

RIS DISCUSSION PAPERS

**Status and Development of Biotechnology
in India: An Analytical Overview**

Sachin Chaturvedi

RIS-DP # 28/2002



**Research and Information System
for the Non-Aligned and
Other Developing Countries**

Status and Development of Biotechnology in India: An Analytical Overview

Sachin Chaturvedi*

I Introduction

In recent past, two major Indian economic sectors, viz. agriculture and industry have been getting exposed to an entirely new set of technologies. The developments in the area of biotechnology are particularly of great interest. This frontier technology becomes important in a developing country like India where agriculture, with stagnating productivity and crops confronting many biotic and abiotic stresses, aims for higher growth. The industrial sector is expecting a change in production profile with new molecules and new enzymes. These changes assume a different dimension in an intellectual property rights (IPR) regime, where stronger instruments are being used for its protection¹.

However, the emergence of biotechnology is also accompanied by an intense debate on techno-protectionism vis-à-vis the role of nation-state in technological development. In this context, several issues pertaining to the role of government and space for public sector supported R&D have been raised². The rapid economic development in many developing countries, especially in South East Asian countries, has demonstrated that national technological capability remains a key factor in competitiveness (Lall 1992). Many studies in the recent past have underlined the importance of country specific institutional mechanism as a determinant of technological capability (Dosi, Pavitt and Soete (1990) and Nelson (1993).

The increasing role of knowledge in agricultural production and the growing challenge of environment management in particular has to be acknowledged. This trend suggests that it has become increasingly important to bring dynamism in the functioning of the science and technology system at the national level. While the existence of a strong physical infrastructure is necessary for the development of an effective S&T system, the critical factors remain the institutional set-up that supports this system and the cohesion between the overall developmental objectives and the R&D endeavours in different streams. In this context, one idea that emerges forcefully is the development and competence of public sector R&D institutions in the realm of frontier technologies. In this light, it is also important to have accurate information and reliable

* Research Associate, RIS. This paper is part of a wider research project supported by OECD and supervised by Dr. Nagesh Kumar, Deputy Director General, RIS. Author would like to thank Dr. V. R. Panchamukhi and Dr. Nagesh Kumar for their comments on an earlier draft.

statistical data about developments in this sector as that can only provide right feedback for desired policy formulations.

This paper is an attempt to provide a comprehensive survey of these issues and aspects with respect to India, as several achievements in biotechnology in India promises to take major economic sectors, like agriculture, out of the current state of technology. Accordingly, Section II discusses the institutional infrastructure to support R&D, while Section III attempts to briefly present the broad contours of training and human resource development in public sector biotechnology institutions. Growth of biotechnology and share of private sector is discussed in Section IV. This section also attempts to discuss the role being played by various financial institutions in India. Section V summarizes the initiatives undertaken by several State Governments. Various facets of IPR regime and features of bio safety regulations are discussed in Section VI. The last section summarizes the various issues discussed and highlights the policy options available at this juncture of developments in such technology.

II Institutional Setup and Budgetary Allocations

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 country³. The plan document proposed to strengthen and develop capabilities in areas such as immunology, genetics, communicable diseases, etc. In this context, referring to 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. Programmes in the area of biotechnology included, tissue culture application for medicinal and economic plants, fermentation technology and enzyme engineering for chemicals, antibiotics and other medical product development; agricultural and forest residues and slaughterhouse wastes utilization and emerging areas like genetic engineering and molecular biology⁴.

The existing national laboratories under the S& T agencies, such as Indian Council of Medical Research (ICMR) and Council for Scientific and Industrial Research (CSIR) had initiated several research programmes to fulfill the above plan objectives. 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), 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.

As Table 1 shows the allocations for all of these agencies have gone up in the last decade. 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. Thus separately accounting for biotechnology becomes difficult. It would probably become possible only if a detailed survey at the institutional level is undertaken. Table 1 gives a broad idea about total allocations by major

Indian funding agencies to science and technology related projects and not necessarily to biotechnology alone. In case of UGC it gives a broad idea not only about S&T related projects but also about other research streams. The various programmes supported by UGC would be discussed in Section III while rest of the agencies are being discussed below.

Table 1: Budgetary Allocations of Major Funding Agencies in India (Rs. Million)

	1990/91	2000/01
Department of Scientific and Industrial Research (DSIR)	131.3	583.8
Department of Science and Technology (DST)	2588.9	7798
Department of Biotechnology (DBT)	655	1361
Indian Council of Agriculture Research (ICAR)	3236	13990
Indian Council of Medical Research (ICMR)	396	1470
Council of Scientific and Industrial Research (CSIR)	2351	9120
University Grants Commission (UGC)	3495	14070

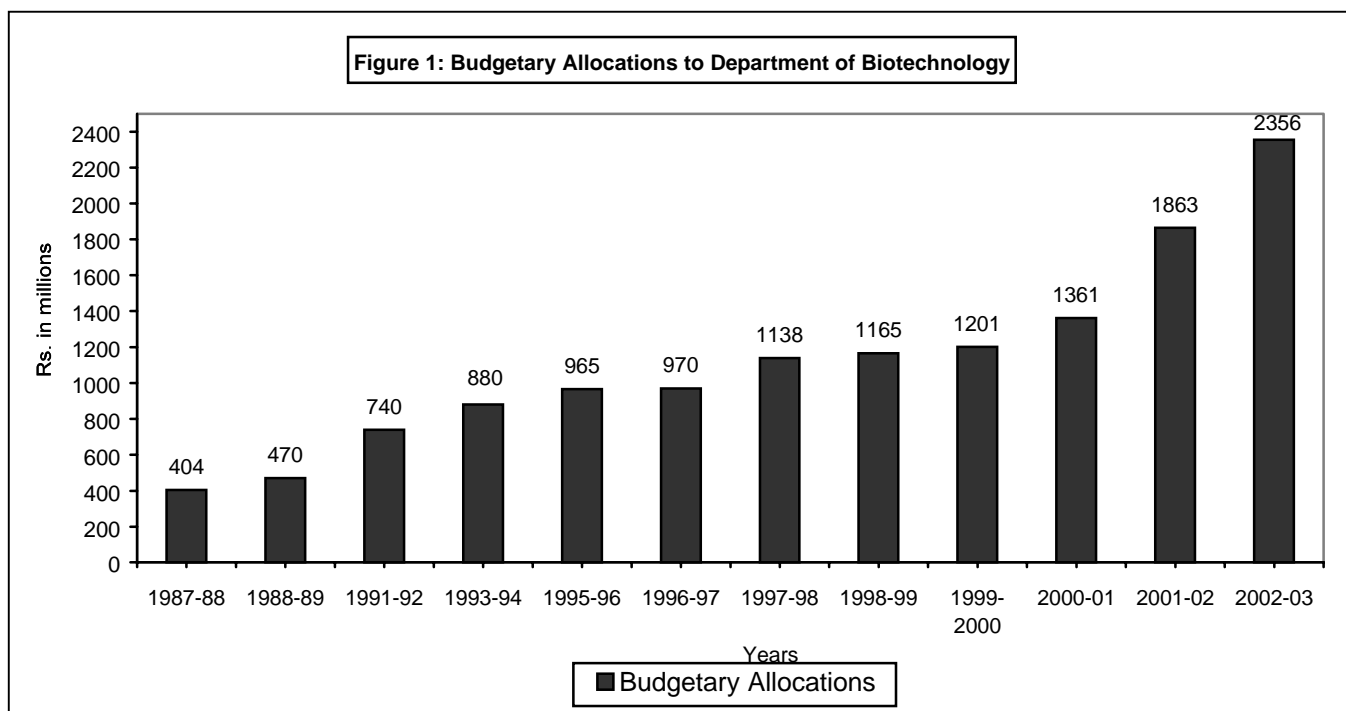
Source: RIS based on budgetary papers of relevant years, Ministry of Finance, Government of India.

II.1 Department of Biotechnology (DBT)

There has been a significant increase in Government of India's outlays for biotechnology over the past decade. Since the time of establishment, in 1986, the allocation for the Department has increased manifold. The budgetary allocations have gone up from Rs. 404 million in 1987-88 to Rs. 1,138 million in 1997-98 and by 2001-2002 it became Rs 1,863 million. Though the current price allocation figures may not give a complete picture but the budgeted figure for 2002-03 shows a doubling of allocation to Rs. 2,356 million. (Figure 1).

In India the developmental allocations are generally made for five years under the National Five Year Plans. The Government has recently finalized the Tenth Five Year Plan (2002-2007). The Working Group on Science and Technology for the Tenth Five Year Plan, constituted by the Planning Commission, has proposed an outlay of Rs. 20,750 million for the period 2002 to 2007 (Table 2). This marks a sharp increase of 234 per cent from the budgetary provisions made during the Ninth Plan period (1997-2002) which totaled at Rs. 6,215 million only. The Vision

Statement for the Tenth Five Year Plan enumerates the proposal for human genome sequences, proteomics, structural biology and bioinformatics.



The DBT has established a huge infrastructure for bioinformatics. There are almost 55 bioinformatics centres working as a strong information network in the country, linked with databases and networks around the world for easy access by large number of scientists. Similarly, the DBT has supported 51 courses at different academic institutions all over the country to meet the growing demand of skilled manpower in the country as discussed later.

The DBT has 17 task forces in different areas of importance each comprising 12-13 experts who help in recommending and monitoring of R&D projects⁵. The DBT has launched an innovative scheme of developing institutional clusters to exploit the institutional and academic synergies and economise on resources. Recently, micro propagation technology parks have been established at the Tata Energy Research Institute, New Delhi and the National Chemical Laboratory, Pune. They are serving as an important interface not only between the industry and the developers of technology in the areas of plant tissue culture but also among the academic institutions. Technologies for Eucalyptus, Teak and Bamboo have been transferred to Cadila Pharmaceuticals Limited. On the similar lines three turn-key projects have been developed by these centres for three different federal states in collaboration with respective academic institutions.⁶

Table 2: Allocations for Biotechnology under Five Year Plans

(Rs. In Million)

S.No.	Name of the Scheme	Ninth Plan	Tenth Plan
01	Biotech Facilities, Centres of Excellence & Programme Support	680.46 (10.95)	900.00 (4.34)
02	Research and Development		
	2.1 Agriculture Biotechnology	1651.26 (26.56)	550.00 (2.65)
	2.2 Medical Biotechnology	808.88 (13.01)	4130.00 (31.46)
	2.3 Environmental Biotechnology	128.72 (2.07)	200.00 (0.96)
	Total	2588.86 (41.65)	7280.00 (35.08)
03	Biotechnology for Societal Development	---	250.00 (1.20)
04	Bio-Process and Product Development		
	4.1 Food Biotechnology	---	250.00 (1.20)
	4.2 Microbial and Industrial Biotechnology	---	250.00 (1.20)
	4.3 IPR & Biosafety	7.51 (0.12)	100.00 (0.48)
	4.4 Programmes Merged with other heads	513.05 (8.25)	---
	Total	520.55 (8.38)	600.00 (2.89)
05	International Cooperation	109.37 (1.76)	400.00 (1.93)
06	Human Resource Development	1000.00 (16.09)	160.00 (0.77)
07	Bioinformatics	700.00 (11.26)	120.00 (0.58)
08	Autonomous Institutes		
	08.1 National Institute of Immunology	642.74 (10.34)	2080.00 (10.02)
	08.2 National Centre for Cell Science	343.86 (5.53)	800.00 (3.86)
	08.3 Centre for DNA Finger Printing and Diagnostics	313.62 (5.05)	1130.00 (5.45)
	08.4 National Brain Research Centre	130.00 (2.09)	700.00 (4.92)
	08.5 National Centre for Plant Genome Research	101.00 (1.62)	700.00 (3.37)
	08.6 Institute of Bioresources and Sustainable Development	---	170.00 (0.82)
09	I & M Sector	---	3620.00 (17.45)
	Secretariate	100.00 (1.61)	10.00 (0.05)
	Grand Total	6215.42 (100.00)	20750.00 (100.00)

Source: RIS Based on DBT Reports. Note: Figures in parentheses are share in total.

