a significant way. See Table 2. Further, we also need to recognise that R&D expenditure of the top 15 Indian pharmaceutical firms is still nowhere near the expenditure being incurred by the generic companies of Israel and Europe.[7] See Figure 3 for the details. However, it is quite clear from the pattern of marketing and advertising expenditure and royalty payments being made to local and foreign sources that the in-house capability development culture and management is of conventional nature and does not show the features of any kind of unique or distinct institution.

**Figure 3** Top generic players by R&D spending – 2008 (see online version for colours)

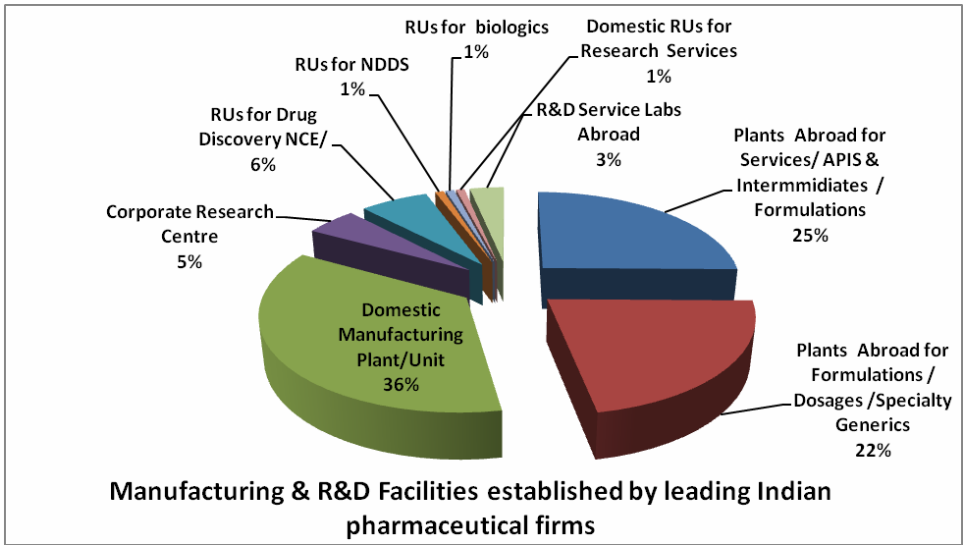



Note: *Acatavis data for 2007, Stada data for 2006

*Source*: Annual reports; Cygnus Research

Take the establishment of specialised R&D laboratories at home and abroad for the benefit of product development. The scale of progress being shown by these firms is hardly promising. In terms of the establishment of research units abroad these firms have done far less as compared to the erection of manufacturing plants abroad. Those who have established their R&D facilities are far more for the purpose of dossier preparation for generic entry rather than for the development of new products. See Figure 4 for the emergent pattern of establishment of facilities for manufacturing and research abroad by these companies. From the above figure, it is clear that the objective of gaining an entry in to regulated markets for the introduction of generics seems to have remained a major focus of building the firm specific competencies for these firms. Firm specific capabilities were mainly built for the filing of drug master files (DMFs) and abbreviated new drug application (ANDA) work prior to registering products (generics) in US and EU. See Figure 5 which compares the number of DMFs and ANDAs filed by each of these 14 firms in the USA during the period of 1990.

**Figure 4** Pattern of creation of R&D and manufacturing facilities (see online version for colours)

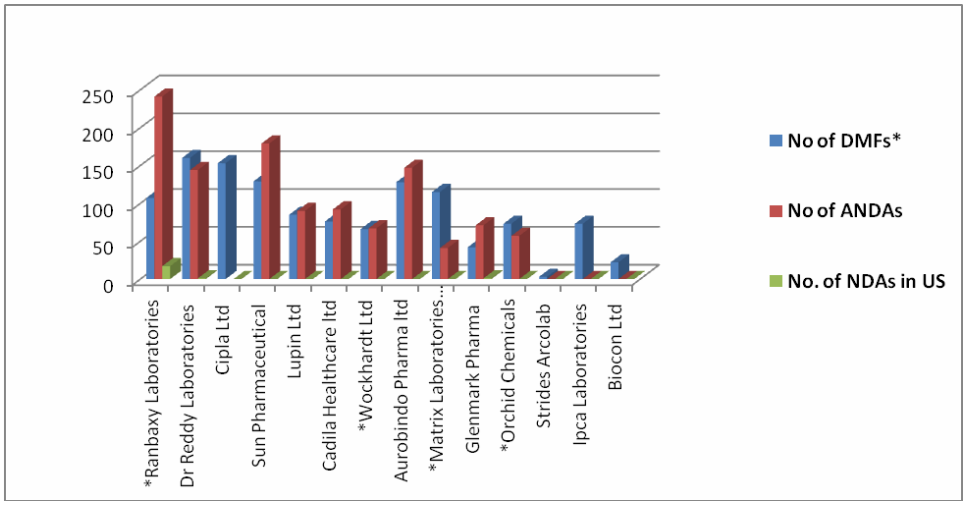



Notes: *Companies are now became foreign companies after the acquisition of Ranbaxy by Daiichi Sankyo in 2009, and acquisition of Nicholas Piramal (Health Unit) by Abbott Laboratories, acquisition of a part of Orchid Pharma by Hospira Inc. US, acquisition of Wockhardt Ltd. (Nutritional Arm) by Abbott Laboratories.

*Source:* Individual Company websites, data accessed as on November 2011

Evidence is compiled on the patenting activity of Indian pharmaceutical companies on the basis of patents filed by them in USPTO in Table 3. It clearly shows that product development is even today not the main strength in the case of emerging Indian pharmaceutical multinationals. Table 3 shows a lack of balance in inventive activity being carried out by them during the post-TRIPS period. Bulk of the 'innovative outputs' still belongs to the areas of dosage/formulation/composition of matter and process-related R&D. Their patenting activity continues to be largely tilted in favour of the development of processes, new forms of substances, dosages and formulations, new drug delivery systems. The number of patents granted to these companies for the NCEs is small. Assessment indicates that attempts are still limited to the activity for product development being confined to the development of analogue molecules. The chemistry driven process research capable of giving non-infringing processes for the manufacture of APIs and identifying and characterising the impurity profiling pertaining to APIs have been the priority objectives. The other area of R&D pertains to formulations where Novel Drug Delivery System (NDDS)-based products are also introduced. The focus on NCE development is quite recent for the emerging Indian multinationals. Even the latest period of post 2005 does not show any significant change in the thrust away from the development of processes, analogue products, new forms of substances and formulations and dosage forms.

