Open Innovation Networks in Indian Pharmaceutical Sector

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Summary

The Indian pharmaceutical sector grew spectacularly in a process patent regime, which enabled to entrench itself in the global market with generics and cost effective manufacturing processes. The legislative environment in India for the pharmaceutical sector underwent changes in 2005 leading to product patent protection. The sector was ready to embark on a smooth journey to path breaking innovation, equipped with enhanced process capabilities as well as expertise gained in modular aspects of drug innovation. Is innovation taking place in a manner as would have been expected?

The aim of this paper is to understand how the changes in patent regime have influenced the scientific innovation networks, through the lens of national innovation system and open innovation. This study examines an important and unexplored facet of open innovation and the findings may have important implications for organizations to further their innovation agenda.

Track: Innovation

Word Count: 1967 words

Purpose of research

Over the past forty years, the Indian pharmaceutical sector has participated in the changes in regulatory regime, from a process patent environment in 1970 to a product patent environment in 2005. The implementation of Trade Related Intellectual Property Rights (TRIPS) agreement and the ensuing Patent Amendments Act in 2005, engendered new policy initiatives, increased funds for research and development (R&D) and efforts to boost state-industry-academic relationship. The question, how changes in the national environment influences formation of innovation networks in an Indian setting, remains an under-researched area. This, therefore, forms the primary objective. The interplay of various factors influencing interactions taking place between the key innovating factors forms the secondary objective. These objectives are pursued through the theoretical lens of national innovation system (Nelson Richard, 1993, Freeman, 1992, Lundvall, 1992) and open innovation (Chesbrough, 2003a, Chesbrough, 2003b), which underpin the concepts of science-industry interaction and open approaches in R&D.

Theoretical Background

National Innovation System Perspective

The literature on national innovation systems has evolved since the 1980s (Gregersen, 1992, Freeman, 1987, Lundvall, 1992, Mowery, 1992, Nelson Richard, 1993) and emphasized the role of innovation in influencing the growth and productivity of national output (Baumol, 2002, Tidd and Bessant, 2011, Schumpeter, 1934, Nelson and Rosenberg, 1993). This research focuses on two main strands of literature in NIS – a) selection environment and b) innovation networks - linkages formed between industry and science for innovation.

Selection Environment. Two important factors which play a determining role in shaping selection environment and influencing firm behaviour are: a) *market element* that focuses on commercial and profitability considerations b) *non-market element* which encompasses public agency, financing sources, policy issues, political constraints and regulatory issues (Nelson and Winter, 1977, Dosi, 1982, Utterback and Suárez, 1993). The interplay of both these factors has warranted intervention from policymakers in the form of financial support, education and training facilities, R&D institutions, infrastructure facilities, and regulations (Gregersen, 1992, Hall, 2002).

Innovation networks. A considerable body of research illustrates the different roles university, public research labs and firms play in the innovation ecosystem and their linkages for basic and applied research (Cockburn and Henderson, 1996). The role of public policy has been to coxswain linkages and mobilize competencies between public and private research sectors (OECD, 2002). The figure below depicts the mechanisms through which science industry interactions take place.