The DBT has taken special precaution to find crucial balance between different sections of society as far as technology absorption is concerned apart from promoting industrial development (see box). It is supporting low-cost biotechnology adoption programmes for socially backward communities. The programmes include vermi-composting, use of organic manure, silk-worm rearing, mushroom cultivation, etc. Some training cum demonstration programme are also being supported for them. Efforts are also on for gender mainstreaming. The DBT has launched 11 projects for women in the areas of waste management, bio pesticides, bio fertilizers, floriculture, fish farming for poor women in the rural areas. At the Golden Jubilee Biotechnology Park for Women, industrial modules have been allotted to women entrepreneurs for setting up units in the above-mentioned areas. This park was inaugurated in 1998 near Chennai the capital of a southern Indian state Tamil Nadu. The park is located in Siruseri, adjacent to Information Technology Park in an area of about 20 acres. It would have some central facilities for the entrepreneurs for technology resourcing, training and marketing. This is a first unique project of a joint effort by the central and state government in the realm of biotechnology.

Changing Role of DBT

In recent times, DBT has taken up a proactive role in promotion of industry. DBT proposed a single window application-processing cell as part of a new regulatory system for the domestic biotechnology sector. The move formed part of the recent recommendations on biotechnology sector made by the Confederation of Indian Industry (CII)⁷. Besides recommending setting up of a single window application-processing cell at DBT, CII had also suggested a fixed time frame of 150 days for clearing new biotech proposals.

In this regard, CII had recommended a process whereby a new application would be sent by the single window agency to the Review Committee on Genetic Manipulation (RCGM), which in turn would be required to submit a scientific evaluation report within 60 days of receiving the applications. This report will be submitted to the relevant approval committee, identified by the end product category. For example, in case of agricultural products, it would go to the Genetic Engineering Approval Committee (GEAC), in case of pharmaceutical products to the Drugs & Pharma Approval Committee (DPAC), and in case of food products to the Biotech Foods Approval Committee (BFAC). The GEAC/ DPAC/ BFAC would be required to accord approval or rejection within 90 days of receiving the evaluation report from RCGM. In case of rejection of the application, the applicants will also have the right to appeal to the concerned approval committee. CII had also suggested that any additional information required by RCGM for completeness of the application form would have to be called for within 30 days of receipt of the application. Besides DBT, the recommendations were submitted by CII to 14 other agencies, including seven ministries. Most of the recommendations submitted by CII have been accepted by DBT.

II.2 Council of Scientific and Industrial Research (CSIR)

The Council of Scientific and Industrial Research was established in 1942. It is India's largest research and development organization. It has 40 laboratories and 80 field stations/extension centres spread over the length and breadth of the country. The total allocation for CSIR in the year 2000-01 was Rs. 9120 million, which is 13 per cent higher from 1999-2000 (Rs. 7940 million). CSIR's Centre for Cellular and Molecular Biology (CCMB) incubated India's first recombinant protein product from a private company, Shantha Biotech, a hepatitis B vaccine, and it has numerous industrial relationships, including a joint venture with Biological E and Amersham Pharmacia to build DNA micro-arrays.

CSIR proposes to continue programmes in the area of agro-biotechnology, industrial biotechnology, and toxicant identification control, with a strategy for controlled change in direction as dictated by market needs. Strategic alliances would thus be sought for programmes for understanding the processes, molecular genetics and control of gene expression, genetic manipulation of microbes, recombinant DNA products, engineering new protein molecules/new chemical entities, development of immuno-diagnostics and biotechnology of prospective medicinal and aromatic plants. Some of the other CSIR led initiatives are listed in Annex 1.

II.3 Indian Council of Medical Research (ICMR)

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.

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 thalassaemia⁸. ICMR has

established four centres for developing molecular medicine at All India Institute of Medical Sciences (AIIMS), New Delhi, Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGIMS), Lucknow, Jawaharlal Nehru University (JNU), New Delhi and Post Graduate Institute of Medical Education and Research (PGIMER), Chandigarh. Apart from this, ICMR has also established six biomedical informatics units in different parts of the country. It has proposed an allocation of Rs. 1000 million for the Tenth Five Year Plan.

II.4 Indian Council for Agriculture Research (ICAR)

In India, agricultural research is being spearheaded by the Indian Council of Agricultural Research (ICAR) under the Ministry of Agriculture. The Council is engaged in conducting research in the field of agriculture, soil and water conservation, animal husbandry, fisheries, dairying, forestry and also agricultural education. The allocation for ICAR from the Ministry of Agriculture was Rs. 13,990 million in 2000-01, which was Rs. 12,060 million in the previous year. It has several research laboratories all over the country conducting research in biotechnology, besides using traditional breeding techniques for different research projects.

ICAR has established a National Research Centre on Plant Biotechnology (NRCPB) at the Indian Agricultural Research Institute (IARI), Pusa, New Delhi, which is fully dedicated to work on plant biotechnology. Annual expenditure over the projects at NRCPB is Rs. 150 million. Apart from this ICAR has also supported two research networks, combining ICAR and even non-ICAR research laboratories to work on crops like rice, cotton, brinjal and brinjal. ICAR is also implementing a World Bank supported programme called National Agriculture Technology Programme (NATP) through which huge allocations have been made at different research laboratories for strengthening infrastructure for biotechnological research.⁹

ICAR has also collaborated with DBT and Rockefeller Foundation to jointly launch a National Rice Biotechnology Network (NRBN) in 1988¹⁰. This project helped in evolving a culture of collaboration among different institutions, which has led to publication of several international papers in established journals. This network put together plant breeders and molecular biologists on the one hand and also provoked interests of private sector in R&D. For instance, Mahyco and Rockefeller Foundation worked together on identifying the relevant genes for saving Indian rice from brown plant hoppers. In this collaborative effort, interaction was not limited to private entities only. It is between private and public sector organisations also. Several universities also have tie ups with private sector organisations. For instance, Tamil Nadu Agricultural University

(TNAU) attempted joint trials with Monsanto on weed resistance in soil.¹¹ TNAU was also partner in monitoring the Bt Cotton field trials of Mahyco-Monsanto alliance. TNAU is also holding in exploratory talks with Rasi seeds (it is also in alliance with Monsanto) to conduct and monitor field trials of Bt crops. Similarly, rice research work at National Research Centre for Plant Biotechnology has attracted business interest of companies like Nath Seeds Ltd. and JK Agri-genetics.

III Human Resource Development and Training

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. In the first phase (1984-85), 5 universities were selected for initiating M.Sc./M.Tech programme in this multi-disciplinary area. Subsequently, in 1985-86 and 1986-87, the DBT has added 8 universities/institutions for M.Sc/M.Tech/Post-doctoral teaching programmes. Subsequently, DBT was entrusted with the responsibility of evolving curriculum for biotechnology courses and meet the demand for human resources in the field of biotechnology. In 1986-87 a model system of post-graduate/post-doctoral teaching in biotechnology in 7 universities/institutions was launched¹². Some of the specialised M.Sc. courses in marine and agricultural biotechnology were launched in 1988-89 at 3 universities. In 1992-93, DBT supported a five year Integrated Programme in biochemical engineering and biotechnology in Indian Institute of Technology, Delhi and a post-doctoral programme at Indian Agricultural Research Institute, New Delhi.¹³

Now, DBT is supporting 20 M.Sc. courses in general biotechnology, 4 in agricultural biotechnology, one each in medical and marine biotechnology while couple of diploma courses in molecular and biochemical technology¹⁴. The total intake of students in the various post-graduate courses supported by the DBT in the country is around 550 per year. As a part of restructuring of the post doctoral research and training programme, DBT has scrapped the on going 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.

DBT is also supporting overseas associateship and short-term training courses for at least 22-25 scientists in a particular year for exposing Indian scientists to newer trends in R&D. This helps

working researchers and scientists to upgrade their knowledge and research areas of interest. In this context, services of Biotech Consortium India Limited (BCIL), New Delhi, a DBT floated organisation, are also being used to bridge the scientific knowledge of DBT supported associates and industry requirement. The State Governments are also exploring various options to finance higher education in such advanced technologies. Recently Karnataka government has established an Institute of Bioinformatics and Applied Biotechnology (IBAB), in collaboration with ICICI Ventures to offer a postgraduate course in bioinformatics on its International Technology Park campus¹⁵.

As part of a wider effort for capacity building in institutes of higher learning, full-fledged departments of biotechnology are being set up. The Indian Institute of Science, Bangalore, Indian Institute of Information Technology and Management, Gwalior; and select Regional Engineering Colleges are setting up departments of biotechnology. The All India Council for Technical Education (AICTE) has already approved B.Tech. programmes in biotechnology in eight engineering colleges and has since been advised to develop a model curriculum for undergraduate programmes. All the new departments will have undergraduate, post-graduate and doctoral programmes. Special funding will be provided for the purpose in the Tenth Five Year Plan. Apart from expanding teaching of biotechnology at higher educational institutions a separate module on biotechnology would also be integrated with the school curriculum. The Department of Biotechnology of Government of India will provide the necessary outline of this module so that the National Council of Education Research and Training (NCERT) and the Boards of School Education would be accordingly advised¹⁶.

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 biotechnology¹⁷. 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. The new integrated programme in life sciences will reduce the time taken by a scholar to complete his Ph.D by at least within two years. Now the scholar will not be required to undergo a separate M.Phil programme. JNU is aiming at 10 seats for the integrated course and another 20-25 seats in the School of Life Sciences. The

University has so far received 40 proposals for possible projects, which can be pursued by them in these fields in the future. Out of the funds that JNU has finally managed to get from the University Grants Commission on its selection as the University with potential for excellence, Rs. 100 million have been set aside for upgradation of facilities and equipments. The rest of the Rs. 200 million would help University to subscribe to some of the 8,000 online journals, both in the field of science and social sciences. Besides this, JNU also announced recruitment of more researchers. The tie-ups with industry are also likely to grow. For instance, researchers at the Center for Biotechnology (CBT) at Jawaharlal Nehru University in New Delhi have been working for four years on a recombinant anthrax vaccine and soon would start Phase I clinical trials in collaboration with Panacea Biotech Ltd. (New Delhi).