**Figure 5** ANDAs and DMFs filed by these firms in US (see online version for colours)




Notes: As at March 2009 the sales data for Matrix, Glenmark is for the financial year 2007 to 2008, Sun Pharma includes in Subsidiary Caraco; *Companies are now became foreign companies after the acquisition of Ranbaxy by Daiichi Sankyo in 2009,and acquisition of matrix by Mylan in 2007,acquisition of Shantha Biotecnics by Sanofi Aventis in 2009,acquisition of Nicholas Piramal (Health Unit) by Abbott Laboratories, acquisition of a part of Orchid Pharma by Hospira Inc. US, acquisition of Wockhardt Ltd. (Nutritional Arm) by Abbott Laboratories.

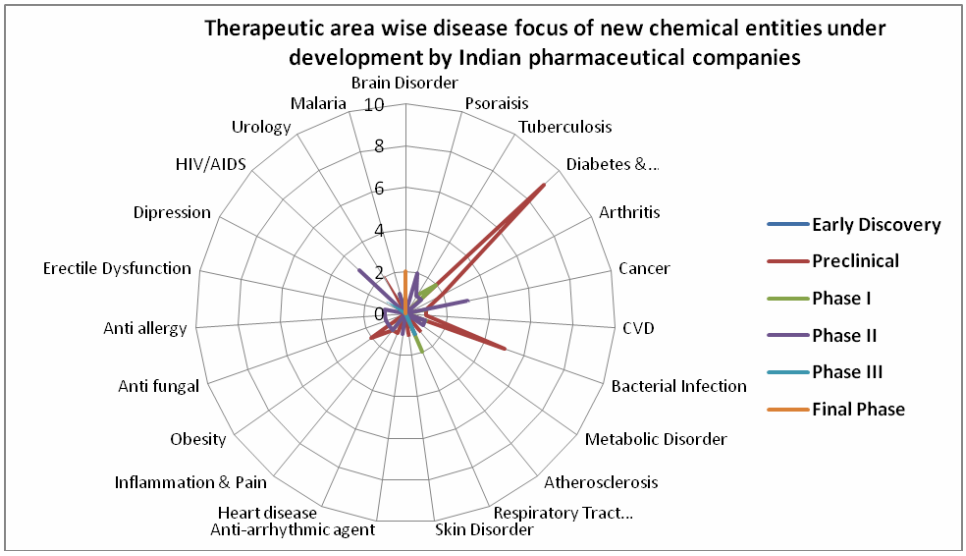
*Source:* No. of DMF Data from http://www.betterchem.com (DMF database) and no. of ANDA from individual company website; data accessed as on December 2009

**Table 3** Evolution of domestic pharmaceutical industry patents in USPTO 1992–2007

| *S. no* | *Nature of patent* | *1992–1995* | *1996–1999* | *2000–2003* | *2004–2007* | *Total* |
|---|---|---|---|---|---|---|
| 1 | Process patent | | 11 | 51 | 133 | 195 |
| 2 | NDDS patent | | | 18 | 23 | 41 |
| 3 | NCE patent | | 3 | 6 | 10 | 19 |
| 4 | Method of treatment | 14 | 26 | 102 | 261 | 403 |
| | Dosage, formulation | | | | | |
| | Composition, combination and product patent | | | | | |
| 5 | New forms of substances | | 6 | 63 | 156 | 225 |
| Grand total | | 14 | 46 | 240 | 583 | *883* |

Notes: Emerging patterns of pharmaceutical Patent innovations, data collected from USPTO of 1992 to 2007 and Patent classification (Process, product, NDDS, method of treatment, NCE, dosage, formulation, composition, new forms of substances (salt, polymorphs, derivative, amorphous, analogue, conjugate, crystalline, esters, isomers, metabolite, solvates) is done by using *International Patent Classification* (*IPC*). Abbreviation: NDDS – new drug delivery system, NCE – new chemical entity.

**Figure 6** Status of outcomes of product innovation by stage of development and disease (see online version for colours)




Notes: *Companies are now became foreign companies after the acquisition of Ranbaxy by Daiichi Sankyo in 2009, and acquisition of matrix by Mylan in 2007, acquisition of Shantha Biotecnics by Sanofi Aventis in 2009, acquisition of Nicholas Piramal (Health Unit) by Abbott Laboratories, acquisition of a part of Orchid Pharma by Hospira Inc. US, acquisition of Wockhardt Ltd. (Nutritional Arm) by Abbott Laboratories.

*Source:* Company annual reports and websites, accessed April 2010

At the moment, there is only a small amount of activity going on in respect of NCEs in DRL, Glenmark, Lupin and Sun Pharmaceuticals for the benefit of foreign markets. Analysis undertaken of the R&D objectives confirms that the Ranbaxy Laboratories had the highest level of achievement with regard to filing of patents for all kinds of inventions except in respect of NCEs. In the case of NCEs Dr. Reddy's Laboratories (DRL) has the highest level of achievement. Even the higher end competitive strategies adopted by Indian pharmaceutical firms differ in terms of their emphasis. Glenmark Cipla and DRL are into actively focusing on specialty generics.[8] Only a few of them are still trying to gain-related drug discovery abilities. In India, the firm specific processes for NCEs-based drug discovery started in 1994 with Dr. K. Anji Reddy of DRL, earlier working an important public sector unit namely Indian Drug Pharmaceutical Limited (IDPL), setting up the first new drug lab at Hyderabad as a distinct facility for drug discovery work.

There are at least 10 to 12 Indian Pharmaceutical companies that are working on the development of new products in the sector of drugs and pharmaceuticals. An estimated 60 new compounds are known to be in various phases of development and testing. But not too many of these compounds are expected to be successful and are being abandoned and discontinued or further R&D work. Out of 47 compounds analysed over 20 compounds were abandoned by these companies at various stages of development (Abrol et al., 2011). See Figure 6 for the latest status of the outcomes of new drug development activity in terms of their stage of development and disease orientation for the Indian pharmaceutical firms. This figure also confirms that the current portfolios of NCEs under

development through these firms are mostly at their early stage of development at the moment and the drug that is in final phase is not a high burden disease.

But at the moment the emerging Indian pharmaceutical multinationals are compelled to depend on the capabilities of their competitors in respect of pre-clinical and clinical research. None of the Indian pharmaceutical companies is engaged in the entire process of drug development. No Indian company claims to have all the resources to pursue the cutting edge and take a new compound through all stages up to marketing. While costs of conducting research in India are lower compared to the developed market economies because of low cost scientific manpower, the fact is also that at this stage India is still weak in respect of the early stage of drug discovery capabilities. Even this happens to be the case with regard to the capabilities for the stage of drug development.

