Forthcoming in 'Technological Forecasting and Social Change'

Please cite this article as: S.E. Reid, S.V. Ramani, The harnessing of biotechnology in India: Which roads to travel? Technol. Forecast. Soc. Change (2012), doi:10.1016/j.techfore.2011.12.008

The harnessing of biotechnology in India: Which roads to travel?

By

Susan E. Reid* and **Shyama V. Ramani**
Williams School of Business, Bishop's University
2600 College Street, Lennoxville, Quebec J1M 1Z7, Canada
sreid@ubishops.ca

Maastricht University, UNU-MERIT
Keizer Karelplein 19, 6211 TC Maastricht, The Netherlands
ramani@merit.unu.edu

November 2011

ABSTRACT

In India, as in most developing countries, biotechnology was ushered in through public policy rather than individual firm initiatives. Throughout the 1980s and until the mid 1990s the focus of public policy was on creation of scientific capabilities and building of awareness of the potential of biotechnology. With the adoption of economic liberalization in the 1990s, the Indian State also began to sponsor private initiatives in capacity building. Today, the leading Indian firms have commercialized generic versions of original innovations developed by US and Japanese firms, using the traditional route of re-engineering. In addition, a number of start-ups have emerged to make use of opportunities to provide contract research services to Western and Japanese multinationals. But can a focus on bio-generics and contracting for multinationals be used as a route for competence building and as a stepping stone to become original innovators? The present article shows that while India has 'strong scientific and technological capabilities', it is constrained by weak 'social capabilities' of its labour force, lack of 'institutional capabilities' in regulation and financing, infrastructural constraints and absence of national programs to achieve concrete targets in terms of biotechnology innovations to promote a more inclusive development.

Key Words: India, National Systems of Innovation, Biotechnology, Biopharmaceuticals, Agricultural Biotechnology

*Please address correspondence to Dr. Susan E. Reid, Associate Professor, Williams School of Business, Bishop's University, 2600 College Street, Lennoxville, Quebec, Canada J1M 1Z7; Telephone: 1-819-822-9600 x2353; Fax: 1-819-822-9720; e-mail:

sreid@ubishops.ca

The harnessing of biotechnology in India:
Which roads to travel?

1. Introduction

Modern biotechnology refers to a set of generic technologies[1] that involve manipulation or change of the genetic patrimony of living organisms for industrial application in sectors such as pharmaceuticals, seeds and chemicals. After its emergence in the USA during the late 1970s, scientists in many developing countries, including India, recognized that scientific, technological and industrial capabilities must be built in biotechnology in order to maintain international competitiveness and economic growth. Indeed, prospects seemed bright, as the industries in which biotechnology could be integrated were well developed in India, with local firms being the market leaders. Moreover, over the previous decade, Indian firms had developed highly refined re-engineering skills, which had been crucial to building up technological and industrial capabilities.

From 1995, however, the time-tested (by many developed and developing countries) path of catching-up via effective absorption of knowledge from international markets was made much more complex by the international homogenisation of intellectual property rights (IPR) regimes and the signing of the Trade Related Intellectual Property Rights (or TRIPS) convention by the member countries of the World Trade Organization. TRIPS made product and process patent protection mandatory in all branches of manufacturing, effectively eliminating the possibility for second innovators in developing countries to create, manufacture and sell new products via the re-engineering route. It also homogenized the period of protection to 20 years and banned discrimination between imported and domestic products – opening local markets to foreign competition.

For emerging countries like India with sound scientific capabilities as well as a high poverty burden, institutional shortcomings, technological retard and financial constraints, TRIPS made participating effectively and profitably in technological revolutions like biotechnology an even greater challenge than for other more developed economies. For economists studying the processes of catching-up in knowledge intensive sectors by developing countries, TRIPS opened a Pandora's box for speculation. In response, the objective of the present paper is to make a contribution to this debate by seeking to answer the question: what are the possible routes for firms in an emerging country like India to build

[1] The list of generic technologies included in modern biotechnology has evolved over time. A recent report by the OECD includes: techniques used on DNA/RNA, gene and RNA vectors, proteins and molecules, tissue and cell culture and engineering, process biotechnology techniques, bioinformatics and nanobiotechnology (Van Beuzekorn and Arundel, 2009).

competence and/or become original innovators in a hi-tech sector such as biotechnology? Detailed case studies such as this which will be presented herewith can also yield insight on policy design for catching-up in the post-TRIPS era, when technical knowledge is increasingly fenced within an anti-commons structure.

How do countries accumulate industrial capabilities? This is the query that catch-up theories of the evolutionary school of economics sought to address through detailed case studies of the historical evolution of countries and sectors. One of the main off-shoots of this literature is the 'national system of innovation' or NSI framework. Spearheaded by the seminal work of Lundvall [1], Nelson [2] and Freeman [3], the NSI approach starts from the premise that the commercialization of innovations in any country in a new science-based sector is a collective process embedded within an NSI. In other words, the creation, development, adoption and diffusion of innovations, is taken to evolve as a function of the existence and functioning of networks, between the State and a variety of organizations such as firms, public laboratories, universities, financial institutions and civic associations, impacting the creation and commercialization of innovations. The catching-up process is then traced as the outcome of the strategies implemented by the other actors in the innovation system, taking into the account the interdependence between their actions, Nevertheless, the NSI approach remains a conceptual framework rather than a theory, open to many forms of interpretation and investigation [4, 5]. In order to move towards a workable theory of NSI, and arrive at a typology of systems, with an understanding of their concomitant impact on catching-up in new knowledge intensive sectors, more empirical studies are called for. The present article may be considered as a step in this direction.

Despite its generality, a major achievement of the catch-up and NSI literature has been to throw light on a puzzling question. Conventional economic growth theory postulates that if knowledge is codified and freely available, developing or backward countries will grow faster than advanced countries for the reason that the former will benefit from existing technologies developed by the latter. This assumption conformed to pre-TRIPS reality, because until 1995 most countries were signatories to the Paris Convention of 1883 for the protection of industrial property, which was quite open and gave nations freedom to set up their own IPR systems, according to their individual needs. However, despite access to knowledge and superior technology there is no evidence of significant convergence of economic growth or development between countries worldwide over time. The detailed historical case studies of sectors and countries of the catch-up and NSI literatures explained this paradox by demonstrating that even if codified knowledge is readily available, follower countries may not be able to effectively exploit it, unless a variety of other complementary capabilities are also developed. For instance, such capabilities include new financial-institution capabilities to bear the costs of risky investment [6], an educated work force with social capabilities [7], public labs and firms with technological and absorptive capabilities [8, 9] and a benevolent and rational government policy (see [10] for survey) may be needed.

In the last three decades, the NSI approach has emerged as a useful framework to organize historical evidence and study the 'catching-up' processes of 'late-comer' countries with respect to the accumulation of industrial capabilities. It has also inspired the notion of a sectoral system of innovation (SSI) as well as regional innovation clusters [9, 11]. A common result of these complementary approaches has been to demonstrate that catching-up is not a systematic process, neither is it costless or easy. It involves country, context, region, and path – dependent processes. And now, with TRIPS, one of the basic assumptions of this literature is no longer valid, the jury is clearly out on the best ways to catch-up. Keeping this in mind, in what follows we will examine the prospects for the evolution of the Indian biotechnology sectors given the scientific, technological and institutional capabilities acquired so far. In addition, biotechnology being multisectoral, we will focus on the intersection of the NSI and the SSI, highlighting sectoral specificities whenever possible.

In the post-TRIPS world, emerging country firms seem to have five possible options for technological catching-up in any hi-tech sector. First, they can continue to hone their re-engineering skills and continue to build their competitive advantage as generic producers. Keeping a close watch on products whose patents are close to expiry, they can capture new markets by being the first to introduce an effective substitute to a branded product. Second, in order to improve upon their innovation capabilities, firm can initiate or widen the scope of their cooperation with public laboratories and jointly develop new technology. Third, they can attempt to learn through the initiation of strategic technology alliances with more technologically competent firms, typically foreign ones. These can take the form of offering services as a 'contract research organization' (CRO) or as a partner for 'contract research and manufacturing services' (CRAMS). Fourth, they can acquire new technology through purchase of a license or even a firm. Finally, they can invest in the creation of original innovations through internal R&D and firms which invest solely in this strategy in the realm of biotechnology are known as dedicated biotechnology firms ("DBFs"). So, which combination of these options is most likely to lead to the best short-term profit and sustained long-term market share through innovation creation? Further, do any of them lead to desirable developmental outcomes? These are the central questions we seek to answer with respect to biotechnology firms in India in the context of its NSI. In the above perspective, the present paper attempts to contribute to two streams of literature: first to catch-up theories albeit in the new context of TRIPS, and second to studies on the evolution of the Indian biotechnology sectors.

2. Methodology

The case study is constructed by applying an NSI framework to the biotechnology sectors thereby circumscribing our field of analysis to the intersection of the NSI and the SSI. This effectively means that our study examines the role of the Indian State, the nature of the capabilities accumulated so far, the strategies being pursued by the different actors of the innovation system and the possible

outcomes of such interdependent strategies. The case study method is useful whenever the purpose of the scientific query is to understand the 'how' rather than the 'why' of a process [12, 13]. In the present context, the process refers to capacity building in the Indian biotechnology sectors – assuming that it is an objective to which the NSI actors are committed.

The research was organized in three stages using multiple data sources. Publicly-available government, industry policy documents and the economics and management literature on the Indian biotechnology sectors comprised the sources of secondary data. In the first stage, the secondary data was organized to trace the role of the State and identify the nature of the capabilities accumulated so far. These yielded a set of findings on the strengths and weaknesses of the NSI with respect to the biotech industry. In a second stage, these findings were compared with the verdicts of the economics literature on the Indian biotechnology sectors. Applying a meta-analysis we were able to rank the importance of the earlier findings. In the third stage, this construct was again validated and refined in a series of interviews conducted with 30 selected representatives of public agencies, industry associations and firms. Several other firms and agencies were contacted, however not all were willing or able to participate in the research during the period when the interviewers were in India. The interviews were semi-structured, but in-depth and lasted between 1 to 2 hours during 2009/2010. Where required, transcripts were sent to the interviewees for confirmation and corrections. In the fourth and last stage, the findings of all preceding steps were integrated into our final analysis.