To sum up, as Annex 2, shows there are almost 30 universities offering Masters of Science in Biotechnology through a joint entrance examination being conducted by the Jawaharlal Nehru University (JNU). Apart from this Goa University is offering a two years Master of Science course in Marine Biotechnology, while All India Institute of Medical Sciences (AIIMS) offers a similar course in medical biotechnology. There are a couple of institutions offering Post Graduate Diploma Courses in molecular and biochemical technology. Indian Institute of Technology (IIT) at New Delhi and Kharagpur offer a Five Year integrated course in biochemical engineering and biotechnology. There is a Post MD/MS Certificate Course in medical biotechnology being offered by Post Graduate Institute of Medical Education and Research, Chandigarh and Sanjay Gandhi Post Graduate Institute of Medical Education and Research, Lucknow.

IV Private Sector Participation and Role of Financing Institutions

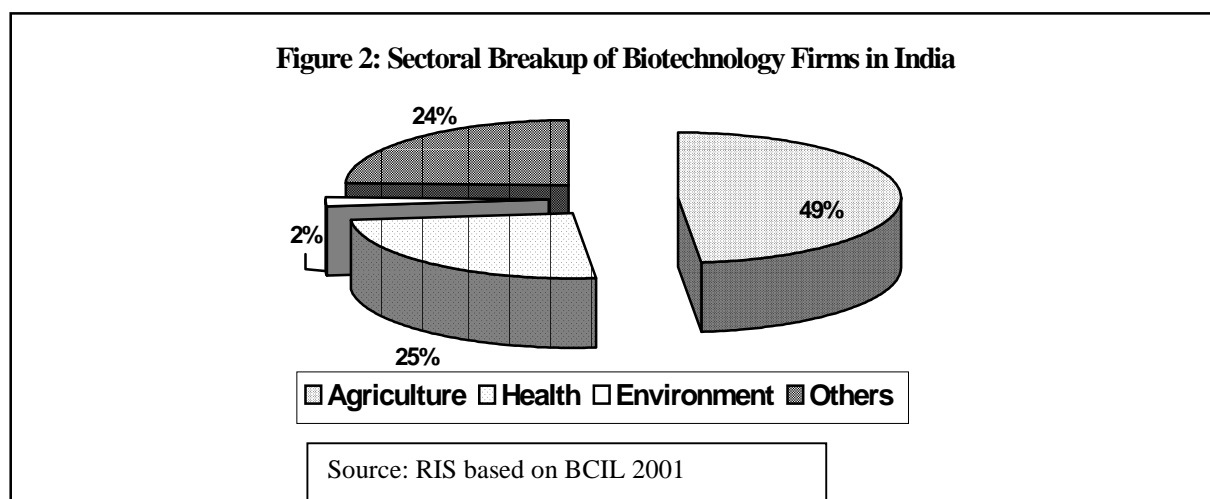
In India, biotechnology industry has grown over the past few years at a very rapid pace to reach a sizeable scale in terms of turnover. According to the available estimates, the size of India's market for biotechnology products could be between US \$ 1.5 to US \$ 2.5 billion as shown in Table 3 depending upon, among other factors, how a biotechnology product is defined. Of this the agriculture sector market is valued between US \$ 450 to US \$ 500 million and diagnostic/vaccines market at US \$ 150 to US \$ 420 million.

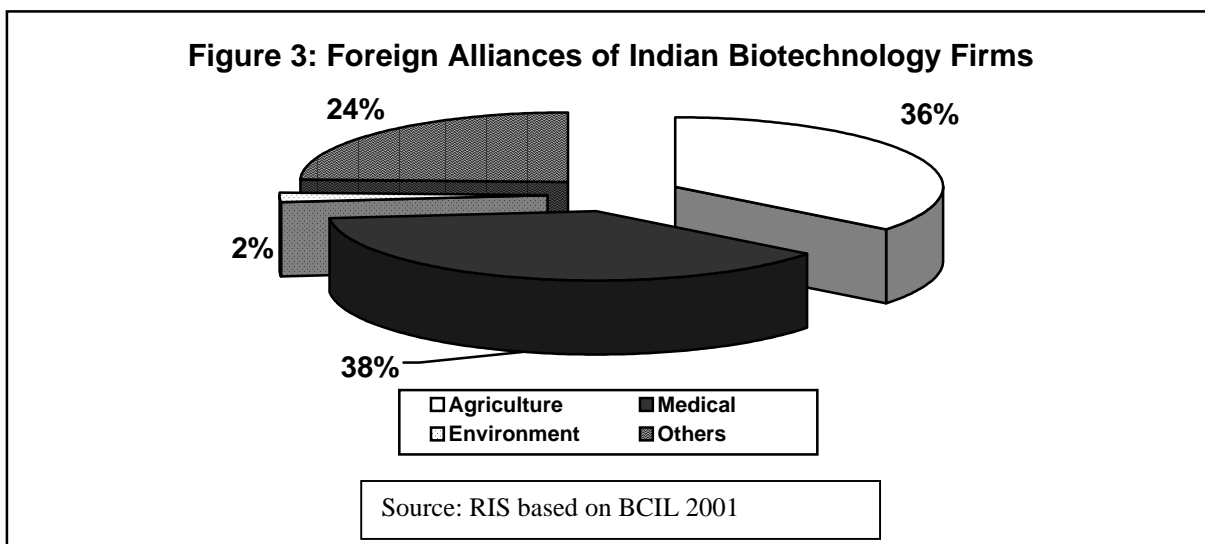
Table 3: Differing Perspective on Biotech in India (2001)

	CII	DBT	The Economist ⁱⁱⁱ
Biotech Market	\$ 2.5 billion ⁱ	\$ 1,849 million	\$ 1,475 Million
Agri/Seed Market	\$ 500 million ⁱⁱ		\$ 450 million
Bio Informatics Market	\$ 2.2 million ⁱⁱⁱ		
Diagnostic/Vaccine Market	\$. 420 million	\$ 150 million	\$ 375 million

Source: RIS based on i *Financial Express*, 10th October 2001, ii *Business Standard*, December 24th 2000, iii *Business Line*, July 9th 2001, iv *Economist*, September 1st 2001.

According to a BCIL (2001) report there are total 176 biotechnology based companies in India. Figure 2 presents a sectoral break up of these companies. As many as 49 per cent of the companies are agriculture-based companies having interests ranging from tissue culture to bio pesticides. Almost 25 per cent of the companies are active in health related activities and are in medical sciences while 26 per cent have varied interest including environmental biotechnology. Although in terms of numbers health biotechnology companies are lesser than those active in the agriculture sectors but they account for a much higher proportion of foreign alliances. Figure 3 shows the composition of these foreign alliances entered into by Indian biotechnology companies. The changing profile of health biotechnology scenario in India is quite evident from its growing external orientation. In the next section, this is examined in greater detail. Actually a large number of generic pharmaceutical companies are diversifying into molecule research and stem cell research. A number of Indian companies have achieved notable successes. For instance, Bangalore based Biocon claims a quarter of the world market for pectinase, an enzyme that breaks down the pectin in fruit juice. In its latest fiscal year, it reported net profits of about \$8m on sales of \$52m¹⁸.





IV.1 Agricultural Biotechnology

Some of the private foundations such as M. S. Swaminathan Research Foundation (MSSRF), Chennai have taken important initiatives in terms of bridging gap between technology development, its commercialisation and ultimately its diffusion¹⁹. One of the important project MSSRF launched in early 1990s was establishment of Biovillages in India and China. The Biovillage approach aims at covering principles of ecological sustainability and economic profitability with equity. This project actively promoted interaction between society, industry and R&D institutions. Some of the firms such as Indo-American Hybrid Seeds Company, Bangalore and R&D institution such as Tamil Nadu Agricultural University were the prominent partners. This project boosted the demand for biofertilisers in the Southern Indian Villages.

IV.1.A Seed Industry

In the agriculture sector a large number of companies have taken up activities related to biotechnology. Leaving aside subsidiaries of TNCs in India, the agribiotech companies can be classified into three broad groups. One, the larger integrated seed companies which are expanding their R&D to cover biotechnology like Mahyco, Indo-American Hybrid Seed, etc. to develop their own transgenics. Second group is that of smaller companies which have not been active in research or product development but have started employing techniques such as tissue culture for their breeding programmes e.g. companies like Kastur Rangan and Adikeshevalu. The third group may cover highly specialized technology companies that undertake services for specified research, like contract research organisations. This is a relatively new concept in the agriculture R&D in India. Some of the companies like Avesthagen qualify in this group.

At this moment all Indian firms are under lot of pressure for technological improvement of their seeds. This pressure emanates largely from their consumers and the growing market penetration by multinational seed corporations. As a result these firms are now exploring the possibilities to embark on biotechnology related research. For instance, a large sized seed company, JK Agri – Genetics has set up a separate division for biotechnology research in those crops in which its owning a larger share in the hybrid seed market. However, on the other side of the spectrum one finds old hands in the field of biotechnology like Indo-American Hybrid Seeds, Bangalore. This was one of the premier companies, which entered in the scene way back in 1992-93 but is still struggling with identification of relevant gene sequences, high capital cost of R&D leading to resource crunch for research and then, on top of that, shortage of skilled manpower. The company officials point out that despite of so many institutes and universities they are not getting relevant manpower for absorption in R&D units. They are continuing with this urge simply because a breakthrough in biotechnology may help them in retaining their market share in vegetable hybrid seeds as their competitors are gradually tying up with TNCs for accessing their vast pool of gene sequences for crop improvement²⁰. Their problem become further confounded from the growing number of relevant genes or gene sequences coming under patent ownership of TNCs.

However, some of the larger companies, which have readily gone for alliances with TNCs, are engaged in back crossing only. For example Maharashtra based Mahyco Seeds which has a tie-up with Monsanto has developed transgenic cotton seeds through back-crossing with the genes borrowed from Monsanto for pest resistance. Some companies like Ankur and Rasi, which are not that big in size, have also alliances with Monsanto for similar endeavors. The combined market share of Monsanto through these three tie-ups (in cotton) comes closer to 20 per cent which is next to the public sector National Seeds Corporation (NSC) (45 per cent). In fact, NSC is also concerned about its declining share over the years and growing concentration in the private sector. In India, almost 8.9 million-hectare of land area are under cotton cultivation with 2.86 million tonnes of cotton lint a year. Since, independence nearly 150 hybrid varieties of cotton have been released and hybrids account for 60 per cent of cotton cultivation²¹. Similarly, small companies such as Bangalore based Kastur Rangan and Adikeshevalu have entered in up-scale tissue culture research and related plant development.

The third group is of the upcoming companies with strong science base. This group has companies such as Meta Helix and Avesthagen. The details about Avesthagen are mentioned in

the section on venture capital (IV.B.1). They have entered in the area of contract research for DNA finger printing and data mining. They are also providing identification facilities of viral diseases in plants and animals.

Recently, Chinese companies have started entering the Indian market. One of the major Indian company Nath Seeds has forged a strategic alliance with the Biocentury Transgene Company, a Chinese biotechnology company, to introduce transgenic technology in the cotton crop²². The tie-up aims at significantly reducing the cost of cotton production by reducing the consumption of pesticides and improving cotton yields. Biocentury has patented technology for Bt and Bt+ genes developed by the Biotechnology Research Institute (BRI) of the Chinese Academy of Agricultural Sciences. Nath Seeds has the license for the exclusive use of Chinese Bt+ genes in India. The gene will be incorporated into the parent lines of cotton hybrids bred by Nath Seeds for the Indian market. Nath Seeds, with this alliance, hopes to compete in the area of transgenic technology for seeds, which is currently a monopoly of multinational firms such as Monsanto, Novartis and Dupont. The company plans to boost the top and bottom line of Nath Seeds as it has the right to sub-license Bt to other seed companies, besides using Bt gene in its own hybrids. The first commercial sale is expected in 2004.