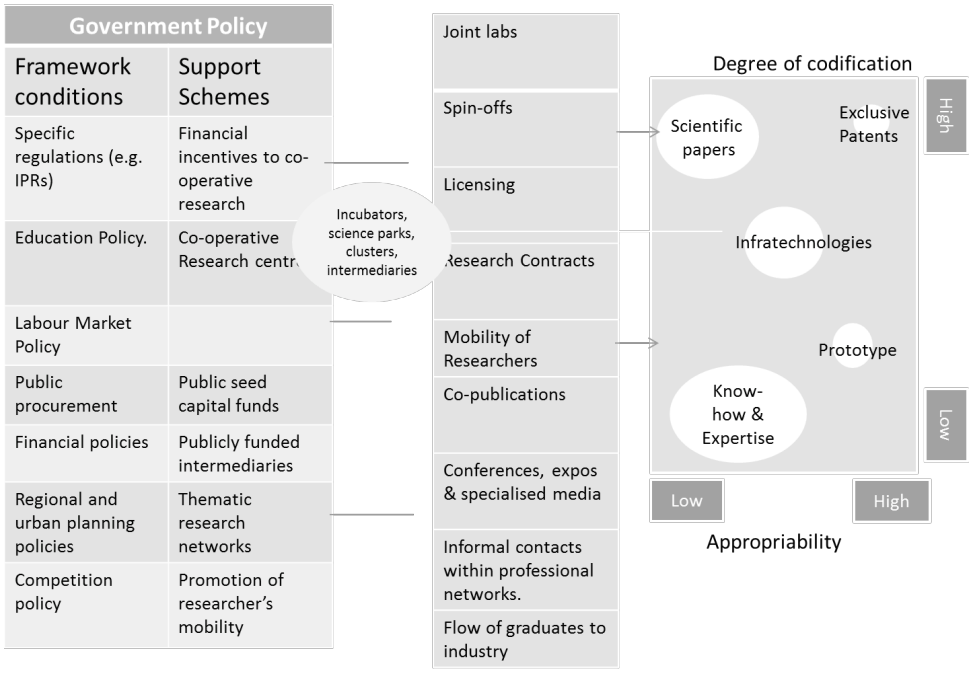

Figure 1 - Science Industry Interactions

Source: (OECD, 2002)

Open approaches in pharmaceutical innovation

The open innovation approach (Chesbrough, 2003b) rests on the underlying argument, that the traditional in-house R&D structure is losing ground (Chesbrough, 2003b, Chesbrough et al., 2006) and becoming modularized at each stage of drug discovery and development process (Sampath, 2008, London School of Economics and Political Science, 2005). Increasing costs, complexity and multidisciplinary nature of pharmaceutical innovation, compounded with drug failures, and patent expirations of blockbuster drugs have formed a basis for the emergence of innovation networks (Arora and Gambardella, 1990, Cockburn and Henderson, 1996, Hess and Rothaermel, 2011, Melese et al., 2009, Powell et al., 1996). A recent proposal of World Health Organization (WHO) to reformulate the patent based R&D model of pharmaceutical sector to a more open approach, by means of sharing funds, grants to developing countries, milestone based payments, and patent pool, signifies the need for more open innovation in this sector (Correa, 2012). Table 1 summarizes the dimensions of open innovation approach by various authors.

Table 1: Dimensions of open innovation approaches

Dimensions of open innovation approaches		Industry/Sector	Study
In-house R&D with outsourcing activities	Internationalization of R&D Outsourcing of R&D External commercialization of intellectual property	Companies with R&D Labs	(Gassmann, 2006, Chesbrough, 2003a, Chesbrough and Crowther, 2006)

	Pharmaceutical outsourcing to China and India Low risk partnering options for multinationals	Biotech Pharmaceuticals Fine chemicals	(Rosebush et al., 2012, Bhatt, 2007)
Collaborative Innovation mode	Firm-centric network with offshore outposts	Across range of R&D companies	(Jelinek et al., 2012)
	Bidirectional Information exchange Transfer of basic knowledge from public funded institutions to firms Extensive co-authoring between researchers of industry and public sector	Pharmaceutical firms	(Henderson and Cockburn, 1996)
	Innovation networks between academia and industry o One company-one investigator o One company-one university o One company supports a university consortium o One company supports a university institute o Industry consortium (pre- or non-competitive) o Competition o Venture capital investment o Fee-for-service	Biopharmaceutical innovation	(Melese et al., 2009).
	Industry wide, targeted, collaborative innovation efforts	Across range of R&D companies	(Jelinek et al., 2012)
	Academic patenting Licensing Technology transfer office	Medical technologies and drugs	(Sampat, 2010)
	Open approaches to R&D Pooled funds Grants to companies in developing countries Prizes for milestones and end products Patent pools	New drugs	(Correa, 2012)
Virtual Labs	Virtual, ad hoc networks of resources.	Drug R&D	(Jelinek et al., 2012)
	Network position and firm performance Alliances for resources learning	Biotechnology	(Koput and Powell, 2000)
	Public private partnerships for neglected diseases Modular approach to R&D	Neglected diseases	(London School of Economics and Political Science, 2005)
	Open Source Model in drug discovery	New drugs	(Årdal and Røttingen, 2012)

