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Indian Pharma Within Global Reach?

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Abstract

The Indian pharmaceutical industry is presently going through a phase of transition and potential consolidation, owing to India's new TRIPS-compliant intellectual property regime and other rules aimed at enhancing the industry's credibility nationally and internationally. Appropriate policy interventions can play a large role in cushioning the transition (and gradual consolidation) of the industry post-2005. Using firm level data collected in 2004-2005, this paper seeks to make two major contributions in this regard. The research findings show that the Indian pharmaceutical sector is a heterogeneous mix of firms with vast differences in innovative capabilities. Based on these differences, the groups can be categorized into specific "innovation modes" (the innovator, the niche operator and the manufacturer), each mode being a step closer towards the innovative pharmaceutical firm. Second, the paper highlights how the emerging strategies of firms in all three groups, although different, underpin the importance of systemic coordination in the pharmaceutical sector. The analysis links both these findings to

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policies pursued in the pharmaceutical sector over the past four decades and highlights the role of differential innovation policy in ensuring optimal sectoral performance.

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1. Introduction

Innovation is the process of acquiring technological knowledge and building further upon it, from a variety of market and non-market institutions. Technological knowledge for innovative activities can either be codified (in the form of publications, patents, blue prints), or tacit (embedded in know-how, informal habits and practices of organizations). It can also be scientific knowledge such as basic principles of a technological discipline; or technological knowledge in the form of "technical solutions"; or even entrepreneurial knowledge related to product attributes, consumer tastes and market conditions (Karlsson and Johansson, 2004; Johansson and Lööf, 2006).

Traditional approaches to study how the structure of firms affects innovation trends and innovation outputs centred on a firm's R&D efforts: using a firm's R&D intensity with R&D expenditure as inputs and patent filings as outputs, or explaining a firm's R&D intensity using a firm's size and market characteristics as explanatory variables. More recently, four different approaches seem to be significant (see Johansson and Lööf, 2006). Scholars looking at firms from a dynamic capabilities building perspective view firms in terms of their aggregate human and material resources, and analyze the efficient building of technological capabilities within the administrative organization of the firm (Penrose, 1959; Pisano and Teece, 1995, Teece et al, 1997, among others). Other studies look at how the characteristics of firms and markets affect a firm's ability to innovate from the perspective of corporate structure, specifically, by creating a distinction between local and multinational firms (see Pavitt and Patel, 1999; Narula, 2003, among others). There are others who seek to explain innovation activities of firms by looking at the functional characteristics of the region in which they locate (clustering), and the basis for such agglomeration (see Saxenian, 1994; Porter, 1998). A fourth approach stresses on the characteristics of the innovation system in which the innovative activities of a firm are entrenched and how this determines capabilities (see Lundvall, 1992; Nelson, 1993).

1.1. Firms and 'catching-up': the relevance of institutional arrangements

Firms play a central role in driving the innovation process by combining knowledge from both internal and external sources, but they do not act alone (OECD, 1999; 2002). Firms tend to pass through "cycles" of learning and maturation, driving the innovation process ahead with them. Broadly, firms transit through four main stages in their search for innovative capabilities: the static firm, the self-generating firm and the innovative firm (Little, 2001).[2] At one end of the spectrum is the static firm; one which is not involved in systematic innovation, but may have a stable market position so long as *status quo* continues. The surviving firm is one that has the ability to adapt to newer environments, can question existing rules and routines. It is able to learn new learning processes, and reinvent itself to compete in newer environments. The self-generating firm is one step further; it not only has the ability to question rules and routines and learn new processes to adapt to new environments, but also has the capacity to strategically re-position its activities and thrive. At the other end of the spectrum is the innovative firm, which is a firm operating a linked set of processes that are involved either in concept generation or market identification, product and process development, and subsequent production, marketing and feedback of the products (Little 2001). Although firms are constantly involved in learning at each one of these stages, the kind of learning and associated innovative intensity differs.

Information and knowledge are the primary inputs to the process of building innovative capacity in firms, but they originate from within the firm and outside (from the system). All infrastructural elements, human-capital and physical, for assessing demand for products, manufacturing, marketing, forging customer relationships, accumulating information related to production, form part of the system. The particular system of innovation within which a firm operates is the basic institutional arrangement that determines how its links with other organizations both research-based and market-

[2] Innovation scholars have struggled for quite sometime now to classify firms similarly. One of the early attempts of this kind was made by Freeman and Soete (1997). This classification here is adapted from Little (2001). Little (2001) identifies four forms of firm stages: the static firm, the learning firm, the self-generating firm and the innovative firm. The term 'learning' firm has been changed to the 'surviving' firm here.

oriented, such as universities, public research institutes, suppliers, manufacturers, consumers and producers occurs and how collaborative and competitive relationships will be built upon. Institutions, such as universities (for human capital provision), financial institutions (for venture capital and financing of research), industrial infrastructure (for manufacturing products or acquiring information related to production), entrepreneurial associations (for marketing and assessment of market-based conditions), all provide incentives (or disincentives) for interaction, thereby facilitating or limiting a firm's ability to tap all knowledge sources, both internal and external. Therefore, learning efficiency of firms depends on numerous country-specific institutional, infrastructural and cultural elements that pre-determine interactive capabilities, organizational efficiencies and mobility of skills (see for example, OECD, 1999). Secondly, knowledge accumulation can occur in firms only if there is competence locally that can be used to build innovative capabilities in the first place. And finally, innovation is not an activity that can merely be measured by how much is spent on R&D, but rather by how much of research inputs get translated into research/commercially viable outputs by the creative use of technological knowledge (Amsden and Cho, 2003). All these factors stress on the extensive and complementary relationship between firms and the system of innovation in which they are embedded for building innovative capabilities. Systemic efficiency is critical in explaining the success of firms in reaching the innovative stage: not only do firms which do not have these facilities fail, but firms which have these facilities but lack innovative capabilities sometimes manage to succeed, and often do so, at the cost of innovative firms that lack them (Chesbrough and Teece, 1996).[3]

Different countries offer very different basis for firm-level innovation activities, most of which can be attributed to country size and general level of development (OECD, 2002). Institutional arrangements required to promote a particular innovation system are influenced largely by the context-specific nature of the process (level of technology and the quality of scientific and technological infrastructure) as well as the nature of

[3] Teece (1986) and Chesbrough and Teece (1996) note the same although applying a different approach to study the process of building innovative capability. In Teece's words, a firm's capability to innovate is influenced by the "appropriability regime" in which it operates.

institutions within the country (the scientific culture, norms and practices of actors and support systems) (Oyeyinka and Sampath, 2006). These account for why some systems are able to perform and adapt to changing circumstances and demands better than others. In catching-up economies, despite the availability of a global stock of advanced technology to draw upon, systemic limitations like the availability of human capital, finances and scientific infrastructure can act as major limitations.[4] Alternatively, catching-up economies that have been doing reasonably well in certain sectors may be facing a transition having reached a stage where their latecomer advantage is close to exhaustion, either due to technological or other factors, such as globalization and international trade rules (see for example, OECD, 2002). In such cases, affirmative policy and institutional support that aim at enhancing the effectiveness of the national innovation system will play a large role in securing firm-level competitiveness.

In the pharmaceutical sector, India is often cited as an example of an "innovative developing country" with significant capacity to carry out health innovation.[5] Indian generic firms are an important source of medicinal supply domestically and internationally, presently produce 22% of all generic drugs world-wide (Verma, 2005, p. 436).[6] The Indian pharmaceutical sector is undergoing a transition ushered in by a number of factors, intellectual property protection due to India's full scale compliance with the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) and introduction of uniform standards for good manufacturing practices (GMPs) being two important ones. Appropriate innovation policy interventions can play a large role in cushioning this transition post-2005. Using firm level data collected in 2004-2005, this paper focuses on the Indian pharmaceutical sector to make two main points. Firstly, the Indian pharmaceutical sector is a very heterogeneous mixture of firms, from large scale

4 Economic catch-up is a process by which countries that are followers in technological terms, are learning through the acquisition of technological capabilities to catch up with the leaders (see Abramovitz, 1986; Amsden, 1989).