Dr. Reddy's Group was the first domestic company to file the first two product patent applications for anti-cancer and anti-diabetes substances in the USA. For the further work on product development DRL licensed out its diabetes molecule to Novo Nordisk in 1997. This molecule had to be dropped later at the stage of clinical trials due to toxicity issues. But it is also clear that Dr. Reddy's Group still does not want to engage autonomously in drug development. It is interested in selling its rights to the partners abroad for the reason that it does not have the capacity to invest further and stopping after the stage of drug discovery work. Examples of Wockhardt joining hands with Rhein Biotech GmbH, Germany, Ranbaxy shaking hands with Eli Lilly and Schwartz Pharma AG for development work, Cipla undertaking custom synthesis, collaborations with Japanese and Swiss firms, indicate the limitations of and opportunities available to Indian firms.

Almost all the emerging Indian companies are pursuing the strategy of R&D collaborations to lower their costs and risk factors. Strategy pursued is to find a new drug within an existing family that has been discovered-finding a compound that is analogous to a discovered compound like DRL where originally Sankhyo was doing work on Giltazones. This strategy cuts down on the risk. A company can reduce some of the uncertainties of new drug research though this may not produce a drug as big as a blockbuster. The second strategy is out licensing where the Indian company takes some leads to pre-clinical stage. Then it may strike a deal with MNC who will have the right to market the compound in a particular market if all tests are cleared. The Indian company gets milestone payments for each stage of clinical trials the compound clears. Companies like Ranbaxy, DRL and Glenmark are all following the out licensing the route. DRL has tried a deal with Novratis too for further work on an anti-diabetic compound DRF 4158. Ranbaxy entered into a deal with Bayer for Cipro NDDS and RBx 2258 (BPH). Glenmark has tried a deal with Forest of North America and Tejin of Japan for compounds that could provide treatment for asthma. However, the level of success obtained by these companies through the routes currently under perusal has not yet yielded the desired results in respect of new product development.

## 8 Types of ties of interdependence emerging at the level of industrial networks and science industry links

Assessment of the relationships forged through the acquisitions, alliances, collaborations and agreements while undertaking OFDI indicates that for the establishment of appropriate industrial networks these firms have failed to give priority to the objective of

capability for new drug development. See Table 4 for the details of the pattern of functions being served through the acquisitions of firms and divisions bought abroad by these 14 firms.

**Table 4** Type of R&D & Marketing acquisitions pattern of Indian pharmaceuticals 1999–2011

| *Companies* | *R&D acquisitions* | | *Sub total* | *Marketing/productions acquisitions* | | *Sub total* | *Total of all acquisitions* |
|---|---|---|---|---|---|---|---|
| | *Industry* | | | *Industry* | | | |
| | *DO* | *FO* | | *DO* | *FO* | | |
| Top 14 leading Indian Pharmaceutical | 2 | 20 | 22 | 3 | 72 | 75 | 97 |

Notes: Top 14 leading Indian Pharmaceutical Industries are: *Ranbaxy Laboratories, Cipla Ltd., DRL, Cadilla healthcare, Biocon Ltd., Sun pharmaceuticals, Lupin Ltd., *Piramal healthcare, Glenmark pharmaceuticals, Torrent pharmaceuticals, Strides arcolab, *Wockhardt Ltd., IPCA laboratories, *Orchid pharmaceuticals.

*Source:* Individual company website press releases, news, archive, etc., data accessed as on November 2011

Similarly, when we analyse the details of the emerging pattern of alliances and collaborations to study the pattern of acquisition of assets by all these companies, in the case of all the 14 firms the number of alliances, collaborations and acquisitions remained right through skewed in favour of the purposes relating to marketing, manufacturing and supply of R&D services. Their acquisitions were mainly for the strengthening of their foreign marketing. Assessment also indicates that even a smaller number of firms are involved in the asset augmentation for the purpose of manufacturing. R&D alliances and collaborations involved still fewer firms.

Compared to the acquisition of manufacturing and distribution arms abroad by each and every firm in the sample only a smaller number of firms have acquired firms abroad with the motive of upgrading R&D capabilities. As far as the number of acquisitions made for boosting the drug discovery R&D purpose is concerned, it is a tiny number reflecting the bias of OFDI connections. R&D acquisitions were mostly for the acquisition of research service facilities needed to be established for the benefit of generic entry. Research services function seem to have dominated the acquisitions made because the main objective of these acquisitions was limited to getting facilities in the host country for the preparation of dossiers and undertaking laboratory work. See Table 5 for the details of the types of R&D purpose being served through the acquisitions that these firms made during the period under observation.

Foreign firms account for the maximum number of alliances, collaborations and licensing agreements entered into by these firms during the period under observation. In the case of R&D-related ties, research services function dominated the relationships forged with the foreign industry. It is also clear that these firms did very little to use the alliances, collaborations and agreements to strengthen their drug discovery. Discovery R&D was the objective of relationship forging with foreign firms in far fewer cases compared to research services and clinical trials. While these firms have hardly used the relationships capable of being established with foreign public research institutions for the strengthening of R&D function and new drug discovery and development, but even in their relationships with foreign firms it is the short-term objectives which seem to have

dominated. See Table 6 for the details of type of alliances, collaborations and agreements signed by these firms with the research institutions and firms, both foreign and domestic.

**Table 5** Type of R&D acquisitions with Industries 1999–2011

| *Companies* | *Discovery R&D* | | *Sub total* | *Clinical development* | | *Sub total* | *Research services* | | *Sub total* | *Grand total* |
|---|---|---|---|---|---|---|---|---|---|---|
| | *DO* | *FO* | | *DO* | *FO* | | *DO* | *FO* | | |
| Top 14 leading Indian Pharmaceutical | | | | | | | 2 | 20 | 20 | 22 |

*Source:* As provided in Table 4

**Table 6** Type of R&D alliances, collaborations and licensing agreements 1999–2011

| *Top 14 Pharmaceutical Industry in India* | | *R&D alliances* | | | *R&D collaborations* | | | *IN licensing* | | | *OUT licensing* | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | *Discovery R&D* | *Clinical development* | *Research services* | *Discovery R&D* | *Clinical Trial* | *Research services* | *Discovery R&D* | *Clinical Trial* | *Research services* | *Discovery R&D* | *Clinical Trial* | *Research services* |
| RI/ academia | Domestic | 2 | | 1 | 5 | 3 | 1 | | | 1 | | | |
| | Foreign | | | | 2 | 4 | 3 | | | | | | |
| Industry | Domestic | | 1 | | 1 | 1 | | | | 1 | | | |
| | Foreign | 2 | 2 | 8 | 12 | 17 | 19 | | 5 | 6 | | 4 | 5 |
| Grand total | | *4* | *3* | *9* | *20* | *25* | *23* | | *5* | *8* | | *4* | *5* |

*Source:* As provided in Table 4

Not only domestic pharmaceutical firms have been ready to out license clinical development of their NCEs to the firms that have considerable market operations in the sector of drugs and pharmaceuticals in India, but also they are entering in to in-licensing deals for undertaking bio-equivalence studies in case of formulations and dosages. In-licensing arrangements are being used to build up the portfolio for the purpose of growing in the domestic market. For example, Nicholas Piramal has had arrangements with Roche for launching products of Roche dealing with cancer, epilepsy and AIDS. Glenmark has in-licensed Crofelemer, Napo's proprietary anti-diarrheal compound. Wockhardt has had arrangements for the in-licensing of Syrio Pharma SpA for dermatology products. Ranbaxy has had arrangements with KS Biomedix Ltd. for EMRs to market Trans MID in India with an option to expand to China and other South East Asian Countries.

