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RIS
Research and Information System for Developing Countries
Core IV-B, Fourth Floor, India Habitat Centre
Lodhi Road, New Delhi – 110 003 (India)
Tel: +91-11-2468 2177/2180; Fax: +91-11-2468 2173/74
Email: dgoffice@ris.org.in

Indian Innovation Systems and Emergence of Biopharmaceutical Sector: Issues and Prospects

Sachin Chaturvedi*

Abstract: The prospective entry of generic dominated Indian pharmaceutical sector in the ambit of new technologies is likely to give filip to emergence of strong biopharmaceutical sector.It is pertinent in this context to draw a policy roadmap which takes into account sectoral dynamics and draws upon regional and international linkages. An appropriate balance between national system of innovation (NSI) and sectoral system of innovation (SSI) would determine trajactory of growth of this sector.

Keywords: NSI, SSI, Biopharmaceutical and India.

I. Introduction

With the advent of biotechnology in the pharmaceutical sector, the Indian innovation system seems to get set for a major paradigm shift. The shift from chemistry driven drug development to biobased drug development with sharp focus on biotechnology and genomics, accompanied with upward movement of the generic firms and growing public allocations for drug development are some of the factors bringing in a major shift, which may transform the innovative abilities of the generic producing Indian drug industry.

The evolution of knowledge, institutions and firms within the pharmaceutical industry may define new trajectory of their interlinkages especially in context of the growing global linkages of the sector, which go beyond national specificities. The pervasive entry of biotechnology into the pharmaceutical industry is well captured (Quéré 2003). The contours of this new paradigm will depend in part on the ability of Indian policy makers

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* Fellow, (RIS). Email: sachin@ris.org.in
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to address the interlinkages between the national innovation system and the sectoral innovation system and how firms respond to these changes in policies. The processes of specialisation would further enhance complexity of innovation system. The Indian biopharmaceutical market is valued at around $1.05 billion and it is growing at nearly 32 per cent.[1] Biopharmaceuticals are therapeutic or preventative medicines that are derived from living cells, using recombinant DNA technology. Conventional pharmaceuticals are generally small molecules, whereas biopharmaceuticals are typically proteins, peptides, nucleic acids or inactivated viruses/bacteria. The biopharmaceuticals include insulin, Hepatitis B vaccine, Erythropoietin, Human Growth Hormones.

In the new paradigm, strategies such as product differentiation based on incremental innovation may not go far, as the new technology infuse a different level of dynamism, and this transforms the very settings in which the drug industry function which is also held responsible for the slow growth of global biotechnology drug industry (Pisano 2006). The process would become much more radical and risky – features which Indian pharmaceutical industry predominantly generic based industry has never experienced before. The question that arises here is to what extent institutions are prepared for this shift. Would the earlier policies of promoting National System of Innovation (NSI) focussed prescriptions work, when, sectoral boundaries are no more static and deeper changes in technology do not facilitate any straight jacket delimitation of the sectors. The challenges emanating from the introduction and adoption of new technologies may give further impetus to the need of having a framework in which specific measures are identified for strengthening of innovation systems at national and sectoral levels.

Since the seminal work on national innovation system by Nelson (1993) the concept of innovation systems has been addressed from different standpoints. The technology systems approach developed by Carlsson (1997), focussed on technology linkages beyond the national borders. The regional dimension of the innovation system has been explored by Saxenian (1999), Cooke (2000) and Braczyk *et al*. (1998). Malerba (2002) Malerba (2005) has developed a sectoral approach for analysing the innovation system. McKevey and Orsenigo (2001), Malerba and Orsenigo (2002)

specifically articulate the relevance of analysing pharmaceutical sector in the framework of sectoral innovation system. However, Archibugi *et al.* (1999) have argued that the concept of national (or spatially bounded) systems of innovation and sectoral systems of innovation should not be viewed as mutually exclusive and that efforts to establish inter-linkages may yield valuable insights.

The central question of this paper are: to what extent Indian innovation system is prepared to respond to policies and initiatives based on national and sectoral level innovation system framework at a given point of time. In light of the growing complexity of both the innovation process and also that of the regulatory environment, it is pertinent to evolve new coordination mechanisms and dynamic responses, as the traditional institutional frameworks would have very limited role to play. Generally, the pharmaceutical industry can be easily considered as a system or a network because innovative activities involve directly or indirectly a large variety of actors, including: (different types of) firms, other research organizations like universities and public and private research centers, financial institutions, regulatory authorities, consumers.[2] The additional question is to look into the flows and links between the systems.

The emerging policy options would have to be explored for application of new technologies in the production processes with special focus on institutional environment, which provides sectoral resources to the innovation system and may facilitate the interaction among various actors. In this paper we make an effort to look into some of these issues. In Section II the debate on the interplay of the two conceptual frameworks, viz. NSI and SSI is summarised along with presenting an analytical framework for the paper. the Section III presents the evidences from the Indian pharma sector are presented. The last section draws the conclusions.