Pharmaceutical Innovation System in India

The evolution of the Indian pharmaceutical industry took place in a policy environment, which restricted FDI and encouraged process patent regime. This enabled the domestic firms to hone their capabilities of reverse engineering, learn and adapt technology, in a protected environment (Iyer, 2012, Feinberg and Majumdar, 2001). Post 2005, the change in patent regime caused the government to step up measures to support innovation (Department of Science and Technology, 2013). As noted in the classic works of (Arrow, 1962), a strong appropriability regime enables the ability to profit from innovation and acts as a major incentive for firms to conduct R&D. In the Indian pharmaceutical set up too, a change in patent regime coupled with policy measures, resulted in R&D investment by established firms (Chowdhary, 2010b, Gehl Sampath, 2006), setup of startups and university spin-off for new drug research.

Conceptual Framework

The conceptual framework is a congruence of two bodies of literature the national innovation system and open innovation and aims to study the open innovation networks formed between firms, public research institutes/universities for new drug research. The scope of the study is, new drug innovation in the Indian pharmaceutical industry.

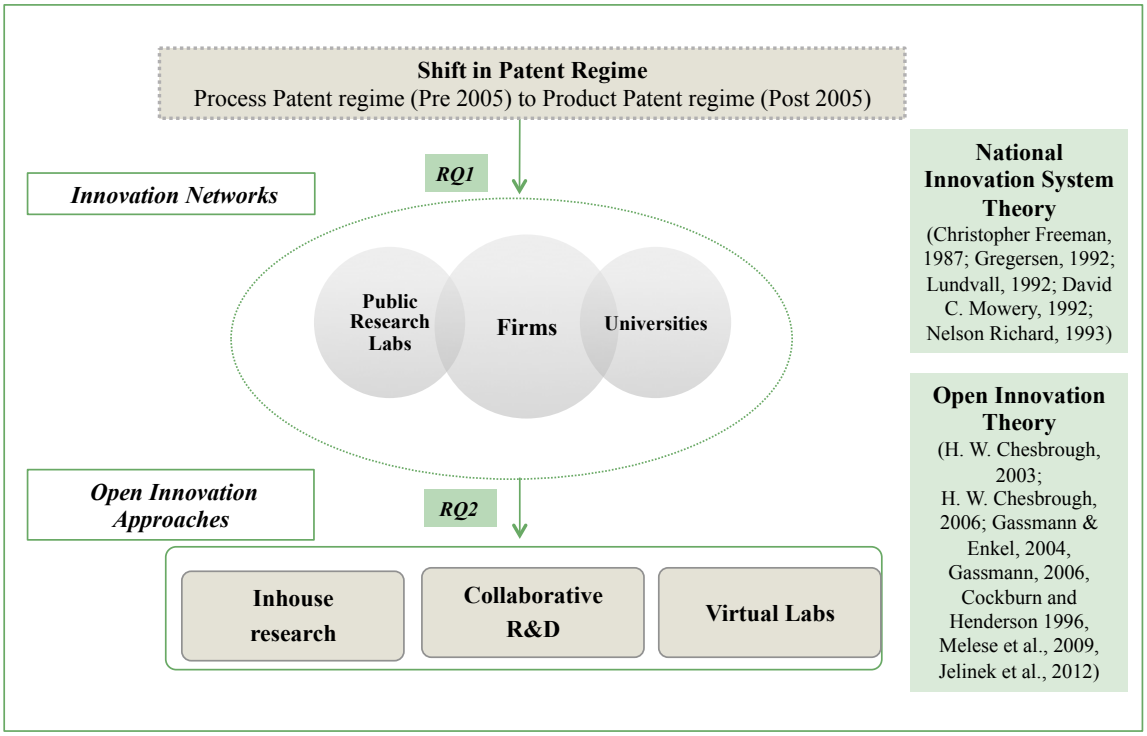

Figure 2: Conceptual Framework

The main research questions are:

RQ 1: How does the patent regime influence formation of innovation networks between innovating institutions?

RQ 2: What are the different open innovation approaches adopted by different innovating entities to undertake new drug research?