The remainder of the paper is organized in a similar fashion. We start the examination of the Indian NSI with respect to the biotechnology sectors by tracing the role of the government in section 3 and the nature of scientific and industrial capabilities in the biotechnology sectors in section 4. Then section 5 compares our main findings on the strengths and weaknesses of the Indian NSI with the main verdicts of the economics literature on the Indian biotechnology sectors and the opinions voiced in the interviews. Finally, section 6 concludes by integrating the different points of view into our inferences on future options and recommendations.

3. Role of the State: Public investment, policy trends and regulation

In India, as in most developing countries, biotechnology was ushered in through public policy rather than individual firm initiatives. In 1982, at the request of members of elite research laboratories aware of developments in the USA and Europe, the government created a National Biotechnology Board (NBTB) to formulate a road map for capacity building in biotechnology. Throughout the 1980s, the focus of public policy was on the creation of scientific capabilities and building of awareness of the potential of biotechnology and public investment was mainly in the agricultural sector. But the biotech industry really began to emerge only after 1991, when the economy was liberalized and de-licensed. With economic reform, it was no longer necessary to get a license from the concerned Ministries to expand the manufacturing base, export or import

goods in any sector. Hot on the heels of liberalization, India became a member of the World Trade Organization in 1995 and thereby changed its regulatory framework to comply with TRIPS. Between 1994, when TRIPS was ratified, and 2005, when it came into effect, three amendments to the patent law of 1970 were passed in the Indian Parliament in 1999, 2002 and 2005 successively to make it TRIPS compliant.

During the 1990s, a number of large firms from the pharmaceutical and specialty chemicals industries began to invest in biotechnology. They found it challenging to expand their knowledge base, which was firmly embedded in organic and synthetic chemistry, in order to integrate the life sciences-based and associated techniques. The latter was new, different and much more complex requiring a multi-disciplinary team to create a product [14] and resulting in firms which could be classified as integrated bio-pharmaceutical and bio-chemical companies. Four types of strategic positioning of Indian biotech firms could be distinguished at this point of time: (i) marketing of biotech diagnostic kits, vaccines and drugs for western firms, in order to test the waters; (ii) producing diagnostic kits (which were technologically less complex than therapeutics or vaccines); (iii) undertaking contract research or manufacturing biological products; and (iv) producing speciality chemicals [15].

Thereafter, tracing the details of the public investment during the 1990s and during the early years of the new millennium, Chaturvedi [16] concludes that there has indeed been a paradigm shift in the leading firms in pharmaceuticals, with the production systems moving away from a pure chemistry driven drug development to incorporating bio-based drug development, thanks to growing public allocations. He further notes that the framework of NSI policies are being more sector-tailored, recognizing sectoral requirements from the perspective of growing global integration of innovation chins and production systems.

Today, the salient feature of State involvement that gave impetus to the emergence of the biotech sectors still holds true. The Indian government is still the leading financier of scientific capability building. However, public investment on R&D in both absolute terms and as a % of GDP is lower than in neighbouring China or leading developed countries, clearly illustrating the consequences of attending to a high poverty burden. For example, in 2006, while the R&D spending as a % of GDP was only 0.80 in India (as compared to 2.76 in the U.S., 1.61 in China and 3.40 in Japan); 80% of that R&D investment issued from the public sector (as compared to 30% in the U.S., 30% in China and 18% in Japan) [15]. Since 2006, figures for public R&D spending as a % of GDP from 2008 to 2010 show a slight improvement for India vis-à-vis the rest of the world jumping from 0.8% to 0.9% [17]. Bringing these statistics down from total country R&D spending to just focus on the relevant biotechnology spending in 2005, the situation is similar, as shown in Table 1. A more recent estimate from India's Ministry of Science and Technology (2007/2008), suggests that the Indian Department of Biotechnology (DBT) spent Rs. 174.43 Crores or about $45 million US in 2006 (DBT = 422 projects and = 15% of all publicly funded R&D by the MST in that year).

Table 1: Public R&D Spending on Biotechnology in USD Billion PPP, 2005[c]

U.S.	23.2
Japan	1.9
Korea	1.2 (1.5)[d]
Canada	0.6 (0.7)[d]
Singapore	0.6
China	0.5
India	0.2

[c] T. Jonsson, Competitiveness of the European biotechnology industry, in: a working paper, European Commission, Enterprise and Industry DG, 2007.
[d]Statistics in brackets from B. Van Beuzekorn, A. Arundel, OECD Biotechnology Statistics 2009, in: OECD, 2009.

Indeed, the Indian Government is constantly scaling up its support of innovation. Funding for the sector has more than quadrupled in India since 2006. Many initiatives have been started to provide soft loans and grants for early stage research and commercialization of technology of firms that have at least 50% Indian equity holding (e.g. Technology Development Board's commercialization loan for technology development; Technology Development and Innovation Programme (grant and loan), Technology Development and Demonstration Programme for start-ups (soft loans) and the New Millennium Indian Technology Leadership Initiative (grant and soft loan) and Small Business Innovation Research initiative (grant and soft loan))[2].

In terms of current policy change, a possible incentive scheme to promote the generation of technological innovations by university and public research centres is drawing much debate. 'The 'Protection and Utilization of Publicly Funded Intellectual Property Bill, 2008,' commonly known as the Indian Bayh-Dole act is currently under review by the Parliamentary Standing Committee on Science, Technology, Environment and Forests. The bill aims to codify standard rules and protocols for ownership and servicing of intellectual property resulting from public funded research. Although the bill mirrors its American counterpart in several ways, it takes a much broader view of IPR including copyright and trademarks in addition to patents [18]. Its necessity and possible impact are not clear. In India, most of the patent applications are already from public laboratories and the focus has to be on devising incentives for private firms to patent more. Furthermore, adding more pressure on public researchers to patent might results in a glut of sitting patents that eat up tax-payer's funds for maintenance. The CSIR, which between 2002 and 2006, obtained more patents from the US patent office than the total number granted to its counterparts in

[2] We thank Mr.Vivek Singhal, President of the All India Biotechnology Association for this information.

France, Japan and Germany combined has already been criticized, because the revenues generated by its patents do not cover by any means the funds required to maintain them [19]. Finally, Indian industry, especially the pharmaceutical and agriculture sectors, have greatly benefited from public-private technology transfers under non-competitive conditions. It is therefore not clear if promoting the growth of the 'knowledge anti-commons' would help either catching-up in terms of industrial capabilities in biotechnology or moving towards a more inclusive economic development.

The regulatory bureaucracy in India is improving. Starting in 1986 with the setting up of the DBT, functioning under the aegis of the Ministry of Science and Technology at the central level, India now has a well established regulatory system with respect to biotechnology (for the architecture and evolution of regulatory institutions in India see [14] and [16] for biopharma and [20] for agbiotechnology). Until the mid-2000s, though the biotechnology policy was formulated by DBT, it was implemented by at least five different committees[3], operating under different Ministries. There was little coordination or regular interaction between them and each worked at a different pace. At the State level, each State also had its own agencies to regulate the biotechnology industry. Thereby, there were both contradictions with respect to decisions and duplication of effort. Given complaints from industry, civic associations and academic bodies, there is currently an institutional transition towards a single window mechanism for all regulatory approvals with respect to biotechnology under a new institution – a 'National Biotechnology Regulatory Agency/Commission (NBRA/NBRC)' [21]. The entry of foreign firms and the return of non-resident Indians is also being facilitated. During the first decade of the Millennium, the licensing policy was further simplified and liberalized with foreign equity holdings of 100% permitted in almost all sectors with minimal bureaucracy.

Despite all this progress, nevertheless the regulatory infrastructure remains extremely weak and has a bad reputation for being home to petty corruption. Even in the Indian patent office, Barpujari [22] points out that there is a 'human resource crisis'. The patent bureaucracy was built up only after the signing of TRIPS in 1995, and though a lot of efforts have been made, there is a serious lack of patent officers learned in both 'legal matters' and 'the science of biotechnology'. There is a need to train qualified labour to handle patent applications in India.

There are also wide gaps between theory and practise of regulation as enforcing compliance is a major problem. Sometimes, it is downright impossible as was the case in the commercialization of Bt cotton. The main private stakeholders, the firm (Monsanto-Mahyco-Biotech Ltd) and the intermediate

[3] As Reddy of Shantha Biotechnics (Reddy, 2009) explains, the various committees comprise: (i) the Recombinant DNA Advisory committee (RDAC); (ii) The Review Committee on Genetic Manipulation (RCGM); (iii) The Institutional Biosafety Committee (IBSC); (iv) The Genetic Engineering Approval Committee (GEAC); and for clinical trials with recombinant drugs there is also (v) Drugs Controller General of India (DCGI).

buyers of the genetically modified seed – namely farmers, openly fluted regulation. Both parties could not be punished in any way, and therefore, time and time again, regulation was changed to make their actions 'legal' [23]. Still, there are flourishing illegal markets in Bt cotton in India.

What of the future? In 2007 the Government of India issued its 'National Biotechnology Development Strategy'[4] with a clear road map, following a two-year consultative dialogue with a variety of stakeholders drawn among policy makers, academics, civil associations, international experts etc. It recognized biotechnology as a 'sunrise industry' that could promote inclusive economic growth and announced a clear change from the previous policy of uniquely helping public research institutions with programs to financing public-private partnerships in R&D, private sector R&D and innovation in small and medium size enterprises[5]. Furthermore, it proposed to develop more focussed quality human resources with the creation of a network of centres of excellence in both training of students and research. Support for technology parks was also to be scaled up. Presently, 15 of the 28 State Governments have biotech policies and support biotech parks, which facilitate infrastructure sharing and platforms, crucial for start-ups [24].