5 "Innovative developing country"; a developing country that has demonstrated a significant promise in carrying out activities in health innovation (Morel et al, 2005, p. 2; Mashelkar, 2005).

6 Indian pharmaceutical firms produce 22% of all generic drugs world-wide and also actively supply vaccines (Verma, 2005, p. 436). The Indian vaccine market, estimated at approximately ~$150 million to 260 million USD, accounted for 57% of the total Indian biopharmaceutical output in the year 2002-2003 (Srinivas, 2006).

firms that are doing innovative research to firms that are seeking to specialize in niches in the drug discovery, development and production process to pure manufacturers. Based on the firm level data, the paper shows that the sector can be broken up into three groups of firms, each having a very different level of technological capabilities to conduct pharmaceutical innovation. The analysis also links the policy framework over the past four decades to the varying levels of capabilities of the three groups of firms, thereby clearly establishing the link between innovation policy and capabilities of firms. Secondly, the analysis highlights the point that innovation is not just R&D; a range of systemic factors, such as quality of infrastructure, collaborative linkages, skilled manpower are key to achieving innovative capabilities. These systemic factors determine whether firms move from being merely static to being self-generating or innovative. In making this point, this paper argues that the strengths of the sector that are reflected in India's success stories (of a few firms) are not representative of the entire potential of the sector. The tendency to flaunt just the few success cases and ignore the laggards has to be avoided if India is to harness the strength of the sector as a whole, and not that of just a few successful firms. The need for differentiated policy support is highlighted.

1.2. Data and Variables

The data used in this paper was collected in a firm-level survey of the top 103 firms in the Indian pharmaceutical sector, ranked on the basis of their export potential, annual sales and R&D investment figures. The survey was conducted between October 2004 and January 2005. An innovation system-oriented and policy-relevant innovation survey at the firm level is complex and not too many such surveys have been conducted in the pharmaceutical sector in India. In order to draw policy-relevant conclusions from the information gathered, the survey was specifically designed to focus on two key variables, namely, learning and innovation processes in Indian pharmaceutical firms and how these will be impacted by stronger intellectual property protection, which is an important instrument of innovation policy.

A background country report of the Indian pharmaceutical industry was first prepared to feed into the survey. A range of semi–structured interviews with experts in the area of pharmaceutical innovation and intellectual property rights were conducted as the second step in order to help clarify the structure and content of the survey and to provide content validation to the survey questionnaire. The questionnaire was then administered to the top 103 firms in an industry list created using data on export potential, R&D investments and annual sales from online databases on the Indian pharmaceutical sector, such as the *India Infoline* and *Pharmabiz*. Additionally, a total of forty five face-to-face interviews were conducted, with CEOs, heads of R&D and marketing of the companies that were surveyed. Some of the top governmental executives in the Ministries of Health, Industries and Commerce were also interviewed.

The paper is structured as follows. Section 2 of the paper discusses the main phases of policy interventions in India over the past four decades that led to the building of technological capabilities in the sector. It shows how the nature of innovation in the sector is strongly linked to the emphatic thrust placed on developing local production technologies by the government, and also discusses the varying levels of capabilities between the three groups of firms as they stand presently. Section 3 looks at emerging innovation strategies, and section 4 uses empirical data to emphasize on how lack of systemic components affects product and process innovative capabilities amongst the three groups of firms. It brings forth two important points of relevance to policy; that there is a need for much more than R&D for the innovative firm to emerge and it also identifies the systemic factors that foster this transition, such as collaboration, intellectual property protection, presence of skilled manpower, venture capital and mobility of labour, that affect innovative capabilities. Section 6 concludes.

2. Structure of the Indian Pharmaceutical Sector

The Indian pharmaceutical sector is amongst one of the largest within developing countries and is reported to have had an overall production value of US$ 7 billion in the year 2003 (IBEF and Ernst and Young, 2004a, p. 8).[7] Presently, it is the second largest export industry in India, exporting to over a 100 countries in total. Its main export regions are USA, Western Europe, Asia (especially China) and the middle-east (see Gehl Sampath, 2006). India also has the largest amount of FDA approved drug manufacturing facilities outside of the USA (OPPI, 2003). The industry growth rate during the 1990s was on an average around 15% for bulk drugs and 20% for formulations (IBEF and Ernst and Young, 2004a).

2.1. Main triggers and actors for innovation

The pharmaceutical sector employs technological capabilities that are rooted in innovative drug discovery and development activities (product development), technological capabilities related to discovering different processes of producing drugs (process development), and finally, technology related to producing and packaging formulations (manufacturing) (Srinivas, 2004, p. 44). Certain limitations in the macro, meso and micro environment render it hard for developing countries to build these capacities in the pharmaceutical sector. At the macro level, a disjuncture between demand for health research and on-going activities in the sector, a lack of scientific culture amongst scientists and researchers (including emphasis on collaboration), weak public support and bureaucratic rigidity are some of the main problems that challenge the system (CHRD, 1990, p. 47). At the meso-level, there are issues of access to information and technological inputs that are important for health research, inadequate human capital formation, institutional instability and weak scientific infrastructure. And at the micro-level, issues of intellectual isolation of researchers and lack of incentives for collaborative research, such as low salaries, restriction of career opportunities due to

[7] The IBEF (Indian Brand Equity Foundation) is a public-private partnership between the Ministry of Commerce, Government of India and the Confederation of Indian Industry (CII).

bureaucratic bottlenecks in adequate research budgets, and lack of on-job training possibilities make it hard to create an efficient innovative environment (Ibid.).

Although India's chosen path to achieve self-sufficiency in the sector was one of an "independent latecomer" (Amsden and Cho, 2003), the government's main focus was on achieving local production of all antibiotics needed by the Indian population.[8] From the 1960s until now, policy changes that have had impact on the sector broadly belong to three identifiable phases.

The first set of policy changes, mainly attributable to India's socialist vision in the 1960s and 1970s, were instrumental in laying the fundaments of the sector. The setting-up of government-held companies to boost local pharmaceutical production of drugs, the Drug Price Control Order and finally, the Indian Patent Act of 1970, was accompanied by other policies to augment these major changes, such as restrictions on foreign direct investment (see Gehl Sampath, 2005a). As a result of the changes introduced by the Patent Act, the number of patents granted per year within India fell by three quarters between the years 1970-71 and 1980-81 (Lanjouw, 1998, p. 4). The Drug Price Control Order acted as an added disincentive, by setting a ceiling on the overall profits of pharmaceutical companies. It was harshly criticized by multinational companies operating in India at that time on grounds that it will reduce the incentives for investments in the sector (Ramani et al, 2001). The criticism also found basis in reality: when the Order came into force, multinational companies operating in India lost interest in expanding their operations in the Indian market, which included R&D efforts, due to the low profit margins involved (Ibid). In order to boost local production of drugs, the main policy pursued by the government was to import the penultimate intermediate required for bulk drug manufacture, so that the last step of the reverse engineering

8 In India, the government's vision to reduce dependency on multinational firms for drugs, especially antibiotics, was the starting point of building self-sufficient local production facilities in the pharmaceutical sector. The focus on antibiotics came from the predominant public health and 'access to medicines for all' perspective that ruled Indian thinking in the 1950s and 1960s. This, in Amsden and Cho's definition (2003), is a clear case of the "independents", which are countries that invest heavily in their own technologies and national enterprises to generate proprietary cutting-edge skills (p. 2).