II. National and Sectoral Innovation Systems

The relationship between country specific institutional frameworks and technological capabilities have been discussed at length in the literature on NSI. Instead of providing definite relationships between variables, NSI highlights the importance of looking at relations between various components (Nelson 1993). This percepective is complemented in sectoral innovation system thinking and, for example, the integration of basic and applied research, required for innovation is viewed as taking place as a result of interaction between firms and research institutions, rather than within firms alone. However, there are differences between the two frameworks.

In the NSI literature a few categories have been developed which can be used to reflect on the status of different innovation systems. These have been summarised in Lundvall (1992). As is clear from Table 1, Malerba (2002) identifies the framework elements for sectoral innovation system and points to differences between SSI and NSI.

Lundvall (1992) suggests internal organisations of firms, inter-firm relationships, role of public sector, institutional set up of the financial sector, R&D intensity and R&D organisations as key aspects of NSI. The NSI framework emphasizes on drawing upon their differences for international comparisons but at the same time also emphasizes understanding the dynamics of relationships between these various elements. However, as has been discussed earlier, the dynamics of innovation may be very different at the sectoral level and may have its own peculiarities (Malerba, 2002). These

Table 1: Key Elements of National and Sectoral Innovation Systems

National Innovation System	Sectoral Innovation System
Innovation Policies	Knowledge (Static and Dynamic Complementarities)
Research and Education Policies	Technological Domain
Corporate Activities	Actors and Networks (Organisations;
Financial System	Individuals; Non Firm Organisations; Group of Organisations; Larger Organisations).
Regulations	Institutions
***Source*:** Lundvall (1992)	***Source***: Malerba (2002)

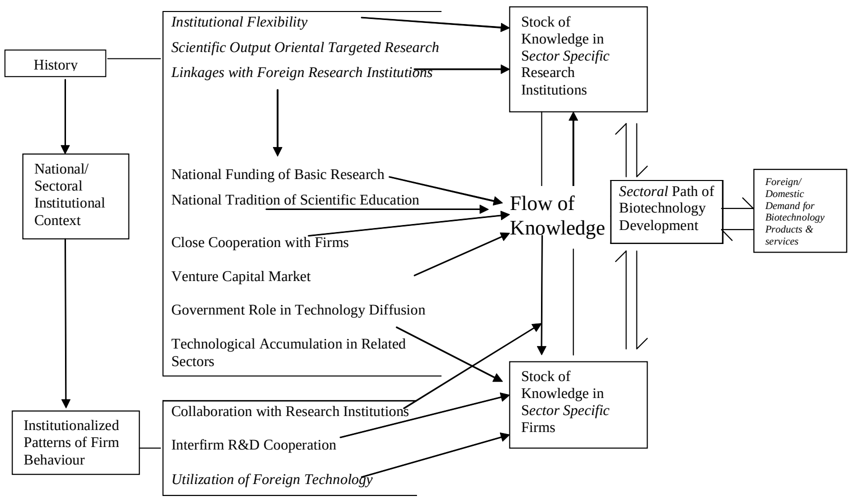
peculiarities are specific in the sense that each sectoral system of innovation and production may have set of new and established products for specific use and set of agents for operationalising the production and sale of those products which would be governed by specific sectoral regulatory policies. The biopharmaceutical sector would have dynamics, which would be very different from that prevailing in the pharma or any other R&D intensive sectors. There is a possibility of national innovation system influencing the various constituents of a sectoral innovation system like the actors and networks, institutions and technological domains. The SSI identified three crucial areas for drawing distinctions across sectors, which covered knowledge and technological domain; actors and networks and institutions. However, the linkages between the NSI and SSI should not be overlooked. Some of the papers such as Bartholomew (1997) and Senker (2001) have attempted to analyze sectoral innovation system focusing on biotechnology, which they have called as National System of Biotechnology Innovation (NSBI).

Incidentally, both the studies have a predominant focus on developed economies. In these studies the foundation pillars of NSBI have largely emanated from the dynamics of NSI, which has evolved, over a decade, as a conceptual research framework rather than a formal theory. The biotechnology innovation may be conceptualized as the product of the accumulation of scientific knowledge in research institutions and firms (stock) and the diffusion of that knowledge between them (flow). The conceptual framework as developed by Bartholomew (1997) focus on eight particular features of national institutional context, which affect these stocks and flows of scientific knowledge. They are tradition of scientific education; pattern of basic research funding; linkages with foreign research institutions; degree of commercial orientation of academia; labour mobility; venture capital system; national technology policy; and technological accumulation in related industries. This model also considers three R&D practices at the level of the firm: collaboration with research institutions; and inter-firm R&D cooperation and utilization of foreign technology, as the key factors, contributing to the innovation process.