Methodological Considerations

The Indian pharmaceutical industry dealing with contemporary issues entails posing of 'what' is happening and 'how' or 'why' questions and this provides a rationale to pursue case study research than other methods (Gummesson, 2007). The research framework leads to qualitative case study-based research design and the primary data collection mode is semi-structured interviews based on purposive sampling (Bryman, 2011, Creswell, 2009, Mark Easterby Smith, 2008). Empirical evidence is drawn from 39 semi-structured interviews with senior management executives of pharmaceutical companies, academics, public research scientists and experienced

professionals. The cases of universities, public research labs and pharmaceutical companies are populated as a collective case study (Stake, 2005) for cross case analysis (Huberman and Miles, 2005).

Initial findings and discussions

Patent Regime and Innovation Networks

The Patents Act 1970, which abolished the product patent protection (Chowdhary, 2010a) enabled firms to reverse engineer drugs that were product patented in other countries (Chittoor et al., 2009). The initial success of these companies instilled confidence and they then diversified their business into generics, active pharmaceutical ingredients, biogenerics, biotechnology, contract manufacturing and research activities for preclinical and clinical research (Chowdhary, 2010a). Engagements with foreign companies for contract research work enabled India to gain expertise in modular stages of drug discovery research (Sampath, 2008).

While the Indian pharmaceutical companies were busy etching out their businesses, state funded Indian universities primarily continued as teaching institutes. Throughout this period, research activities and patenting at universities remained at ebb. Indian firms followed a closed in-house R&D program with minimal interaction with universities or pubic research labs. The disconnect between public and private organizations widened over a period of time until the TRIPS patent regime resurrected the innovation scene.

TRIPs regime: Plethora of opportunities

The patent regime brought with it other enabling changes such as increased budgetary allocations for research, IP awareness programs, and policies to link science with industry and other scientific community (Department of Science and Technology, 2013).

Universities: Ostensibly, funding has increased significantly for research grants and capacity building. Intellectual property departments have been established as part of the initiative in major Indian universities.

> *"We have been earlier very conservative when it came to dealing with IP but I suppose we have understood the need for creating and capturing value through formal intellectual property"- Managing Director, Innovation and Technology Transfer, University*

Public research labs: State funded research institutes were the biggest beneficiaries of the budgetary allocations in research. The Council for Scientific and Industrial Research (CSIR) have initiated an Open Source Drug Discovery (OSDD) research consortium, which has leveraged the virtual lab concept to encourage collaboration among Indian researchers (Årdal and Røttingen, 2012)

> *"Its an open source drug discovery platform funded by the government of India. We have currently more than 7,500 registered users in the OSDD website which shows that this initiative is much more than few individuals and few institutes"*– Project Director, OSDD

Firms: A host of policy initiatives such as university-corporate R&D spending, lab to industry conversion, soft loans, and indigenous innovation has proved beneficial for firms to stimulate research and development for new drugs.

> *"In terms of financial incentives, we have got new grants from the government to help us develop novel chemical entities; either we take them during the discovery, pre-clinical development or clinical development"* – Chief Scientific Officer, Pharmaceutical Firm

Collaborative scene in India

There is a general consensus among the interviewees about the need for forming teams of scientists with different expertise for more engaged new drug research. Pharmaceutical companies believe that research in universities is useful in the early stages of drug discovery as *"they can work on different strategies and look at different chemical pathways, which companies can cherry pick and pursue"* (Chief Scientific Officer, Pharmaceutical Firm). Although empirical research suggests that many collaborative deals have been inked, a notable pharmaceutical expert suggested that there *is "more fluff than wheat"* (*Author and CEO, iDDPartners USA).* The figure below summarizes the broad range of interactions between industry and science in the innovation system.