Foreign firms are apparently gaining in terms of financial gains and control far more from the R&D and marketing relationships than that these companies could forge for R&D and marketing functions through OFDI. Take the examples of out licensing and in licensing agreements being signed by these companies. In the case of in-licensing agreements payments to foreign firms are on a recurrent basis and are guaranteed returns.

Imbalance is also evident at the level of number of agreements entered into by these companies for marketing and research. Marketing as a purpose dominates the agreements. However, when we also analyse the impact of agreements entered into for R&D purpose by these companies on the capability building, there is an imbalance evident. In-licensing agreements in R&D area are for bio-equivalency studies. In respect of product development, the area of bioequivalence is not a gap that has to be filled through in-licensing agreements. However, this is not the case when one analyses the out-licensing deals because the agreement pertains to the clinical development of earlier phases and pre-clinical toxicology studies, etc.

Domestic ties with research institutions and academia have received a least amount of attention from the emerging Indian pharmaceutical multinationals. Although domestic firms are the major beneficiaries of R&D services sourced from public sector research laboratories, but there are very few alliances for undertaking collaborative drug discovery and development-related R&D work between domestic firms and public sector research institutions. Just two firms used the domestic R&D institutions for the purpose of R&D alliances. See Table 7 for the pattern of ties built with the domestic R&D institutions for clinical and discovery R&D by these firms during the period of 1999 to 2011.

**Table 7** Type of R&D alliances with RI/Academia

| *Companies* | *Clinical & discovery R&D* | | *Sub total* | *Research services* | | *Sub total* | *Grand total* |
|---|---|---|---|---|---|---|---|
| | *DO* | *FO* | | *DO* | *FO* | | |
| IPCA laboratories | 1 | | *1* | | | | *1* |
| *Piramal healthcare | 1 | | *1* | 1 | | *1* | *2* |
| Total | 2 | | *2* | 1 | | *1* | *3* |

Notes: As provided in Table 4 (among 14 leading Pharmaceutical companies IPCA and Piramal have R&D only concluded alliance style cooperation with RI/academia).

*Source:* As provided in Table 4

See Table 8 for the details of the strengthening of marketing function through their new ties with the foreign firms. Evidence is quite clear that what really dominates at present the scene of alliances and collaborations is the marketing activity-related relationships. Some of the Indian pharmaceutical firms have preferred to rely only on marketing alliances abroad instead of setting up subsidiaries or production facilities

Further, we also note with some concern that most of these firms have also chosen to enter into alliances, collaborations and agreements with the foreign firms having presence in the Indian market. By forging a close relationship for the supply of contract research and manufacturing services with the very foreign actors which have a global presence quite a few of these firms are making clear that they do not have any plan to compete with the Big Pharma in future in either the domestic or the foreign markets. Lupin had a marketing alliance with Cornerstone to market Suprax. DRL has an alliance with Pilva, for development and marketing of oncology products in Europe; DRL and Glaxo-Smithkline have a multi-product agreement; DRL is collaborating with Pharmascience Group for development and marketing of generic products in Canada; Glenmark's supply and marketing agreement with Lehigh Valley. Certainly some of these marketing alliances reflect an element of strategic choice. At the moment DRL, Glenmark and

Lupin are seemingly the examples of strategic elements guiding them in their relationships, but it is not the case with most of the firms whose relationships we have analysed.

**Table 8** Pattern of Marketing alliances, collaborations and licensing agreements 1999–2011

| *Top 14 Pharmaceutical Industry in India* | *Marketing alliances* | | *Marketing collaborations* | |
|---|---|---|---|---|
| | *Domestic* | *Foreign* | *Domestic* | *Foreign* |
| Industry | 10 | 111 | 5 | 101 |
| Grand total | *10* | *111* | *5* | *101* |
| | *IN licensing (marketing)* | | *OUT licensing (marketing)* | |
| | *Domestic* | *Foreign* | *Domestic* | *Foreign* |
| Industry | | 21 | 2 | 6 |
| Grand total | | *21* | *2* | *6* |

*Source:* As provided in Table 4

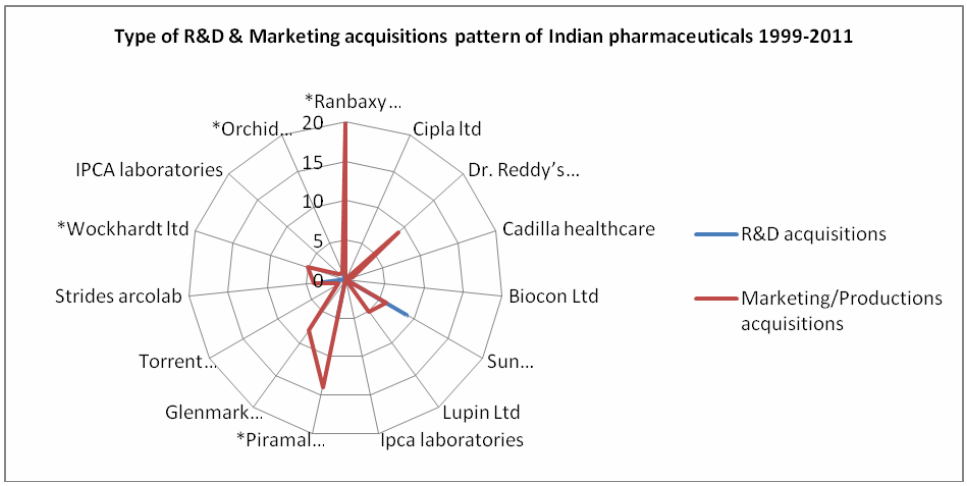
Figures 7, 8, 9 and 10 show the dominance of marketing function in terms of the different types of relationships forged by each of the 14 firms. In a very few cases domestic R&D institutions have been targeted for in-licensing agreements. In some cases the global pharmaceutical companies are out-licensing their products to Indian firms. This relationship brings about regular royalty payments at minimum investments with a wider geographical coverage for their products. Strides Acrolab Ltd. has entered into a number of such deals with companies in the USA, UK, Japan and Europe. Clinical outsourcing is also being treated as a lucrative strategy by some of the Indian firms. Cadila Healthcare has entered into alliances with Atlanta Pharma, Schering AG, and Boehringer Ingelheim. Lupin has a licensing agreement with Cornerstone Bio Pharma Inc. for clinical development of NDDS for an anti-infective product.