process could be conducted within India by local firms to produce active pharmaceutical ingredients (APIs). Technology required to enhance reverse engineering skills, specifically those related to imitative process R&D, formulation and production technologies was acquired through public sector efforts, and then passed on to the private sector (see for example, Srinivas, 2004). The local industry, a large part of which developed through spin-off entrepreneurship of employees of government-held pharmaceutical firms, were quick to take cue from the conducive environment: they developed extensive skills in chemistry-based reverse engineering which forms the core of their product and process development skills until today. Indigenous local capacity for production was thus built through a combination of the right policy environment, access to international technology, education and promotion of entrepreneurship, among other factors while the main impetus for learning came from learning-by-doing activities (Mashelkar, 2005). Over a period of time, even when the Price Control Order reduced its coverage in the 1980s and 1990s, the threat of reverse engineering by the local firms kept subsidiaries of multinationals operating in India from introducing new products in the Indian market.[9]

This first phase of policy changes also included policies that targeted India's higher education and health research spending, placing an extraordinary emphasis on science-based university education and specialized public research institutes (PRIs). The government has been instrumental in investing in setting up excellent university education facilities in key disciplines of relevance to pharmaceutical research (such as

[9] Several subsidiaries of multinational companies who were interviewed underscored the point that the ability of Indian forms to produce generic copies of successful drugs was a big factor in their lack of interest to introduce innovative drugs that had huge markets in other Western countries in India. Lanjouw (1998) presents several examples on this point – Indian companies were able to introduce copies of Ciprofloxacin within seven years of its introduction in India, Glaxo was similarly faced with several local competitors on the very day it introduced its drug Ranitidine (Zantac) in India (at p. 9). Even in the case of off-patent drugs, MNCs operating in India have been wary of Indian competence to replicate drugs and create price competition in the local market. A good case is that of Teramycin (Oxytetracyclin), a patent on which was held by Pfizer that expired in the 1960s. Despite the expiry of the patent, Pfizer did not want to share the know-how with Indian companies, for fear of strong price competition in the local generics market. Dr. Sarabhai Laboratories, the first Indian firm to produce Tetracyclin, did so through reverse engineering skills (Pers. Comm, D.G. Shah, 13 January 2005).

those in medicine, pharmacology, chemistry, biochemistry, biology, molecular biology and biotechnology among others), as well as set up public research institutes such as the Centre for Science and Industrial Research (CSIR), Indian Drugs and Medical Research Institute (IDMR), All India Institute of Medical Sciences (AIIMS), Indian Institute of Chemical Technology (IICT), Indian Institute for Science (IISC) among others. This trend has continued well into the present, with institutes such as the Institute for Human Genetics, the Centre for Biotechnology, Institute of Microbial Technology all being established with the mandate of conducting research on emerging areas of importance to drug research. Throughout the past four decades, governmental spending on health research has been extensive, with up to 90% of all research funds being sourced internally for both the public and private sector (CHRD, 1990, p. 49).[10] The creation of extensive scientific infrastructure and skilled human capital that can be absorbed into the sector, coupled with a regulatory environment that expressedly encouraged learning-by-copying and learning-by-doing meant that Indian firms thrived and invested into several kinds of generic activities. They branched out from just importing the bulk drug in its penultimate form, to importing raw materials and creating bulk drugs themselves, and into formulations business in a big way (Srinivas, 2004).

A second phase of policy changes was triggered off by India's trade liberalization in the end of the 1980s. By this time, the pharmaceutical sector was exporting bulk drugs and formulations, and was recognized to be of strategic importance due to its technological and export potential. Several of the policy changes undertaken in this phase were aimed at enabling the sector take advantage of India's shift from an import-substitution economy to a liberalized one, and helped boost the potential of the sector as an exporter of generic formulations. This, supported by India's continuing minimalist IPR regime created a comfortable and stable economic climate where several of the larger firms, like Ranbaxy and Dr. Reddy's ventured out to acquire facilities in developed countries in the 1990s (for example, the USA).

[10] A 1986 cross-country comparison of several developing countries including Brazil, Mexico, Philippines, Thailand, and India ranked in the top category of government spenders for health research within developing countries (CHRD, 1990, p. 49).

These two phases of policy transformations were responsible for the radical changes in the foreign versus local firm ratio in the Indian market. From a virtually non-existent domestic sector in 1970 (15% of Indian firms as against 85% foreign firms in the local market), the market structured transformed into one where both Indian and foreign firms held a 50% share in 1982, to a 61% Indian and 39% foreign share in 1999 (OPPI, 2000). From 2001 onwards, eight out of the ten top firms in the sector are Indian firms and only two are subsidiaries of multinational companies (Business World, 2006). Indian firms also hold a local market share of 75%, and the sale of retail formulations in the domestic market reached an estimated US$ 4.3 billion in the fiscal year 2003 (IBEF and Ernst and Young, 2004a, p 8).

In the present context, the main actors in the Indian innovation system are:

- Government-held companies and private companies, spread across a wide range of specializations, chemistry based pharmaceutical formulations, clinical research and testing and biotechnology
- Governmental agencies especially under the umbrella of the Ministry of Science and Technology, Ministry of Health and the Ministry of Industries, Trade and Commerce.
- The Organization of Pharmaceutical Producers of India (OPPI), the Indian Pharmaceutical Alliance (IPA) and the Indian Drug Manufacturers' Association (IDMA).[11]
- Public research institutes such as the CSIR, IDMR
- Hospitals and medical service agencies, especially training hospitals
- The traditional medicinal sector

A third phase of policy changes is presently underway, having been triggered off by India's compliance to the Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement). India has changed its intellectual property regime for pharmaceutical products radically between 1999 and 2005, becoming fully TRIPS-compliant in 2005 with

[11] There are also other associations that are active in representing pharmaceutical companies in India, but these are comparatively smaller and therefore have not been mentioned here.

the grant of product patent protection. The changes induced by intellectual property protection will be profound, because they are accompanied by potential losses to the sector since generic versions of drugs that are patented elsewhere can no longer be produced by Indian firms (see Fink, 2000, Cheri, 2004 and 2005; Gehl Sampath, 2005a). It has also been accompanied by several other changes aimed at enhancing the industry's credibility nationally and internationally, one such change being the introduction of good manufacturing practices (GMPs) applicable uniformly across the sector.

2.2. Nature of innovation and firm groups in the Indian pharmaceutical sector

The Indian pharmaceutical sector is a heterogeneous mixture of firms, both organized and unorganized (Ramani, 2002). They range from large firms that are either subsidiaries of large multinational firms or wholly Indian, such as Cipla, Ranbaxy and Dr. Reddy Labs, to medium and small-sized firms that also extend to garage operations. As against the commonly quoted figure of 20,000 manufacturing units in the pharmaceutical sector,[12] an expert committee set up by the government of India in 2003 has clarified the number of active units on the basis of drug manufacturing licenses issued (Expert Committee, 2003, p. 3). According to the Committee, the total number of manufacturing units engaged in the production of both bulk drugs and formulations within India is not more than 5877.[13] The market is highly fragmented with only around 300 companies accounting for almost all of the domestic market.

The 6000 odd firms that form part of the sector demonstrate significant technological differences that reflect in their annual sales turnover, export potential, R&D investments and most importantly, the nature of innovative activities. Using country level data collected on these variables, the firms can broadly be classified into three main categories.[14] The first group of firms (hereafter, group 1) comprises large-scale

12 See for example, CII (1999), which quotes 18,000 small-scale units and 250 large-scale companies in the Indian pharmaceutical sector.

13 This can be further broken up into 1333 bulk drug units, 4534 formulation units, 134 large volume parenteral units and 56 vaccine-manufacturing units.

