Format for updated State-of-the-Art Report

1. **Name of the country :** INDIA
2. **Name, address and contact details including telephone, fax, email, etc. of the focal Ministry/Institution on Biotechnology :** Secretary, Department of Biotechnology, Block-2, 6-8 Floors, CGO Complex, Lodi Road, New Delhi – 110 003.
3. **Name, address and major activities of the key R&D organizations / academic institutions involved in biotechnology activities (Government, NGOs and private organizations) :** There are more than 2,000 such R&D organizations / academic institutes in biotechnological activities. A detailed directory may be obtained from Biotech Consortium India Limited, New Delhi or Consultancy Combine, New Delhi.
4. **Present status of different areas of biotechnology:** The present status of different areas of biotechnology is provided in brief.

4.1 Plant Biotechnology :

Bt cotton, approved in March 2002 is the first, and until now the only crop biotech product in India that has been released for commercial cultivation after regulatory approval. Introduction of Bt cotton in India is an example of how timely introduction of new technology can break productivity barriers and help crop production in a sustainable manner as indicated in the table given below:

Table: Area, production and productivity of cotton in India, 2002-07

Year	**Area (million ha)**	**Production (million bales) 1 bale = 170 kg**	**Productivity (kg of lint/ha)**
2002-03	7.67	13.6	302
2003-04	7.63	17.9	399
2004-05	8.92	24.3	463
2005-06	8.87	24.4	467
2006-07	9.14	28.0	520
2007-08	9.55	31.5	560

Source: Cotton Advisory Board, Government of India, 2008

National research emphasis has been on genomics of rice, wheat and tomato, and on tolerance to biotic- (diseases and pests) and abiotic (drought, salinity) stress. Bt rice is under field testing. Other priorities include enhancement of nutritional quality (beta carotene in rice and mustard and protein quality in potato through *ama 1* gene) and improvement of shelf life in fruits and vegetables especially through delayed ripening. There is a strong pipeline of biotech crops in India (see Table given below) but Bt brinjal may become the first transgenic food crop to be introduced in India.

Table Biotech Crops in Field Trial in India, 2008

No.	Crop	Organization	Transgene/ Event
1.	Brinjal	• Indian Agricultural Research Institute, New Delhi • Sungro Seeds Ltd., New Delhi • Mahyco, Jalna • Tamil Nadu Agricultural University, Coimbatore • University of Agricultural Sciences, Dharwad • Bejo Sheetal, Jalna	*cry1Aabc* *cry1Ac* *cry1Ac* *cry1Ac* *cry1Ac* *cry1Fa1*
2.	Cabbage	• Nunhems, Gurgaon • Sungro Seeds Ltd., New Delhi	*cry1Ba and cry1Ca* *cry1Ac*
3.	Castor	• Directorate of Oilseeds Research, Hyderabad	*cry1Aa and cry1Ec*
4.	Cauliflower	• Sungro Seeds Ltd., New Delhi • Nunhems, Gurgaon	*cry1Ac* *cry1Ac,cry1Ba and cry1Ca*
5.	Corn	• Monsanto, Mumbai	*Mon89034, NK603*
6.	Groundnut	• International Crop Research Institute for Semi-Arid Tropics, Hyderabad	*Rice chit and DREB*
7.	Okra	• Mahyco Mumbai • Sungro Seeds Ltd., New Delhi • Bejo Sheetal, Jalna • Arya Seeds, Gurgaon	*cry1Ac* *cry1Ac* *cry1Ac* *CP-AV1*
8.	Potato	• Central Potato Research Institute, Shimla • National Institute of Plant Genome Research, New Delhi	*RB* *ama1*
9.	Rice	• Indian Agricultural Research Institute, New Delhi • Tamil Nadu Agricultural University, Coimbatore • M S Swaminathan Research Foundation, Chennai • Directorate of Rice Research, Hyderabad • Mahyco, Mumbai • Bayer CropScience, Hyderabad • Avesthagen, Bengaluru	*cry1Aabc,DREB,GR-1 & GR-2, (Golden Rice)* *Chi11* *MnSOD* *cry1Ac* *cry1Ac, cry2Ab* *cry1Ac, cry1Ab, bar* *NAD9*
10.	Tomato	• Indian Agricultural Research Institute, New Delhi • Mahyco, Mumbai • Avesthagen, Bengaluru	*Antisense replicase, osmotin, DREB* *cry1Ac* *NAD9*

Source: Indian GMO Research Information System (IGMORIS), 2008; Department of Biotechnology; ISAAA, 2008

Other priorities in plant biotechnology include forestry, horticulture and plantation crops, medicinal and aromatic plants.

4.2 Animal Biotechnology

In the area of animal biotechnology focus is on : Development of quality feed; Animal reproduction; Animal byproducts; and Genetic characterization of indigenous breeds of livestock. Candidate vaccine against *Haemorrhagic septicaemia;* vaccine against *Clostridium perfringens;* DNA vaccine against bovine brucellosis and vaccines for bovine tuberculosis are under different stages of development. Sector status on animal diagnostics is as follows: development of a rapid diagnosis kit for leptospirosis, diagnostic techniques for *Dichelobacter nodosus*, development of molecular methods for rapid detection of Johne's disease, PCR test for detecting major pathogens of bovine mastitis, diagnostic(s) for chicken anaemia virus for echinococcosis in animals and its environment. Transgenic mice models have been developed. Two bacterial artificial chromosome (BAC) genomic libraries of male Murrah buffalo have been prepared and are available. Comparative fiber degradation capacity of various biomaterial of bovine origin for reconstructive surgery in animals was developed and its acceptance as surgical material are also being studied.