It is important to realize that evolution of biotechnology in a particular science and technology system is also a function of demand for

Figure 1: National/Sectoral Systems of Biotechnology Innovation:

A Framework for Analysis



Source: Bartholomew, 1997 (italics added)

biotechnology related products. The level of interaction among the various actors is the key to success. It also depends on the institutional dynamism within the system. The Figure 1 attempts to present the systemic dynamics. As the system responds to the emerging demand this may even lead to sectoral specialization within biotechnology. NSI in case of developing countries is often found to be less developed in terms of institutional composition, the sophistication of scientific and technological activities and the linkages between organizational units. Moreover, Shulin (1999) points out that for developing countries, as against developed ones, it is the capital, which plays key role in achieving technological excellence rather than knowledge and learning.

III. Framework for Analysis

The elements identified in this are described below and are also put together in the Figure 1 for further analysis to bring in the flow and linkages among

various actors in an innovation network. In terms of desiderata for SSI especially in the context of developing countries particularly India, one may like to add a couple of additional components which may play an important role in the working of SSI. India always had strong preconditions like the scientific traditions. The entry of generic based pharmaceutical industry into the biopharmaceuticals hints at the cumulative path dependency model of learning processes. Apart from this, the model for NSBI should also consider the demand in the system as well as the public acceptance of biotechnology products. The policy support to encourage targeted research and ability to outsource R&D at firm and institutional level are other important constraints.

In light of the earlier discussion, we refer to the analytical framework developed in Kaiser *et al*. (2004) on the basis of the five indicators developed in the NSI for our current analysis. The five indicators identified which are described below bring in various points at which firms respond to various challenges emanating from new technology based innovation systems both at sectoral and at the national level. As an emerging science based industry biopharmaceuticals pose a specific nature of regulatory and institutional demands on the NSI. The fact that specific sectoral institutions have come up among these five indicators to address the sectoral requirements reinforces the relevance of these indicators.

1) Regulation

In the case of pharmaceuticals, regulation for drug trials is important but it assumes additional significance in the case of biopharmaceuticals. It is not the only requirement of a regulatory regime applicable to transgenics additional provisions related to ethical guidelines, stem cell guidelines, etc.,which are highly sectoral in nature, are also needed.

2) Financial System

The Indian government has set up pharmaceutical R&D funds to address a wide-ranging gap in the industry. The policy for promotion of venture capital fund may facilitate entry of small and medium sized firms.

3) Innovation Policies

Support mechanisms required for promotion of the biopharmaceutical industry are very different from the broad innovation thrust required for the pharmaceutical industry. This is particularly true for countries like India. It is dominated by generic-producing export-oriented firms and is yet to move up the value chain.

4) Research and Education System

Biopharmaceutical products in vaccines, therapeutics and diagnostics require highly specialized and focussed manpower. The research and education system had to be geared for specific requirements. The setting up of new institutions like National Institute for Pharmaceuticals Education and Research (NIPER) are important initiatives.[3]

5) Corporate Activities

The emergence of contract research organisations (CROs) in the biopharmaceutical sector with their local and international linkages provide impetus to the growth of this sector.

While capturing the growth of the biopharmaceutical sector in India we have taken care of the flows and linkages among various actors from the network viewpoint. Since the large number of entrants for pharmaceuticals are generics producers, the networks across national and sectoral institutional systems are very much criss-crossing – providing opportunities for interaction in terms of linkages and flows connecting the actors in a network. In the next section we make an effort to see the status of innovation system in India.

IV. Emerging Contours Indian Biotechnology Innovation System

IV.1 New Regulatory Regime for Pharmaceuticals

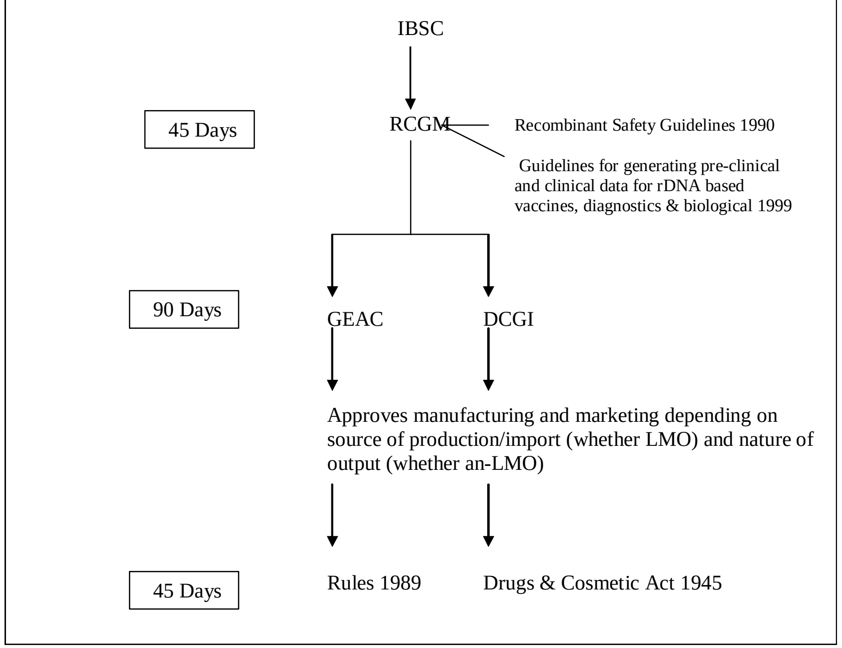
India is making efforts to streamline regulatory structure. The Ministry of Environment and Forest appointed a Task Force on Recombinant Pharma to recommend regulatory mechanisms and processes for use of living modified organisms (LMOs) in the pharmaceutical industry during the