14 I thank Mr. Dilip G. Shah, President, Indian Pharmaceutical Alliance for taking out the time and helping me to organise the secondary and primary data to arrive at this classification.

pharmaceutical firms that are both subsidiaries of MNCs in India or wholly-owned Indian firms. Group 1 includes firms like Ranbaxy, which is the largest pharmaceutical company in the country, also ranked in the top 100 companies worldwide; Cipla, which is the largest producer of generic drugs in India with around 800 products in the market (Interviews). Group 1 firms have an annual sales turnover of more than 300 crore rupees (US$ 650,000), have extensive brand marketing networks for their brands that help in creating and promoting brand identity of their products amongst consumers across the country. The second group of companies (hereafter, group 2) comprises medium sized operators who are either generic producers or specialists in niche areas of contract research and small scale units which manufacture drugs for the bigger firms within India. These companies supply predominantly to the Indian market as well as to other semi-regulated and unregulated markets. Firms classified as group 2 have an annual sales turnover between 100-300 crore rupees (US$ 210,410 to US$ 650,000). The third and final group of companies (hereafter, group 3) comprises those that mainly perform manufacturing activities for bigger Indian companies, both local and multinational companies. Companies that fall into group 3 have an annual turnover of less than 100 crore rupees (US$ 210,410) annually. The 6000 odd firms can be broken up into 100 firms belonging to Group 1, 200 firms to group 2 and the remaining 5700 fall into group 3, when both bulk drugs and formulations are taken into account (Gehl Sampath, 2005a, p. 27). This categorization helps pin point the extreme variance in industry structure because it embodies the vast differences amongst firms in terms of firm size, employment capacity, innovation potential, R&D investments and exports. Out of the 103 firms surveyed as part of the empirical investigation, 31 belonged to group 1, 27 to group 2 and 44 to group.

3. The Innovator, the Niche-Operator and the Manufacturer: Different Innovation Modes?

Group 1 comprises mainly of big pharmaceutical firms, whose pharmaceutical activity can be classified into two main categories: generics and innovative R&D. These 'innovative' firms already have large market shares domestically, and are supplying to regulated, semi-regulated and non-regulated markets. Their R&D activities mainly

focused on process development until recently and the R&D expenditure of the companies is presently around 6% of their annual turnover, and this is projected to rise up to 10% by the year 2010.[15] Extensive process development capabilities have enabled these firms to venture into innovative options, such a specialty generics, and the firms are keenly developing marketing infrastructure abroad to penetrate foreign (regulated) markets. This has been the driving force behind the recent wave of international acquisitions and alliances such as Dr. Reddy's acquisition of Betapharm in Germany (the 4th largest generic company locally), Ranbaxy's acquisition of RPG Aventis in France (amongst the top five generic companies) and Terapia in Romania, and Matrix Laboratories acquisition of DocPharma in Belgium (the second largest generic company locally) (Krishnan, 2006a, p. 48). The experience of group 1 companies has been that while the entry barriers to regulated markets for the supply of generics are very high, the monetary returns and the ease of business that follows entry into these markets are both higher than in the semi-regulated and unregulated markets worldwide. These added profits earned by the sale of generic products in regulated markets allow group 1 firms to increase their R&D spending locally.

Group 2 companies have an annual turnover between 100-300 crore rupees and have much more limited investment capabilities to indulge in R&D. They are either pure generic suppliers, or are shifting to product development categories that involve specializations. Companies in group 2 are trying to establish themselves as niche players in contract research and manufacturing by choosing specific areas where they can be competitive. Some of these companies that are quite high up in the profitability chain presently are also planning to expand their activities and gradually move into regulated markets following the example of group 1 companies, thereby climbing up the industry value chain.

The activities of both group 1 and 2 companies show that R&D efforts and process and product innovation are not isolated phenomena in the Indian pharmaceutical sector as projected by many scholars, but well inter-linked. Adaptive and incremental innovation

[15] See Srinivas (2004) in this context, who notes similarly that the emphasis of even the very big firms such as Ranbaxy, Cipla, Cadila was mainly on antibiotics production until recently.

activities are non-trivial activities. Reverse engineering, for instance, presupposes a deep understanding of the processes and products in the pharmaceutical industry. As Kline and Rosenberg (1986) observe, quite often *design* is the initiating point of innovation. What Indian firms have been doing falls clearly in this domain. They further note that innovation has three major aspects to it: (a) innovation is not a linear process but one involving many interactions and feedbacks in knowledge creation; (b) innovation is a learning process that involves several inputs at the same time; and lastly, (c) on-going innovation processes can be initiating factors to invention processes that involve formal R&D (Kline and Rosenberg, 1986). This observation too fully applies to the pattern of expanding R&D activities of Indian firms. Despite the emphasis on generic filings in regulated markets to secure higher revenues and the edge in process development, focus on original product development activities is gradually increasing within the sector. Several large companies are very good examples of this, but there are also other medium-sized companies that are moving into niche operations for exports mainly, which help emphasize this transition in the Indian pharmaceutical sector. Their strengths in process development and manufacturing are helping to adopt a combination of cooperative and competitive strategies, in order to adapt and as well as capitalize on opportunities created by the new TRIPS-compliant patent regime.

Group 3 companies, contrary to popular misconceptions; are mainly threatened by the standards on minimum GMPs introduced under the new Schedule M of the Drugs and Cosmetics Act. This will be the main reason, and not product patent protection, that will force unviable units to close down in this group subjecting it to maximum consolidation in the next decade. Although many of the group 3 firms are also strategically aiming to benefit from contract manufacturing, either for larger Indian firms or even for foreign firms post-2005, only those who can upgrade their plants to at least the GMP standards contained in the Schedule M of the Drugs and Cosmetics Act will tend to benefit. Even such a generalization has to be made with a note of caution, since the standards contained in Schedule M of the Indian Drugs and Cosmetics Act are much below the WHO standards on GMPs. In this context, it remains unclear as to whether group 3 companies that do upgrade their facilities to the standards specified under Schedule M

can indeed target contracts for manufacturing from MNCs/ firms operating outside India. In order to be able to manufacture for foreign partners from regulated markets, standards of foreign inspectors such as USFDA will need to be met by group 3 firms, which are much more stringent than both the Indian and WHO standards on GMPs. It therefore seems more likely that most such companies which do adhere to GMP standards as specified by Schedule M will perform contract manufacturing for group 2 companies in India who are looking at filling in the demand for generics in the unregulated and semi-regulated markets or foreign partners directly from the unregulated and semi-regulated markets. Alternatively, group 3 companies that comply with Schedule M will also supply to companies that are targeting the domestic Indian market.

Tables 1 and 2 below have a list of emerging strategies amongst firms in the three groups. As the tables go on to show, the 'innovative' firms in group 1 are using the revenues they derive from the sale of generics in regulated markets to move higher up into the R&D chain. Group 1 companies in India are therefore choosing a mix of cooperative and competitive strategies to deal with challenges and opportunities post-2005.[16] Although Indian companies acknowledge that producing the next blockbuster new chemical entity (NCE) is still some way off for them, their competitive and collaborative strategies are centered around increasing internal technological competitiveness and securing higher revenues from more sales in regulated markets (by tapping the marketing networks of the non-Indian partners) to invest higher amounts into innovative R&D. Their R&D strategies include the development of non-infringing processes, biopharmaceutical research and drug discovery and development, either in-house through analogue research strategies (research that focuses on finding new drugs within a family of molecules where useful drugs have already been discovered) or by offering drug discovery services. Out-licensing strategies (identifying a number of new compounds that are likely to work, takes them until the pre-clinical stages and then

[16] This is mainly applicable to the Indian firms in Group 1. The subsidiaries of MNCs that belong to this group are also planning to expand operations or entering into collaborative arrangements, but are waiting to see progress under the Indian Patent (Amendments) Act, 2005.

strikes a deal for clinicals with a MNC) are also becoming common. On the generics front, they continue to venture deeper into specialty generics[17] and novel drug delivery systems (NDDS)[18] and production of biogenerics in order to increase their revenues from regulated markets (Interviews; IBEF and Ernst and Young, 2004a, p. 11; see Table 2 below). Their marketing strategies are geared towards using their marketing prowess to market newer drugs in the Indian markets (co-marketing alliances with MNCs), and mergers and acquisitions in foreign markets to tap into a greater share of the market in the EU and USA.