4.3 Health Biotechnology

The following vaccines are under different phases of clinical trials

Rotaviral diarrhoea vaccine (116E)
- Safe and immunogenic
- cGMP material ready
- Entered into Phase-III clinical trial

Malaria Vaccine
- Three candidates i.e. P. falciparum- PfF2; PfMSP-119 and P. vivax- PvRII; PvMSP- 119 developed
- P. vivax: PvRII globally accepted candidate for vaccine development
- Produced GMP grade material for clinical trials
- Establishing partnership with MVI, EMVI, Gates Foundation for clinical Development

Cholera (recombinant oral)
- Completed Phase-I &II clinical trials
- Being manufactured by M/s Shanta Biotech in a contractual mode
- Ready for Phase II/III

Rabies (combined DNA based)
- Completed clinical trials
- DCGI clearance awaited for launch

Typhoid Vi-conjugate
- Technology transferred to USV, Mumbai for GMP production and pre-clinical toxicology studies

Tuberculosis
- Antigen 85C, ESAT and SOD-based candidates ready for clinical trials after encouraging animal data

Dengue (recombinant tetravalent)
- Accelerated development vaccine through industrial partner
- Animal studies being conducted in collaboration with Emory, USA

JEV (Vero cell based)
- DBT-NII vaccine transferred to M/s Panacea Biotech
- Ready for Phase-I clinical trial

HPV
- Indian efforts based on HPV oncogenic are going on
- Collaboration with Merck and Wellcome Trust being worked out
- Indian Company entered into partnership on one candidate

Immuvac – An Immunomodulator
- Based on inactivated Mycobacterium indicus pranii
- Shown significant immuno modulatory effects in Leprosy.
- Rediscovering for treatment of Tuberculosis and Cancer

Other priorities in health biotechnologies include diagnostics, stem cell research (both adult and embryonic), biomedical devices and implants, human genetics and genome analysis.

Industrial Biotechnology:

The biotech industrial sector in India crossed the $ 2.5 billion (Rs. 10,273.70 crores) mark during 2007-08. The past five years have witnessed a spectacular growth rate of more than 30% although because of the global meltdown there was a slump to 20% in 2007-08. Biopharma segment continues to contribute the lion's share (67%) followed by bioservices (15%), agribiotech (12%), bioindustrial (4%) and bioinformatics (2%) segments. Exports constitute about 56% share of the sector (Rs. 5733.68 Crores). In 2007-08, the investment touched Rs. 2750 Crores, up 21% over the previous fiscal. Industry sources forecast that by 2015 the sector would be worth $ 13-16 billion in revenue. The top 25 biotech companies in India, ranked by revenue may be seen in the table given below.

Top 25 Biotech Companies in India

Sl. No.	Company	Biotech Revenues in Rs. Crore			
		2007-08	2006-07	2005-06	2004-05
1.	Serum Institute of India	987.00	950.95	703.00	505.00
2.	Biocon	912.00	849.00	689.00	661.00
3.	Panacea Biotec	677.98	701.13	437.82	217.29
4.	Nuziveedu Seeds	303.00	226.42	62.52	
5.	Rasi Seeds	293.28	333.33	309.49	86.87
6.	Novo Nordisk	260.00	222.00	175.00	140.00
7.	Novozymes South Asia	225.00	100.00	83.00	69.00
8.	Indian Immumologicals	196.00	157.90	102.20	83.00
9.	Mahyco	170.00	110.69	117.76	166.00
10.	Syngene International	160.00	132.00	98.00	66.00
11.	Jubilant#	159.00	--	--	--
12.	Shantha Biotechnics	150.00	115.00	82.20	66.50
13.	Bharat Serums	140.00	108.49	78.05	79.68
14.	Eli Lilly	137.00	114.00	85.00	68.38
15.	Bharat Biotech	126.00	70.00	48.10	38.00
16.	Themis Medicare	110.00	68.00	38.00	34.00
17.	Aventis	105.00	119.65	114.50	84.30
18.	Haffkine Biopharma	88.61	65.69	36.60	33.50
19.	Rossari Biotech	82.00	66.00	--	--
20.	GlaxoSmithKline	80.40	79.00	--	--
21.	Ankur Seeds	75.00	69.50	--	--
22.	Advanced Enzymes	69.30	68.00	56.00	39.60
23.	Ocimum Biosolutions	65.00	--	--	--
24.	Nath Seeds	62.00	11.92	--	--
25.	Concord Biotech	60.00	45.00	18.00	--

 # The revenues of Jubilant mentioned here are for the drug discovery and development services only.

Note: (a) All except those at serial nos. 6, 7, 14, 17 and 20 are home-grown companies.

(b) The Top 3 companies account for 25 percent share of the total biotech revenues of Rs 10,274 crores, with combined revenues of Rs. 2576.98 crores.

4.4 Other Areas

Other areas of focus include cleaner environmental technologies (biofertilisers, biopesticides, greener processing) and pollution remediation. Conservation and mapping of the country's bioresources is an area of priority. A major thrust is on bioenergy (biodiesel and bioethanol)

5. **Government policy / legislation regarding application of biotechnology in national development**

Department of biotechnology has been entrusted with the task of setting up the National Regulatory Authority (NBRA), as a science based, professionally-led efficient and transparent body for biosafety regulation. The bill for the same will soon be introduced to provide legislative teeth to NBRA.

"Protection and Utilization of Public Funded Intellectual Property Bill, 2008" addresses early licensing and commercialization of intellectual property has been introduced into the Rajya Sabha.