Despite, the confirmation of continued State support for capacity building in biotechnology, it is of utmost concern that there does not seem to be any focussed effort to bring out biotechnology innovations that will impact the poor in a major way – barring the introduction of genetically modified plant varieties which are controversial and not considered by all to be pro-poor innovations. Though the 'National Biotechnology Development Strategy' recognizes that biotechnology innovations can promote inclusive development, there is no national program targeting concrete goals involving public laboratories or firms. The reigning premise seems to be that supporting the accumulation of industrial capabilities in the biotechnology sectors is sufficient and positive results will percolate in some measure to the poorer masses on their own. Clearly, this need not happen.

4. On capabilities in the biotechnology sectors

4.1. Evolution of Scientific capabilities: Scientific publications and personnel

Scientific publications are a good indicator of the evolution of scientific capacity in a country or across countries [25]. The year-on-year publication totals in biotechnology are summarized in Table 2. The breakdown for the period by sector is shown in Table 3. They prove a clear strengthening of scientific capabilities as publications grew from 1996 to 2007, starting at 495 articles in 1996 and growing to 2,065 published in 2007, with a total during the period to

[4] http://ec.europa.eu/research/biosociety/pdf/nbds_india.pdf
[5] http://dbtindia.nic.in/biotechstrategy/National%20Biotechnology%20Development%20Strategy.pdf

mid-2008 of 14,532. The focus areas are health and agriculture in conformity with world trends. In comparing these totals to the world total for the same period, the growth went from 1.5% of the world total in 1996 to 4% by 2007, thereby illustrating good growth on the whole in terms of building scientific capacity.

Table 2: Number of Biotechnology Publications per Year 1996 to 2008[e]

	96	97	98	99	00	01	02
India	495	524	618	668	681	839	995
World	31266	31687	32145	32798	34188	35894	36273

	03	04	05	06	07	08*	96-08
India	1162	1161	1597	1871	2065	1856	14532
World	38160	40985	44337	48257	51323	45734	503047

[e]Scopus Database

Table 3: Number of Biotechnology Publications by Sector 1996 to 2008[e]

	Health	Agriculture	Other	Unknown	Total
India	8152	2934	2988	458	14532
World	361126	55240	73752	12929	503047

[e]Scopus Database

Additionally, co-authorship of publications is a good indicator of the research networks and collaborations in which scientists are invested; and provide additional evidence of openness to the adoption of new technologies [25]. For the biotech sector, while the number of publications by Indian institutions has shown an increase year-on-year, the inter-country collaboration has not changed over the period, and in fact, have shown a slight decrease over the period as a percentage of total articles in collaboration (106/495 – 21% from 1996 compared to 322/1856 – 16% for 2007) (Scopus, 2010) as shown in Table 4. The distribution of collaborations with OECD countries is representative of strengths in the collaborating countries, with the highest number being with the U.S. for the period 1995 to 2008 (Scopus, 2010) as shown in Table A.1 in the appendix. It is not clear exactly why international collaborations, which mark the scientific publications issuing from the leading nations and China, is so low in the Indian case. We can only surmise that this is due to a combination of cultural factors as well as inadequate public investment to promote international collaboration in public institutes.

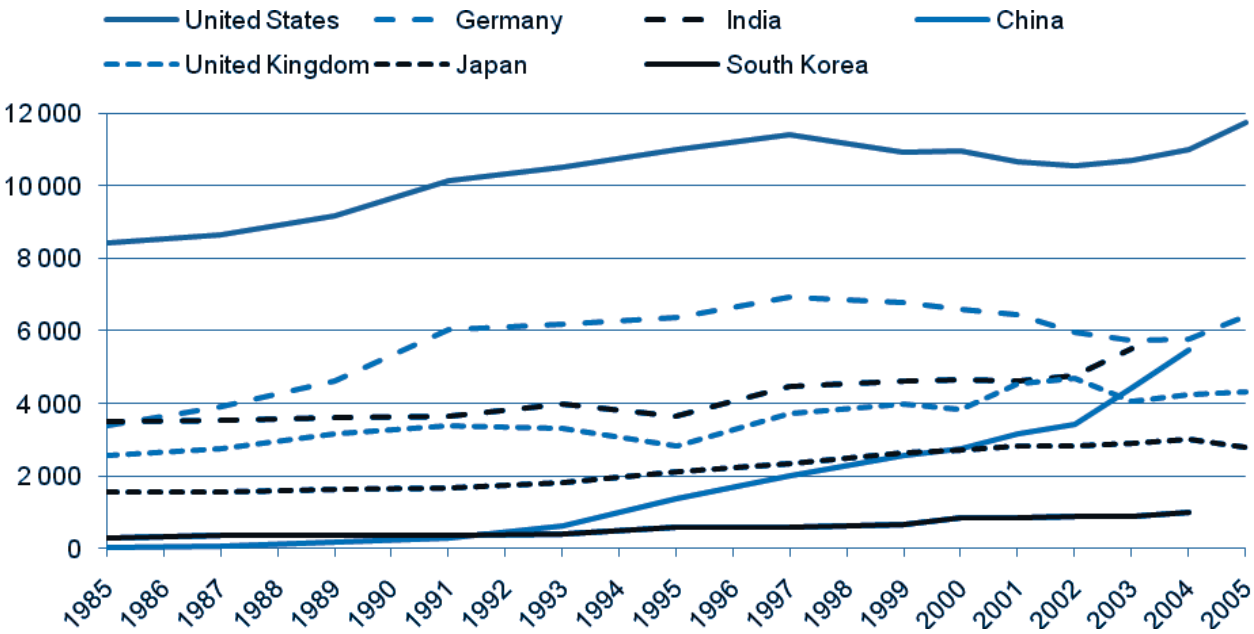
Table 4: Indian Scientific collaboration as % of Total Publications in Biotech 1996-2008[f].

Year	Collaboration	Total Articles	% in Collaboration
1996	106	495	21%
1997	87	524	17%
1998	103	618	17%
1999	128	668	19%
2000	109	681	16%
2001	98	839	12%
2002	145	995	15%
2003	198	1,162	17%
2004	182	1,161	16%
2005	260	1,597	16%
2006	272	1,871	15%
2007	322	2,065	16%
2008	291	1,856	16%

[f]Scopus Database(2010)

The gap between India and the rest of the world is constantly narrowing in terms of impact of public investment in the creation of qualified labor as indicated by Figure 1. The statistics shown in this figure indicate that strong potential for development, based on the absolute figures, exists for countries such as China, Japan, India and the UK, at least as far as participation in the science of biotechnology goes. That said, India still remains one of the countries to "export" large numbers of qualified labour. The novelty of the millennium is that while many Indian students and researchers stay abroad for an extended period or permanently and continue to contribute to development of biotechnology in the US and other industrialised countries, a small proportion has started returning back to India bringing with them the knowledge, experience and networks accumulated abroad.

Figure 1: Doctoral degrees awarded in the physical, biological and agricultural sciences; selected countries, 1985 – 2005



Data from OECD, [17], NSF, [23].

4.2. Evolution of technological capabilities

Technological capabilities can be evaluated in terms of patent applications, new product or technology creation and provision of contract research or technology services. It is easiest to collect and analyze data on the first indicator, and therefore this will be our point of focus, after which, we will refer to trends on the rest in the next section on industrial capabilities.

Predictably, after the enforcement of TRIPS, the number of patents for biotechnological inventions granted by the USPTO to Indian assignees (universities, research laboratories and companies) has increased, but still is on a very small level when compared to the international leaders. The vast majority of the USPTO patents for India are awarded to universities and public laboratories (195 out of 208) while companies are just starting to enter the game, as indicated in Table 5. For example, in India, only a handful of USPTO patents have been awarded to companies such as Bharat Biotech and Ranbaxy (through their biotech subsidiary Metahelix) [26] [6] This said, as of the beginning of 2010, several

[6] According to Sundaramoorthy et al. (2009) a patent is classified as "biotech" if it protects (a) a recombinant enzyme; (b) a reaction carried out by an enzyme or a method to detect enzymatic activity; (c) a method to detect whether a molecule affects the activity of or expression of an enzyme; (d) a bioreactor or fermentor, or the product from use of such a device; (e) bacteriophages, or bacteria infected by such phages; (f) an algal strain and the process of culturing it; (g) stem cells and methods of growing them; (h) a design patent covering an umbilical cord collection bag. Patents covering "pharma" are those that involve non-bio chemical processes or compounds. Given this definition, the authors found 19 patents to 2007; we generally agree with their cultivation process, however were even more selective, not including the 3 Gangagen filings since

more Indian companies have patents pending at the USPTO (based on interviews). At the same time, according to the data available through the Indian Patent information Retrieval System[7], there has been a concomitant decrease in the number of domestic patent applications in India among the top 50 companies based on sales (781 in 2004; 660 in 2005; 574 in 2006; 332 in 2007), as companies attempt to rationalize their post-TRIPS portfolios. Also, according to Niosi et al. [27], more than two thirds of biotech patents awarded by the USPTO to Indian inventors are attributed to US assignees (universities, research laboratories and companies), and are therefore not captured in the Indian company assignations.

The story is different, however, for international PCT filings (EPO designations)[8]. According to van Beuzekorn and Arundel [28], India from 2004 – 2006 applied for 423 biotech patents (applications based on priority date and inventor's country of residence). This represents 423/11,310 total filings for India in that period or almost 3.75% This compares to 7 biotech filings out of a total 49 in the period during 1994 to 1996, thereby showing a drastic increase in filings since that time.