The firms in group 2 qualify to be called niche-operators because they are slowly moving into areas of clear specialization in the drug discovery and development value chain. There is an enormous emphasis being laid upon specialized contract research the areas of clinical research, drug discovery, non-infringing process development and the manufacturing of biogenerics. Several group 2 companies specialize in developing non-infringing processes for drugs. Apart from Strides Acrolab India, another group 2 firm that has been a huge success and has even moved into group 1 in a really short span of six years is Matrix Laboratories.[19] Avaant Pharmaceuticals' main focus is to secure drug development licenses for compounds that were discovered by global pharmaceutical firms, but subsequently ignored either due to research difficulties, change in R&D focus or management changes in the company. Avaant presently has licenses for drug development from several big companies, like Bayer (Krishnan, 2006c). Several other group 1 companies are themselves setting up niche R&D centres as standalone organizations, such as the new R&D centre set up by Sun Pharmaceuticals, called Sun Pharma Advanced Research Company (Krishnan, 2006b). There are others who are seeking to specialize in generics business, focusing their attention on the business opportunities created by the shift of group 1 firms into regulated markets and innovative drug research. Several group 2 firms are actively supplying off-patent

17 Speciality generics are generics of reformulated older molecules, but made using new drug delivery technologies.

18 Specialty generics are generics of reformulated older molecules, but made using new drug delivery technologies.

19 Matrix Laboratories, a firm specializing in developing non-infringing processes, is now ranked as the 13th best pharma company in India (Business World India top 500 Rankings, 3 April 2006). The firm has moved on from being a group 2 company into a group 1 company in a short span of six years.

generics to the semi-regulated and unregulated markets, by setting up manufacturing plants outside India or strengthening supplier partnerships. Ajantha Pharmaceuticals is a good example: apart from having a big presence in Russia, it has set up a manufacturing plant in Ukraine and is seeking gradual entry into regulated markets.

In contrast to such accounts, group 3 firms are not exactly making headlines, since their activities are basically geared towards surviving by upgrading their manufacturing facilities, and continuing to manufacture to either supply to big manufacturers within India, or directly export to unregulated markets in Africa. Most of these firms are struggling to cope with changes to *status quo*, although learning continues in those who manage to upgrade their production activities, hence qualifying to be called 'manufacturers'.

Table 1: Emerging firm strategies: a categorization[20]

Firm group	Drivers	Emerging R&D Strategies	Positive effects of the transition
Group 1 *Innovators*	• Entry and establishment in regulated markets • Higher gains from sale of products in regulated markets • Pressure to strengthen product portfolios to be able to compete internationally	• Greater investment into innovative R&D using revenues earned by product sales in regulated markets • Increase science-based in-house infrastructure, with highly qualified staff • Greater innovation in generics; new products and processes.	• Intellectual property rights. • Collaborative arrangements with foreign firms for R&D as potential technology sourcing and learning opportunities. • Boost to already strong local/ regional marketing networks through co-marketing alliances with foreign firms.
Group 2 *Niche operators*	• Increased sales in semi-regulated and unregulated markets due to the shift in focus of group 1 companies to regulated markets • Pressure to strengthen competitive advantages, to make use of opportunities such as CRAM in the new environment	• Active supply of off-patent generics to the semi-regulated and unregulated markets • Focus on establishing themselves as niche players for contract research by choosing specific areas that give them competitive advantage: e.g., clinical research. • Moving up the industry's value chain gradually.	• Intellectual property rights • Contract R&D and collaborative arrangements with foreign firms for R&D as potential technology sourcing and learning opportunities. • Opportunities to occupy the semi-regulated and unregulated markets, and also follow group 1 firms into regulated markets
Group 3 *Manufacturers*	• Survival in the light of Schedule M of the Drugs and Cosmetics Act and India's full fledged TRIPS compliance	• Upgrading facilities to Schedule M standards in order to continue manufacturing for group 1 and 2 companies.	• Move up the industry's value chain through upgrading production technology.

Source: WHO-INTECH survey conducted by author, 2005

[20] Sridharan (2005) presents a similar categorization of the industry split into three main groups: the innovator, the collaborator and the endangered.

Table 2: Collaborative and Competitive Strategies of Group 1 Firms
Competitive strategy: Indian generics in regulated markets A favoured strategy of top Indian generic companies has been to challenge patents on blockbuster drugs in the US market, and get a 180 days Exclusive marketing right (EMR) to launch their generics by filing early. According to US laws, the generic company that wins such a challenge can hold a 180 day EMR, if it was the first-to-file for marketing approval. Dr. Reddy's early win of the 180 day exclusivity of Prozac when it went off patent in the US market set this trend. But not only have Indian generic companies not won a single EMR since then, cut throat generic competition and the strategy of granting 'authorized' generics by US companies have meant a series of losses for firms like Ranbaxy and Dr. Reddy's in recent times. Dr. Reddy's challenge of Eli Lilly's Zyprexa (a $ 2.6 million drug that went off patent) in 2004 and Ranbaxy's challenge of the Pfizer drug Lipitor (a $8 billion drug that went off patent) in 2005 failed, in addition to which prices of drugs like ciprofloxacin that both companies introduced in the US market crashed to 80% within weeks due to the presence of too many generic companies. Only recently, Ranbaxy has again won another EMR for a 80 mg generic dosage of the statin Zocor (a Merck patent, with sales of $ 4.3 million) and Ranbaxy is awaiting its EMR for the 80 mg dosage of Pravastatin. Yet, the new strategy seems to be to combine securing EMRs which bring in huge profits, with launching generics even when there is no EMR. This may mean that profits per generic launched are lesser since Indian firms will be competing with several others in the US market supplying similar generic versions, but can still be a huge grosser since there are about 40 drugs going off patent between 2006 and 2008 (with a total worth of US$ 50 billion). Firms are also trying to secure licenses as "authorized" generic producers for US companies, instead of constantly competing with other generic companies that get "authorized" to produce the drug from the original patent holder company. They are also exploring partnerships to jointly contest and introduce generics with other top generic companies, such as Teva. Ranbaxy and Teva recently launched the drug Quinapril jointly, based on a successful EMR that Ranbaxy contested and won in the USA.
Collaborative strategy: out-licensing research Another commonly used strategy is to identify a number of new compounds that are likely to work, work on them until the pre-clinical stages and then license them out to foreign firms for clinical trials. Several molecules have been out-licensed by Indian firms for clinical trials presently. ***Ranbaxy*** has identified 11 compounds in the categories of infectious respiratory, urinary disease, and diabetes categories, of which 2 are presently in Phase 1 trials. ***Dr. Reddy's*** Labs has identified 37 promising compounds in cardio vascular, diabetes and cancer categories of which 9 are in Phase 1 and 2 trails. Similarly, Wockhardt has two compounds in clinical trails which are in the flouroquinolines category, but are believed to be antibiotics that work in the new drug-resistant categories of infections.
Collaborative strategy: Discovery services out-sourcing The term refers to services that support drug discovery and help test efficacy of a potent molecule. Recently, GVK Biosciences and Wyeth USA have entered into a contractual agreement whereby GVK Biosciences will set up a R&D centre on its campus in Hyderabad and hire 150 scientists exclusively before the end of 2007 to work on drug discovery projects for Wyeth.

Similarly, Jubilant Organosys and Eli Lilly have a contractual arrangement on which 100 scientists within Jubilant will work solely for Eli Lilly's drug discovery programmes.

Source: Krishnan, 2004; 2006a, p. 46-48; 2006b; 2006d

Data gathered in the survey corroborated this categorization of innovative activities and R&D spending. Although the percentage of annual sales turnover that is spent on R&D by all three groups is quite low (less than 10%), it has increased notably since 2000 (see Table 3). Group 1 firms that were surveyed spent 8.09% of their annual sales on R&D in 2004, as compared to 5.15% in group 2 and 7.74% in group 3. Whereas the amount indicated by groups 1 and 2 clearly represent their respective activities, the figure for group 3 needs to be clarified. The amount is indicative of the investments that group 3 firms are making on upgrading their manufacturing facilities and enhancing their process technologies.