6. **Priority areas for cooperation**
   - Agriculture Biotechnology (Biotic and abiotic stress)
   - Medical Biotechnology (Infectious diseases)
   - Environmental Biotechnology (Bioresource mapping, sustainable utilization of bioresources and bioremediation)
   - Animal Biotechnology
   - Marine Biotechnology
   - Bioinformatics

7. **Areas of expertise available for cooperation**
   - Agriculture Biotechnology
   - Medical Biotechnology
   - Environmental Biotechnology
   - Animal Biotechnology
   - Marine Biotechnology
   - Bioinformatics

8. **Recent biotechnology products / processes developed / ready for transfer**

List of technologies transferred: 2008-09

Agriculture

- 'Use of Constitutive viral promoter: DD- 7, derived from Rice tungro bacilliform virus for constitutive gene expression in plants' developed at University of Delhi (South Campus), New Delhi under DBT project has been transferred to M/S Beejo Sheetal Seeds, Jalana.
- Transgenic chickpea with insect resistance: Regeneration and transformation protocols of chickpea with cry genes and garlic lectine gene Insect pest resistance through the use of Bt (cry1Ac and cry2Aa) technology for podborer; Insect pest resistance through the use of Lectin (ASAL–Garlic lectin) technology for sucking pests.

Environment:

- Poultry waste treatment with biogas production developed by ANGRAU and IICT, Hyderabad.
- Odour (Sulphurous odorants) removal from the Pulp and Paper Industries developed by NEERI, Nagpur.

- Oil Zapper – Bioremediation of polluted sites by Petroleum Industries/Installations using Oil Zapper technology developed by TERI, New Delhi successfully transferred to a group of Petroleum Companies (ONGC, IOC, HP and BP).
- Pulp and Paper mill waste treatment technology developed by IGIB, Delhi.

National Institute of Immunology, New Delhi

- Use of tea catechins and triclosan as anti-malarial: under negotiations with Polyphenon, NYC, U.S.A.;
- Biotherapeutic Buffalo- and Human-Growth Hormone: under negotiations with Indian Immunologics Limited, Hyderabad, India.

Centre For DNA Fingerprinting Diagnostics, Hyderabad:

- Technology related to "Tuberculosis diagnostics" licensed to M/s Arka Nanomeds Pvt. Ltd. (Agreement was signed in April, 2008) and an amount of Rs.1.0 lakh as upfront fees received from M/s Arka Nanomeds Pvt. Ltd. towards licensed invention.

Rajiv Gandhi Centre for Biotechnology, Thiruvananthapuram

- MCF-7 Bid Ds Red stable cell line for anticancer drug screening. The cell line has been deposited with ATCC for patent purpose. Not yet transferred to industry.
- RAGEP Marker System.
- Universal Protocol for Generating 100 bp Size Standard for Endless Usage.
- A techniques for sensing intracellular calcium transients has been developed. This has been adapted to detect the activities on neuronal NMDA-type glutamate receptor and Capsiacin receptor. Not yet transferred to industry as patent application is pending.
- Platform for simultaneous detection of dengue and chickungunya viruses.

9. Issues and challenges

- Skilled / trained Human Resource
- Lack of Public Private partnership
- Weak entrepreneurial skills

Biotechnology sector in India: Strengths, limitations, remedies and outlook

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Key Words: Indian Biotechnology Sector, barriers, strengths, limitations, outlook

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Abbreviations: CSIR, Council of Scientific & Industrial Research; **DST**, Department of Science & Technology, Government of India; **MHRD,** Ministry of Human Resource Development, Government of India;

Abstract

The Indian government was quick to grasp the importance of biotechnology sector and, as early as 1986, established an independent Department of Biotechnology in the Ministry of Science & Technology. Government funding to the S&T sector increased by eight times from the 8th Five Year Plan to the 11th and support to life sciences sector rose by16 times in the same period. This helped in creating a scientific workforce, a large infrastructure network, and strong support to R&D in life sciences. The private sector with several homegrown companies, meanwhile, has done well, growing at ~ 30% annually, mainly leveraging its strengths in services and manufacturing. Its strong impact has been on promoting low cost vaccines and other novel healthcare products and forcing price reduction on bioproducts of MNCs. In the agri-sector, Bt cotton is the first and only commercialized transgenic crop as of now, but most of the area under it features genes sourced from Monsanto and bred into local hybrids. There is a long pipeline of other crops in late stage trials, though Bt brinjal is likely to become the first biotech food crop to be approved for commercial introduction. Clearly, it is time to take decisive steps towards discovery and innovation and yet in doing so, India faces several barriers such as lack of human resource of the right quality, weak entrepreneurial skills, feeble public-private partnerships, risk-averse industry, non-availability of venture funding, and a regulatory process that has been noticeably streamlined but could be further improved. In September 2007, the government approved the National Biotechnology Development Strategy, which seeks to build coherence and connectivity between disciplines and bring together the variegated skills across sectors to enhance synergy. The strategy also seeks to address a number of challenges to the Indian biotech sector relating to research and development; creation of investment capital; technology transfer, absorption and diffusion; management of intellectual property; regulatory issues; building public confidence; and tailor-made human capital for all these. Many of the promises made in the strategy document have already been acted upon. The national government has taken several bold and far-reaching steps on a hitherto unprecedented scale. In that sense, India is engaged in a phase of 'operation rational redesign' of its science enterprise, firmly committed to knowledge creation and application. Whether and how far it succeeds depends on a number of factors. Judging by recent developments there is reason to believe that it will rise to the occasion.