Ranbaxy entered into a few collaborative research programmes involving global pharmaceutical firms, e.g., with MMV, Geneva for an anti-malarial molecule, Rbx 11160; with GlaxoSmithKline for drug discovery and clinical development for a wide range of therapeutic areas; with University of Strathclyde, UK in new drug delvery system (NDDS); Ranabaxy has a collaborative relationship with Eli Lily, Pfizer and Novartis in drug discovery and with Vectura, a drug delivery company for the development of platform technologies in the area of oral controlled release system. Ranabaxy, Reddy's Laboratories, Lupin, Glenmark, Torrent, Sun pharmaceutical, Cadila and Biocon figure prominently in the agreements, collaborations and alliances entered into for the R&D purpose. But there are only a few examples of collaborative R&D programmes which follow one or another kind of risk sharing involving joint venture or collaboration with another pharmaceutical company in order to develop and commercialise a product. They are largely entering into one-way relationships which are hardly going to give them advantage in the long run.

Torrent has entered into a collaborative research programme for the drug discovery in the area of treatment of hypertension with AstraZeneca. Dependent or potentially compromising relationships would not benefit the firms as much and can the affect the national system of innovation adversely when pressures are being mounted on the industry to accept TRIPS plus provisions of data exclusivity and so on. Of course, there are still some exceptions. Cipla has entered into a collaborative programme of risk

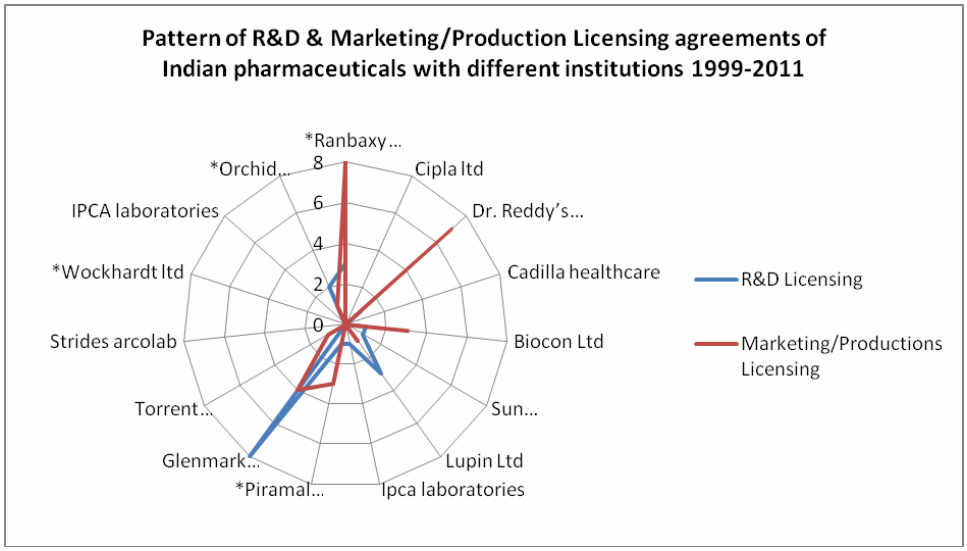
sharing type with a domestic company setup by a non-resident Indian namely Avesthagen Laboratories to produce biogeneric drug for Arthritis, N-Bril. Although Avesthagen has an ongoing collaborative programme with Nestle, BioMereleux, France and other companies, but the relationship of Cipla with Avesthagen is unlikely to prove compromising and can be handled independently.

**Figure 7** Pattern of R&D and marketing acquisitions of Indian pharmaceuticals 1999–2011 (see online version for colours)