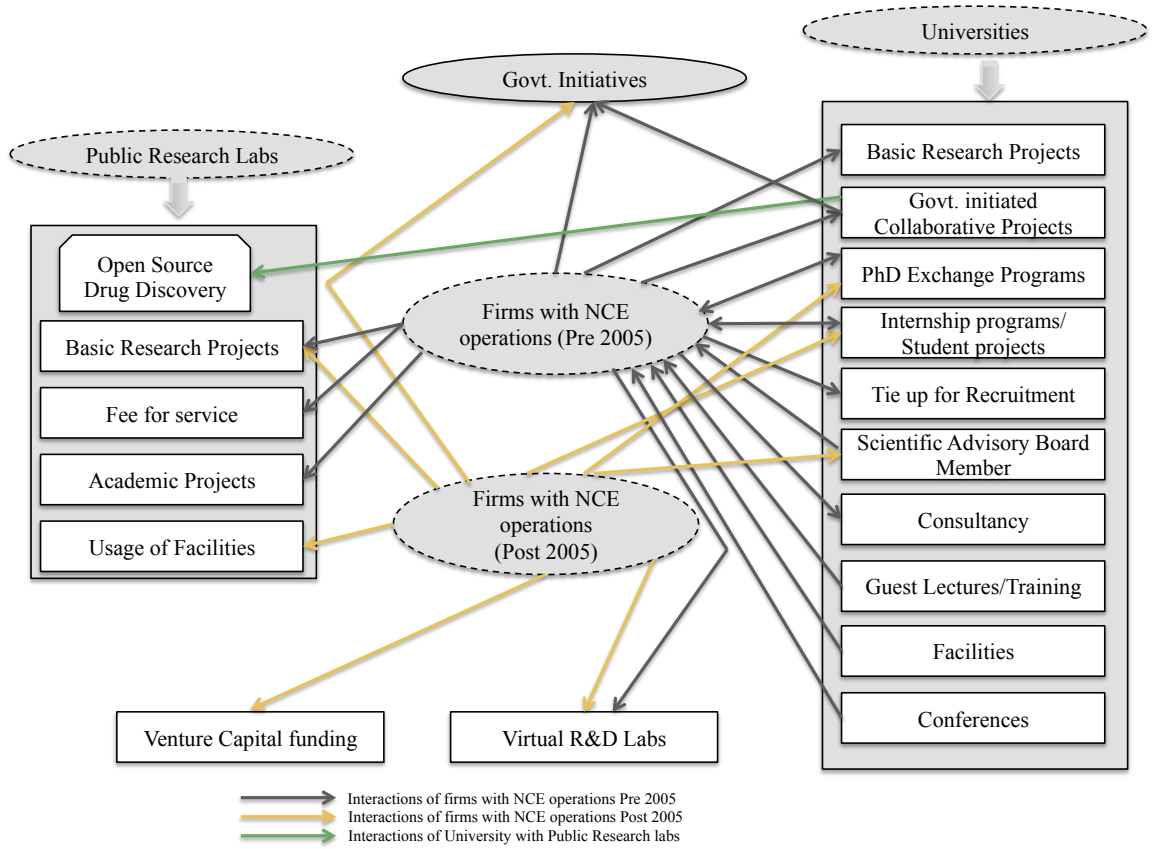

Figure 3: Innovation Networks for New Drug Research in India

The nature of innovation networks formed by firms engaged in NCE research, prior to 2005 are primarily of the nature of exchange programs at PhD level, employment of scientists trained in public universities, funding short term academic projects, guest lectures, student internships and practical training courses offered by the industry to students. Most of the companies, which initiated new drug research before 2005, are expected to engage in such linkages due to longer periods of interactions within the innovation system, relative to startups. Other forms of interactions by established companies for new drug research includes incorporating distinguished scientists as members of scientific advisory board and consultancy projects with scientists.

Paradoxically, companies which, newly started their NCE research operations (post 2005) seemed to engage with the scientific community in much more integrated ways such as research projects with public research labs and academics, participation in virtual research consortium. Newer companies also explore the venture capital funding option, which is somehow non-existent in India for the risky new drug research business. Startups also make use of the instrumentation and testing facilities available in public research labs. Despite some promising examples of collaborative research projects of firms with universities and public research labs, the emergent picture is that of disconnected and loose interactions between the entities for new drug innovation. Table 2 summaries the issues faced by each of the entities in undertaking collaborative research.