Actually the tuning point in India's history of seed industry development was the announcement of Seed Policy (1988). This policy statement and related institutional reforms have given a boost to the participation of private sector in the growth of the industry. The private companies have increased their share in the industry from 20 per cent in 1981 to 73 per cent in 1997²³ and 76 per cent in 2001²⁴. There are nearly 150 registered seed companies. As Table 4 shows the market size for seeds has grown from Rs. 10,000 million in 1994-95 to Rs. 22,000 million in 1998-99. The interesting point to be noted is that the concentration in favour of organized private sector has grown many folds. The share of public sector seed supply has declined from 40 per cent to 25 per cent while share of unorganized sector has declined from 25 to 15 per cent in the same time period. The share of organized seed sector has grown from 35 per cent to 60 per cent.

Table 4: Indian Seed Market

Sector	1994-95		1998-99	
	Market size (Rs. Million)	Per cent	Market size (Rs. Million)	Per cent
Public Sector	4000	40	5500	25
Private Sector				
Organized	3500	35	13200	60
Unorganized	2500	25	3300	15
Total	10000		22000	

Source: (Sadananda 2002)

IV.1.B Biofertilisers and Biopesticides

In recent past, private sector participation in production of biofertilisers has grown at a very high pace. As Table 5 shows the production has gone up from 2.5 tonnes in 1992-93 to 10.38 tonnes in 1999-00. Accordingly, the number of firms engaged in biofertilisers has also gone up from 35 in 1992-93 to 95 in 1999-00. The Biofertilisers Statistics being regularly brought by the Fertiliser Association of India shows that the production of fertilisers is concentrated in Western Indian states (37). They are Gujarat (3 units), Madhya Pradesh (7 units), Maharashtra (24 units) and Rajasthan (3 units). However, some of the Southern states like Tamil Nadu have also encouraged private industry to set up biofertiliser units. In three years time more than 13 units have come up in the state. There are several types of biofertilisers being marketed in India. Some of the prominent ones are *Rhizobium*, *Azotobacter* and *Azospirillum*. The Indian Council for Agriculture Research and Department of Biotechnology have actively encouraged application of rDNA technology for better quality *Rhizobium* and *Azotobacter*. In order to help industry, DBT has established certain repositories to keep micro organisms²⁵. In case of biofertilisers, the established repository for microbes is “National Facility for *Rhizobium* Culture Collections”, Division of Microbiology, IARI, New Delhi. The others are National Centre for Conservation and Utilisation of Blue-Green Algae, IARI, New Delhi, Microbial Type Culture Collections, Institute of Microbial Technology, Chandigarh, National Facility for Marine Cyanobacteria, Bharatidasan University, Tiruchurapalli, Facility for Mycorrhizal Culture Collections, Tata Energy Research Institute, New Delhi. However, its important to mention here that the demand for biofertiliser suffers from three major factors: poor and uneven quality, short shelf life and small contribution of crop yield for biopesticides.²⁶ DBT established a Biocontrol Network

Programme in 1989. The major emphasis in this programme is to develop better formulations and cost effective commercially viable biopesticides including microbial pesticides, parasitoids and bacteria for use under IPM. The project has 80 R&D projects and total allocations of 1.8 million.

Table 5: All India Production of Biofertilisers

Year	Biofertiliser (‘000 tonnes)	No. of Producing firms
1992-93	2.5	35
1994-95	5.8	72
1997-98	8.5	80
1999-00	10.38	95

Source: Biofertiliser Statistics, various issues, FAI, New Delhi

IV.2 Medical Biotechnology

The companies in medical biotechnology in India can be divided into three broad categories. One is that of small startup 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, for instance, Dr. Reddy’s Laboratory (DRL), Ranbaxy Laboratories and Wockhardt Ltd. 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 pharmaceutical sector, so eventually encompass our first and second category. Biocon set its sights on biopharmaceuticals and using its capabilities in a wide range of fermentation technologies by 1995. Two years on, Biocon established Helix – a wholly owned subsidiary to develop its biopharma operations, which began with a range of anti-cholesterol statin drugs. Another subsidiary of this company, Clinigene International, was set up to initiate longitudinal clinical studies in select disease segments. Thus there is a synergy-based expansion, Biocon is now recognised as the country’s leading biotech conglomerate²⁷.

Shantha Biotech

This is one of the leading examples of our first category of firms – small start ups with their own biotech products. Shantha Biotech has the credit of developing India's first world class Hepatitis-B vaccine and making it available at one third of the prevailing market price of imported vaccines. This company has an active biotechnology programme since 1994. Now Pfizer Ltd., the major pharma TNC, has obtained the first refusal rights from the Hyderabad based Shantha Biotechnics Pvt. Ltd. for exclusively marketing the products to be developed by the latter in future. Earlier, Pfizer had entered into a co-marketing agreement with Shantha Biotech for marketing the latter's recombinant DNA vaccine for Hepatitis-B. Shantha Biotech is currently in advanced stages of discussion with one European pharma major and about three US based pharma companies for its research projects. The company plans to research on protein purification, molecular cloning and expression of native and synthetic genes. Shantha Biotech will also be offering polyclonal and monoclonal antibody development and formulation of certain types of vaccines. Shantha Biotech has developed in-house expertise in recombinant DNA technology and are very strong in development of cell lines for development of recombinant products. The company has invested Rs. 100 million in the biotech facility with external funding (from Bank of Oman).

Dr Reddy's Laboratory (DRL)

Some of the companies like DRL have grown in the recent past. It was established in 1984. DRL is a big pharmaceuticals company and now is setting up biotech production facilities as per the US FDA specifications. The company has also identified biogenerics as significant market area which is estimated at \$14 billion. It has pegged its brand value at Rs. 9,160 million as against last year's value at Rs. 2,850 million²⁸. The biotechnology facility includes setting up of three class 10,000 bulk recombinant protein production suites and new formulations facility as well. The biotechnology business would cover therapeutics, vaccines and diagnostics. DRL has a research alliance with Centre for Cellular and Molecular Biology (CCMB) Hyderabad. DRL has also established a research subsidiary in Atlanta called Reddy US Therapeutics Inc., as well as a contract research subsidiary that will focus on genomics.

Ranbaxy Laboratories

Ranbaxy, India's largest pharma company with sales of more than \$500 million in the year 2000, also views innovation in biotechnology as key to its future. It is one of the oldest post-independence firm founded in 1968. The company has branched out from creating new

formulations of existing drugs and has half a dozen molecules under development. Ranbaxy has collaborations with several U.S. and European companies to develop new formulations and technologies. For example, Ranbaxy and Vectura Ltd. (Bath, U.K.) announced in 2001 that the Indian company's Ranbaxy B.V. subsidiary (the Netherlands, Antilles,) will develop oral formulations using Vectura's controlled release drug delivery technology, with Ranbaxy providing clinical development, scaleup, manufacturing and marketing expertise. Ranbaxy has set a model in India in terms of drug development. The model suggests that develop a molecule upto the level a domestic company can afford to do generally upto the first phase of the clinical trial and then outsource it to a leading MNC for further development and later on explore the possibilities for marketing tie-ups²⁹.

Wockhardt Ltd.

Wockhardt Ltd. established nearly four decade ago, is the fifth largest pharmaceutical company of India. Wockhardt has grown at over 20 per cent annually for the last 5 years³⁰. In the year 2000, it acquired Merind from the Tata's and besides Wallis Laboratories, a company in the UK, apart from entering into marketing alliance with the American Sidmak Labs. The company is formulating its biotechnology strategy around these initiatives. It has decided to split its business into two separate entities. Wockhardt Ltd. will remain as a pharmaceutical company while the new entity would focus on Life sciences only. The new company (the name of which has yet to be finalized) will have all the other businesses namely hospitals, nutrients, IV fluid and agrovet (Crop protection). The R&D activity is also being categorized into three divisions. The first division concentrates on developing new bulk drugs (Novel drug delivery system (NDDS)) and generics. The second division concentrates on recombinant biotechnology. At present, the second division is focusing on technology absorption with the assistance of scientists from abroad. The third division is dedicated for discovery of new molecules. Wockhardt is expected to come out with its first investigational new drug (IND) in anti-infective therapeutic segment by end of 2002.

At present, the turnover of CROs is very close to \$100 million³¹. The major companies in this category are Quintile India, Lambda, Welbeck, Lotus and SIRO Clinpharm Ltd. 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 own³².

IV.B Role of Financial Institutions

In recent times, liberalisation has unleashed competition for garnering capital in the Indian market. This is more so for technology companies. Some of the major firms in IT and pharmaceutical sector have already achieved a listing at Nasdaq. The venture capital (VC) industry in India is also emerging as a vibrant sector to support information technology, biotechnology, telecommunication and food processing related industries.

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 purposes³³. 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. While only 8 domestic VCFs were registered with SEBI during 1996-98, more than 30 additional funds have already been registered for 2000-01.

In the last Budget Proposals 2000-01, the Finance Minister announced SEBI as the single point nodal agency for registration and regulation of both domestic and overseas venture capital funds. Now, there are almost 70 VCFs with a focus on India³⁴. 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 billion³⁵. It is being hoped that by 2005, India would have \$10 billion invested through VCFs.

As Table 6 shows, India witnessed the second highest disbursement of venture capital in the Asia-Pacific region during 2001 at \$ 1.1 billion across 91 companies.³⁶ 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 million³⁷. 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.

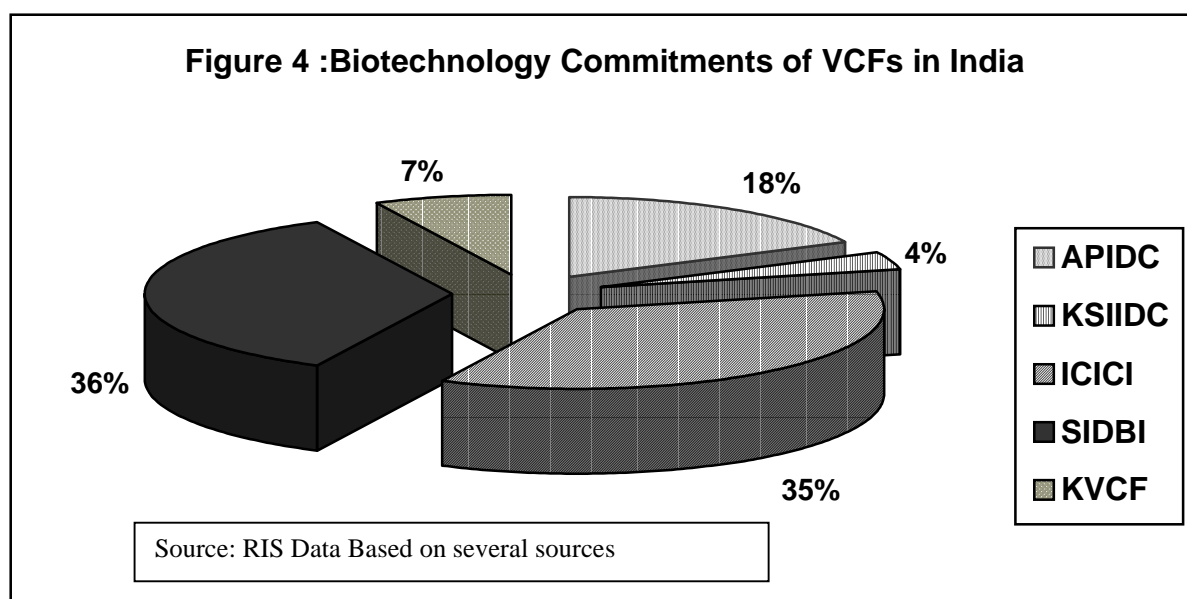
Table 6: Venture Capital Disbursements in India (2001) (\$ Million)

Country	Investment	No. of Recipient Companies
Japan	1,858	39
India	1,105	91
South Korea	1,054	19
Singapore	965	26
Australia	548	81
China	393	11
Hong Kong	263	23

Source: Nasscom (2001)

The biotechnology commitments by different VCFs amount to almost Rs. 3000 million (Figure 4). 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 Kerala 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 biotechnology VCFs in India along with their specific initiatives are being discussed herewith.