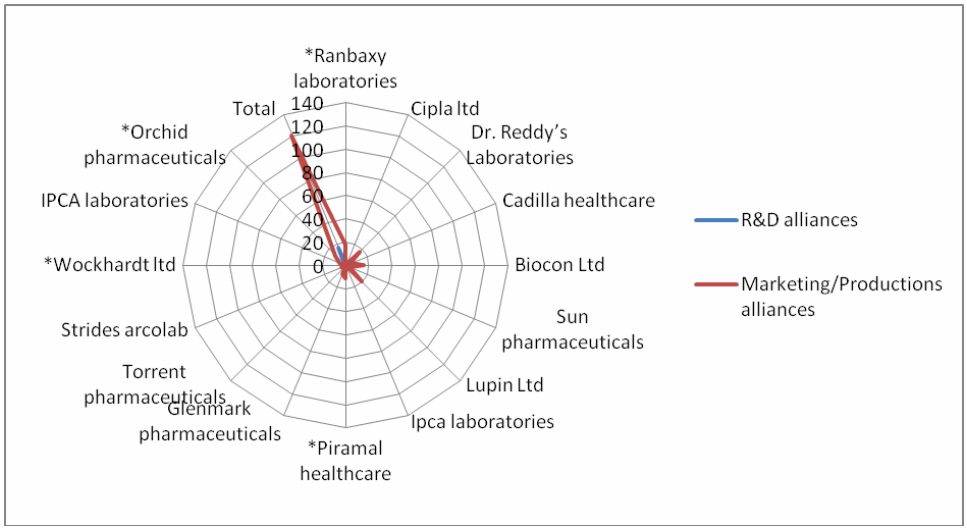

*Source:* As provided in Table 4

**Figure 8** Pattern of licensing agreements undertaken for R&D and marketing 1999–2011 (see online version for colours)



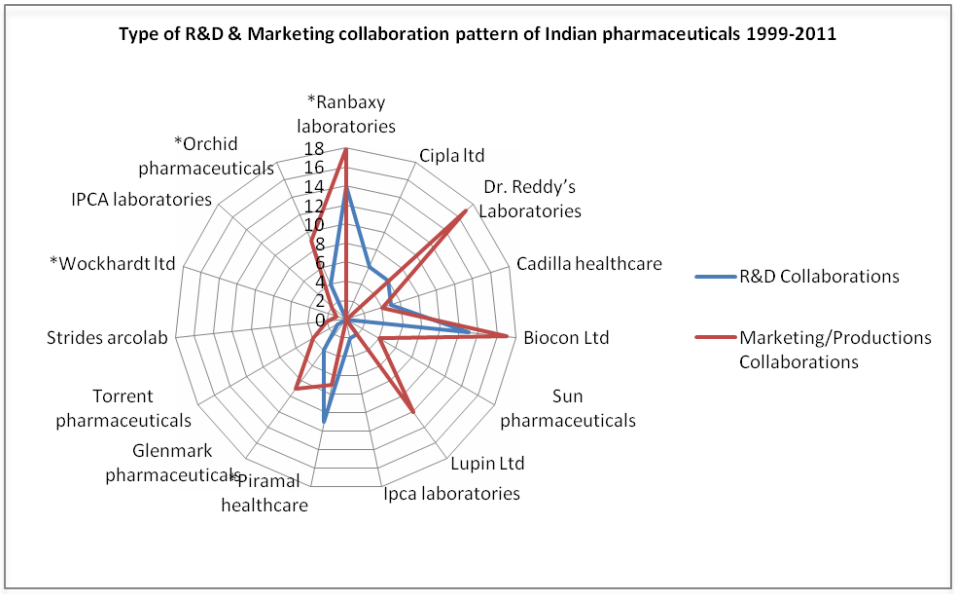

*Source:* As provided in Table 10

**Figure 9** Pattern of R&D & marketing alliances of Indian pharmaceuticals 1999–2011 (see online version for colours)




*Source:* As provided in Table 4

**Figure 10** Pattern of R&D and marketing collaborations of Indian pharmaceuticals 1999–2011 (see online version for colours)




*Source:* As provided in Table 4

The emerging Indian pharmaceutical multinationals consider the domestic market to be of small size and not sufficiently attractive for taking up the development of new products in the drugs and pharmaceutical sector. See Table 9 for the pattern of disease orientation of compounds launched. Most of the compounds belonged to the category of

Type I diseases in which there exists the demand. In the absence of stimulus for augmentation of home demand within the country the conditions continue to favour the target of low value added products required by the global markets. It is this imbalance in the policy design which is now reinforcing skewed research priorities in the public sector research system too. From the point of view of prevailing public health situation this certainly does not suit the country on whose shoulders the domestic industry still depends.

**Table 9** Domestic pharmaceutical activities of commercialised/launched generic compounds

| *Domestic companies* | *1999–2001* | | | *2002–2004* | | | *2005–2007* | | | *2008–2011* | | | *Total* |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | *Disease type* | | | | | | | | | | | | |
| | *I* | *II* | *III* | *I* | *II* | *III* | *I* | *II* | *III* | *I* | *II* | *III* | |
| Top 14 leading pharmaceutical industries | 5 | | | 27 | 4 | 2 | 52 | 6 | 4 | 79 | 20 | 3 | 202 |

Notes: *Disease type-(Type-I, Type-II, Type-III): *Type-I – diabetes, cancer, metabolic diseases, hepatitis, influenza, cardiovascular, infectious diseases, inflammatory diseases, allergy, respiratory diseases; *Type-II – HIV/AIDS, tuberculosis, malaria; *Type-III – Leishmaniasis, trypanosomiasis, lymphatic filariasis, leprosy, and diarrhoea.

*Source:* Data collected from individual website and latest annual report of individual pharma companies and Cygnus research, data accessed as on November 2011

**Table 10** Pattern of coverage of different types of burden of diseases in academic collaborations and alliances 1999–2011

| *Companies* | *Collaborations and alliances for discovery and clinical R&D with RI/academia* | | | | | |
|---|---|---|---|---|---|---|
| | *Domestic institutions* | | | *Foreign institutions* | | |
| | *High burden disease areas* | *Medium burden disease areas* | *Low burden disease areas* | *High burden disease areas* | *Medium burden disease areas* | *Low burden disease areas* |
| Top 13 leading pharmaceutical industries | 4 | 15 | 3 | | 1 | |

Notes: *Data available on the burden of disease from GOI; 1 – *high burden diseases*: infectious diseases/injuries (16.1), maternal and prenatal problems (11.6), cardiovascular (10.0), brain disorders (8.5), diarrhea (8.2), childhood disease (5.4); 2 – *medium burden diseases*: cancer (3.4), tuberculosis (2.8), HIV/AIDS (2.1), malaria (1.6), respiratory diseases (1.5), blindness (1.4), diabetes (0.7), 3 – *low burden disease/conditions*: oral diseases (0.5), leprosy (0.1), otitis media (0.1), inflammatory diseases, arthritis, bone disease, otitis media, ulcer, psoriases, depression, hypertension, allergy, hepatitis, prosthetic hyperplasia, others (25.4).

*Source:* Individual company website press releases, news, archive, etc., data accessed as on November 2011

There is evidence of the shift of R&D priorities. Analysis of the evidence processed by us shows that all the important developments that we see in respect of the creation of R&D capabilities for new drug discovery and development within the Indian firms have a global market favouring R&D orientation. As the situation has stood so far their pharmaceutical research is largely directed to the needs of the regulated markets of the USA and Europe. Even the high burden disease areas of the Indian nation have not been able to attract the locally bred firms. Analysis indicates the preponderance of medium burden disease areas: Cancer (3.4), Tuberculosis (2.8), HIV/Aids (2.1), Malaria (1.6), Respiratory diseases (1.5), Blindness (1.4), Diabetes (0.7) being covered more by the firms in their relationships with the academic institutions and industry networks. See Table 10 for the pattern of coverage of different types of diseases in academic alliances and collaborations.

See Table 11 for the pattern of coverage of diseases as a focus of development of NCEs by these firms. This table shows the development of NCEs through the alliances formed for drug discovery and clinical trials formed with foreign firms. The focus is on medium burden diseases which include areas affecting both, developed and developing countries like Cancer, Tuberculosis, HIV/Aids, Malaria, Respiratory diseases, Blindness and Diabetes.

**Table 11** Pattern of coverage of different types of disease burden for NCEs under development by Indian pharmaceutical companies 1999–2011

| *Companies* | *NCE's pipeline* | | |
|---|---|---|---|
| | *High burden disease areas* | *Medium burden disease areas* | *Low burden disease areas* |
| Top 13 leading pharmaceutical industries | 17 | 34 | 32 |

*Source:* As provided in Table 10

**Table 12** Pattern of coverage of different types of burden of diseases in industrial collaborations and alliances 1999–2011

| *Companies* | *Collaboration and alliances for discovery and clinical R&D with industry* | | | | | |
|---|---|---|---|---|---|---|
| | *Domestic firms* | | | *Foreign firms* | | |
| | *High burden disease areas* | *Medium burden disease areas* | *Low burden disease areas* | *High burden disease areas* | *Medium burden disease areas* | *Low burden disease areas* |
| Top 13 leading pharmaceutical industries | 1 | | | 15 | 31 | 19 |

*Source:* As provided in Table 10

Concern about the shift in R&D priorities is quite prominent when we analyse the pattern of coverage of diseases in the case of alliances and collaborations that these firms have entered into with the foreign firms for the purpose of drug discovery and clinical research. Markets for which the capability development is being undertaken with the help of foreign firms are those diseases where the developed world has more interest. High

burden disease areas of the Indian nation are of lower interest. See Table 12 which depicts this shift quite prominently.