Biotechnology sector in India: Strengths, limitations, remedies and outlook

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Introduction

Biotechnology is an umbrella term that covers a wide spectrum of scientific applications used in many sectors. Biotechnology must be seen in the context of a large number of other disciplines and technologies such as systems biology, synthetic biology, bioinformatics and nanotechnology, whose convergence will drive new products and technologies in the future. It has been described as a classic example of "disruptive technology" [1], similar to the steam engine, electricity, or information technology. Disruptive technologies are often initially resisted because their potential is not recognized, even as large pharmaceutical companies initially dismissed biotechnology in the beginning. The global biotechnology industry is now at the beginning of a technology curve whose upside potential appears limitless. Governments around the world are embracing biotechnology as the next driver of innovation and economic growth. Biotechnology is already beginning to usher in complex, rapidly emerging and far reaching new changes in several areas, particularly food and nutrition security, health care and environmental sustainability. It has at the same time sparked off a number of controversies. These range from seeking an optimal balance between rewarding innovation and ensuring the broadest possible access to the benefits of biotechnology, ethical issues related to 'modifying life' and 'playing god', as well as concerns related to environment and health safety. Society at large has to learn to grapple with these through effective and transparent application of science-based processes to address these vexing issues. In addition to these, generation of employment, creation of intellectual wealth, expansion of entrepreneurial opportunities, and augmenting industrial growth are a few of the compelling factors that warrant a focused approach for this sector.

Global Biotechnology

Over the last two decades, world biotechnology has been dominated by the US and Japan. US based life science companies generate lion's share of over $ 500 billion in revenues [2], followed by Japan. Recently, other markets are looking up as well. Between 2000 and 2005, government research and development (R&D) expenditure recorded double digit growth respectively in Western Europe and Asia Pacific whereas in North America it recorded a more moderate growth of 6% [3]. The venture capital investment in the biotech industry surged to US $ 3.7 billion in 2004, up 31% from US $ 2.8 billion in 2003, as private equity investors continued to view life sciences as an essential investment [3]. Life sciences industry in the Asia Pacific (not including Japan) registered US $ 103.59 billion in 2007, growing at 13% [2]. Biotechnology industry continues to grow rapidly, with over 6,000 companies engaged in activities related to discovery, consumables and equipment and the number is increasing at 6% annually [3]. It is noteworthy that in spite of much larger R&D investments in the big pharma sector, more and more approvals granted by the US FDA are for bio-drugs (Fig. 1).

The rate of adoption of GM/biotech crops is striking. From a mere 1.7 million ha in 1996, the cultivated area under biotech crops spread to 125 million ha in 2008 [4], registering a 73.5-fold increase. During these 13 years, the number of countries growing biotech crops increased from 6 to 25, of which 15 are developing countries. This trend is likely to continue during the next decade of commercialization [4,5]

The Indian Biotechnology Enterprise

Government initiatives: India's biotechnology sector is at a crossroads. On the one hand, it must find affordable solutions to the pressing national needs in agriculture, health and energy, but on the other, it must be competitive enough to take advantage of the lucrative international markets. The Indian government was quick to grasp the importance of this sector and, as early as 1986, established an independent Department of Biotechnology (DBT) in the Ministry of Science & Technology. Government funding to the S&T sector increased by eight times from the 8^{th} Five Year Plan to the 11^{th} and support to life sciences sector steadily increased by16 times in the same period (Fig. 2). As a result, a firm foundation of life sciences and biotechnology has been created over the years in public-funded institutions over which a strong edifice of innovation and enterprise could be built. Fiscal incentives include relaxed price controls for drugs, subsidies on capital limits, and tax holidays for R&D spending. Several state governments (e.g. Andhra Pradesh, Karnataka, Maharashtra, Himachal Pradesh, Uttar Pradesh, Kerala and Gujarat have come up with added financial (e.g. tax concessions), and policy incentives (biotech parks, incubators, of their own) to spur investment in biotechnology. DBT has proactively taken up a number of initiatives in creating trained human resource, institutional infrastructure (e.g., microbial culture collections, cell & tissue lines, gene banks, laboratory animals, facilities for oligonucleotide synthesis etc.) and a strong research base in the country in areas relating to agriculture and forestry, human health, animal productivity, environmental safety and industrial production.

Creating a scientific work force: DBT's post-graduate teaching programme in biotechnology has currently expanded to some 70 academic institutions that train ~1000 students each year. There are doctoral and post-doctoral fellowships as well. The initial hype surrounding biotechnology led to misinformed private institutions starting specialized undergraduate (BSc) programmes in biotechnology. This is an undesirable development since at that stage students ought to have a solid foundation in all the areas of science rather than having a blinkered vision of any one. The National Biotechnology Development Strategy (see later) approved by the Government of India in 2007 clearly recognizes the need for a wholesome education at the undergraduate level. A finishing school programme for MSc/ MTech students to provide industry training started in 1992 did not find too many takers initially, but the introduction of a bench fee of Rs 50,000 per student in 2004-05 saw a dramatic increase in the number of companies offering training. During the four years between 2004-05 and 2007-08, 185 companies have offered 6-month training to 665 post-graduates and ~ 27% 0f these have been absorbed by the industry (Fig. 3). About 700 mid-career scientists have obtained training for 6-12 months in some of the best laboratories across the world through DBT's Biotechnology Associateships.

Bioinformatics network: Thanks to DBT's early initiative, a strong bioinformatics programme known as Biotechnology Information System (BTISnet-BioGrid India) was envisaged as early as 1986-87, with more that 150 bioinformatics centres located across the country. This acts as a distributed database and network and has become very successful as a vehicle for transfer and exchange of scientific information, knowledge and technology packages in the country. A national facility for *in silico* drug development has been set up at the Indian Institute of Technology, Delhi. Over 150 subject-specific databases and software packages are now available on the BTISnet for open access.

Private sector initiatives: The ingenuity and efficiency of the private sector has contributed in no small measure to the success and resilience of the biotech sector, especially in the manufacturing and service sectors. In the face of several odds – e.g. dearth of financial resources, stiff competition among multiple domestic manufacturers, and the need to balance between doing innovative R&D and delivering affordable quality products – the Indian companies have done reasonably well and commercialized a number of products.