various stages of R&D, testing, manufacturing and use.[4] In India, the biotechnology products are cleared through a hierarchy of committees which operate at different levels. The most important committees are: the Institutional Biosafety Committees (IBSC), responsible for the local implementation of guidelines at the institutional level; the Review Committee on Genetic Manipulations (RCGM) hosted by Department of Biotechnology and is responsible for monitoring safety related aspects in ongoing research projects involving genetically engineered organisms and micro-organisms; and the third committee is Genetic Engineering Approval Committee (GEAC), housed at Ministry of Environment and Forests responsible for monitoring the large scale and commercial use of transgenic materials especially from the environmental perspective. The GEAC is supposed to be assisted at the post-release stage by the *Sta*te Biotechnology Coordination Committees (SBCC) and District Level Committees (DLC). In case of pharmaceutical products the clinical safety part is assessed by the Recombinant Drugs Advisory Committee (RDAC) which works as part of the Drugs Controller General of India (DCGI) under the Drugs and Cosmetic Act, 1940. As discussed earlier, the Task Force has attempted to delineate the key responsibilities between RDAC and GEAC for faster clearance. As is clear from the Figure 2, the Task Force has also proposed the timelines within which products are to be cleared by these committees which was often a problem for many drugs companies.

Indian government has made efforts to liberalise the import regime to facilitate the import of biotechnology products. This now may be done under the scheme called the “Open General” category of the import regulations, which does not require any government approval. The import duties have also been reduced to encourage import of capital goods and raw materials.

The guidelines for biomedical research, in India, had been in place since 1992 and were renewed in 1997. They define human material with potential for use in biomedical research as organ and parts of organs, cells and tissue, sub-cellular structures and cell products; blood, gametes (sperm and oval), embryos and foetal issues, wastes (urine, faeces, sweat, hair, epithelial scales, nail clippings, placenta and cell lines from human tissues. The Bioethics

Figure 2: Biopharmaceutical Regulatory Institutional Structure in India



Committee set up by the DBT in 2003 has announced a Bioethics Policy. This would not allow human cloning in the country, but would promote embryonic stem cell research, provided a consent form is filled up with each study.

The Department of Biotechnology has written to all the major biotechnology companies to make it clear that any transfer of biological material would be subject to clearance by the Ministry of Health and Family welfare and the Indian Council of Medical Research (ICMR). This precautionary move has come in the wake of a global debate on the existence of stem cell lines in India; after the Bush Administration identified India on its list of sources of stem cell lines among other institutions (Table 2). A National Bioethics Committee has been formed to grant such permissions and to monitor such research endeavours.[5] It has since been established that human stem cell lines do exist in the country, with Reliance Life Science (RLS) making it public that it had

filed a "provisional patent" in the field of embryonic stem cells in the US.

Table 2: Some of the Prominent Labs Developing the Stem Cells

Lines	University/Institutes	Place/Country
19 Lines	Goteborg University	Goteborg, Sweden
9 Lines	Cythera Inc.	San Diego, US
7 Lines	Reliance Life Sciences	Mumbai, India
5 Lines	Karonlinska Institute,	Stockholm, Sweden
5 Lines	Wisconsin Alumni Research Foundation	Madison, Wisconsin US
3 Lines	National Centre for Biological Sciences	Bangalore, India

Source: Chaturvedi (2005).

Though there is a great potential for imports and investments in the field of Indian healthcare biotechnology, the industry faces several challenges. The first of these is inadequate intellectual property (IP) protection.