Table 5. Indian Biotech Assigned Patents, USPTO 1979-2007[g]

Date	Total USPTO Indian Biotech Patents	Corporate USPTO Indian Biotech Patents
1979	1	
1995	1	
1996	1	
1997	2	

---

the company is registered in the U.S. and similarly we did not include the 3 patents granted to Reddy U.S. Therapeutics. Instead, we did include the 2 patents granted to Metahelix which are Ranbaxy's Indian biotech play. We have 4 filings rather than 6 for Biocon using this definition. As such, our number of Corporate USPTO biotech patents for India to 2007 is 13. We are in agreement with these authors for the rest of the division of the pharma and biotech patents.

[7] Domestic biotech patents were downloaded from the Indian Patent Information Retrieval System periodically during 2008 and 2009. Access is publicly available from http://www.patentoffice.nic.in/ipirs1/patentsearch.htm.

[8] Biotechnology patents are identified using the International Patent Classification (IPC) system: one or several classification codes are attributed to the patent during the examination process. For emerging technologies, however, a specific category or class might not yet be incorporated into the patent classification system, which means that some biotechnology patent applications couldbe missed. Biotechnology patents are identified using the following list of IPC codes: A01H1/00, A01H4/00, A61K38/00, A61K39/00, A61K48/00, C02F3/34, C07G(11/00,13/00,15/00), C07K(4/00,14/00,16/00,17/00,19/00), C12M, C12N, C12P, C12Q, C12S, G01N27/327, G01N33/(53*,54*,55*,57*,68,74,76,78,88,92)]. For further details on the IPC, 8th edition, see:http://www.wipo.int/classifications/ipc/ipc8/?lang=en.

1998	6	
1999	7	
2000	6	
2001	15	1
2002	27	
2003	31	1
2004	23	1
2005	23	3
2006	33	7
2007	32	
Total	208	

[g]USPTO Database

In short, more than 60% of biotechnology patents issuing from India have been filed by foreign entities. Moreover, it is not clear to what extent this represents their latest innovations or whether it is a ploy to sell their older products with protection in the Indian market. The foreign direct investment in both agriculture and pharmaceuticals is among the least as compared to other industries and most of it is in the form of opening of subsidiaries or mergers and acquisitions which are least conducive to technology transfers [29]; [30].

4.3. Evolution of financial capabilities: Private investment in biotech

As noted, early investment from the private sector came from companies already invested in pharmaceuticals and the chemical industry, primarily those looking to develop vaccines, or working with bio-generics. As of 2006, this mode of funding was not unsubstantial and tallied almost the same amount as that invested publicly, at approximately $43 million U.S. as estimated by the Ministry of Science and Technology (2007-2008) for a grand total of public and private funding of R&D taken together of $88 million US (or 350 Crores) during 2006.

Funding from the private equity sector, taken on the whole, was far less developed up to 2006. A large component of private investment went to developing private healthcare alternatives in India such as those offered by Apollo and Fortis, and these institutions continue to grow and leverage their growth to develop their own R&D initiatives which are quite impressive. Thereafter, Indian VC funds almost doubled from 2006 to 2007, with an important share coming from abroad. Similarly, while the total VC investment in Indian biotech was approximately $500 million in 2006, it looked to be doubling by mid-2007 [31].

Though, venture capital in India appears to be growing quickly in India, it is still less developed than in industrialized nations. Venture Capital, or lack

thereof, is likely related to the lack of patenting in the sector, as patenting is one of the major benchmarks used by venture capitalists as an indication of how well developed a new technology is and whether it is yet capable of industrial application. As such, while the hard data does indicate an overall trend in venture capital in the right direction for Indian biotech, the overall numbers are still low [32], point out that the lack of domestic venture capital available has meant that Indian companies have grown without surrendering equity, however, on the other side of the coin, the lack of venture capital has also meant that some firms are now surrendering to multinational or MNC buyout instead (to be detailed in next section) as a way to finance their R&D in order to develop their marketing capabilities.

4.4. Evolution of Industrial capabilities: The biotech market

The Indian biotech industry is doing well, generating nearly $4 billion through domestic sales and exports according to the 2011 biotech industry survey produced by industry associations [33]). For example, leading biotechnology firms such as the top three Indian companies in 2008/2009 enjoyed impressive revenue from sales: Serum Institute ($250 million USD), Biocon ($205 million USD) and Panacea Biotech ($134 million USD) [34]. The estimate of the total number of firms in 2010 was over 400, employing some 50,000 scientists [35]. The key findings are summarized in Table 6. It is indeed striking that 51% of the revenue generated by the Indian biotech industry comes from exports. One particularly successful example of a firm that has gained in competitive advantage through exports is Dr. Reddy's. It increased its exports by 20% from 2008/09 to 2009/10 in Russia and CIS countries such as Brazil (from 7,623 Rs to 9119 Rs) and also, an increase of 13% in North America during the same period (from 12,655 to 14,274 Rs) [36]. This success, in part, is also due to Reddy's strategic alliance with GlaxoKlineSmith in 2009 to develop and market select products across several key growth markets outside India [36].

Table 6: Salient features of the Indian Biotechnology Industry

	Product/service	**Leading firms in this niche (ranking in terms of revenue generated among top 15 firms)**	**Revenue generated in $**	**Percentage share%**	**Exports in $**	**Percentage share%**
BioPharma	Vaccines, therapeutics, animal biologicals, diagnostics	Biocon (1), Serum Institute of India (2), NovoNordisk (7), Transasia (10), Bharath Biotech (13), Indian Immunologicals (14)	2424.4	61.73	1255.6	62.53
BioService	Contract research & manufacturing organisations (CROs & CRAMs)	Biocon (1), Panacea Biotec (3), Syngene international (12), Reliance Life Sciences (4), Quintiles (6)	738.4	18.80	677.4	33.74

BioAgri	GM seeds mainly Bt cotton	Nuziveedu seeds (4), Rasi seeds (8), Mahyco (9), Ankur Seeds (11), Krishidhan seeds (15)	564	14.36	16.9	0.84
BioIndustrial	Speciality chemicals, Enzymes	Biocon (1), Reliance Life Sciences (5)	142.3	3.62	34.1	1.70
BioInformatics	Speciality software	Strand life sciences	55.1	1.40	24	1.20
Total			**3927.6**	**100.00**	**2008**	**100.00**

Source: Association of Biotechnology led Enterprises (Able)
http://www.ableindia.in/pdf/9th_survey.pdf

Figures pertain to fiscal year 2010-11 and are in US$ million

Unfortunately, the above cheery picture has to be tempered with some harsh realities. As of 2011, about 90% of the world's biotech companies are based in the USA and Europe and they account for about 95% of the revenues generated worldwide from biotechnology [37]. The residual 5% of the revenues is shared between firms located mainly in Canada, Australia, Singapore, Israel, China, India, and Brazil. Industrial capabilities in biotechnology in the future will crucially depend on the accumulation of innovation capabilities. In defining innovation capabilities, we distinguish between 'reengineering skills' and 'new drug product creation skills'. Usually a late-comer country firm starts by building reengineering skills i.e. by independently developing new processes to produce copies of existing innovation. Once a firm learns to manufacture the copy, it can envisage investing in the development of 'new product creation capabilties' which can involve a number of stages. Furthermore, developing country firms have to build up complementary competencies in handling regulation that go beyond technology, if they want to commercialize an innovation. To date, no developing country firm has patented a new chemical entity, or created a biotech blockbuster. There is a serious technological retard and this is particularly flagrant in biopharma and agbiotechnology. Nevertheless, Indian biotech firms regularly receive accolades for their technological feats. For instance, recently Sanofi-Aventis, a Western pharma, paid Glenmark, an Indian biotech company, $613 million for a license of a novel anti-inflammatory monoclonal antibody, that Glenmark had developed after purchasing an earlier version for $1 million from the Canadian biotech firm, Chromos Molecular Systems [38].

On the demand side also there is continuous growth. Being the most populous country of the world and enjoying high economic growth (average growth rate above 7% since 2000) has many advantages. The market for some of the applications of biotechnology is driven by growing domestic demand, and in particular, a growing middle class. On the biomedical side, a growing middle

class, new private infrastructure such as the hospital complexes offered by companies such as Apollo and Fortis, and new government programs to promote inclusive healthcare are leading to market growth for preventatives, diagnostics and therapeutic medicines and assured markets for future innovations based on biotechnology. With respect to the poor, concerns about food shortages are pushing the cause of genetically modified plant varieties, though public and government reaction to the use of such strategies has been mixed. Demand in rural areas for healthcare products and services, including biosimilars, received a boost with the initiation of the 'Rashtriya Swasthya Bima Yojana' (RSBY) program in 2008. The RSBY provides health insurance to the rural poor in the form of a cashless coverage for hospitalization with few exceptions, through the use of 'smart card' or biometric cards that permits full traceability of the ailments of the patient and the treatment received. All of these taken together have led to the estimated market overall industry market value as of 2011 of U.S. $4 billion [33].

Having covered the main features of the supply and demand, we now turn to some trends in the industry that are likely to impact the industrial organization and market leadership in the Indian biotechnology sectors in the future.

Changing market composition: The corporate landscape appears to be changing – in the 2009 [39], 11 of the top 50 companies in terms of sales revenues from 2008 to 2009 were new companies (either new spinoffs from large pharma, or brand-new players) in the last 3 years and this new cohort appears to understand the value of patenting, as reflected in the interviews in their stated intentions for the future. Further, most of these new companies are investing in human health as 39/50 companies in terms of top sales in 2009 were invested primarily in the human health sector [39]. This reflects a large shift in terms of the typology of firms in the sector. Chaturvedi [40], noted that while in 2001 the breakdown of players in the industry was 85 in agriculture; 43 in human health; by 2003, this ratio had shifted to 132 in agriculture; 142 in human health. This trend appears to be continuing as indicated by the breakdown of the database collected in support of the interviews for the current study and the overall trend seems to point to about 65% human health focus for biotechnology firms at this point in 2010.