IV.B.1 ICICI

ICICI Venture currently manages/advises 11 funds, aggregating about US\$ 400, million making it one of the large private equity investors in the country³⁸. Consistent with its strategy of focussing on sectors where Indian companies have a global competitive advantage, all of the ICICI Venture funds make investments only in companies belonging to the IT, life sciences and services sectors. These industries have demonstrated a capability to leverage the intellectual capital in India to effectively address the global markets.

ICICI Venture is currently in the process of constituting a dedicated incubator fund for funding start-ups in the area of biotechnology and life sciences. As in the area of information technology, the ICICI Venture Incubator team would be extending support services to its incubatee companies, including basic research infrastructure in tie-up with ICICI-Knowledge Park Limited. The targeted fund size is Rs.1 billion. Recently ICICI Venture Funds and Global Trust Bank

have invested \$1.5 million in Avestha Gengraine Technologies Pvt. Ltd. (Avesthagen), a fully-integrated biotechnology and bioinformatics company based in International Tech Park Ltd (ITPL), Whitefield.³⁹ Avesthagen, operational since August 1999, would be going in for the second round of funding by April 2002 and expect a turnover of Rs 500 million in five years. The company currently employs 40 workers, out of which 34 are researchers. Focused on genomics and bioinformatics, with expertise in marker-aided selection, genome sequencing, gene discovery, plant transformation, database management, 3D structure-function analysis.

IV.B.2 SIDBI

Small Industries Development Bank of India (SIDBI) and Department of biotechnology (DBT) have decided to set up a Rs 1000 million Biotechnology Development Fund in 1998. This is to encourage private-public partnerships in the small-scale sector as well as to promote entrepreneurship in biotechnology. It is proposed that the DBT would put in Rs 200 million, while SIDBI would contribute the rest of Rs. 800 million for the fund. Earlier the proposal was of DBT-Sidbi for a Rs 500 million (Rs 250 million each) National Biotech Venture Fund but the Planning Commission of India did not agree with that proposal on the pretext that it would be better to leave it to the financial intermediaries (FIs) as it would entail nurturing and monitoring apart from financial management which FIs can do much better⁴⁰. At this stage, finer details of the proposal such as whether to give assistance as soft loans or set in place a programme with an exit clause that would help the fund sustain itself through royalties and so on are being worked out. The proposal is part of a larger industry orientation proposed by the DBT in its Tenth Plan Approach Paper. In collaboration with the Agriculture Ministry, a large number of decentralised production units (at least 1000 for biofertilisers and biopesticides) in the small scale sector are proposed to be established all over the country with new technology packages by the end of the Tenth Plan.

V Initiatives by State Governments:

In recent past several State Governments in India have launched different initiatives to attract biotechnology industry to their respective States for instance, Tamil Nadu has announced its biotechnology policy in September 2000, while Karnataka followed suit in February 2001. In the same year Andhra Pradesh was seeking to leverage its strengths in the pharmaceuticals, agriculture and IT services to put it at the forefront of the biotechnology race among the various

State Governments. Not surprisingly, the States have extended similar concessions, already available to the IT sector.

V.1 Andhra Pradesh (AP)

As part of the AP-BT policy, among other things, the companies would enjoy a lower sales tax of just one per cent, down from the present 8 to 16 per cent, on all high-end biotechnology products produced within the State. They would also be able to book space at concessional rates at the proposed 600 square kilometer Genome Valley. The policy proposes setting up an exclusive Rs. 500 million venture capital fund⁴¹. The policy also speaks of funding the biotechnology start-ups through the existing APIDC Venture Capital Ltd. The aim of the policy is to leverage on the existing strengths of the state for rapid commercialisation of biotechnology so that innovative biotechnology products and services could be produced in the State. AP has already numerous centres of excellence in healthcare, agriculture, and biotechnology. Its capital Hyderabad has earned an image of being the pharmaceutical and science capital of the country. The government is also trying to use its strength in the IT for the growth of bioinformatics in the State. For the rapid growth of this sector, the government has identified field diagnostics, therapeutics, pharmacogenomics, bioinformatics, agriculture, marine, industrial biotechnology and contract research as some of the thrust areas.

ICICI has planned a Knowledge Park at Turkapally near Hyderabad, for promotion of life sciences. Thus far, Rs 310 million have been invested in the Knowledge Park, developed on a 200-acre site. It is a joint initiative of ICICI and the Andhra Pradesh Government. The ICICI Knowledge Park and the Biotechnology Park together form part of a larger blueprint of the Genome Valley project, which the Government plans to develop on a 600 sq. km area encompassing Medchal, Shameerpet, Kesara mandals in Rangareddi district and Uppal-Tarnaka corridor⁴².

ICICI has signed an MOU with the Indian Institute of Chemical Technology (IICT), Centre for Cellular and Molecular Biology (CCMB) and the University of Hyderabad, in a new 'knowledge network initiative'. This project has also been assisted by the Department of Scientific and Industrial Research (DSIR), to the tune of Rs 15 million to set up a Virtual Information Project taken up by the Knowledge Park. The Park has been licensed under Section 25 of the Companies Act, 1956, and is approved by the Department of Scientific and Industrial Research, Government of India for the benefit of Customs duty exemption and Excise duty waiver. Under the initiative,

partners in the Knowledge Park will get on-line access to library-based information expertise from these national labs and university system. It would also encourage undertaking collaborative research between corporates and research companies based in the park. The park has identified another 20 premier research organisations and universities during the first phase of the programme. At this point, only two start-ups - Medicorp Technologies and Pulsar Electro-Optics Ltd, have moved into the park with their projects. Two more companies are actively considering to move in. They are Bijam Biosciences Ltd, a Nagarjuna Group company which wants to set up a research centre in agri-biotech and MedGene Biotech, which plans to start a research centre for new drug discovery and genomics research⁴³.

Interestingly, one of the beneficiaries of the Knowledge Park is the proposed Rs 900 million Biotechnology Park coming up within the vicinity. The Biotechnology Park, to be developed on a 150-acre site, has been initiated as a joint venture of the Andhra Pradesh Government and Shapoorji Pallonji, a Mumbai based construction company. In the MoU the state government would be a minority stakeholder. The private promoter would be responsible for designing, construction, financing, marketing and maintaining the park⁴⁴. During the first phase, the park would focus on therapeutics, diagnostics and industrial biotechnology. Revenues would primarily come through leasing of premises, equipment and rental for operations. Meanwhile, the company has applied for a Central Government grant of Rs 150 million. The Department of Biotechnology, Government of India has rolled out a programme for biotechnology parks in various states, under which grants would be sanctioned depending upon the nature of the business plans.

V.2 *Karnataka*

The Karnataka Government has announced a biotechnology policy to promote this sector and is setting up an institute for bioinformatics in Bangalore. The Government is also creating a biotechnology fund which will have inflows from biotechnology companies. This would be used for incubation of new projects and promotion of the sector in the State. The policy statement spells this out as an attempt to tap on the synergy between information technology and biotechnology as IT can immensely help in biotechnology research to achieve results faster.

The Karnataka Government is putting in Rs. 50 million and an equal amount is being brought in by ICICI to develop the Institute of Bioinformatics and Applied Biotechnology in Bangalore⁴⁵. The renowned biotechnology expert, Dr H Sharat Chandra will look after the institute as a

Chairman. The institute will have four primary objectives: conducting research in biotechnology, providing education and training in similar areas; providing incubation facilities for start-up projects with common facilities and creating a platform for educationist, scientists, industry, venture funds and Government, to interact with each other for the development of the sector in India.

Karnataka has planned to launch India's first state-sponsored biotechnology venture capital fund to boost their initiatives. The fund is likely to have an initial seed capital of Rs. 100 million to be operated through Karnataka State Industrial Investment and Development Corporation (KSIIDC)-Karnataka State Finance Corporation (KSFC)⁴⁶. Karnataka was also the frontrunner in setting up the first state financed IT VC fund. It now proposes to extend Bangalore's numero uno position in IT to other knowledge-based industries by floating a fund to support subjects like biotechnology, genetic engineering and pharmaceuticals. To supplement the modest initial contribution, the state has plans to mobilize additional funds for the biotechnology corpus from other domestic and global FIs and multilateral agencies. Recently, Karnataka's IT and commerce-industries team tried to pitch for a share in the \$ 1.2 billion incubation fund of Singapore's National Science and Technology Board (NSTB).

The Karnataka officials scoured for opportunities for financial, technical and marketing assistance for biotechnology ventures, besides aiming for joint R&D between Institute of Bioinformatics in Bangalore and Centre for Cellular and Molecular Biology, Hyderabad, and two top Singapore agencies namely Institute of Molecular & Cellular Biology (IMCB) and Institute of Agribiology (IAB). Incidentally, as part of the biotechnology buildup. The Karnataka government is also setting up an ultra-modern Centre for Human Genetics at the Agriculture University campus in Bangalore over a 20-acre plot. It has also engaged Arthur Andersen to prepare a biotechnology strategy paper spelling out the infrastructure and policy framework required to boost its growth and to extract optimum advantage from this stream of new business.

V.3 Tamil Nadu (TN)

The Tamil Nadu Industrial Development Corporation (TIDCO) has linked a technical service agreement with Cornell University, USA for setting up a biotechnology park in Chennai, christened TICEL (Tidco Centre for Life Sciences), the park proposes to attract fresh investment of Rs. 10,000 million from 50 new companies to be set up in the park and fuel bio-entrepreneurship. Among the states, Tamil Nadu is the only state, with such kind of foreign

collaboration. This initiatives will put Chennai on the global network of Cornell, which has technical collaboration in 36 countries⁴⁷.

TICEL is modeled on the TIDEL Park, the information technology park set up by TIDCO, As per the MoU, valid for five years renewable for another five years, Cornell University will help from the conceptual stage to the commissioning stage of the park. The state-of-the-art park will provide complete technical and other allied services under one umbrella including technology transfer, monitoring, networking, contract and collaborative research work, product validation, documentation, commercialization, training and a separate intellectual property rights (IPR) cell which will support in the areas of patents, licencing, royalty sharing and copyrights. The total cost is pegged at Rs. 625 million. TIDCO will be investing Rs. 90 million as equity. The Tamil Nadu government would bring in Rs. 200 million, while the remaining Rs. 330 million would be raised from various banks and financial institutions. It is stated that State Bank of India, Industrial Development Finance Corporation and Exim Bank have also shown interest in picking up equity state. The financial closure of the park is over in November 2001, and the park would be made ready for occupation by December 2002.