The sector crossed the $ 2.5 billion (Rs. 10,273.70 crores) mark during 2007-08 [2]. The past five years have witnessed a spectacular growth rate of more than 30% (Fig. 4), although because of the global meltdown there was a slump to 20% in 2007-08. Biopharma segment continues to contribute the lion's share (67%) followed by bioservices (15%), agribiotech (12%), bioindustrial (4%) and bioinformatics (2%) segments. Exports constitute about 56% share of the sector (Rs. 5733.68 Crores). In 2007-08, the investment touched Rs. 2750 Crores, up 21% over the previous fiscal. Industry sources forecast that by 2015 the sector would be worth $ 13-16 billion in revenue (see Fig. 4). The top 25 biotech companies in India, ranked by revenue may be seen in Table 1. This list includes multinationals as well as home-grown companies.

Biopharma segment: The biopharma segment mainly concentrates on vaccines, non-vaccine therapeutics, other novel products and contract services [4]. Its strong impact has been on promoting low cost commodities and forcing a price reduction on MNC bioproducts. The following examples should suffice to illustrate this point. India's first domestically developed and marketed rDNA product – *Shanvac-B*, a recombinant hepatitis B (Hep B) surface antigen from Shanta Biotechnics, Hyderabad – was cost-efficiently produced in the *Pichia pastoris* expression system in 1997. Subsequent local competition from other domestic manufacturers such as Biological E, Indian Immunologicals and Serum Institute of India resulted in a 30-fold price reduction (from $15 to $0.50) over the imported product, which was then the sole Hep-B product in the market.

The recent upsurge in demand for vaccines both in domestic and international markets is important both from public health and economic perspectives. Today there are about 15 companies involved in marketing of over 50 brands for 15 different vaccines. In 2006-07 vaccine business was worth Rs 3,053 cr ($ 745 million) and registered 30.41% growth against Rs 1800 cr in the preceding fiscal. Human and animal vaccines together accounted for 51% share of the total biopharma segment. Indian companies producing vaccines have mastered the art and science of good manufacturing practices for macromolecules and are progressively earning the goodwill and respect of the international community. The impact of affordable vaccines has been felt both in domestic and international domains. For instance, Shanta Biotechnics now supplies 40% of the global requirement of Hep-B vaccine for United Nations International Children's Educational Fund (UNICEF) in many countries. The Serum Institute of India, Pune is not only the largest supplier of vaccines to Government of India's Expanded Programme of Immunization (EPI) but also the country's largest exporter of vaccines with a distribution network in 138 countries. Every second child in the world is vaccinated using Serum Institute's measles vaccine and DPT (diphtheria, pertussis and tetanus) vaccines. Panacea Biotec, New Delhi supplies oral polio vaccine to EPI and UNICEF. Because of these tried and tested Indian strengths in vaccine development and manufacture, newer alliances are beginning to emerge between DBT, Indian companies, public-funded institutions and global philanthropic institutions such as Malaria Vaccine Initiative, Melinda & Bill Gates Foundation, Program for Appropriate Technologies in Health and the Wellcome Trust.

There are other examples of process efficiency and cost-effective indigenous manufacture resulting in better affordability of biopharmaceuticals. Biogenerics (or biosimilars) represent a major future opportunity in economic terms for India and, more importantly, for products at reasonable costs because an unprecedented number of 'blockbuster' drugs are going off patents. Indian companies are set to leverage their cost-effective manufacturing capabilities and take a segment of the global biogenerics pie. Biocon, Bangalore's (now renamed Bengaluru) development of a proprietary process for manufacture of recombinant insulin (*Insugen*) forced international competitors to cut back their price by 40% even before the product entered Indian market. Insugen was priced even lower and remains the most affordable human insulin in the domestic market. Biocon is now developing a recombinant oral insulin. Shanta Biotechnics marketed its recombinant interferon alpha (IFN-α) product *Shanferon*, at Rs 300 (~ $ 6.5), substantially lower than the then imported product at Rs 1200 ($ 26). Other novel homegrown products in late stage development include (a) pentavalent vaccines for protection against five infectious agents including DPT, Hep-B and *Haemophilus* *influenza* type B or Hib (Shanta Biotechnics and Serum Institute); (b) single or combination vaccines against locally relevant diseases such as Japanese encephalitis, anthrax, cholera and meningitis (Panacea Biotec, Biological E, Hyderabad and Transgene Biotek, Medak, Andhra Pradesh); and (c) vaccine against rotaviral diarrhoea (Bharat Biotech International); novel poroducts such as bacteriophages as antibacterial agents against multi-drug resistant bacteria (GangaGen Biotechnologies, Bengaluru) and lysostaphin an anti-infective multidrug resistant *Staphylococcus aureus* [for more details please see reference 6].

The other noted strength of Indian biotech companies is carrying out contract services such as R&D, clinical trials or manufacturing as a route to funding operations and build commercial capacities [6]. India is fast becoming one of the largest hubs for conducting global clinical trials. According to a new research report by RNCOS [*http://www.marketresearch.com/product/print/default.asp?SID=62405602-441622586-434805720&productid=2066259*], in 2007 the country conducted ~220 clinical trials, accounting for < 2% of the global trials. A number of factors such as low cost, large patient pool, easy recruitment, strong government support and strengthening of the intellectual property environment are likely to raise this figure to about 5% of world's clinical trials by 2012. Surging clinical trials market in India is likely to create enormous opportunities for a number of associated industries, including in vitro diagnostics market, education sector and data management.

Bioagri segment: Indian agriculture faces the formidable challenge of having to produce more farm commodities for our growing human and livestock population from diminishing per capita arable land and water resources. Biotechnology, in combination with classical breeding techniques, has the potential to overcome this challenge, to ensure the livelihood security of over 110 million farming families in our country.