## 9 Impact of the OFDI connections on the use of the government R&D schemes

While the industry is known to be complaining of government funding for the direct benefit of R&D in industry being rather small, it can be however seen that they are not even utilising the existing schemes in a big way. Medium burden diseases are a major focus of the projects submitted by the industry. This is because of the attraction of these diseases on account of markets being more attractive due to the worldwide emphasis on many of those diseases at the level of R&D funding. See Table 13 for the pattern of diseases covered by these firms while using the government funded programmes and schemes initiated for the benefit of pharmaceutical innovation.

**Table 13** Pattern of R&D projects obtained by the firms from the government funded programmes and schemes in terms of their burden of disease orientation

| | | | | |
|---|---|---|---|---|
| DPRP | 23 | 30 | 13 | 66 |
| BIPP | 6 | 5 | 1 | 12 |
| SBIRI | 2 | 14 | 10 | 26 |
| Grand total | 31 | 49 | 24 | 104 |

Notes: DPRP – Drugs and Pharmaceuticals Research Programme; #BIPP – Biotechnology Industry Partnership Programme, # *SBIRI-Small Business Innovation Research Initiative*.

*Source:* DPRP, BIPP, SBIRI website, data accessed as on November 2011

To come to the impact of OFDI connections on the lack of balance R&D priorities it is starkly visible in the case of use of government schemes by the emerging Indian pharmaceutical multinationals. See Table 14 whose analysis also indicates that most of the emerging Indian pharmaceutical multinationals have not been leveraging the government funding for undertaking industrial R&D. More than half of these firms chose to ignore the schemes formulated by the government industrial research financing altogether. There were only six firms out of 14 firms that took projects funded by the government for the development of facilities and activities required to be undertaken for the development of new drugs. But even they accounted for just 15 projects in the portfolio of 104 projects sanctioned by the government.

It is clear that these firms have not come forward to use the government schemes for R&D and innovation of therapeutics for tackling the priority diseases. Lack of interest in the schemes from the emerging Indian pharmaceutical multinationals is the case even when the government has agreed to cede to the collaborating firms the ownership of IPRs. Some of these firms have now been sold by its promoters to foreign firms. It is obvious that the national links of these firms are only getting weakened rather than being strengthened. Certainly, the OFDI connections of the strategies of the emerging Indian pharmaceutical multinationals are affecting adversely the plans that the policy makers have for the development of the national system of innovation for the benefit of Indian pharmaceutical industry.

**Table 14** Firm wise pattern of government funding agencies programmes/schemes funded burden of diseases by Indian pharmaceutical industry 2005–2011

| *Companies* | *DPRP* | | | *BIPP* | | | *SBIRI* | | |
|---|---|---|---|---|---|---|---|---|---|
| | *High burden* | *Medium burden* | *Low burden* | *High burden* | *Medium burden* | *Low burden* | *High burden* | *Medium burden* | *Low burden* |
| Total no of projects in different classes of disease burden | 23 | 30 | 13 | 6 | 5 | 1 | 2 | 14 | 10 |
| Torrent Pharma | - | 1 | 4 | - | 1 | - | - | - | - |
| Ranbaxy Laboratories | - | 5 | - | - | - | - | - | - | - |
| Strides Arcolab | 1 | - | - | - | - | - | - | - | - |
| Lupin Pharma | 1 | - | 1 | - | - | - | - | - | - |
| Cadilla Healthcare | - | 3 | - | - | - | - | - | - | 1 |
| Biocon Ltd. | - | - | - | - | 1 | - | - | - | - |
| Total | 2 | 6 | 5 | - | 2 | - | - | - | 1 |

*Source:* DPRP, BIPP, SBIRI website, data accessed as on November 2011

## 10 Implications for firms' management and govern policy

We started the investigations by stating that at the time of the implementation of TRIPS Agreement the Indian policy makers began under the influence of 'there is no alternative' (TINA) syndrome and advocated in the post-TRIPS period by the beginning of two thousands that the neo-liberal pathway of globalisation involving external liberalisation and strong IPRs is the way to accelerate the processes of competence building, learning and innovation making for the benefit of product innovation in the pharmaceutical sector. During the period of last one decade, they believed that OFDI and external liberalisation would give them access to overseas knowledge. They worked on the assumption that the links between science and industry demand the domestic pharmaceutical industry to be subjected to competition at home and abroad, and external liberalisation and OFDI activities would get the domestic firms to be competitive sooner through rapid global integration.

Because the home government chose not to intervene in the process of acquisition of resources and capability building through any other track the pharmaceutical industry was working mainly under the influence of the OFDI learning connections due to the impact of the neo-liberal pathway of globalisation under perusal. The strategic intent to invest remains weak till this day in autonomous product innovation. It is clear that the OFDI learning connections have developed an excessive focus on the acquisition of complementary resources for production and marketing to the detriment of the institutionalisation of the processes of building of firm-specific capabilities and strengthening of the national system of innovation. They have failed to use the foreign and domestic sources of knowledge effectively for the augmentation of firm specific assets and the establishment of product innovation specific interactions and linkages within the national borders. During the post-TRIPS period, the potential sources of firms' location advantage available at home could not be mobilised appropriately for the benefit of technology seeking motive by the emerging Indian pharmaceutical multinationals.

Investigations indicate the emergence of sub-optimal conditions for product innovation in the form of typical systemic failures on account of the perusal of a myopic pathway and lack of balance in the interactions and linkages emerging with the national system of innovation. The contribution of the OFDI learning connections to development of the firm specific technological capabilities is at present marginal for new product development. Not many resources could be leveraged from the acquisitions and strategic alliances entered into by these firms for the upgrading of processes of drug discovery and development. Even after the elapse of almost two decades the learning and innovation making activities of these companies are successfully occurring only in respect of the development of non-infringing processes and low end incremental innovations required to be undertaken for the attainment of successful entry of domestic firms in to the regulated generic pharmaceutical markets of the USA and Europe. Assessment of the motives and outcomes of their international acquisitions, strategic alliances, collaborations and agreements confirms that the gains of these companies continue to relate far more to marketing and production of generics rather than R&D to be undertaken for product innovation. The emerging Indian pharmaceutical multinationals have not been able to acquire the firm-specific technological assets needed for the successful conduct of R&D activities for drug discovery and development from their interactions and linkages with foreign firms.