IV.2 Financial System

Indian government has established a Pharmaceutical Research and Development Support Fund (PRDSF) in 2004-05 with an initial corpus of USD 33 million for providing financial assistance to R&D projects proposed by industry/academic institutions/ laboratories and also for creation of state-of-art facilities in the country.[6] It provides soft loan at simple rate of interest. A Drug Development Promotion Board (DDPB) to operationalise the PRDSF has been established after the amalgamation of an earlier programme entitled "Drugs and Pharmaceuticals Research Programme" has now been merged with PRDSF. Given the excellent performance of the fund in 2004-05, the government decided to turn the corpus into an annual grant. In the following year the amount has been fixed up to USD 29 million.[7]

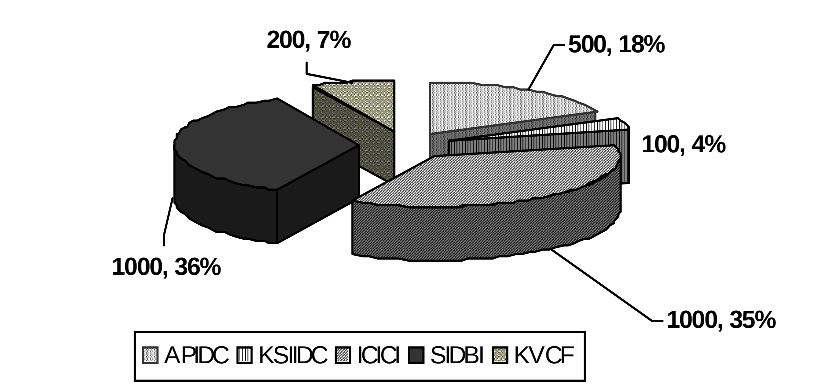
In recent times, liberalisation has unleashed competition for garnering capital in the Indian market. The venture capital industry in India has emerged after the Government of India, in 1988, announced guidelines for setting up venture capital funds (VCFs). These guidelines restricted the setting up of VCFs by banks or financial institutions only. Later, in September 1995, Government of India, issued guidelines for overseas venture capital investment in India whereas the Central Board of Direct Taxes (CBDT) issued guidelines for tax exemption purposes[8]. As a part of its mandate to regulate and to develop the Indian capital markets, Securities and Exchange Board of India (SEBI) framed the SEBI (Venture Capital Funds) Regulations, 1996. SEBI is the single point nodal agency for registration and regulation of both domestic and overseas venture capital funds. There are almost 70 VCFs with a focus on India.[9] Their cumulative assets under management would be somewhere close to $5 billion. The figures from the Indian Venture Capital Association (IVCA) reveal that, till 2000, around Rs. 22,000 million (US$ 500 million) had been committed by the domestic VCFs and offshore funds which are members of IVCA. The figures available from private sources indicate that overall funds committed are around US$ 1.3 billion.[10] It is being hoped that by 2005, India would have $10 billion invested through VCFs.

India witnessed the second highest disbursement of venture capital in the Asia-Pacific region during 2001 at $ 1.1 billion across 91 companies.[11] Japan received the highest disbursement in the region with $1.8 billion being invested in 39 companies. In contrast, China received only $393 million during the year across 11 companies, which placed it in sixth place among the 13 major markets, which constitute the region. While the total disbursement of $1.1 billion in 2001 was marginally lower than the previous year's (2000) $11.3 billion the situation is expected to change during the current calendar year (2002), with total disbursement projected to be in the region of $2 billion, according to the annual strategic review of the Indian IT industry by the National Association of Software and Services Companies (Nasscom). The pattern of VC disbursements last year indicates a preference for late-stage funding. According to the findings of the review, seed funding accounted for only 15 per cent of the total disbursement, while late-stage funding constituted 41 per cent. Deal sizes have also undergone a change. First round funding saw deal sizes in the range of $1-1.5 million, second round deal sizes were in the region of $3-5 million, third round deals ranged between $4-8 million and deals in the fourth round were in the

region of $5-15 million.[12] The 70 VCs operating in India have $5.6 billion in assets under management. There has also been a significant shift to non-internet investments, with the share of non-internet investments increasing to 68 per cent in 2001 against 28 per cent in 2000. VCs have moved to longer gestation investments such as health, biotechnology, IT-enabled services and wireless applications. The consolidated VC pool in the Asia-Pacific region is estimated at $81.2 billion.

The biotechnology commitments by different VCFs amount to almost Rs. 3000 million (Figure 3). Out of this, Indian Credit and Investment Corporation of India (ICICI) and Small Industries Development Bank of India (SIDBI) have almost similar commitments for biotechnology while new entrants like Kerela Venture Capital Fund (KVCF) has committed Rs. 200 million, which is just 4 per cent of the total venture capital. SIDBI and ICICI have devoted Rs. 1000 million and Rs. 1700 million respectively. The two other southern states pro-actively supporting biotechnology through venture capital are Andhra Pradesh and Karnataka. Andhra Pradesh Industrial Development Corporation (APIDC) has devoted Rs. 500 million, which is 18 per cent of the total amount available at the national level while Karnataka State Industrial Infrastructure Development Corporation (KSIIDC) share 7 per cent with an allocation of Rs100 million. Some of the major

Figure 3 :Biotechnology Commitments of VCFs in India



Source: Chaturvedi (2005).

biotechnology VCFs in India along with their specific initiatives are being discussed herewith.