Cornell University in addition to the above, will also be setting up a special project cell at its premises in the USA to provide for advanced training, apart from offering access to its electronic library. It will also facilitate relationships between the tenants of similar parks abroad and in the Chennai park besides exchange of faculty for conducting specific and advanced training programmes. TICEL would be set up in a five acre expense consisting of two major facilities – a bio-resource center of 18,000 sq. ft. and customized laboratories of 1.2 lakh sq. ft. It will explore the Indian genetic pool and exploit the germplasm base available and leverage on the existing pool of Indian biotechnology scientists and low cost software skills.

V.4 Himachal Pradesh (HP)

Himachal Pradesh probably is the only Northern Indian state which has prepared a blue print for promotion of biotechnology industries in the State. This would include setting up of a biotechnology park at Solan, conservation and exploitation of bioresources, intensification of R&D, and promoting biotechnology entrepreneurship through tax concessions and relaxed labour laws. At Solan, land has been earmarked at New Solan to set up the biotech industries. The idea is to tap the huge potential of bio-resources and commercially exploit the state's rare herbal medicines, annual global trade flow of which is close to \$20 billion. HP could help

enhance the country's share as 3,295 plant species were present in the state⁴⁸. It is also proposed to provide research based support to the private companies in form of providing for instance, access to a database of bio resources which is being developed along with separate entries of endangered medicinal plants. Apart from this a germ plasm collection and culture facilities and bioinformatics network is also being established.

In order to tap these strengths, a series of concessions and sops have been chalked out. The industry has been given priority sector status and assured uninterrupted power supply at industrial rates. Labour laws have been relaxed, arrangements made for single window clearance of projects, with mega project status for ones with over Rs. 500 million investment. This would encourage diversification of farming through companies which are already into micro-propagation units in other states for plants and crops like ginger, saffron, potato, strawberry and bamboo.

VI Policy Regime for Biosafety and Protection of Intellectual Property

Recently in India, the debate on biosafety guidelines has come a full circle as Indian Ministry of Environment and Forest (MOEF) reported sowing of unapproved genetically modified (GM) cotton seeds in several hundred hectares of land. The report has stirred the ongoing debate on GM crops in India, as had happened way back in 1997 when, unapproved GM eggplant was located in an agricultural research institute without sufficient safeguards⁴⁹. This has once again brought the implementation-related aspects of biosafety protocol at the centre-stage and has raised several issues concerning the very ability in many developing countries to handle sensitive technologies in such vital sector as agriculture.

The whole controversy started when MOEF appointed committee, called, Genetic Engineering Approval Committee (GEAC) visited a village Mehsana, in agriculturally prosperous western Indian states Gujarat and found cotton crop flowering on a land area of 12,000 hectares. A local seed company, Navbharat Seeds, supplied the seeds. The cotton seeds used, were genetically modified carrying *Cry I Ac gene*, patent for which is with Monsanto. At present, Monsanto has a collaboration with an Indian company, Mahyco is conducting field trials for Bt cotton in some other states. The results of first round of trials were submitted to the DBT almost two years back but government did not grant permission for commercialization of these seeds as Ministry of Agriculture had objections about it.⁵⁰

VI.1 Biosafety Guidelines

Though India established the bio safety guidelines way back in 1989, till now no commercial trials of GM crops have been allowed except the one permission granted last month (March 2002). India's Biosafety and Recombinant DNA Guidelines (1990) falls under the Environment (Protection) Act of 1986. In 1994, after India signed the Convention on Biodiversity, the DBT revised its earlier guidelines to accommodate the safe handling of GMOs in research, application and technology transfer. This includes the large-scale production and deliberate release of GM plants, animals and products into the environment. The guidelines are also provided for the shipment and importation of GMOs for laboratory research. While the relative hectareage of transgenic crops in industrial and developing countries during the period 1996-2000 has gone up from 1.4 million hectares in 1996 to 33.5 million hectares in 2000, amounting to a growth of 96 per cent, the proportion of transgenic crops in developing countries has increased from 0.1 million hectares to 10.8 million hectares in the same period. The area under GMO in the developing countries grew at a rate of 14 per cent in 1997 to 16 per cent in 1998 and 18 per cent by 1999. In 2000, it showed a rise of 24 per cent. The total area under transgenic crops at present is 44.2 million hectares. Out of this, the USA and Canada, among the developed countries, and Argentina and China, among the developing countries, show a wider adoption of this technology. Developing countries have almost 11 million hectares under transgenic crop cultivation. Now some Latin American and CIS countries have also embarked on the GM adoption path. Accordingly, the global market of biotechnology has grown rapidly in the last few years. In 1995 it was at \$75 million while in 1998 it was \$1.5 billion. This is now being projected to \$6 billion by 2005.

In India, there is no permanent secretariat to monitor the trials of the GMOs. Instead the regulations are implemented by various ad hoc committees. The most important committees are; the *Institutional Biosafety Committees (IBSC)*, responsible for the local implementation of guidelines, the *Review Committee on Genetic Manipulations (RCGM)* responsible for issuing permits; and the *Genetic Engineering Approval Committee (GEAC)*, responsible for monitoring the large scale and commercial use of transgenic materials. These committees have statutory authority. Most of the committee members are from the scientific community and staff of Department of Biotechnology (DBT) and the *Ministry of Environment and Forestry*. DBT appoints the members to the committees. The GEAC is supposed to be assisted by the *State Biotechnology Coordination Committees (SBCC)* and *District Level Committees (DLC)*.

However, none of the states have established SBCC and DLC committees, not even in areas where field trials are already taking place. Moreover, while committee members are drawn from the scientific community, many are not well versed with socio-economic issues and consequential risk assessment.

At present in India, almost 22 genetically modified plants being tested by different organisations for different purposes (Annex 3). This includes endeavors by private sector also for instance Pro Agro - PGS is conducting test of Brassica, Brinjal, Cabbage, Cauliflower and Tomato for developing resistance to different pests and extending the shelf life value. Among the other private companies Rallis India and Mahyco are the prominent ones working on vegetable crops and cotton respectively. In the public sector institutions Delhi University, South Campus Delhi University led network on rice, sorghum and vegetables is working very actively with several other institutions. IARI, Pusa is working on Brinjal, Mustard, Rice and Tomato while Bose Institute, Calcutta and Tamil Nadu Agricultural University (TNAU) are also working on Rice. JNU, New Delhi is working on different varieties of transgenic potatoes alongwith Central Potato Research Institute, Shimla.

VI.2 Guidelines on Stem Cell Research

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 7). A National Bioethics Committee has been formed to grant such permissions and to monitor such research endeavors⁵¹. 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. While much of the debate centers around possible US-funding for such research, the Indian government is now getting concerned about the possibility of a Singapore and Australia like scenario where stem cells from aborted fetuses and frozen embryos in IVF clinics are reportedly being sold in the US.

The guidelines for biomedical research, in India, were framed as far back as in 1992 and renewed in 1997. It defines 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 Committee set up by the DBT two years ago is set to announce a Bioethics Policy in near future. This would not allow human cloning in the country, but would promote embryonic stem cell research, provided a consent form is part of each study.

There seems to be only one private company, Reliance Life Sciences (RLS), that is all set to come out with its product in this field by early 2003. The product, *Christened Relicord* contains cord blood stem cells⁵². Cord stem cells are obtained from the umbilical cord of human babies. The stem cells - undifferentiated cells with the ability to regenerate and grow into different tissue can be used to treat patients with disorders like thalassaemia or leukemia. It can also be used as a back up for patients who have to undergo chemotherapy, which results in depression of the bone marrow. Though *Relicord* will be the first product of its kind in the country, the procedure is performed at a few hospitals across the country. But while hospitals have to depend on donors for the cells. RLS plans to have as many as 50,000 samples almost making it an off the shelf product. Earlier this year, RLS filed a provisional US patent for *Relicord*.

The company is now awaiting the approval by the Drug Controller General of India, following which it will launch the product. The first *Relicord* transplant was recently performed at Kothari Hospital in Kolkata. The promoters of the Reliance group will be investing \$25m in RLS over the next two to three years. The Life Sciences Company will focus on research and development in stem cells and tissue engineering. Its cell biology centre at the HN Hospital in Mumbai has already isolated seven stem cell lines, at least four of which are in the initial stages of development. The areas of research include assisted reproduction, embryonic stem cells which can be used to develop tissues of the body, haematopoietic stem cells, skin cells, genetics, molecular diagnostics, gene therapy and tissue engineering.

Table 7: 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: *The Times of India*, September 5, 2001

VI.3 Patent Regime

Since 1970, India has adopted a patent regime that provides only process patents for foods, chemicals and pharmaceutical products with a patent term of seven years. All other patents have a term of 14 years. The Patent Act, 1970, is widely believed to have helped the Indian pharmaceutical industry to develop its process innovation capabilities that is now recognized worldwide. India amended the Patents Act 1970 to provide for exclusive marketing rights (EMRs), as per her obligation under the provisions of the WTO/TRIPS agreement in 1999⁵³. EMR allows foreign firms to market their products on which they have obtained patents in any WTO member country. According to the WTO agreement, EMRs are to be provided in those countries where product patent is yet to be adopted as a practice for legal protection of intellectual property. In any case all the member countries would have to adopt product patents by 2005.

Now when the government has already decided in favor of EMR it must ensure a speedy adoption of the product patent regime with a clear guideline on establishment of the 'mail box' for receiving the product patent applications⁵⁴. EMRs can only be given until 2005 and that too in cases where the patent application has been granted in or after 1995. Ranbaxy Laboratories has filed an exclusive marketing rights (EMR) application for Cipro-OD, its once-daily form of antibiotic ciprofloxacin. Ranbaxy could well be the first Indian firm to make an EMR application⁵⁵. So far only MNCs with product patents are known to have made EMR applications.

VI.4 Plant Variety Protection

As part of India's commitment at TRIPs under WTO India had to enact a legislation protecting plant varieties. In the year 1999 Government introduced a bill to this effect in the Parliament which was later referred to a Joint Parliamentary Committee (JPC) so as to ensure protection of farmers interests. After getting recommendations from this committee Government has enacted the Plant Variety Protection Act, 2001 (2001).

In the present form the PVPA attempts to ensure the delicate balance between the interests of plant breeders and farmers. The farmers now can raise crops of a protected variety every year from their saved seeds. Under this legislation the plant breeders can make profit from the first time sale of self-perpetuating plant species. The Act has taken care of farmers' interests by putting a clause (Article 17), requiring a plant breeder to provide an affidavit that the newly bred variety does not contain the terminator gene⁵⁶. The Act has a strong provision for compulsory license to undertake production, distribution and sale of the seed/planting material of a particular variety, if the same is not available on reasonable price or in adequate amount.

However, interest of breeders are proposed to be duly taken care of while settling the terms and conditions of granting a license. Similarly, there is a provision for revocation of the compulsory license if the licensee fails to provide seeds/planting material at a reasonable rate.