Bt cotton, approved in March 2002 is the first, and until now the only crop biotech product in India that has been released for commercial cultivation after regulatory approval and it would be interesting to examine it more closely. Most of the area under transgenic cotton feature Bt genes sourced from Monsanto, but bred into local hybrids. From some 50,000 ha in the year of its introduction, the acreage reached 7.6 million ha in 2008 – an incredible 150-fold increase, occupying 82% of the 9.3 million ha under cotton in India [4]. In 2008, 30 seed companies were engaged in production of 274 Bt cotton hybrids in nine states [4]. Notably, the first indigenous Bt cotton variety *Bikaneri Narma* – incidentally the first public sector genetically modified crop developed by the Central Institute of Cotton Research and University of Agricultural Sciences, Dharwad – was approved in 2008 and will be planted in 2009. Since this is a variety and not a hybrid, the farmers can save seeds for planting in the following season. Parallel with the introduction of Bt cotton, which protects against damage by bollworms, the yield of cotton increased from 308 kg/ha in 2001-02 to 560 kg/ha in 2007-08 (Table 2) and is projected to increase to 591 kg/ha in 2008-09 season. Half of this is attributable to Bt cotton hybrids that have generated impressive economic gains for Indian farmers, halved insecticide requirements and enable India to emerge as a net exporter of cotton from being a net importer. Government of India's Cotton Advisory Board estimates that there has been a positive impact of Bt cotton on cotton seed oil production as well in terms of 22% increase or 1.1 million tons in 2007-08, from 0.9 million tons in 2006-07. According to the Solvent Extractor's Association of India, recovery of cotton seed oil is higher from

Bt cotton hybrids [8], which has contributed towards pushing production of cotton seed oil up. Bt cotton is an example of how timely introduction of new technology can break productivity barriers and help crop production in a sustainable manner. However, it has also thrown up some lessons on regulatory issues, and need for clearer communication with the consumers and public.

Considering that agriculture is vital to India, there is substantial public sector investment in agri-biotech. Private sector investments, by comparison, are still comparatively low. National research emphasis has been on genomics of rice, wheat and tomato, and on tolerance to biotic- (diseases and pests) and abiotic (drought, salinity) stress. A number of public-funded R&D initiatives focus on the identification of quantitative trait loci and genes and their deployment into cultivars. [see ref. 8 for a recent review]. Bt rice is under field testing. Other priorities include enhancement of nutritional quality (beta carotene in rice and mustard and protein quality in potato through *ama 1* gene) and improvement of shelf life in fruits and vegetables especially through delayed ripening. There is a strong pipeline of biotech crops in India (see Table 3) but Bt brinjal may become the first transgenic food crop to be introduced in India [9].

Bioenergy: India faces formidable challenges in meeting its energy needs. In order to maintain an annual GDP growth of 8% over the next 25 years to meet its goals for poverty elimination, the country needs to triple its primary energy supply and quadruple its electricity supply [10]. India now imports about 65% of its petroleum and with demands mounting this could surely increase to 90% by 2025. In this scenario renewable energy sources such as biofuels represent an attractive option. India's thrust is on producing ethanol from cellulose biomass including agricultural & forestry waste, biodiesel from varied feed stocks, and optimally harness the energy potential of natural resources for conversion to alternative fuel. The main challenge is to apply biotech tools for improving biomass production system, promote the bio-refinery concept aiming at integral use of biomass and maximizing the cost effectiveness of final product. Biotech interventions are being used to reengineer feed stock for enhanced ethanol recovery and reengineer microorganisms for increased productivity. DBT has established an Energy Biosciences Centre at the University Institute of Chemical Technology, Mumbai to develop economically & ecologically sustainable technology for biofuel from biomass and provide a platform for evaluating bioenergy- related technologies.

International collaboration: In the knowledge-base economy, no country can afford to isolate itself today. Moreover, a number of problems related to health, food and agriculture, energy and environment can be solved effectively only through international partnerships. Indian biotechnology, while solidly rooted in the home soil has to have a global outlook. International alliances are necessary with public- and private sector partners joint IP generation, for harmonizing regulatory processes, smoothening trans-boundary movements of biological and to leverage better markets for biotech products and processes. Homegrown companies such as Biocon, Serum Institute, Bharat, Shanta, Mahyco and others have entered into collaborative arrangements with overseas companies and agencies. DBT has forged strategic and enduring partnerships (see Table 4) in specific R&D areas with a few well chosen countries and institutions [11,12]. The partnerships in the past were only with academic institutions but recently industry has been included as well (e.g., DBT-European Commission collaboration on food and health and wellbeing). Other notable partners include the Wellcome Trust, UK (see later);

Stanford University, California for bringing together medical and engineering experts for the 'biodesign' programme for medical devices; Biotechnology and Biological Sciences Research Council, UK, for the Biotechnology Young Entrepreneurship Programme (YES); University of Wisconsin, Madison for exchange of doctoral scholars; and PATH, Gates Foundation and MVI for partnership on late stage development of vaccines.

Barriers that impede innovation and discovery

From the foregoing, it is obvious that India must build on its manufacturing and service strengths. However, there is a growing realization that cost advantage that has served it well in the past will not last too long. Clearly, it is time to take a decisive step towards discovery and innovation in life sciences and biotechnology. Yet, in doing so, Indian biotechnology sector faces a number of challenges.