Table 3: Group-wise R&D and exports

Variable	Group 1 Mean	Group 2 Mean	Group 3 Mean
R&D intensity in 2000	3.4 (0.042)*	1.3 (0.041)	5.3 (0.072)
R&D intensity in 2001	4.4 (0.063)	2.8 (0.067)	6.5 (0.095)
R&D intensity in 2002	6.7 (0.066)	4.2 (0.076)	7.4 (0.100)
R&D intensity in 2003	7.3 (0.064)	4.6 (0.080)	7.8 (0.104)
R&D intensity in 2004	8.1 (0.073)	5.2 (0.090)	7.7 (0.088)
Non R&D performers	12.9 (0.341)	34.6 (0.485)	26.1 (0.444)
Exporting firms	83.9 (0.374)	73.1 (0.452)	56.5 (0.501)
N	31	26	46

*Standard deviation

R&D Intensity = percentage of total sales spent as R&D

Source: WHO-INTECH Study conducted by author

4. The role of policy interventions in sectoral performance: major challenges

Much more than just R&D investments go into making an innovative firm. But since the emphatic focus of policy changes was on encouraging the local production of drugs at affordable prices and not on building an innovative sector until the 1980s, policy action has resulted in a strange assemblage of strengths, and significant differences in technological capabilities of firms in the sector. These strengths are reflected in the way

the sector has been able to thrive beyond mere production of generics into innovative territories, expand and tap into modern technologies like health biotechnology. These strengths, albeit promising, are challenged by the many shortcomings that the innovation system presently suffers from. Clearly, the first phase of policy changes were the ones that had a definite impact in shaping the nature of pharmaceutical activity and sectoral growth. Their impact was pervasive; even today the main strengths of firms belonging to all three groups are in anti-infectives, including companies like Ranbaxy, Cipla, Dr. Reddy's, although group 1 companies have diversified into other segments (Srinivas, 2004, p. 51). Although the other two phases of policy changes also have been important for the sector, they were not as well-coordinated and dynamic, and their impact was not as profound as the first set of changes. The successes of Group 1 and 2 firms today are not attributable to a well-coordinated innovation policy for the sector, but rather, stimuli to innovation activities have come from several factors acting in tandem. The government's continued support in the form of investments into good quality higher education in relevant disciplines, and very sophisticated scientific infrastructure to carry out pharmaceutical research has played a large role in the way the sector has been able to thrive. India's liberalization has paved the way for lower governmental interference on export and imports, foreign exchange issues, apart from guaranteeing market based institutions. These have helped the growth of venture capital and external finance institutions and enabled firms sharpen up market-based, entrepreneurial skills, all of which group 1 and 2 firms are using to their advantage.

The biggest failing of the policy process has been the neglect of the dynamic evolution of the sector and its activities from a production-based sector to an innovation-based one. This is reflected in the failure of policies to target enhanced systemic coordination and collaboration. When this reality is juxtaposed against emerging strategies of firms, three points stand out. Firstly, the wide range of strategies that Indian firms are choosing in order to gain and compete in the new environment unanimously underpin the importance of systemic factors, such as collaboration, intellectual property protection, skilled manpower and venture capital to facilitate the scale up from a "static" firm to a "surviving" or "self-generating" firm to an "innovative" firm. Group 1 firms who are innovating in the present environment could perhaps perform better if these elements

were present, but more importantly, the systemic factors discussed here will definitely affect how many firms in groups 2 and 3 make the transition to innovative activities. Finally, accounts of how the Indian pharmaceutical sector is thriving have a tendency to flaunt just the few success cases and ignore the large majority of firms in group 3 which are adrift with challenges of surviving in the present environment. In this section, both descriptive statistics and econometric analysis based on the empirical data have been discussed to substantiate these points.

4.1. Factors promoting new product/ process innovations

Table 4 below contains the responses of firms in each group towards various policies and how important they are for promoting innovation. The figures presented represent the mean in an interval between 0 and 1, where 0 is unimportant and 1 is extremely important. Therefore, any response above 0.5 indicates that the particular set of policies is important to promote innovation.

Table 4: Contribution of factors in promoting new product/ process innovation

Variable	Cluster 1 Mean	Cluster 2 Mean	Cluster 3 Mean
Innovation incentives by the government	0.387 (0.495)*	0.462 (0.508)	0.304 (0.465)
Skilled manpower	0.935 (0.250)	0.923 (0.272)	0.891 (0.315)
R&D collaboration with universities	0.613 (0.495)	0.423 (0.504)	0.630 (0.488)
R&D collaboration with PRIs	0.581 (0.502)	0.385 (0.496)	0.522 (0.505)
IPR protection	0.839 (0.374)	0.577 (0.504)	0.739 (0.444)
Quality of infrastructure	0.903 (0.301)	0.962 (0.196)	0.739 (0.444)
Venture capital availability	0.839 (0.374)	0.808 (0.402)	0.630 (0.488)
Local SMI participation	0.645 (0.486)	0.385 (0.496)	0.435 (0.501)
Govt. firm tech. transfer	0.548 (0.506)	0.345 (0.485)	0.370 (0.488)
Transfer of personnel	0.839 (0.374)	0.423 (0.504)	0.500 (0.506)
Other policies	0.000 (0.000)	0.038 (0.196)	0.000 (0.000)
Govt subsidies 2000-2005	0.258 (0.445)	0.269 (0.452)	0.130 (0.341)
N	31	26	46

*Standard deviation
Source: WHO-INTECH survey conducted by author

The responses in the table show that whereas government incentives are not considered important by firms belonging to all groups, skilled personnel, IPR protection, quality of infrastructure, venture capital availability, and mobility of labour between firms, universities and research institutes were ranked to be very important factors in promoting both product and process innovation.

4.1.1. Intellectual property protection and innovative capabilities

All the firms surveyed rated intellectual property as an important factor affecting process and product innovations. It was thought to be very important by firms belonging to group 1 (0.839) and group 3 (0.739), and as being moderately important by group 2 firms (0.577) (see Table 4). Patenting activities have clearly been on the rise in India, accompanied by a growing realization that it is a primary factor in leveraging global competition to their advantage. Almost all group 1 and some group 2 firms are keen to secure intellectual property protection on their innovative efforts, wherever possible. Several models of intellectual property protection seem to be emerging, depending on the kind of innovation services being offered. Some firms, like Matrix Laboratories and Cipla are pursing defensive patenting strategies (See Gehl Sampath, 2005a). Matrix's main research focus is on developing non-infringing propriety processes for the production of APIs, in order to establish its position as a global supplier of APIs to major generic companies in regulated markets. Their intellectual property strategy is to acquire (ring fence) mostly all proprietary technologies that are needed for their alternate processes. Other firms that are branching out into product development like Biocon, are keenly looking at joint intellectual property ownership on such products with the company that originally discovers the successful compound (Hari, 2006a). For several specialized Indian firms, their value is increasingly getting associated with the value of the intellectual property they own. For example, intellectual property assets are key to Avaant Pharmaceuticals since it specializes in drug development using promising molecules from other firms (Krishnan, 2006c). Group 1 and 2 firms also fear that intellectual property protection will adversely affect their ability to access new technologies (Gehl Sampath, 2005b).

Group 3 firms view intellectual property rights as equally important, but from a completely different perspective. For this group of firms, intellectual property and India's TRIPS compliance is synonymous with severe losses due to escalating industry standards for manufacturing (GMPs). Several group 3 firms are also very vary of changes in industrial organization of the sector, owing to the entry of foreign firms, and fear negative impacts. There is also a tendency amongst group 3 firms to wrongly view the possibility of securing compulsory licensing for producing patent protected drugs as a venue of profit-making, since group 1 and 2 firms will now no longer be able to produce generic versions of patent-protected drugs freely (see Gehl Sampath, 2006).