Buy-outs of star Indian firms in pharmaceuticals: In 2008, the leading pharmaceutical firm Ranbaxy was bought off by the Japanese firm Daiichi-Sankyo for USD 4.6 billion, which was to enable Ranbaxy to retire debt and expand its generics production, principally to serve Japanese markets [41]. In 2009, Shantha Biotechnics, which was the first to produce an indigenous recombinant product (shanvac B-hepatitis B vaccine) was acquired for €571 million by Sanofi-Aventis of France. One of the key attractors for the investors may well have been the $340 million UN International Children's Emergency Fund awarded contract for pentavalent vaccines from 2010 to 2012; as noted by

[42] investments and partnership from international or non-traditional sources such as this or another collaboration of Shantha with the US NIH not only bring in high levels of expertise from research to regulation, but also are of acute interest to investors. Again, the attractiveness of Shantha lay in its manufacture of bio-generics as well as its lucrative contracts for the supply of vaccines to international agencies like WHO, which proved its capacity to meet international regulatory requirements. In 2010, Abbott acquired Piramal Healthcare for USD3.7 billion to exploit its generics manufacturing capacity as well as gain the marketing rights to Piramal's branded generics to increase its market share in India. There have been also bids on Cipla, Wockhart and Dr. Reddys[9].

Foreign presence strong in key biotech niches: From Table 6 it is clear that some of the leading players in biopharmaceuticals are foreign multinationals. Furthermore, as noted above, some of the star Indian firms are being bought out in this niche. In the agbiotechnology segment, though there is absolutely no mention of Monsanto in the website of Mahyco the seed leader, it is widely known that their GM seed technology comes from Mahyco Monsanto Biotech (MMB) - a 50:50 joint venture between Mahyco and Monsanto Holdings Pvt. Ltd. which has also sub-licensed the Bt cotton technologies to 28 other Indian seed companies, each of which has introduced the Bollgard technology into their own germplasm. In the bioservices segment, the contract research niche is dominated by foreign multinationals [33]; for example, the top ten MNC players in India are: Quintiles, PPD, Parexel, ICON, Pharmanet, Kendle, i3InVentiv, Omnicare, Clinical Research and Inveresk Research.

CROs as a learning vehicle: During the 1990s, a modest group of Indian biotech firms became active as outsourcing partners for contract research and manufacturing services (CRAMS), bioinformatics services for genomics based drug research, and clinical trials [43]. However, this set has grown enormously, and as of 2010 by one count, the number of Indian CROs tallies 280 [35].

'Upstream research' brings research knowledge and 'downstream clinical trials' brings knowledge of handling regulation. For new CRO entrants in India, it is easier to start downstream, and this is reflected in the much higher number of CROs focusing on clinical research, vs. a very small number focusing on upstream preclinical work; not only is this a reflection of the contracting needs of MNCs either importing to India or who are setting up shop there, but it is also due to the fact that learning to undertake clinical trials is easier than trying to initiate a multi-disciplinary team to obtain the required knowledge and skills to run animal toxicology and metabolism studies, or even more complex preclinical trialsThe further an Indian firm is from the final market, in terms of contract work, the more it needs to get into complex experimentation, as required by contracting companies – further, many large MNCs already have their own in-

[9] As reported in the national dailies.

house toxicology labs, but they do not have the experience with the Indian market.

Forging international collaborations and acquisitions: Links with foreign research institutions and/or firms are increasing. In 2003, the total number of strategic alliances between Indian biotech interests and foreign firms was 129 (35 ag; 70 human health; 1 environment; 11 industrial and 12 others) [40]. This number jumped to 180 in 2010 and a strong number of alliances are South-South (54) out of the total, showing good potential for biotechnology development in areas specific to Southern regional needs, such as vaccines [44]. This also compares favourably with China's more modest move to embrace technology alliances, whereby Chinese firms as of 2010 have 27 South-South alliances and 99 North-South for a total of 126. Acquisitions of foreign firms are occurring steadily. For instance, there 35 in 2008 and 13 in 2009 with most being in the CRAMS niche, for buying a brand, entering a new market, gaining access to new technologies or acquiring regulatory capabilities [45].

Increasing conflicts between multinationals and civil society groups: As may be recalled, in order to make the Indian patent systems TRIPS compliant, it underwent a series of Amendments. One of the sections – termed section 3(d) of the 'Patents (Amendment) Act of 2005', prohibits the grant of a patent on a derivative form of a known substance, it "does not result in the enhancement of the known efficacy of the substance". Barpujari [22] explains that this clause might prove a problem for Indian firms developing combination vaccines – which might indeed using known substances and combining them with novel ones. However, this clause which was introduced to protect the interests of the public against 'ever-greening' of patents in the case of life saving drugs has already proved to be most useful for the same. For instance, in 2005, when Novartis was granted exclusive marketing rights for its anticancer drug Glivec by the Indian patent office, Indian generic producers challenged it on the grounds that the API was based on a derivative of a molecule known before 1995. Furthermore, civic associations and NGOs staged protests. The end result was that Novartis lost its exclusive marketing rights and its patent application was not granted [46]. A further refinement might be necessary to ensure that Section 3(d) does not hinder innovation in recombinant drugs and diagnostics, while continuing to promote access. In addition, market leadership in the future is going to surely depend on the 'litigation handling' capabilities of firms.

New wine in old bottles? Growth of firms using traditional biotechnology: Another sector with a long and successful past is that of traditional medicines and food supplements. Some companies with this background are exploring the potential for marrying traditional technologies with modern biotechnology techniques to explore their potential. For example, some of the traditional medicine firms, like Dabur, may also be well positioned given some resistance in terms of consumer acceptance with respect to GMOs and other related technologies in the agricultural sector to use capabilities with plant selection and

tissue culture techniques to successfully develop drought-resistant varietals and other "products" aimed at helping solve some of the food shortage issues specific to India and other Southern countries. Further, companies like Dabur are well respected and well known, and this can translate to trust and brand awareness in the marketplace. So, while the overall age of companies in the sector may be higher than desirable for a fledgling industry, there may in fact be some advantages in the long run due to both accumulated technology expertise and also trust from the market.

5. Strengths and weaknesses of the Indian NSI as applied to the biotechnology sectors: Verdicts of literature review & direct interviews

The main findings of the preceding two sections on the strengths and weaknesses of the Indian NSI with respect to biotechnology are as follows.

- State policy continues to support biotech research strongly upstream and focuses on ensuring safety of products in final markets downstream through regulation.
- But regulatory capabilities are still weak and the support of the State to transform knowledge into technology via the Indian Bayh-Dole Act is contest.
- Scientific capabilities are sound though international collaborations ought to be improved.
- The transformation of scientific knowledge into usable technology or patent applications is still weak.
- The VC market is very sluggish.
- Leading Indian firms have technological prowess in biotechnology and marketing skills but still are not near to creating blockbusters.
- Market competition is strong in all biotech niches.
- Foreign firms have a strong presence in some biotech niches and have a significant technological advance over Indian ones in terms of new biotech product creation and regulation handling capabilities.

5.1. Validation by the literature review

The corpus was built by using the research equation: 'India' and 'biotechnology' and 'innovation' and 'system' and extracting articles published in economics or management sciences journals after 2000[10]. We limited the time

[10] These are also listed in the references section.

period thus because we wanted to identify the ranking of the strengths and weaknesses of the Indian NSI in the current context. Our findings are summarized in Table 7.

Table 7. Features of the National System of Innovation of India that impact the evolution of the biotechnology industry – A summary of the literature*

Feature of the National system of innovation	**Very strong**	**Strong/Present**	**In need of further strengthening or on the right track but still in need of improvement**	**Weak/Not Present**
1. Scientific capabilities (SCI)		12	2	1
2. Magnitude of public investment in basic research research (BAS)		7	3	4
3. Alliances with foreign research institutions and/firms (FOR)	1	11		1
4. Degree of commercial orientation of academic and public institutions (COM)		1	2	7
5. Venture capital system (VC)			2	9
6. National technology policy (POL)		3	9	3
7. Technology accumulation in related industrial sectors (REL)	1	7		
8. Collaboration with domestic research institutions (ICO)		5	3	5
9. Domestic interfirm R&D cooperation (FCO)		1	1	6
10. Foreign technology utilization &/or market access through acquisition or license (FTU)	1	9		1
11. Age profile of firms Or entry of new firms (AGE)				1
12. Need for Human health focus and capabilities (HH)		4		3
13. Strategy of patenting original innovations (PAT)			9	4
14. Market orientation to international markets or exports (EXP)		5		1
15. Access to a large patient population (POP)		6		

16. Speedy approval process (APP)		3	2	
17. Hub or Cluster Development Strategy (HUB)		2		
18. Consumer acceptance (CAP)				1

*The numbers in the table represent the number of articles which affirm this evaluation. The literature considered in this analysis includes the following references: [47]; [48]; [49]; [50]; [20]; [16]; [35]; [32]; [51]; [52]; [53]; [54]; [55]; [56]; [57]; [58]; [15]; [59]; [14]; [60].

The table clearly indicates that scientific capabilities are the best feature of the Indian NSI. Most authors felt that there was an excellent tradition of scientific education in India (SCI) and additionally, that India was moving in a positive direction with respect to patterns of basic biotechnology research funding (BAS). However, there is a consensus that the Achilles heel of Indian NSI is the capacity to transform scientific knowledge into technology with commercial potential (COM). While [49] show that there is not a high degree of commercial orientation from academia, they also stress the entrepreneurial culture of extant pharma firms in India.

The picture is however mixed with respect to public policy related to biotechnology (POL, APP). In particular, there are elements of regulatory policy that still require an overhaul (a sentiment that was echoed in the primary interviews conducted in this study). In particular, the speed of the regulatory process has been considered by some in the literature to require improvement [47], and this was later echoed by several interviewees.

Given the literature pointing to the lack of commercial orientation on the part of public institutions, it is not particularly surprising that one of the major hurdles that seems to be facing the biotech industry is the lack of technology and "know-how" transfer between the public and private sectors. It seems that companies have largely had to "go it alone" with little support either in the form of institutionalized collaboration between Indian institutions and Indian firms (ICO), inter-firm domestic R&D cooperation (FCO). Interestingly acquisition of knowledge from abroad (FOR and FTU) are regarded as being in a more healthy state than synergy created by cooperation with domestic research institutions (FCO) and between Indian firms (ICO).