Lack of quality human resource of the right kind: India's footprint in the biological sciences is relatively small, and not consistent in keeping with the size of its population or potential. Much of the high end biology research is pursued at a few universities and ~15 research institutes. Unfortunately, the Indian university system has been in serious decline for some time and unequal to the task of building excellence in life science training [13]. There is a sad deficiency in terms of research intensive universities, with heavy teaching loads leaving little time to pursue serious research interests. This is also true of the medical, agricultural and veterinary schools as well where patient burden or extension activities take a heavy toll of research. Archaic rules on faculty hiring and promotions and insufficient infrastructure further aggravate the problems. While technology institutions (Indian Institutes of Technology or IITs) have been traditionally strong in engineering and physical sciences, they do not have enough muscle in biological research, although plans are now afoot to rectify this historic omission. In comparison, the research institutions (set up by federal government) fare better in terms of good research projects but train no students. Thus the dichotomy between teaching and research has thwarted the building up and increasing the supply of highly qualified and globally connected graduates in biotechnology. Even at the research institutes, the number of faculty is relatively small [14] and needs urgent expansion with quality. Meanwhile, the brightest and the best of students are no longer opting for a career in science, and those that do are not skilled enough to be able to take up leadership positions. Leaks in the pipeline at multiple levels further exacerbate the problem [14,15]. Hence, while India has been successful in producing a strong scientific workforce, the system has not been good enough to generate a critical mass of scientific leaders. Some decisive initiatives have been taken by the Indian government that auger well for the future (Table 4).

Weak entrepreneurial skills: Most academic and research institutions in India are not geared to undertake innovative and translational research. As Carl J. Schramm, President and CEO of the Ewing Marion Kauffmann Foundation, reminds us we live today not only in the information age but also in the entrepreneurial age [16]. While the benefits of information age are well appreciated, the basic realities of the entrepreneurial age are not. It is no coincidence that world GDP has grown more than 10-fold since 1970 – and four-fifths of that growth occurred after the developing economies and countries once behind the iron curtain began to liberalize their economies [16]. Now entrepreneurship is driving growth everywhere – including India and China. Yet, "enterprise" is a term wholly lacking in discussion about higher education and research intensive universities. US universities have traditionally close relations with industry and act as economic engines rather than ivory towers, with burgeoning science parks, technology offices and venture capital funds. There is no comparable situation in India. Few Indian academics nurse entrepreneurial ambitions. This tendency has its origin in a society that frowns on failure and the weak mechanisms and infirm policy structures for technology transfer between public institutions and private firms. Needless to say that graduates emerging from this environment are never linked to businesses that can make use of their talent. There are not enough mechanisms to expose students to research openings in the private sector, thereby losing an opportunity to stimulate business interest in S&T by demonstrating the benefits of hiring highly qualified people.

Lack of public-private partnerships: Most of the public-funded research centres in India are not industry friendly. On the other hand, industrial houses in general including life science-associated companies do not actively seek partnerships with domestic research labs, preferring instead to go abroad in search of partnerships. There is also a difference in expectations from such partnerships. Both industry and academic institutions have to meet half way in making adjustments. Institutions also lack units or structures that can flexibly handle interactions with industry, without the barriers of bureaucracy. One outcome of this is a fragile and only incrementally increasing public-private partnership in biotechnology.

Risk-averse nature of industry: In general, Indian industry is risk averse. This is probably a reflection of the reluctance of Indian banks and investors to invest in biotech ventures. Industry-led R&D is still not adequate in scale or quality when it comes to innovation and discovery research. The government has provided fiscal incentives such as relaxed price control for drugs, removal of foreign ownership limits, subsidies on capital expenses and tax holidays for R&R spending, but until recently, direct investment in industry R&D was not available. A recent survey of 424 homegrown Indian biotech and pharmaceutical companies revealed that till December 31, 2007 just 57 (< 15% of the total) held US patents [17]. While there were 425 pharma patents, the study could identify only 19 biotech patents starting from 2001. Among the biotech patents, two (11%) were categorized as 'product' patents, nine (47%) as process patents, seven (37%) as both 'product and process' patents and merely one (5%) as a 'design' patent. Clearly, IP generation has commenced but its scaling up is a challenge.

Lack of venture/ angel funding: Angel funding for companies that want to do pure research and go to the market six or seven years down the line is still hard to come by in India. Increasing domestic and international competition requires a continuous capacity for innovation and bringing innovations to the market, not merely "technology catching up". Generous investment in R&D, and synergy between public and corporate sector R&D will help, but in a market economy the institutional framework must be appropriate to ensure access to seed- and start-up financing, and for sharing the risks and rewards of innovation. In the life sciences sector, information asymmetry between the scientist/technologist, the entrepreneur and the financier is the most challenging and requires a role for public sector institutions in the incubation and nurture of technology start-ups. Recent government initiatives (Table 4) in this regard are noteworthy.

Streamlining the regulatory process: Lastly, research and application of in biotechnology has to be guided by a process of decision making that safeguards environmental, human, animal and plant health. A science-based, rigorous, transparent, efficient, predictable and consistent regulatory mechanism for biosafety evaluation is vital to the growth and flowering of the biotechnology sector. In recent years, Indian biosafety regulation has become noticeably streamlined but there is still room to prepare it to respond rapidly to changing technologies, and develop more effective and transparent processes. There is an urgent need to increase the pool of dedicated regulatory experts in India with proficiency in dealing with biologicals, and set up institutional mechanisms for in-service training and retraining of professionals dealing with scientific risk assessment and management of transgenic crops.

The problems identified above and the remedial action already taken or proposed to be taken by the Government of India may be seen in Table 4.