IV.3 Public Policies and Approach to Innovation Capabilities

India is one of the first few countries, among the developing countries, to have recognized the importance of biotechnology as a tool to advance growth of agricultural and health sectors as early as in 1980s. India's Sixth Five Year Plan (1980-85) was the first policy document to cover biotechnology development in the country. The plan document proposed to strengthen and develop capabilities in areas such as immunology, genetics, communicable diseases, etc. At the top, an apex official agency, viz. National Biotechnology Board (NBTB) was set up in 1982, to spearhead development of biotechnology. The NBTB was chaired by Member (Science) of the Indian Planning Commission and had representation of almost all the S&T agencies in the country, viz. Department of Science and Technology (DST), Council for Scientific and Industrial Research (CSIR), Indian Council of Agricultural Research (ICAR), Indian Council for Medical Research (ICMR), Department of Atomic Energy (DAE) and the University Grants Commission (UGC). NBTB was formed with the specific purpose of the identification of priority areas and for evolving a long-term plan for the country in biotechnology as well as to initiate and promote such activities as conducive for further development of various areas in biotechnology. The NBTB issued the "Long Term Plan in Biotechnology for India" in April 1983. This document spelt out priorities for biotechnology in India in view of the national objectives such as self sufficiency in food, clothing and housing, adequate health and hygiene, provision of adequate energy and transportation, protection of environment, gainful employment, industrial growth and balance in international trade. Later in 1986, NBTB graduated to a full-fledged government department called Department of Biotechnology.

At present in India, there are six major agencies responsible for financing and supporting research in the realm of biotechnology apart from other sciences. They are Department of Science and Technology (DST), Department of Biotechnology (DBT), Council of Scientific and Industrial Research (CSIR), Indian Council of Medical Research (ICMR), Indian Council of Agriculture Research (ICAR) and University Grants Commission (UGC),

Table 3: Budget allocations of major biotechnology funding agencies in India

(millions of USD PPP)

	1990/91	2000/01	2002/03	2003/04	2004/05
Indian Council of Agriculture Research (ICAR)	667	1 647	1 667	1 615	1 934
University Grants Commission (UGC)	720	1 656	1 774	1 749	1 832
Department of Scientific and Industrial Research (DSIR)	511	1 142	1 180	1 219	1 439
Department of Science and Technology (DST)	533	918	1 150	1 262	1 420
Council of Scientific and Industrial Research (CSIR)	484	1 073	1 145	1 184	1 399
Department of Biotechnology (DBT)	135	160	267	293	358
Indian Council of Medical Research (ICMR)	82	173	185	179	197
Total	**3 133**	**6 768**	**7 368**	**7 501**	**8 579**

Source: Chaturvedi (2005).

Department of Scientific and Industrial Research (DSIR). DST, DBT and DSIR are part of Ministry of Science and Technology while ICMR is with Ministry of Health, ICAR with Ministry of Agriculture and UGC with Ministry of Human Resource and Development. DSIR is the funding agency for CSIR and both of them independently fund biotechnology related research programmes. The Council of Scientific and Industrial Research (CSIR), the document suggested to ensure coordination on inter-institutional, inter-agency and on multi-disciplinary basis, full utilization of existing facilities and infrastructures in major areas including biotechnology.[13]

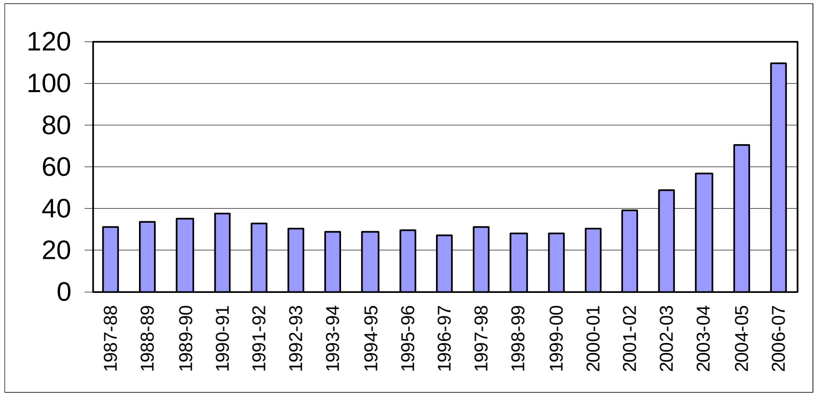
Budgetary allocations for all of these agencies have gone up in the last decade (Table 3). Out of this, DBT is the only agency completely devoted to R&D in biotechnology. It is very difficult to estimate the total allocations for this sector *per se* from other aforementioned agencies as in some cases the allocations are not separately marked as allocations for biotechnology. One faces this kind of constraint especially with those organisations, which are focusing on technological solutions and are not committed for X or Y nature of technology.