Lacking in the strategic intent to build the interactions and linkages for the learning activity within the national borders the emerging pharmaceutical multinationals are advancing towards creating sub-optimal conditions for the conduct of product innovation. Links between public sector science and emerging Indian pharmaceutical multinationals remain weak and the barriers to diffusion of knowledge into the national system will persist. This is the case even when most of the Indian pharmaceutical companies fulfil now the criteria of 'resource rich' large firms. The OFDI-based relationships of these firms are lacking in emphasis on the products needed for high burden diseases of the country. Goal misalignment and weakened national identity are manifest; most of these firms have preferred to invest more in hospitals and pathology laboratories.

Internationalisation will have to be pursued in a balanced way without ignoring the investments and processes to be put in place for the perusal of technological learning for product innovation. There is an urgent need to get the firms to build their firm specific assets and ties with the public sector science with a view to strengthen the national system of innovation for the benefit of both foreign and domestic markets. The government is required to intervene on supply as well as demand side to fill the gaps. There is an urgent need to strengthen the system of public sector science with a view to play its due role in drug discovery, preclinical and clinical research and to take appropriate steps in the form of advanced market commitments and public funding of clinical trials in the case of national priorities.

## 11 Concluding remarks

The experience of establishment of post-TRIPS period learning trajectory confirms path dependent systemic failures and the limits to learning on account of the OFDI learning connections being constrained by the neo-liberal pathway of globalisation. From the perspective of international business theory, the emerging Indian pharmaceutical multinationals are failing to acquire the sources of firms' ownership (O) advantages. Failure to build the required sources of firms' location advantages is the result of their inability to contribute to the creation of appropriate institutions for the development of innovative competences at the national and firm level. From the perspective of national system of innovation, the Indian policy makers need to get right the processes of institution building to upgrade the national system of pharmaceutical product innovation which alone would allow the emerging Indian pharmaceutical multinationals to realise appropriately the technology seeking motive of OFDI. There will be undoubtedly heterogeneity in the firm behaviour whose determinants also need to be studied but it is our understanding that the pathway matters and the OFDI learning connections would not undergo a radical change unless a large number of firms are aligned to contribute to the building of national system of innovation for technological autonomy and health security of the Indian nation. And this cannot happen without changing the assumptions of policy making underlying the choice of pathway of neo-liberal globalisation.

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## Notes

1 Nightingale (2004) points out that the tangible infrastructure takes the form of instrumentation, apparatus and analysis technologies that enhance problem-solving by purifying experiments from external influences, and embodying uncontroversial parts of explanations. These technologies provide and define the parameters needed to embody and diffuse the conditions of predictability in physical form, typically as physical capital goods. The intangible part of the infrastructure (i.e., mathematical methods, surgical techniques or design methods) involves trained scientists and engineers who have the ability to understand socially distributed explanations, (through access to national and international research networks), as well as the tacit, technical 'tinkering skills' to apply them. In both cases there are substantial advantages from having this infrastructure in the public sector associated with a larger community of practice engaging in open science. Private infrastructure is dependent on, rather than an alternative to, this public infrastructure, which is why industrial voices continue to call for investment in high quality academic basic research rather than applied problem solving. Since the benefits of public research cannot be provided for by firms, and are primarily related to tacit skills and infrastructure that remain within national boundaries (and support the capabilities of the state) they remain within the remit of state action. The justification for the public funding of science is not based on unquantifiable, abstract theory or market failure arguments about the provision of public goods. It instead revolves around the empirical requirement for the infrastructure needed to produce technology and allow markets to work.

2 Pradhan (2008) points out that unlike in the past, a significant chunk of Indian pharmaceutical OFDI in early 2000s was to acquire new products and foreign knowledge to overcome existing limitations in the innovation strategy. Apart from the Greenfield investment of US$2.7 billion the value of 105 overseas acquisitions done by a total of 43 Indian pharmaceutical companies targeted at 28 countries stood at US$2.9 billion during 2000 to 2008. It is noted that developed region with 82.6% share in the total acquisition value is indicative of the trend that Indian pharmaceutical firms were compelled to use acquisition as a strategy to overcome their prominent innovation limit, namely inadequate product development capabilities. The broad range of their acquisition activities involved product and brand acquisitions, world-class manufacturing facilities and taking over of companies with significant intangible assets like products and technologies.

3 See the reports of 'Technology Policy Implementation Committee' (TPIC, 1987) and the Abid Hussain Committee Report (Council of Scientific and Industrial Research, 1986). Subsequently the Mashelkar Committee (Council of Scientific and Industrial Research, 1999) dealt directly with the rationale of public intervention and recommended collective action for the creation of new mechanisms for pharmaceutical product innovation in the post-TRIPS period.

4 Before the beginning of '70s in the sector of drugs and pharmaceutical the national system of innovation was lacking in the processes of establishment of large domestic pharmaceutical firms. The decade of '70s is known for the introduction of a new patent legislation and the adoption of drug policy 1978. The Patent Act of 1970, which did not allow product patents in the area of pharmaceuticals, was adopted to step up the building of technological capabilities and innovation making for process development for the development of generic industry currently operating in India. As under the Indian Patent Act, 1970 the country's national system of innovation was free to develop alternate processes for the drugs that were still under product patent protection (on-patent drugs) in the developed countries, several domestic firms came on the local market scene using the technologies for alternate processes developed in-house and by the public sector research laboratories of Council of Scientific and Industrial Research (CSIR) during the decade of '80s. Over 50 new processes were developed during the period of 1965 to 1980 in the CSIR system for the benefit of Indian pharmaceutical firms. For over 100 essential drugs the CSIR laboratories gave new processes, many of which were based on the development of new steps and involved the development of close to 50 new reactions in chemistry.

5 This was an important industrial policy intervention which could enable the young firms that did not originate from within the big business but were developed by the technical entrepreneurs to operate successfully to beat the barriers being erected by the multinational corporations in the Indian markets through their advertising investments and construction of the sales and distribution networks. These young firms got an opportunity to emerge in the local Indian market as the viable generic suppliers for even all those drugs that were still under product patent in the USA and Europe.

6 Although after the adoption of Hatch-Waxman Act of 1984 in the USA these firms had the access to these regulated markets for generic entry, but the Indian pharmaceutical firms were late by a few years in terms of engineering their entry into these markets. Their in-house capabilities were seemingly not developed enough to give them competitive edge over the generic companies originating from Israel and Europe. It only became possible for these firms to enter into regulated markets during the period of late '80s.

7 Ranbaxy is now no more a domestic company and has been sold by its Indian promoters to Daichi Sankhyo, a Japanese multinational. Of course, DRL, Cipla, Glenmark, Lupin, Cadila, Wockhardt, and Torrent are still around as integrated Indian pharmaceutical companies which have also built substantial foreign sales.

8 A company not only obtains a patent on active ingredient involved in the new drug but also have secondary patents relating to the same active ingredient, such as, new formulations and compositions, e.g., new dosage forms; new salts, esters, etc. of existing ingredients; new uses and new process for manufacturing.