There is a general agreement that Indian firms are attempting to grow by serving the international market (EXP); while both Indian and foreign firms are aware of the advantages provided by having access to a large patient population (POP). Related to this, a certain level of technological accumulation, through increased capabilities and ownership of technology, in areas such as vaccines (for example, companies such as Bharat Biotech, Panacea Biotech, Biological E, Shantha, etc) and other related industrial developments in pharmaceuticals, chemicals and software (REL), in addition to moving to more of a cluster model (HUB) in some of the sectors, means that some firms are well positioned to engage with these markets [60].

It is clearly recognized that the two main challenges faced by the Indian biotech firms are technology retard (PAT) and lack of support from an active VC

market (VC). The conveyance of the importance of patenting (PAT) as an international signal to industry and the market, and in particular, potential investors is still weak. On this last point, there is still quite some debate within India regarding whether patenting is an acceptable strategy in India or whether it will result in a 'medical anti-commons' as noted by [61]. However, this argument is really more of concern for public institutions. As well, in the global biotech R&D community, patenting is already the norm, and given the signing of TRIPs, and an increasing rate of patenting by Indian biotech and biopharmaceutical companies, this seems to be the way that things will continue to evolve.

Surprisingly there are some authors who note that Indian firms ought to focus more on human health problems (HH) though this is already where they are concentrated. Finally, neither consumer acceptance (CAP) nor the age profile of firms (AGE) are noted as important factors in the NSI.

5.2. Interview results on main opportunities and challenges

Data was obtained from in-depth interviews with about 25 leading representatives from the government, members of industry associations and firm executives. Both qualitative and quantitative data were requested from these respondents with regard to public policy issues related to development of the biotechnology sector.

In terms of the quantitative responses to the in-depth interviews, a few key questions were asked to determine the key challenges for public policy and the ranked format responses to these questions enabled a simple numerical calculation of the responses. The first question was focused on ranking of the key problems for growth of existing biopharma firms where 1 = biggest challenge and 7 = least challenge.

The averaged responses were as follows: regulatory issues (3.00), difficulties in procuring costly machinery (4.04), petty corruption (4.38), access to markets (3.92), access to capital (3.42), access to intellectual property (3.38) and access to knowledge/skilled workers (3.83). While the number of responses does not allow testing for statistical significance, we certainly see a fairly clear indication that the number one biggest challenge for biopharma firms is with regard to regulatory issues. The next biggest issues, ranked fairly closely together, are access to intellectual property and access to capital. The same list was then presented to determine how these same issues impact new firm entry in biopharma and the responses were as follows: regulatory (3.30), difficulties in procuring costly machinery (3.57), petty corruption (4.39), access to markets (3.96), access to capital (2.43), access to intellectual property (3.26) and access to knowledge/skilled workers (3.87). Not surprisingly, the top two issues for new entrants in biopharma are access to capital and access to intellectual property, closely followed by regulatory issues. Individuals were also asked to assess the main focus of Indian firms (with 1 = highest focus); the averages showed that the feeling is that the vast majority are focused on "second-order" or incremental innovations (1.63) followed closely by a focus on CRO activities (2.06), followed by import focus (2.50) and by far the last, focus on first-run innovations (3.38).

Therefore, among the challenges identified, the three main issues mentioned both for large incumbents and new entrants are regulatory problems/lack of infrastructure, lack of access to intellectual property and lack of capital. Further, another issue mentioned often during interviews with firms, was that while the abundance of training provided at the university level has been good at the theoretical level (and therefore publications), it has not translated into a skilled labour force or one that is able to work well in teams and this is indicated in both low levels of patenting within India by Indian inventors and also by the low levels of cooperative arrangements with other countries and companies.

The refinement of the findings of the academic literature by the examination of policy documents and direct interviews is summarized in Table 8.

Table 8: Strengths and Weaknesses of the Indian NSI with respect to biotechnology

Feature of the National system of innovation	**Evaluation in academic literature**	**Further refinement through policy documents and interviews**
1. Scientific capabilities (SCI)	++	→ Publication record impressive but low level of international collaboration
2. Magnitude of public investment in basic research research (BAS)	–/+	→ Magnitude of public investment low compared to international leaders but proportion to basic research high
3. National technology policy (POL)	–	→Increasing support of knowledge and new technology creation but no targets goals to bring out innovations impacting the poor and overall vision is diffuse
4. Degree of commercial orientation of academic and public institutions (COM)	– –	→A lot of patents from public research laboratories but less collaboration with firms, and very little private patenting →Unemployable graduates
5. Speedy approval process (APP)	–	→ Needed; Petty corruption a problem
6. Alliances with foreign research institutions and/firms (FOR)	–/+	→ Opportunity for technical and market learning and access
7. Foreign technology utilization &/or market access through acquisition or license (FTU)	+	→ Access to intellectual property is a problem → At the same time good experience with acquisitions in past and strategy can continue for Indian firms
8. Collaboration with domestic research institutions (ICO)	–/+	→ More needed
9. Domestic inter-firm R&D cooperation (FCO)	– –	→ Not attractive but could provide some power to domestic players; in terms of scale economies, learning and power go together
10. Need for Human health focus and capabilities (HH)	–/+	→ Improving
11. Strategy of patenting original innovations (PAT)	–/+	→ Improving
12. Venture capital system (VC)	–/+	→ Improving
13. Technology accumulation in related industrial sectors (REL)	+	→ A major strength

14. Market orientation to international markets or exports (EXP)	+	→ Opportunity
15. Access to a large patient population (POP)	+	→ Opportunity
16. Consumer acceptance (CAP)	–	→ Not a major problem, except potentially in agbiotech
17. Age-profile or entry of new firms (AGE)	–	→ Petty corruption and access to markets are main problems.

6. Conclusion

The purpose of the present paper was to examine the possible routes for firms in an emerging country like India to build competence and catch-up in a hi-tech sector such as biotechnology, given that in the post-TRIPS era technical knowledge is increasingly fenced in anti-commons. In order to respond to this query, the role of the State and the size and nature of the biotech capital in India were examined consulting a variety of government publications and publicly accessible databases. Next, the results so obtained were compared with the views offered in the economics literature on the Indian NSI as applied to the biotechnology sectors, and further validated through a series of interviews with leading stakeholders. We now turn to the answers obtained on the central questions and the recommendations that emerge therein.

6.1 Discussion of main results

Our main findings concern the impact of TRIPS, the strengths and weaknesses of the Indian NSI with respect to the biotechnology, the roads to travel to strengthen dynamic capabilities in biotechnology and contribution of the case study to the existing catch-up literature. They are summarized in four main results as follows.

First, though TRIPS has eliminated an important source of cash generation, namely via creative duplication of branded products, it has not stalled the processes of catching-up and building up of innovation capabilities. Today, there are Indian firms, which have become integrated bio-pharmaceutical and bio-chemical companies and are the market leaders in their respective niches. A number of start-ups and incumbents are making use of opportunities to provide contract research services to Western and Japanese multinationals. A handful of firms, DBFs, are actively engaged in the process of first-order innovation. This trajectory of learning was, of course, highly dependent on the functioning of the Indian NSI. The government played a crucial and positive role in this outcome, by investing in the creation of scientific capabilities in biotechnology and making Indian firms aware of its commercial potential.

Second, all actors in the Indian NSI are active, exhibiting their strengths in different ways. The Indian government is interested and willing to support

capacity building in biotechnology. In addition to supporting academic research and regulatory agencies, it is emerging as a major sponsor of R&D projects from the private sector, in order to partially make up for a weak VC market. Nevertheless, the VC market is also growing, although still extremely small in comparison to its American and European counterparts. The production of graduates and publications by academic institutes are notable. Further, leading Indian bio-pharma firms are showing impressive revenue figures. The private sector has reached an important nexus in terms of next steps for catching up and is looking now to various mechanisms such as external alliances with MNCs to further their development. Civil society groups are active as watch-dogs to protect citizen's welfare. Foreign multinationals are expanding their manufacturing and marketing base in India, including through acquisitions of Indian firms.

Third, the NSI suffers from a number of shortcomings, which are obstructing the catch-up process. There are four main challenges as follows:

(i) Indian firms and laboratories still do not have the same expertise as the leading international firms in the different stages of the new product creation process and many of them are also wanting in regulation handling capabilities.

(ii) India's challenge is to make inroads in biotechnology markets with a shoe-string budget as compared to developed countries. There is a serious bottleneck in terms of financial capital, which is crucial for moving from science to technology and then to commercialization.

(iii) Regulatory capabilities need to be strengthened. Petty corruption in State agencies is the most serious drawback of the regulatory system. The lack of qualified personnel in patent offices is another major hurdle. Formulation of regulation is often not checked against the realities of 'compliance' before enactment.

(iv) Though in terms of quantity, scientific personnel is not lacking, there is a serious problem of quality. While the abundance of training provided at the university level has been good at the theoretical level (and therefore publications), it has not translated into a skilled labour force or one that is able to work well in teams and this is indicated in both low levels of patenting within India by Indian inventors and also by the low levels of cooperative arrangements with other countries and companies.

Fourth, returning to the central question of the paper on the roads to travel, the evaluation of the Indian NSI refines the initially hypothesized 5-path model to a 3-path model, as indicated in Table 9, as being the most likely. Indian firms are most likely to travel a combination of three paths to catch-up in biotechnology.