IV.4 R&D and Education Capacity Building

There has been a significant increase in Government of India's outlays for biotechnology education over the past decade. Since the time of establishment, in 1986, the allocation for the Department of Biotechnology has increased manifold. The budgetary allocations have gone up from USD 28 million in 1987-88 to USD 34 million in 1997-98 and by 2001-2002 it became USD 39 million. Though the current price allocation figures may not give a complete picture but the budgeted figure for 2006-07 shows a doubling of allocation to USD 110 million. (Figure 4).

Another major institution working in the area of biotechnology is the Indian Council for Medical Research (ICMR) under the Ministry of Health. It is the apex body in the country to promote, coordinate and formulate biomedical and health research. Central Government gives full maintenance grant to the council, to research in communicable diseases, contraception, maternity and child health, nutrition, non-communicable and basic research.

Figure 4: Budgetary Allocations to Department of Biotechnology



Source: Chaturvedi (2005).

The total allocation for ICMR from the Central Government (Ministry of Health) was Rs. 1470 million in 2000-01, which was 21 per cent higher over the allocation of the previous year, that is 1999-2000 (Rs. 1160 million). The Council is also engaged in research on tribal health, traditional medicine and publication and dissemination of information. In the year 2001 ICMR has launched a major programme in the field of genomics (vector, microbial, human) with the initial allocation of Rs. 510 million. One of the major areas of focus is the disease susceptibility gene identification, especially for communicable diseases like leprosy, tuberculosis, non-communicable diseases as rheumatic fever or genetic diseases as thalissimia.[14]

The National Biotechnology Board had launched an integrated short-term training programme way back in 1984, to cope up with growing demand for highly trained manpower. As a part of restructuring of the post doctoral research and training programme, DBT has scraped the ongoing programme with different institutions and has given this responsibility to Indian Institute of Science (IISc), Bangalore. This is to ensure competitive attitude and quality output in the life sciences. It is being proposed that IISc would award up to 75 fellowships of two-year duration in different streams of biotechnology.

Indian University Grants Commission has come out with a scheme to promote higher centres of learning at one place and assist them as much as possible. In this regard, Delhi based Jawaharlal Nehru University (JNU) has been identified by the UGC as centre for excellence in the areas of genomics, genetics and biotechnology[15]. The University has received funds to the tune of Rs 300 million and is planning to start a new integrated M.Sc./Ph.D programme in life sciences and biotechnology and is setting up a modern animal house for experiments. Efforts are also being made to upgrade equipment and library facilities.

IV.5 Corporate Initiatives

The companies in medical biotechnology in India can be divided into three broad categories. One is that of small start-up companies that have indigenously developed biotech products, e.g. Shantha Biotech and Bharat Biotech. Then there are large companies, which have started responding to biotechnology and have in fact incorporated biotechnology in their work plan. They are from the pharmaceuticals as well as from other business background as well. Among the pharma companies for instance, Zydus Cadila, Nicholas Piramal, Dr. Reddy's Laboratory (DRL), Ranbaxy Laboratories and Wockhardt Ltd have entered in a major way and among the big firms with non pharma background the entry of petro-chemical giant Reliance through Reliance Life Sciences (RLS) is attracting attention as it has entered with major takeovers of foreign firms like that of UK based biotechnology firm GeneMedix with investment of $28 million and an unidentified US based nanotechnology firm for $1 billion.[16] The third group has start-ups, which are all set to emerge as contract research organisations (CROs). Largely their work comes from TNCs. Then there are companies like Biocon India which may not fit well in this kind of classification as they have an established presence in the industrial biotechnology (the fermentation sector) and a growing presence in the biopharmaceutical sector, so eventually encompass our first and second category. Biocon and its two subsidiary companies, Syngene International Pvt. Ltd and Clinigene International Pvt. Ltd form a fully integrated biotechnology enterprise, specializing in biopharmaceuticals, custom research, clinical research and enzymes. Clinigene International was set up to initiate longitudinal clinical studies in select disease segments.[17]