4.1.2. Infrastructure, skilled manpower and venture capital availability

Firms also rate the quality of infrastructure, venture capital availability and availability of skilled manpower as very important factors that affect both process and product innovations. Venture capital climate in India is generally good, and is helping firms come up with innovative ways of adding value to pharmaceutical innovation (Economist, May 2006). Indian venture capital firms, although cautious, are supporting several novel ventures. Initiatives that could be considered risky such as Connexios (India's first pure drug discovery company) and Health Care Global (a joint venture between a network of cancer care centres and a pharma biotech company specializing in cancer cure (Triesta Sciences)) have been funded in India (Hari, 2005; 2006b). Data collected also reveals that group 2 companies are most dependent on venture capital and equity markets whereas group 1 tends to also rely on more traditional sources such as banks and family funds. This is because some of the large group 1 companies are family-run enterprises (Dr. Reddy's for example).

Companies in all three groups acceded to the benefits of infrastructure, scientific and general, there was a clear consensus that the government policies of setting up technology parks, public research institutes and investing in education have all been extremely useful for the sector. Group 1 and 2 firms that were interviewed also admitted

to having had a lot of success in attracting talented Indian diaspora to work in their companies especially onto their R&D teams (interviews). But there seems to be a need to revise/ restructure course outlines or even introduce completely new courses to meet industry needs for skilled manpower (field interviews with group 1 and 2). For example, most Indian universities do not offer clinical research as a course in Chemistry and Pharmacology, as is the case in countries like the USA and UK (Krishnan and Kamath, 2005). There were only three institutes offering clinical research training in India as of 2005, and none of these had been certified by a governmental body (ibid.). As a result, companies venturing into newer areas of research compete intensely for skilled personnel, and in most cases, organizations involved in areas like clinical research end up having to train research associated themselves (ibid.)

4.2. Collaborative linkages and innovative capabilities

The vertically integrated, in-house research oriented, pharmaceutical firm is now passé: no company has all the competencies required for a vertically integrated drug discovery and development program employing new technologies. Not only does this hold for India too, but also each one of the strategic option for innovative R&D lay a definite emphasis on enhanced collaborations with other organizations, each contributing through specialization. India is still lagging behind on several strengths required for drug discovery and biopharmaceutical research. Recent experiences of firms show how expanding from a chemistry base into newer areas can prove formidable. For example, firms are gradually discovering that only having trained chemists is not sufficient, developing excellence in clinical research requires personnel who have a thorough knowledge of good clinical practices, and are conversant in complex chemical synthesis (Krishnan and Kamath, 2005).

But despite its obvious public health emphasis, India has for a long time not been able to promote very effective collaborative linkages between the different components in pharmaceutical innovation. Feedback of local demands for products into the research system is quite low, and this is getting more acute with time since firms tend to devise

export strategies more in keeping with export demands (Gehl Sampath, 2005a). University and public research institutes lack incentives to commercially orient their research. The old time practice of sourcing useful technologies for the private sector through the public research institutes has forged good linkages between PRIs and firms, which continue well into the present.

Table 5 below contains a group-wise collaboration intensity index of the firms that were surveyed. The figure presented represents the mean in an interval between 0 and 1, where 0 is no collaboration and 1 is high level of collaboration. Therefore, any response above 0.5 indicates that collaboration is moderately important. As the table shows, firms in all three groups ranked collaboration intensity as low with all systemic actors (there is no rating above 0.5).

Table 5: Collaboration intensities of firms

Variable	Group 1 Mean	Group 2 Mean	Group 3 Mean
Coll. with PRIs	0.323 (0.475)*	0.308 (0.471)	0.174 (0.383)
Coll. with Industrial associations	0.452 (0.506)	0.308 (0.471)	0.348 (0.482)
Coll. with universities	0.355 (0.486)	0.308 (0.471)	0.174 (0.383)
Coll. with private labs	0.484 (0.508)	0.231 (0.430)	0.261 (0.444)
Coll. with others	0.097 (0.301)	0.038 (0.196)	0.043 (0.206)
Local collaboration	0.548 (0.506)	0.423 (0.504)	0.370 (0.488)
Local extram. R&D	0.161 (0.374)	0.115 (0.326)	0.130 (0.341)
Foreign Extram. R&D	0.226 (0.425)	0.077 (0.272)	0.043 (0.206)
N	31	26	46

* : standard deviation

Source: WHO-INTECH survey conducted by author

The two-limit tobit estimates for collaboration of firms are reported in Table 6 below.

Table 6: Two-limit tobit estimates: collaboration variables

Variable	coefficient	(Std Err.)
	Productivity growth	
Coll. with PRIs in cluster 1	0.495*	(0.243)
Coll. with PRIs in cluster 2	-0.269	(0.224)
Coll. with PRIs in cluster 3	0.042	(0.121)
Coll. with Indus. Ass in cluster 1	0.019	(0.120)
Coll. with Indus. Ass in cluster 2	0.558*	(0.275)
Coll. with Indus. Ass in cluster 3	-0.050	(0.119)
Coll. with Universities in cluster 1	-0.373*	(0.168)
Coll. with Universities in cluster 2	0.052	(0.134)
Coll. with Universities in cluster 3	-0.013	(0.104)
Coll. with Private labs in cluster 1	-0.248	(0.175)
Coll. with Private labs in cluster 2	-0.386*	(0.185)
Coll. with Private labs in cluster 3	-0.046	(0.086)
Local collaboration in cluster 1	-0.256*	(0.102)
Local collaboration in cluster 2	-0.317†	(0.189)
Local collaboration in cluster 3	-0.041	(0.072)
Intercept	0.156**	(0.031)
	Standard deviation of the error term	
	0.186**	(0.023)
N		103
Log-likelihood		-28.598
$X^2(21)$		36.813

Significance levels: † : 10% * : 5% ** : 1%

Source: WHO-INTECH survey conducted by author

The econometric results show that collaboration with PRIs is positive and significant at 5% for group 1 firms, whereas collaboration with universities is negatively significant at 5%. Most firms admitted to having useful collaborations with PRIs as opposed to universities, although several firms that were interviewed admitted to having no local collaborations at all even with the public research institutes, due to the difficulties they face in speedy and efficient performance. Matrix Laboratories, for example, commended the facilities at the Indian Institute for Chemical Technologies (IICT) for sample analysis, but expressed the problems in working with them given the laxity of service and lack ofa market-oriented approach. Since IICT takes a week to analyze samples, firms like Matrix Labs feel that such long delays reduce their competitiveness (interviews).

This sentiment echoed through most interviews, where firms expressed their desire to interact better with PRIs due to their high level of infrastructure and research personnel, but admitted the difficulties in doing so because PRIs lacked the incentives for speedy performance. Factors that hinder effective collaborations with public sector institutions include a lack of incentives amongst researchers to engage in collaborative research with the private sector and bureaucratic rigidities constrain the exploration of newer ideas and techniques in public sector institutions, especially universities. These are exacerbated by micro-level factors such as intellectual isolation of researchers and lack of incentives for collaborative research at the individual level, such as low salaries, bureaucratic hassles that restrict career opportunities, inadequate research budgets, and lack of on-job training possibilities. Furthermore, the survey also showed that most collaboration between firms and PRIs was in the area of research, as opposed to product development, possibly for the same reason. The survey showed that 55% of firms in group 1 have a local collaborator focusing 42% in research activities and 22.6% in product development. And 23% of firms in this group have a R&D contract with institutions or individuals outside India. In group 2, 42% of firms in group 2 have a local collaborator focusing 23% in research and 23% in product development. And, 37% of firms in group 3 have a local collaborator focusing 26% of their efforts in research and 10% on product development.