Table 9: Roads to travel for Indian firms: Strategic business models in the biotechnology sectors

Feature of the National system of innovation	**Strategic Model 1 Focus on Generics/Bio-similars**	**Strategic Model 2 Focus on Alliances (Catching up as CROs)**	**Strategic Model 3 Investing in Original Innovation**
Ease of entry utilizing the business strategy	++	+++	+
Fixed costs of adopting business strategy	+	+	+++
Short term monetary returns	+++	++	+ or –
Learning with new drug discovery	+	++	+++
Learning related to handling regulation	++	+++	+++
Learning related to market positioning	++	+	+++
Long term potential for innovation rents	?	+	+++
Risk of a buy-out	+++	++	+++

A focus on bio-generics and bio-similars and vaccine development in areas of strength will ensure some level of autonomy against the incoming MNC superhighway, and to capture new market pockets as they develop. Contract research opportunities warrant more learning, while generating steady short term revenue. Both these paths can be used to generate the much needed financial capital to invest in original innovation. There are risks of course, associated with each of these options. The financial risk is greatest in case of investment in original innovations. But, when Indian firms develop world-class competencies either through the production of bio-generics/bio-similars or through original innovation, they also put themselves at risk of buy-outs. CROs may be at moderate risk if they become successful, in which case they might merge with a bigger player, rather than being the object of an aggressive take-over by a bio-pharmaceutical player.. In the worst case scenario, if the best Indian performers are acquired and made to focus on manufacturing generics and carrying out clinical trials, while strategic R&D in biotech is carried on in the mother companies outside India, the future of Indian innovation will not be bright though in the short run it will be clearly a win-win deal for all.

As of now, the CRO model has been heralded as the key for catching up, particularly as shown in Table 9, due to the ease of entry, low costs of entry and the reasonably short-term returns on investment. This said, however, this strategy needs to be pursued with caution. First, there is more learning upstream than downstream through clinical trials and the vast majority (i.e., almost all) firms currently involved in the CRO model are pursuing growth primarily through a downstream clinical strategy. While there may be some advantages in

doing so, primarily based on access to the target population and in Phase IV clinical trials, specific knowledge of the market and distribution channels, it will not take long for larger MNCs to acquire such knowledge. This brings about the second major point which is that the large dominant MNC CROs have been, many of them, in business since the late 1970's and therefore many have in excess of 30 years of experience, not only in preclinical and clinical trials, but also the same length of time developing relationships with the large biopharmaceutical players. Reputation and trust counts and this means that when biopharmaceutical companies come to choose an MNC to work with they will likely go to those which (1) cover a wide spectrum of services that they will need in the process; (2) go with those they have worked with in the past and (3) work with those that can leverage learning across multiple country trials. This does not mean that opportunities do not exist for CROs, however, those companies that want to be successful in the long term will need to be able to develop successful long-term strategies which for some, will require the ability to learn how to swim upstream and for others, to develop niche skills that others cannot provide.

Another option to cover the different types of risks and ensure catching-up would be to focus more on innovations that promote inclusive development through public-private partnerships orchestrated in national programs. Indeed, they are individual efforts by scientists, firms and bureaucrats to develop pro-poor innovations, but as of now there is no national program with clear targets. Though the potential of biotechnology to promote inclusive development is clearly recognized and understood by all stake holders, the efforts to promote the same are diffused among specific laboratories, firms and individuals. Given the high level of existing scientific capabilities, dedicated organizations and active social entrepreneurs who have an intimate knowledge of the context of deep poverty, this is a missed opportunity, both to promote inclusive development and to reap the fortune at the bottom of the income pyramid as management science scholars point out [39]. A national programme involving interested laboratories and firms and focussing on a few clear pro-poor innovation targets could be a possible solution. The silver lining to this lacuna is that some of the firms we spoke to were committed to specific pro-poor innovation projects even through they are under no pressure to do so. There are Indian firms whose founders and managers have a social mission in addition to a market one and who are engaged in actions to generate pro-poor innovations. There is even a consideration to make firms contribute to local development via a corporate social responsibility or CSR investment, but this may not promote innovation generation.

Last, in terms of the catch-up and NSI/SSI literature, the above case study indicates that, with TRIPS, an efficient NSI is a necessary but not sufficient condition to make inroads in a high-tech sector such as biotechnology. One of the factors repeatedly noted in the literature as having been key to the catch-up process was the efficient absorption and exploitation of superior technologies developed in other nations, crucially supported by favourable public policy, public investment, State intervention and firm responses [10]. Indeed, Fagerberg [62]) argues that catching-up process is essentially a dynamic process resulting from

the confrontation of two conflicting forces: innovation in advanced countries that tends to increase the economic and technical gaps between backward and advanced countries; and diffusion and imitation of such innovation, which tends to reduce the gaps. Furthermore, Soete [63] illustrates that when such international diffusion of knowledge occurs in combination with transition in technological paradigms, it can sometimes open up 'windows of opportunity' which when exploited optimally can lead not only to 'catching-up' but even technological 'leap-frogging'. Such processes do not apply to the post-TRIPS world. At the same time, even without imitation being possible, new 'windows of opportunity' may be created along any of the three roads discussed above, to which we can also add new uses of old technology, traditional knowledge and traditional medicines. Timely perception and exploitation of such windows of opportunity will further catching-up. But significant catching-up cannot be taken for granted even with an efficient NSI and most certainly 'leap-frogging' can only occur as a random serendipitous event.

6.2 Recommendations

The above analysis leads to the following propositions in terms of recommendations.

For the Indian state – The need of the hour is to strengthen the regulatory bureaucracy. Since it will be very difficult in the immediate period to staff patent offices with qualified personnel, bringing in people with expertise from other countries should be considered. Outside regulatory consultants can also be hired to ensure speedy and efficient implementation of mechanisms. The habit of putting the cart before the horse needs to be stopped if regulation is to be credibly monitored and implemented.

Instead of a diffused vision – there can be a selection of niches for the two main national objectives namely the attainment of international leadership and the promotion of inclusive development. One of the best candidates is vaccines. Another is traditional medicines. Another which has been under-developed to date, although is finally showing signs of organizing to respond to its potential for the market is bioinformatics. As noted by Chaturvedi [35]: "Some of the major ICT firms have also joined the biopharmaceutical industry facilitating convergence of biopharma sector with bioinformatics…as a result of this, the biotechnology clusters have fast emerged in the areas, which were already regarded as a forté of ICT firms".

Policies to encourage foreign investment, can also be fine-tuned to promote knowledge sharing. For example, tech transfer agreements can be made mandatory for MNCs or made to reinvest a certain percentage of revenues emanating from Indian market in local universities. Equity is not as important as tech transfer and opportunities for employment generation, and permitting > 50% equity can be used to attract foreign direct investment.

Further, in India, incentive programs need to be put in place to actively encourage better interaction and collaboration between firms, firms and research organizations and between research organizations themselves. These do not necessarily entail a great amount of spending, but better co-ordination of effort. Cues can be taken from the European programmes which require a variety of organizations to join together in order to apply for a research grant, instead of permitting individual bids as is the common practice in India.

For Indian firms – The most important recommendation that stands out is: patent, patent, patent both to attract VC and MNC investment, and for protection. Form coalitions to have better bargaining with developed country firms. Continue to actively seek export markets as important revenue generators. Actively pursue strategic alliances, rather than MNC buy-out as mechanisms to access external markets, and to engage R&D capabilities. Seek out public labs and government grants - it is difficult to become an original innovator unless backed by public labs cooperation or government grants.

For Indian CROs – There is much hope in India that the CRO model will be the key opportunity for the future, however some caveats need to be kept in mind. Indian CROs need to offer solid niche services that are complementary to the needs of the established CRO labs and internal labs of MNCs. In particular, specialized services that can bank on cluster capabilities of other firms in India will be in demand. For example, rapid testing of new–strain vaccines or working hand-in-hand with bioinformatics companies to provide innovative screening solutions could provide specialized skills both worldwide and for the Indian market. Another possibility is for the strongest CRO players in the Indian market to either form a virtual alliance or coalition across the spectrum of CRO capabilities or to actually merge in an effort to pre-empt entry from the large global CROs. There is a window of opportunity here that, if not taken pretty much immediately, will no longer be available, because this is an extremely competitive field, dominated by Western multinationals. There already exists a large and well-developed CRO industry world-wide with strong capabilities across the preclinical and clinical spectra.

For Western/Japanese firms – Besides the usual reasons given for India to be a good outsourcing hub to reduce costs, basically it makes sense to additionally cooperate in innovation generation because in phase IV clinical trials market tests are required and Indian firms have the necessary access to provide in-situ clinical tests of this nature. Indian markets are growing and so there is ample opportunity for exploiting new and emerging consumer needs/products. Partnerships may be more fruitful *if opportunities for learning* are offered to Indian firms.

On a final note, for Indian biotech firms, the point is not to identify the 'best' road to travel to become original innovators. There is no one path to success in India. The crucial question is how to formulate good 'mixed' strategies given the inroads

being made by MNCs, while at the same time optimizing learning opportunities to move up the value chain. Multiple strategies have to be the norm as they are the optimal response to the multiple opportunities and capabilities required for survival in the Indian marketplace.

Acknowledgements

The authors wish to acknowledge the funding provided in support of this research effort by the Fonds de Recherche Sur la Société et la Culture (the FQRSC, Quebec, Canada). We would also like to acknowledge the valuable assistance of Ms. Sangeeta Venkatesh in preparing for and conducting the primary interviews performed for the study. As well, we would like to thank the other members of the FQRSC research team, in particular Dr. Jorge Niosi and Dr. Petr Hanel, for their helpful comments and contributions on behalf of the development of this article.