Table 4: Biopharmaceutical Products in India

Sector	Type	Product Name	Application	Producer[a]
Vaccines	Recombinant hepatitis B surface antigen	Shanvac-B	Hepatitis B	Shantha Biotechnics
	Recombinant hepatitis B surface antigen	Revac-B	Hepatitis B	Bharat Biotech
	Recombinant hepatitis B surface antigen	Gene Vac-B	Hepatitis B	Serum Institute of India
	Purified capsular polysaccharide Vi of *Salmonella typhi*	Typbar Vi	Typhoid	Bharat Biotech
Therapeutics	Recombinant human insulin	Wosulin	Diabetes	Wockhardt (Mumbai)
	Recombinant human erythropoietin α	Epox	Anemia	Wockhardt
	Recombinant human interferon α-2b	Shanferon	Cancer	Shantha Biotechnics
	Recombinant streptokinase	Shankinase	Cardiovascular	Shantha Biotechnics
		Indikinase	Cardiovascular	Bharat Biotech
	Liposomal amphotericin B injection	Fungisome	Visceral leishmaniasis	Lifecare Innovations (New Delhi)
	Recombinant human granulocyte colony-stimulating factor	Gramstim	Neutropenia	Dr. Reddy's Laboratories
Diagnostics	Immunoblot assays using recombinant HIV-1 antigens gp41 and C-terminus of gp-120 and HIV-2 antigen gp-36	HIV TRI-DOT	HIV-1 and HIV-2	J. Mitra (New Delhi
	Immunoblot assay using recombinant HIV-1 antigens gp-41 and gp-120, HIV-2 antigen gp-36, and HCV antigens NS-3, NC-4 and NC-5	HIV-HCV Combo	HIV and hepatitis C	Bhat Biotech India (Bangalore)
	Enzyme-linked immunosorbent assay for recombinant HCV core antigens 1b &3g, together with peptides for HCV antigens NS-3, NS-4 1, NS-4 2, and NS-5	HEP-Chex C	Hepatitis C	XCyton Diagnostics (Bangalore)
	Enzyme-linked immunosorbent assay for recombinant version of *Taenia solium* excretory/secretory antigens	Cysti-Chex	Neurocysticercosis	XCyton Diagnostics

Source: Updated from Kumar *et al.* (2004).

Another major company Wockhardt has reported its sales recently. The company's business grew by 26 per cent in first half of 2006. Biotech products Wosulin (recombinant insulin) and Wepox (erythropoietin) contributed to 35 per cent and 28 \ of the company's growth respectively.[18] Indian scientists from leading institutions are now actively floating companies. For instance, two scientists from Indian Institute of Scientists (IISc), Bangalore have floated a company called Metahelix Life Sciences with $1.5 million venture capital funding. The company would focus on providing contract research services in genomics, molecular markers and bioinformatics, to begin with and eventually developing new molecules on its own.[19]

In biopharmaceuticals outsourcing is another area in which many Indian firms are engaged in. They are largely in the ambit of clinical trials, contact manufacturing and sales force solutions. At present, the turnover of CROs is very close to $100 million.[20] As is clear from the Table 4 of the 20 recombinant products approved in India, there are nearly 7 of these biopharmaceutical products being produced in India by 6 indigenous companies; rest of all the products are being imported. In the vaccines market it is largely focussed on Hepatitis B vaccine for which price competition has intensified. Similarly, domestic companies are making some headway in the therapeutics and diagnostics as well.

V. Concluding Remarks

This analysis makes it clear that in the biopharmaceutical sector, NSI policies may be structured in such a way that they take cognisance of sectoral requirements from the perspective of growing global integration of innovation chains and production systems. In the new technology based innovation system, sectors like biopharmaceuticals are the ones which have promoted interdependence through contract research organisations and others in a major way which would advance the technology frontier in such a way that it goes beyond the national specificities and brings in regional and global dynamisms at the sectoral level, which would be very different from the existing NSI approach.

In order to achieve this, the sectoral peculiarities should assume importance from the policy formulation point of view. The recent

initiatives by India may go a long way in this context. The draft National Biotechnology Development Strategy from the Department of Biotechnology has outlined the importance being attached to the development of the biopharmaceutical sector. In order to further stream line the regulatory procedures, this strategy documents suggests a single window clearance through the National Biotechnology Regulatory Authority. It also suggests more priority be given to research in molecular and cellular biology, neuroscience, molecular genetics, transplantation biology, genomics, proteomics, system biology, RNA interference and stem cell research. The strategy also calls for building new centres of excellence in the biotechnology field and the establishment of a national task force to develop undergraduate and post-graduate curricula in life sciences and biotechnology.

It may be of interest to note that these policy measures are coming at a time when regulatory routes are opening up in the EU and the US for generic versions of biologic drugs. Moreover, major recombinant biopharmaceutical products are coming off-patent over the next few years. This may gain facilitate further growth of the biopharmaceutical sector.

Endnotes

1 Dogra (2006).
2 McKelvey and Orsenigo (2001).
3 Sinha (2006).
4 MoEF (2005).
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6 DST (2005).
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12 *ibid.*
13 India, Sixth Five Year Plan, 1980-85, New Delhi, Planning Commission, p. 326.
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[17] *The Economic Times*, July 29th 2001.

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Core IV-B, Fourth Floor
India Habitat Centre
Lodhi Road
New Delhi-110 003, India.
Ph. 91-11-2468 2177-80
Fax: 91-11-2468 2173-74-75
Email: dgoffice@ris.org.in
Website: http://www.ris.org.in
Website: http://www.newasiaforum.org