VI.5 Seeds Act

After clearance of Bt cotton by the Genetic Engineering Approval Committee (GEAC) for commercial production, the draft Seeds Act of 2001 would have to include more stringent provisions for genetically modified seeds⁵⁷. The objective of the new legislation, which is to replace the existing Seeds Act of 1966 and the Seed (control) Order of 1986, is to provide an effective system for stimulating investment for research and development. The draft Act aims at encouraging development of new plant varieties by ensuring appropriate returns on all such investment by domestic players. However, the Act should have visualised the domestic commercial production clearance for genetically modified seeds. Against this, the current wholesale revamp exercise on the existing Seeds Act would now have to address this lacuna. The sale of the Bt cotton seeds would be governed by the same provisions controlling other varieties under the legislation such as specific labelling.

There is still no domestic policy on genetically modified crops and all proposals would receive their approval from the GEAC on a “case to case” basis. However, any exercise to pointedly address the lapse in the draft legislation regarding sale and stringent labelling of genetically modified seeds would also lay the ground rules for other seeds in the future. The draft legislation now pending with the law ministry refers to transgenic seeds, in fact, primarily as imports. It holds that the importer of seeds or planting material will be required to declare whether such material is a product of transgenic manipulation or involves genetic use restriction technology. The draft law also proposes the compulsory registration of all such seeds, seed producers and seed processing plants and the regulation of import and export of seeds through the National Seed Board.

VII Concluding Remarks

Over the years India has developed strengths in biotechnology in public sector institutions. The graduation from Biotechnology Development Board to Department of Biotechnology in late eighties was a decisive step to address a wider canvas in biotechnology. In these years DBT has emerged as a major force to direct biotechnology developments in India. Further, the involvement of various agencies dealing with this technology has further helped in developing technology capability at various levels. The size of the industry is estimated to have grown to \$1.5 to \$2.5 billion between 1999 and 2002. There are two major research centres in India working on stem cell line research.

The achievements in biotechnology in India could become possible only because the government took early initiatives for setting up institutional infrastructure for human resource development. As of now more than 62 universities and institutions are engaged in biotechnology training and education related programmes. Efforts are being made to link up human resource development programmes according to industry requirements, and in fact, academic institutions are also being encouraged to work in close tandem with industry. India has attached greater importance to bioinformatics. DBT has set up 55 centres for bioinformatics, which have been developed as a strong information network. They are linked with databases and networks around the world. The whole range of new initiatives to support biotechnology programmes at Indian Institute of Technology and at Jawaharlal Nehru University are aimed in that direction. The micropropagation technology parks at TERI, New Delhi and NCL, Pune have served as an important interface between the industry and the developers of the technology in the areas of

plant tissue culture. National Centre for Plant Genome Research and National Brain Research Centre are some of the recent additions. However, it is difficult to estimate precise R&D allocations at several of these centres. The budgets of major funding agencies like CSIR/ICMR and ICAR give only an aggregate picture. Therefore there is an urgent need to launch a detailed survey to collect specific biotechnology related allocations at the individual institute/ laboratory level. Apart from this, DBT or some other such agency should urgently initiate an exercise for data collection either on its own or through specialised sectoral agencies.

These initiatives coupled with other industrial promotion efforts may encourage industry also to participate in this technology evolution exercise. Despite phenomenal growth and rapid penetration of this technology, However, the local firms are facing an intense competition from a whole range of transnational corporations. The pressure is immensely acute in the agricultural sector where Indian firms are finding it difficult to access relevant gene sequences given the proprietary rights of TNCs as developers of these technologies. In the pharmaceuticals sector, where advanced forms of biotechnology are being used, firms are facing severe liquidity constraints for investment. According to Ernst & Young, technology funding required for Indian biotechnology sector in 2001 was \$2.5 billion while by 2010 it would be \$4.8 billion. A larger part of this funding is for supporting development of an idea and also for diversification of activities of Indian firms.

The biosafety policy was announced in India right in the beginning when this technological revolution was being unfurled. A three-tier structure was put in place to monitor biosafety regulations way back in 1987. Similarly, India has announced a National Bioethics Committee as it implements the Guidelines for Stem Cell Research. The recently promulgated Plant Variety Protection Act has brought in a rare balance between the interests of farmers and industry. Though debate on Article 27(3)b of TRIPs still continues in India, an amendment is being brought in the Patents Bill to facilitate research and development in biotechnology. Another major challenge related to IPR regime in India is of data management. TIFAC is the only agency in India giving patent statistics in electronic form. However, the agency does not collect International Patent Classification (IPC) details, which would help in identifying biotechnology patents. Thus, it is difficult to precisely work out even a broad trend in technology development in this knowledge intensive industry. The increasing number of patents every year may further complicate such estimation.

It is through continuous efforts that India has developed indigenous strengths in developing GMOs, but a policy related to trade in GMOs is yet to be announced. This dichotomy is leading to confusion at several levels of governance of this technology. It is also important to realize that at this stage neither at the Union government level nor at the State governments level, trained manpower is available to look into the technical details of GM crops, if at all being produced. Apart from this, neither the quarantine nor any other agency has necessary gadgets to help in locating transgenic material. In this context, the International Cooperation Division of Department of Biotechnology has shown farsightedness to plan an international training course for government employees for capacity building. The problem is that people from quarantine agencies at the ports and other entry points are not well equipped to detect GMO content in any agriculture product. This calls for quick short term measure to overcome lack of knowledge about the technology and along with that long term analysis to respond to systemic failures at different levels.

Annex –1: Some of the Major Institutions of CSIR active in Biotechnology

<u>Area</u>	<u>Institution</u>
Allergy & immunology	CBT
Diagnostics	CBT, IICB, CDRI, NCL
Development of antibody based diagnostics and site specific drug delivery systems in infectious diseases such as malaria, leishmaniasis and tuberculosis.	IMTECH
Studies on the mechanisms of multi-drug resistance New in yeast	IMTECH
Development of an in vitro endocrine disorders model system for screening due to mutation in steroid receptor gene and possibility of its repair by gene targeting.	IMTECH
Membrane structure, function and to study possible applications in site-specific drug /antigen delivery.	IMTECH
Microbial Genetics.	CCMB
Cell Biology & Development.	CCMB
Biomedicine & Biotechnology.	CCMB
Molecular Biology.	CCMB
Biochemistry & Biophysics.	CCMB
Genetic manipulation of essential oil bearing plants for high yield and value addition for the international market.	CIMAP
Morphine deficient and hyper morphine-codeine yielding genotypes for alternate methods of opiate alkaloid production.	CIMAP
Improvement in productivity and Quality of Hill Area Tea.	IHBT
Plant Molecular Biology.	NBRI
Tissue Culture of Economic Plants.	NBRI
Biodiversity and conservation of lower group of plants (Lichens, Bryophytes and Pteridophytes)	NBRI

Source: CSIR Web Page (www.csir.res.in)

Annex 2: Manpower Development and Training Opportunities in India

M.Sc. General Biotechnology (2 year courses)

- Jawaharlal Nehru University, New Delhi
- Madurai Kamaraj University, Madurai
- MS University, Baroda
- University of Poona, Pune
- Guru Nanak Dev University, Amritsar
- Devi Ahalya Viswavidyalaya, Indore
- University of Hyderabad
- Himachal Pradesh University, Shimla
- University of Calicut, Kerala
- Tezpur University, Tezpur (Assam)
- Gulbarga University, Gulbarga (Karnataka)
- Jammu University, Jammu
- Gujarat University, Ahemadabad
- Guru Jambheshwar University, Hissar
- Kumaon University, Nainital
- Banaras Hindu University, Varanasi
- Indian Institute of Technology, Mumbai Entrance Exam by IIT, Mumbai
- Roorke University Entrance Exam by University of Roorke
- Aligarh Muslim University, Aligarh Entrance Exam by AMU
- Banasthali Vidyapeeth, Banastha Rajasthan (for girls only) Entrance Exam by Banasthali Vidyapeeth
- Mysore University, Mysore. M.Sc. Agricultural Biotechnology (2 years)
- Assam Agricultural University, Jorhat Exam by AAU Jorhat
- Tamil Nadu Agricultural University, Coimbatore, Combined Entrance Exam by JNU.
- G.B. Pant University of Agricultural and Technology, Pantnagar, Combine Entrance Exam by JNU.
- Birsa Agricultural University, Ranchi. Combined Entrance Exam by JNU
- Himachal Pradesh Krishi Vishvavidyalaya. Palampur (H.P.) Combined Entrance by JNU
- Indira Gandhi Agricultural University. Raipur Combined Entrance Exam by JNU

Master in Medical Biotechnology (2 years)

- All India Institute of Medical Sciences New Delhi, Exam by AIIMS

M.Sc. Marine Biotechnology (2 years)

- Goa University, Goa Combined Entrance Exam by JNU

M.Tech/M.Sc (Tech) Biochemical Engineering & Biotechnology (5 years integrated/3 semesters/1.1/2 years course)

- Indian Institute of Technology, Kharagpur, through GATE
- Indian Institute of Technology, New Delhi (5 years integrated) JEE
- Anna University, Chennai. Combined Entrance Exam by UDCT, Mumbai

Post MD/MS Certificate Course in Medical Biotechnology (1 year)

- All India Institute of Medical Sciences, New Delhi Exam by AIIMS
- Post Graduate Institute of Medical Education & Research, Chandigarh. Exam by PGI
- Sanjay Gandhi Post Graduate Institute of Medical Education & Research, Chandigarh. Exam by SGPGI

PG Diploma Course in Clinical Biochemistry & Biotechnology (1 year)

- Utkal University, Bhubneshwar. Exam by Utkal University

PG Diploma Courses in Molecular & Biochemical Technology (1 year)

- Sri Venkateshwara College, University of Delhi, New Delhi. Exam by Sri Venkateshwara College.

Source: Bioinformatics, (Bangalore) January 2001.