References

[1] B.A.E. Lundvall, National Innovation Systems : Towards a Theory of Innovation and Interactive Learning, Pinter, London, 1992.
[2] R. Nelson, National Innovation Systems: A Comparative Analysis, Oxford University Press, Oxford, 1993.
[3] C. Freeman, The National System of Innovation in historical perspective, Cambridge Journal of Economics, 19 (1995) 5-24.
[4] C. Edquist, The systems of Innovation Approach and Innovation Policy : An account of the state of the art, in: Lead paper presented at the the DRUID conference, June 12-15, Aalborg 2001.
[5] B.A. Lundvall, Why study National Systems and National Styles of Innovation?, Technology Analysis and Strategic Management, 10 (1998) 407-421.
[6] A. Gerschenkron, Economic Backwardness in Historical Perspective, The Belknap Press, Cambridge, MA, 1962.
[7] M. Abramovitz, Catching-up, forging and falling behind, The Journal of Economic History, 46 (1986) 385-406.
[8] S. Lall, Technological Capabilities and Industrialization, World Development, 20 (1992) 165-186.
[9] K. Lee, C. Lim, Technological Regimes, Catching-up and Leapfrogging: Findings from the Korean Industries, Research Policy, 30 (2001) 459-483.
[10] J. Fagerberg, M. Godinho, M., Innovation and Catching up, in: J. Fagerberg, D. Mowery, C., R.R. Nelson (Eds.) The Oxford Handbook of Innovation, Oxford University Press, Oxford, 2004, pp. 514-543.
[11] F. Malerba, Sectoral systems of innovation and production, Research Policy, 31 (2002) 247-264.
[12] K. Eisenhardt, Building theories from case study research, Academy of Management Review, 14 (1989) 532-550.

[13] R.K. Yin, Case Study Research, Design and Methods, Sage Publications3rd ed., Newbury Park, 2002.
[14] S.V. Ramani, Who's interested in biotechnology: R&D strategies, knowledge base and market sales of Indian biopharmaceutical firms, Research Policy, 31 (2002) 381-398.
[15] S.V. Ramani, M.S. Venkataramani, Rising to the technological challenge: Integration of biotechnology in the Indian Pharmaceutical Industry, International Journal of Biotechnology, 3 (2001) 95-115.
[16] S. Chaturvedi, Exploring Interlinkages between between National and Sectoral Innovation Systems for Rapid Technological Catch-up: Case of Indian Biopharmaceutical Industry, Technology Analysis and Strategic Management, 19 (2007) 643-659.
[17] Advantage-Business-Media, 2010 Global R&D Funding Forecast, in: sponsored by Battelle and R&D Magazine, 2009.
[18] B.N. Sampath, The Bayh-Dole Model in Developing countries: Reflections on the Indian Bill on Publicly Funded Intellectual Property, in: UNCTAD-ICTSD Project on IPRs and Sustainable Development - Policy Brief Number 5, October 2009. , 2009.
[19] K.S. Jayaraman, Is India's 'Patent Factory' Squandering Funds?, Nature 442 (2006 (13 July)).
[20] S. Chaturvedi, C. Wendy, V. Siva Reddy, D. Ripandelli, Environmental Risk Assessment, Socio-Economic Considerations and Decision-Making Support for GMOs in India, in: RIS Publication, New Delhi, 2007.
[21] V. Reddy, Biotech regulation in India: Problems and Promises, Journal of Biotechnology, 4 (2009) 306-309.
[22] I. Barpujari, The Patent Regime and Nanotechnology: Issues and Challenges., Journal of Intellectual Property Rights, 15 (2010) 206-213.
[23] S.V. Ramani, After the Green Revolution, Bt Cotton in India: Blessing or Regulatory Headache?, in: Working Paper, Ecole Polytechnique, F-91128 Palaiseau Cedex, France, Working Paper, 2008, 2008.
[24] G. Vaidyanathan, Technology parks in a developing country: the case of India The Journal of Technology Transfer, 33 (2008) 285-299.
[25] (NSF)National-Science-Foundation, Science and Engineering Indicators, (2008).
[26] S. Sundaramoorthy, Y. Chandra Bindu, R. Mehditatta, G. Saberwal, The U.S. patent holdings of homegrown Indian biotech and pharma companies, Current Science, 96 (2009).
[27] J. Niosi, P. Hanel, S.E. Reid, The international diffusion of biotechnologies: The arrival of developing countries, in: The International Schumpeter Society Conference, Aalborg, Denmark, June, 2010, 2010.
[28] B. Van Beuzekorn, A. Arundel, OECD Biotechnology Statistics 2009, in: OECD, 2009.
[29] D. Abrol, P. Prajapathi, N. Singh, Globalization of the Indian Pharmaceutical Industry: Implications for the direction, distribution and diversity in drug production, in: Presentation at the Globelics conference, Kuala Lampur, Nov 1-3, 2010., 2010.

[30] D. Abrol, Conditions for the achievement of pharmaceutical innovation for sustainable development: Lessons from India, World Review of Science, Technology and Sustainable Development, 3 (2006) 344-361.
[31] (IVCA)-Indian-Venture-Capital-Association, Venture capital and private equity in India, (2007-October).
[32] S.E. Frew, R. Rezaie, S.M. Sammut, M. Ray, A.S. Daar, P.A. Singer, India's health biotech sector at a crossroads, Nature Biotechnology, 25 (2007) 403-417.
[33] Biospectrum, The business of biotech, 9 (2011, June).
[34] BioSpectrum-ABLE, Biotech Industry Survey, (2010).
[35] S. Chaturvedi, Emerging Indian entrepreneurship in biotechnology and National Innovation System: exploring linkages and prospects, International Journal of Technology and Globalisation, 5 (2010) 76-92.
[36] Dr.Reddy's-Ltd, Annual Report, in, 2010.
[37] Nature-Biotechnology-Editorial, Sharing secrets, Nature Biotechnology, 29 (2011) 291.
[38] K. Jayaraman, Biologic Indian detour adds value Nature Biotechnology, 29 (2011) 561-561.
[39] BioSpectrum-ABLE, Biotech Industry Survey, in, 2009-June9.
[40] S. Chaturvedi, Dynamics of biotechnology research and industry in India, in: OECD Science, Technology and Industry Working Papers, 2005/2006.
[41] S. Basheer, Ranbaxy-Daiichi merger: An emerging Ardhnarishwar model?, in: DNA (India), 2008.
[42] J.H. Chakma, K. Masum, J. Perampaladas, J. Heys, P.A. Singer, India's billion dollar biotech, Nature Biotechnology, 28 (2010) 783.
[43] S. Ramani, V., A. Maria, TRIPS and its possible impact on the biotech based segment of the Indian pharmaceutical industry, Economic and Political Weekly, Feb 12-18 (2005) 675-683.
[44] H. Thorsteinsdóttir, C.C. Melon, M. Ray, S. Chakkalackal, M. Li, J.E. Cooper, J. Chadder, T.W. Saenz, M. Carlota, P. de Souza, W. Ke, L. Li, M.A. Madkour, S. Aly, N. El-Nikhely, S. Chaturvedi, V. Konde, A. S Daar, P.A. Singer, South-South entrepreneurial collaboration in health biotech
Nature Biotechnology, 28 (2010) 407–416
[45] N. Som, India market charged with deals, Biospectrum, April 08 (2010).
[46] S. Srinivasan, Battling patent laws: the Glivec Case, Economic and Political Weekly, (2007) 3686-3691.
[47] S. Athreye, D. Kale, S.V. Ramani, Experimentation with strategy and the evolution of dynamic capability in the Indian Pharmaceutical Sector, Industrial and Corporate Change, 18 (2009) 729-759.
[48] R. Basant, Intellectual Property Rights Regime and Creation of Innovation Based Enterprises in India, in: Presentation at Globelics 2006, 2006.
[49] D.J. Bower, J.C. Sulej, The Indian challenge: The evolution of a successful new global strategy in the pharmaceutical industry, Technology Analysis and Strategic Management 19 (2007) 611-624.
[50] J. Chattaway, J. Tait, D. Wield, Frameworks for pharmaceutical innovation in developing countries - The case of Indian Pharma, Technology Analysis and Strategic Management, 19 (2007) 697-707.

[51] S. Guennif, S.V. Ramani, Explaining divergence in catching-up in pharma between India and Brazil using the NSI framework, Research Policy, (Forthcoming).
[52] A. Hall, Capacity development for agricultural biotechnology in developing countries: An innovation systems view of what it is and how to develop it, Journal of International Development, 17 (2005) 611-630.
[53] D. Kale, S. Little, From Imitation to Innovation: The Evolution of R&D capabilities and Learning Processes in the Indian Pharmaceutical Industry, Technology Analysis and Strategic Management, 19 (2007) 589-611.
[54] N. Kumar, U. Quach, H. Thorsteinsdóttir, H. Somsekhar, A.S. Daar, P.A. Singer, Indian biotechnology - rapidly evolving and industry led, Nature Biotechnology (2004) DC31-DC36.
[55] S. Mani, Institutional support for investment in domestic technologies: An analysis of the role of government in India, Technological Forecasting and Social Change, 71 (2004) 855-863.
[56] K. Mehra, J. Kirti, The enabling role of the public sector in innovation: A case study of drug development in India, Innovation: management, policy and practice, 12 (2010) 227-237.
[57] L.M. Mytelka, Pathways and policies to (bio) pharmaceutical innovation systems in developing countries, Industry and Innovation, 13 (2006) 415-435.
[58] S.V. Ramani, S. Visalakshi, The role of resources and incentives in the integration of biotechnology in developing countries : An Indian case study, International Journal of Biotechnology, 2 (2001) 297-312.
[59] S.V. Ramani, M.E. Aroui, P. Audinet, Partner selection and Contract Design in the Indian biotechnology sectors, The Developing Economies 39 (2001) 85-111.
[60] J. Niosi, S.E. Reid, Biotechnology and Nanotechnology: Science-based enabling technologies as windows of opportunity for LDCs?, World Development, 35 (2007) 426-438.
[61] P.G. Sampath, Breaking the fence: Can patent rights deter biomedical innovation in 'technology followers'?, Technology Analysis and Strategic Management, 19 (2007) 1-20.
[62] J. Fagerberg, Innovation, catching-up and growth, in: International Seminar on Science, technology and economic growth, OECD, Paris, 5-8 june, 1989.
[63] L. Soete, International diffusion of technology, industrial development and technological leapfrogging, World Development, 13 (1985) 409-422.