Universities fare much worse than PRIs due to a dearth of high quality R&D in university departments, partly due to bureaucratic and financial constraints (CII, 1999, p. 20) apart from the fact that several courses offered may need a higher industry orientation (field interviews).[21] But recently, a serious effort is being made to create linkages between university and public research institutes and the private sector (Sotarauta and Srinivas, 2005). The econometric results also show that on the whole, the local collaborations in group 1 were negative and significant at 5%, whereas local collaborations for group 2 are negative and significant at 10%.

[21] Research institutes fare much better than universities on the question of finances and human capital for conducting pharmaceutical research. Several of these public research institutes are also very active partners in international public-private partnerships, such as the Malaria Alliance with Ranbaxy.

Both formal and informal institutions affect the tendency to collaborate within systems. Formal institutions include rules that govern incentives for the production of skilled manpower, scientific infrastructure, venture capital provision and intellectual property, among others. Informal institutions are the customs and practices (unwritten codes of conduct) that govern both research-based and societal interactions. These social processes influence the way both formal institutions and organizations function and deliver results in far-reaching ways.

The analysis sought to establish how different mediating variables affect both local and foreign collaborations. A probit model was estimated, for which the intensity of collaboration was taken to be 1 if collaboration with the corresponding agent was weighted by the firm as 3, 4 or 5 by firms (fairly strong, strong or very strong); and zero otherwise. Foreign R&D was taken to be 1 if the firm admitted to having overseas collaboration and zero otherwise. Local R&D was defined similarly. The results of the econometric regression are presented in Table 7. The explanatory variables in the below presented table are jointly significant at 0.1% level of confidence with Wald chi-square (12) = 39.78 and p-value = 0.0001.

Table 7: Probit Estimates: the effects on local collaboration

Variable	Coefficient	Std. Error
Government innovation incentive	-0.237	-0.365
Skilled manpower	-1.311*	0.632
R&D collaboration with universities	0.093	0.385
R&D collaboration with institutes	0.073	0.376
IP protection	1.192***	0.422
Quality of infrastructure	-0.973*	0.448
Venture capital availability	-0.798*	0.359
Local SMI participation	-0.819*	0.398
Government-firm technological transfer	0.897*	0.381
Transfers of personnel	0.447	0.378
Small firms in 2004	-0.943*	0.399
Medium firms in 2004	-0.496	0.359
Intercept	1.624*	0.731
N	102	
Log-likelihood	-49.846	
chi-square (12)	39.783	

Significance levels: *10%, ** 5% and *** 1%

Source: WHO-INTECH survey conducted by author

The results of the model suggest the following. Skilled manpower, quality of infrastructure and venture capital availability are all negative and significantly (10%) associated with the probability of establishing local collaboration. All these three factors are critical in the build up towards innovative activities of firms in the sector, and in the absence of all the three factors, firms do not have an incentive to collaborate. This is also clearly supported by some other results of the model. The model shows that small and medium firms collaborate significantly less than larger counterparts. In Table 7, local SMI participation is negative and significantly (10%) associated with the probability of establishing local collaboration. Being a small firm in 2004 is negatively and significantly (10%) associated with the probability of establishing local collaboration.

The results show that intellectual property protection is positive and significantly (1%) associated with the probability of establishing local collaboration. All three groups of firms have tended to regard the others as rivals historically, owing to the fact that they competed for a share of the Indian market based on brand name rivalry. All products being manufactured were generics, and brand competition determined market shares before India's TRIPS compliance. Intellectual property protection, clearly associated with innovative R&D in groups 1 and 2, is a factor prompting their strategic realignment towards each other to form collaborative ventures. Government-firm technological transfer is positive and significantly (10%) associated with the probability of establishing local collaboration: firms tend to collaborate more when induced to do so through governmental technology transfer programmes.

5. Conclusion

The Indian pharmaceutical industry and its strengths have been conceptualized broadly from two perspectives: one analyses the potential of the sector to offer price-based competition to the global pharmaceutical industry, by producing cost-effective generic versions of patented drugs. The other seeks to explore how the Indian experience can be

replicated in other developing and least developed countries.[22] These perspectives stress upon the strengths of the Indian pharmaceutical sector to compete globally and help provide price competition in the generics sector to the multinational firms.

The analysis conducted in the paper has shown that firms in the Indian pharmaceutical sector vary considerably in their innovative capabilities. They fall into three groups which are called the innovators, the niche operators/ collaborators and the manufacturers. The analysis shows that these three groups have clearly different configurations of a large number of innovation-related factors, such as export potential, skilled manpower, annual sales and R&D investments, intellectual property rights as well as structural properties. Based on these differences, the clusters can be interpreted as specific "innovation modes", each mode being a step closer towards the innovative pharmaceutical firm. These differences also account for the varied challenges faced by each group after India's TRIPS compliance, the main strategies and their triggers. The emerging firm strategies, especially those of firms in groups 1 and 2 are geared towards achieving higher innovation capabilities, but rely extensively on systemic factors, such as skilled manpower, venture capital, intellectual property institutions and increased collaboration. The paper has used empirical data of firms in the sector to show that the lack of coherence in policy processes aimed at the sector, especially in the two important policy phases after 1980 have not created the right incentives for systemic innovation. Although these policy changes contained some very essential policy aspects required for the sector's growth and performance, there is a lack of a cohesive innovation policy for the pharmaceutical sector in India. The success stories of Group 1 firms that have managed to work well have come to be, because they have been able to capitalize and build further on the positive policy changes of the past four decades, reinforced by the market-based environment created by India's liberalization. This sea-change in policy was reiterated consistently in several interviews with group 1 and 2 firms. In response to what they would like the government to do to support innovation, most firms replied that it would be better that the government does not intervene in any way. To a large extent, the activities of the bigger firms in group 1 have largely been the result not of

[22] This is especially important now, given the new resolution that the WHO has taken on building capabilities.

cohesive innovation policy support, but of organizational incentives to compete, succeed and survive.

Several implications for policy reform flow from the analysis. Consistent with what is know about sectoral systems behavior everywhere, innovation processes of Indian firms are strongly shaped by their specific knowledge base, qualifications and skills, required organizations and institutions involved, as well as specific competitive challenges from a globalizing economy. But the vast differences amongst firms in the sector make the case for differentiated policy intervention in order to harness the potential of the sector as a whole, and not rest our laurels on a few success stories. The analysis conducted using empirical data in section 4 reveals the problems in the innovation system that will affect the ability of firms to transform and compete in the coming years. It shows that whereas some aspects of innovation policy work, many other critical ones do not. Particularly, a small firm has several intrinsic disadvantages. Small firms belonging to group 3 are either static firms (unable to cope with changes to their environment) or surviving firms (one which can adapt and question), using the classification of this paper. The analysis raises a very crucial question from a policy perspective: what could be the implications of technological lock-in into a low equilibrium market by group 3? Several group 3 firms work on very small budgets and are supported through governmental schemes that promote small and medium enterprises. Yet, in the absence of policy foresight, these can be the very policies that adversely affect their movement to group 2. Hence, policies that help their systemic integration, enhance their ability to collaborate with other innovative counterparts and also learn to move up the industry value chain are urgently needed. The thrust of such policies will necessarily be different from those required to support group 1 and 2 firms.

Group 1 and 2 firms, in order to capitalize on emerging market niches and to compete globally require policies that promote systemic innovation and enhance collaboration. This includes the entire range of institutions, from intellectual property to venture capital to skilled manpower provision. India's potential to offer a wide range of services in the pharmaceutical sector competitively will depend on its systemic efficiency. Group

2 firms venturing out into biogenerics need a higher level of skill set to run extensive recombinant biological manufacturing facilities (Kamath, 2005). Until recently, not even ten of the top 20 biopharmaceutical companies could manufacture recombinant biopharmaceutials locally (ibid.). India's emergence as a clinical research hub or a drug discovery player can also be halted by a similar list of factors: lack of proper regulatory environment (to offer data management facilities), lack of skilled labour and lack of organizational skills. Differentiated policy that targets at empowering each firm group to the best possible extent will help harness the potential of the sector as a whole.

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