Table 2: Key emergent themes on reasons for low collaboration

1. Low Technological Opportunities	
• Technical competency	*"Our expertise in the area of biological science is very limited..... as far as basic medical research is concerned, if you look at the scale of 1 to 10, I would say we will be somewhere around number 1 or 2 as compared to countries which already have high ranking"* - Retd. Chief Scientific Officer, Public Research Institute
• Not much research happening • Low quality of publications • Lack of motivation	*"We have to nurture the excellence and we will have to remove the bureaucracy; many people are getting to their comfort zone by not doing anything. So this is something, which is very dangerous because in a government set up it is very difficult to make a person work. In any country but definitely in India it has become more of a norm to enjoy the job you are having. So they are not really feeling that they are part of building this nation"*- Scientist, Public Research Lab B *"There will be people who are interested in drug discovery, but you will not find a department of drug research or even a course for MSc in drug research in universities"* - Professor, University C
• Concentrate on basic research • Lack of regulatory and GMP knowledge	*"I know many scientists in Central Drug Research Institute (CDRI) they have good understanding and knowledge but I don't know why they are more into basic research than in the drug discovery research"* - Vice President, *Pharmaceutical Firm*

• Poor infrastructure • Bureaucracy • Logistic issues	*"Drug discovery is a huge task..the level of activity and the scale at which universities operate abroad is several orders of magnitude different than us" – Scientist, Public Research Institute B* *"It takes so much time with so many clauses in the contract, so its always easy to approach a CRO for a particular service"- Associate Director, Pharmaceutical Firm*
• Fluctuating research funds	*"Funds are getting squeezed and its now in a very bad shape. ….from 40 crore INR (400 million) in the past year we are now at 17 crore INR (170 million) this year. This is a major setback to our research, we do not have any extra money for research" – Professor, University D*
2. Issues related to Intellectual Property	
• Academia more interested to publish than patent	*"Biggest issue is intellectual property protection. Usually academic groups would like to publish the results of their endeavors quickly while companies tend to protect the intellectual property first with patent filing and then start publically disclosing it"- Chief Scientific Officer, Pharmaceutical Firm*
• IP sharing an issue	*"Companies don't want to share the IP with anybody because there is a commercial aspect"- Associate Director, Pharmaceutical Firm*
3. Trust	
• Mistrust	*"In that context few have approached but I am being very cautious because in earlier times, I have been mislead and fooled also. Therefore, now I am very cautious, unless and until its going to be on paper black and white only then will there be knowledge transfer"-Professor, University A*
• Tech transfer issues	*"University or an organization says that they have a certain technology and the company which is collaborating or licensing the technology makes an up front payment only to realize that the technology is not working"- Vice President, Contract Research Firm*
• Ownership issues	*"The issue is the ownership of the technology, the molecules, any kind of platform they are developing. The transparency is not there who is going to own that. If the assets are coming from a pharmaceutical company they feel that academic is just doing a service. An academic professor says that he is not doing just a service. He is helping you to understand what a molecule does in the biology field" - Head, External R&D Innovation, MNC*
4. Mindset	
• Tendency to work in silo	*"Can people really get together and form teams? That is really difficult in India. There are not many successful examples also in the last 15-20 years... ... we do very small level collaborations" - Professor, Public-Private Research Institute C*
• Do not like to share facilities	*"Most researchers don't like to share their facilities. If I buy an instrument for my lab, the same instrument is bought by 10 other labs though the institute could have bought two instruments and everybody could have used it. It's a closed kind of thing" - Professor, Public Research Institute A*
• Divide between academic and industry thinking	*"The major problem is the mindset you know we people in academia are free floating. And therefore we do things the way we like to do. That is the academics way of looking at it. You know in industry there are tight timelines… You ask any academic he doesn't understand what quarterly means. Their approach is we are doing it and it will finish when it has to finish "- National Research Professor, Padma Shri Award Winner, University B*

Conclusions

The change in patent regime has attracted wide interest among the pharmaceutical firms, universities and public research labs to undertake new drug research. Despite considerable efforts by the government, the collaborative efforts are disparate and there is little cohesion in the innovation approach. The build up momentum is not sufficient to compensate for the insufficient capacity at the level of universities, lack of applied research at universities/public research labs, and lack of culture of collaborating between academia/public labs and industry. Given the weight of partnerships and the challenges faced by the organizations, there is an urgent need for introspection by the policymakers to adopt an innovation approach more suitable to the Indian needs. This study is an early attempt to make a contribution to the open innovation and national innovation system literature through case study of an emerging economy like India.

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