Annex 3: Current Profile of GMOs In India

	Crop	Gene	Organisation	Purpose
(1)	Bell pepper	Snowdrop (Galanthus nivalis) Lectin gene.	M/s Rallis India Ltd.	Resistance against pests,
(2)	Brassica / Mustard	Barstar, Barnase, Bar	M/s Proagro PGS (India) Ltd..	To develop better hybrid cultivars
(3)	Brinjal	Cry1A(b)	M/s Proagro PGS (India) Ltd., New Delhi	To develop plants resistant to pests.
(4)	Brinjal	Bt gene	Indian Agricultural Research Institute, New Delhi	To impart lepidopteran pest resistance.
(5)	Cabbage	Cry1H/Cry9C	M/s Proagro PGS (India) Ltd., New Delhi	To develop resistance to pests.
(6)	Cauliflower	Barnase, Barstar and Bar	M/s Proagro PGS (India) Ltd., New Delhi	To develop hybrid cultivars
(7)	Cauliflower	Cry1H/Cry9C	M/s Proagro PGS (India) Ltd., New Delhi	To develop resistance to pests.
(8)	Cauliflower	Bt gene	Indian Agricultural Research Institute, New Delhi	To impart pest resistance.
(9)	Chilli	Snowdrop (Galanthus nivalis)	M/s Rallis India Ltd., Bangalore	Resistance against pests.
(10)	Cotton	Cry1A(c)	M/s MAHYCO, Mumbai	To develop resistance against lepidopteran pests.
(11)	Mustard / rape seed	Bar, Barnase, Barstar	Delhi University, South Campus, New Delhi	Plant transformations completed and ready for green house experiments
(12)	Mustard/ rapeseed	Arabidopsis annexin gene	Indian Agricultural Research Institute, New Delhi	Transformation completed, Green house trial completed, ready for field-trials for moisture resistance stress

	Crop	Gene	Organisation	Purpose
(13)	Potato	Gene expressing for seed protein containing lysine obtained from seeds of Amaranthus plants (Ama-1 gene)	Jawaharlal Nehru Univ., New Delhi	Transformation completed and transgenic potato under evaluation.
(14)	Potato	Bt toxin Gene	Central Potato Research Institute, Shimla	To generate plants resistant to lepidopteran pests. Ready to undertake Green House trials.
(15)	Rice	Bt toxin genes	Bose Institute, Calcutta	To generate plants resistant to lepidopteran pests.
(16)	Rice	Reporter genes like hph or gus A	Tamilnadu Agricultural Univ. Coimbatore	To study extent of transformation
(17)	Rice	Selectable marker genes	Delhi University, South Campus, New Delhi	Gene regulation studies. Transformations completed
(18)	Rice	Bt toxin gene	Indian Agricultural Research Institute sub station at Shillong	To impart lepidopteran resistance.
(19)	Tobacco	Bt toxin gene Cry1A(b) and Cry1C	Central Tobacco Research Institute., Rajahmundry	To generate plants resistant to H.armigera and S.litura.
(20)	Tomato	Cry1A(b)	M/s Proagro PGS (India) Ltd., New Delhi	To develop plants resistant to lepidopteran pests.
(21)	Tomato	Snowdrop (Galanthus nivalis) Lectin gene	M/s Rallis India Ltd., Bangalore	Resistance against pests.
(22)	Tomato	Bt gene	Indian Agricultural Research Institute, New Delhi	To impart pest resistance.

Source: Biosafety Information Network and Advisory Service (BINAS), UNI DO, various years.

References

- Alam Gayur (1994). 'Biotechnology and Sustainable Agriculture: Lessons from India', *OECD Technical Paper No. 103*, Paris, France.
- BCIL (2001). Directory of Biotechnology Industries & Institutions in India, Biotech Consortium India Limited, New Delhi.
- Bhargava, P M (1995). 'Biotechnology's Decade of Stagnation', *Economic and Political Weekly*, December 2.
- BINAS (2001). 'GMO Field Trials; Database of Field Trials by Country', The Biosafety Information Network and Advisory Service (BINAS), United Nations Industrial Development Organisation, retrieved from the internet: <http://binas.unido.org/binas/fieldtrials.php3>.
- Biofertiliser Statistics (2001). The fertiliser Association of India, New Delhi.
- Brenner, Carlene and John, Komen (1994). 'International Initiatives in Biotechnology for Developing Country Agriculture: Promises and Problems', *OECD Technical Paper No. 100*.
- Chaturvedi, Sachin (1997). 'Biosafety Policy and Implications in India', *Biotechnology and Development Monitor*, No. 30, March.
- Chaturvedi, Sachin (1999). 'Amending Patents Act: Options Before India', *Mainstream*, March 6th.
- Chaturvedi, Sachin (1999). 'The Asian Biotechnology Market: Emerging Investment Trends, AgBiotech Net, CAB International, Vol. 1, March.
- Chaturvedi, Sachin (2001). 'Continued Ambiguity on GMOs', *Economic and Political Weekly*, October 20, 2001.
- Chaturvedi, Sachin (2002). 'WTO, Biosafety Regulatory Regime and Trade in Genetically Modified Goods: Options before Developing Countries-An Indian Perspective'. A Paper Presented in an *International Conference on Biotechnology and Development: Challenges and Opportunities for the Asian Region*, RIS, New Delhi.
- Chaturvedi, Sachin (2002). 'The Public-Private Debate in Agricultural Biotechnology and New Trends in the IPR Regime: Challenges before Developing Countries', *The Economic and Political Weekly*, March 30th.
- Department of Biotechnology (1994). 'Biotechnology: Research Development and Demonstration: Thrust Areas', *Department of Biotechnology Annual Report 1993-94*, Ministry of Science and Technology, Government of India.
- Department of Biotechnology (2001). Annual Report 2000-2001, Ministry of Science and Technology, Government of India, New Delhi.
- Dhar, B. and Sachin Chaturvedi (1998). 'India's Biotechnology Plans for the Next Five Years', *Biotechnology and Development Monitor No. 35*.

- Dhar, B. and Sachin Chaturvedi (1999). 'TRIPs and CBD: The Widening Gulf', *Biotechnology and Development Review*, Vol 3 No. 1.
- Dosi, Giovanni, Pavitt Keith and Soete Luc (1990). 'The Economics of Technical Change and International Trade' *New York University Press*.
- Ghosh, P K (1997). 'Genetically Engineered Plants in Indian Agriculture', *Journal of National Botanical Society*, Vol. 51 pp. 11-32.
- Hettel, G. (1997). 'Partners Make Hybrid Rice a Reality in India', *Mimeo*, International Rice Research Institute, Manila.
- Kumar, Nagesh (1988). "Biotechnology in India", *Development* (Special issue on Biotechnology), March.
- Kumar Nagesh (1998). 'India, Paris Convention and TRIPs', *Economic and Political Weekly*, September 5.
- Lall, Sanjay (1992). 'Technological Capabilities and Industrialisation', *World Development*, 20: 165-186.
- Mani, Sunil (1990). 'Biotechnology Research in India: Implications for Indian Public Sector Enterprises', *Economic and Political Weekly*, August 25.
- McGaw, Eric M (2001). 'A Temple of Rice: Success in Biotechnology through Networking', The Rockefeller Foundation, Hyderabad.
- Mehra, K.L., (2000). 'Plant Varieties Bill Does Safeguard Farmers' Rights', *The Economic Times*, December 16.
- Nelson Richard R. (ed.) (1993). 'National Innovation System: A Comparative Analysis', *Oxford University Press*, New York.
- Panchamukhi, V. R. and Nagesh Kumar (1998). 'Impact on Commodity Exports' in *Biotechnology Revolution and the Third World: Challenges and Policy Options*, pp. 207-224.
- Pental, Deepak (1998). 'Plant Molecular Biology and Biotechnology in India', *Plant Molecular Biology Reporter*, Vol. 16, pa. 93-97.
- Prakash, Jitendra (1997). 'The Concept of Biovillage in Proceedings of Regional Training-cum-Workshop on Application of Biotechnologies to Rainfed Farming System, including Bioindexing, emphasizing participatory approach at community level', M.S. Swaminathan Research Foundation, Chennai.
- Ramanaiah, T. V. (2002). 'Indian Acts, Rules, Regulations and Procedures for handling Genetically Modified Organisms and r-DNA Products'. A Paper Presented in an *International Conference on Biotechnology and Development: Challenges and Opportunities for the Asian Region*, RIS, New Delhi.

Rao, S. R. (1999). 'Future of Biofertilisers Research, Commercialisation and Popularisation', Department of Biotechnology, New Delhi.

Sadananda, A. R. (2002). 'Agricultural Biotechnology – An Industry Perspective'. A Paper Presented in an *International Conference on Biotechnology and Development: Challenges and Opportunities for the Asian Region*, RIS, New Delhi.

Sah, D.C. and C.G. Ranade (1983). 'Biofertilisers in Indian Agriculture-A Case Study of Gujarat', *The Economic and Political Weekly*, March 30.

Sethi, Sudhir (2001). 'Venture Capital Reforms: Give Me more on the Platter', *The Economic Times*, 31st January.

Sharma, Devinder (2001). 'Crisis research: Managing Lethal Yellowing Disease', *Biotechnology and Development Monitor* No. 44/45, March 2001.

Visalakshi S. and G. D. Sandhya (2000). 'R & D in Pharma Industry in Context of Biotech Commercialisation', *The Economic and Political Weekly*, November 25.

Wahab, Seema (1998). 'Biotechnology and Economic of IPM in India' in *Biotechnology and Development Review (BDR)*, Vol. 2 No.1, October.

Endnotes

¹ Chaturvedi Sachin (2002)

² Carliene Brenner (1994).

³ Kumar (1988).

⁴ India, *Sixth Five Year Plan*, 1980-85, New Delhi, Planning Commission, p. 326.

⁵ This large focus has been criticized also see Dhar B. and Sachin Chaturvedi (1998).

⁶ DBT Annual Report, 2000-2001.

⁷ The Hindustan Times New Delhi, December 20, 2001

⁸ Personal communication with, ICMR officials, New Delhi.

⁹ Personal communication with IARI scientists.

¹⁰ McGaw, 2001.

¹¹ *Ibid.*

¹² DBT, Annual Report 1987-88.

¹³ DBT, Annual Report, 1993-94

¹⁴ DBT, Annual Report 2000-01.

¹⁵ www.ibab.ac.in

¹⁶ The Hindustan Times, December 8, 2001

¹⁷ Indian Express, January 9, 2002

¹⁸ The Economist, September 1st 2001.

¹⁹ Prakash (1997).

²⁰ Personal communication with company officials.

²¹ Economic Survey, Ministry of Finance, 2001.

²² The Economic Times, December 25, 2001.

²³ Asian Seeds and Planting Material(1999), Vol 6, No.1

²⁴ Personal communication with R S Arora, Seed Association of India.

²⁵ See Rao (1999).

²⁶ Alam (1994).

²⁷ The Economic Times, July 29th 2001.

²⁸ The Economic Times, September 3, 2001.

²⁹ *Ibid.*

-
- ³⁰ IndiaInfoline.Com July 14, 1999.
- ³¹ Personal communication with Chairperson, CII: Task Force on Biotechnology.
- ³² The Economic Times, July, 18th 2001.
- ³³ The Reserve Bank of India governs the investment and flow of foreign currency in and out of India.
- ³⁴ Sethi (2001)
- ³⁵ www.Stpi.soft.net
- ³⁶ The Economic Times, February 11, 2002
- ³⁷ *ibid.*
- ³⁸ Based on ICICI web page.
- ³⁹ Business Standard, January 9, 2002.
- ⁴⁰ The Economic Times, 27th October, 2001
- ⁴¹ The Economic Times, Wednesday 9 May 2001
- ⁴² The Hindu Business Line, April 30, 2001.
- ⁴³ The Hindu Business Line, October 20, 2001.
- ⁴⁴ The Economic Times, Friday 18 May 2001
- ⁴⁵ The Financial Express, February 22, 2001
- ⁴⁶ The Economic Times, Monday 29th January 2001
- ⁴⁷ Pharmabiz.com, August 28, 2001.
- ⁴⁸ The Economic Times, April 6, 2001.
- ⁴⁹ Biotechnology and Development Monitor, No. 30.
- ⁵⁰ See Sharma (2001) for details.
- ⁵¹ The Times of India September 9, 2001.
- ⁵² The Economic Times, December 18th 2001.
- ⁵³ Kumar (1998).
- ⁵⁴ Chaturvedi 1999
- ⁵⁵ The Economic Times, Thursday, January 10, 2002.
- ⁵⁶ Mehra (2000).
- ⁵⁷ The Economic Times, 25th April 2002.