Concluding Remarks

Over the last two decades, the Indian biotechnology sector has taken shape through a number of scattered and sporadic academic and industrial initiatives. A sector like biotechnology in which several stakeholders are necessary for consistent success, requires a long-term perspective, and predictable and transparent fiscal, regulatory and policy support. There was, thus, an urgent need to integrate the efforts and prepare a holistic vision and a roadmap for Indian biotechnology. This was the genesis of the National Biotechnology Development Strategy. The finalized document was approved by the Government of India in November 2007. The key elements of the strategy are displayed on DBT's official website (http://dbtindia.nic.in/biotechstrategy/National%20Biotechnology%20Development%20Strategy.pdf). The cornerstone of the strategy is to build coherence and connectivity between disciplines and bring together the variegated skills across sectors to enhance synergy. The strategy also seeks to address a number of challenges to the Indian biotech sector in terms of research and development; creation of investment capital; technology transfer, absorption and diffusion; intellectual property; regulatory issues; building public confidence; and tailor-made human capital for all these. Many of the promises made in the strategy document have already been acted upon, and a first-year report card on DBT's performance was also published [18].

On the road to transforming India into a global powerhouse of biotechnology innovation, the foremost priority is to increase the density of quality scientists and improve interdisciplinary cross talk as well as a seamless flow of knowledge, technology and consultation between the public and private sector. The Indian government has recently taken several bold and decisive steps on a hitherto unprecedented scale. MHRD has recently set up five new Indian Institutes of Education and Research (IISERs) and two new IITs, and is in the process of establishing 30 new federal universities (Table 4). The primary goal IISERs is to integrate high quality inter-disciplinary research with undergraduate teaching to improve science education and quality of future researchers in the country. Similarly, DBT's decision earlier this year to recognize 30 'star colleges' in life sciences, one in every major city this year, will ramp up undergraduate education trough upgradation of knowledge and skills of teachers, improvement of infrastructure and exposure to platform technologies. DST's latest initiative through the ambitious INSPIRE programme aims to provide one million scholarships at various levels to attract bright students to pursue a career in science.

Obviously, it would not be possible to build human capital through organic growth alone. There is a need to attract fresh talent to work in the country with appropriate salary packages and creation of excellent work ambience. In the past, India did not provide many opportunities for post-graduate training. Lured by the attraction of working in a foreign lab and using it as a stepping stone for jobs overseas, most of the good graduate students left for Europe or US. Today, a number of these would willingly come back to India for a variety of reasons if they could find good working conditions back home. The DBT-Wellcome Trust Fellowships are a step in this direction. The programme will provide opportunities for doing high end biomedical post-doctoral research in good Indian labs through three-tiered fellowships (Early Career, Intermediate and Senior categories). Each year, 70 fellowships will be awarded. The other example is the newly created Ramlingaswami re-entry Fellowship scheme – available in all areas of biotechnology – has already gained popularity, with all the selected 25 applicants in the last two years accepting to relocate to India.

Equally important is the DBT's redesign package for existing universities through improvement in infrastructure and faculty, and encouraging new research agenda. This has begun with University of Hyderabad and the University Institute of Chemical Technology, Mumbai. Following rounds of intensive interaction with the faculty and administration, DBT has negotiated major R&D and training packages and fresh faculty positions. The scheme will be shortly extended to cover more universities. Side by side, DBT and other agencies are trying to ensure that there is a support system of research resources to sustain high end research. (Table 4).

Meanwhile, DBT is setting up a breed of new institutions in basic and applied research (see Table 4) to address areas very vital to India's progress but in which the current strengths are sub-optimal. These have been designed with a strong bias for integrating science and translation and are aimed at producing skilled personnel driven toward entrepreneurship.

Cluster development is a key strategy to promote innovation and hasten the technology and product development. The inter-disciplinary nature of biotechnology dictates that facilities that promote scientific and engineering research, entrepreneurship and infrastructure should be located together to maximize synergy and efficiency as well as to nurture and promote innovation for building a successful enterprise. Clusters and knowledge cities also provide a social milieu for creative people. Three clusters – one each in the national capital region, Faridabad, Mohali, Punjab and Bengaluru are currently under active design by DBT (Table 4); more will be added to the list.

By far, the more far-reaching initiatives are industry-oriented. In the past, while government has been indirectly supporting industry through fiscal concessions and tax rebates, the recognition of the need to directly support innovative research in the private sector is only recent. DBT has decided to devote one third of its budget to public-private partnership programmes. Supporting early stage research, especially in small and medium sector enterprises is crucial since the majority of these businesses are unlikely to have the scale or the resources to engage in in-house research. DBT's Small Business Innovation Research Initiative (SBIRI) has been widely welcomed by the community and is being expanded. The Biotechnology Industry Partnership Programme (BIPP) has set aside Rs 350 crores during the current Plan to promote high risk, path-breaking industry research in frontier, futuristic technology areas and make Indian industry globally competitive and focused on IP creation and ownership in biotechnology. The recent approval of the CSIR proposal to allow scientists to set up start-up companies while retaining their jobs in academic institutions is a landmark decision and will go a long way in giving a major boost to enterprise development based on scientific innovation. Similarly, the establishment of the Biotechnology Industry Research Assistance Programme (BIRAP) is likely to act as a support system for bridging the gap between science and the marketplace and navigating through the 'valley of death'. The Public-funded R&D (Protection, Utilization and Regulation of Intellectual Property) Bill, 2007 table in the Indian Parliament will address the challenges of transfer and management if IP.

So, what does the future hold for Indian biotechnology? A major handicap is that India has not been able to discover and own many genes. Here is a great opportunity for a country that boasts of being the 10^{th} richest in terms of biodiversity for launching a strategic programme for discovery of genes and small nucleotide proteins. While discovery and innovation are long term goals, in the short- and medium term, acquisition of important genes and promoters relevant to our national needs by DBT and other agencies for use by both public and private sector is a viable option, especially in the agri-biotech sector. Partnerships with globally-reputed philanthropic organizations or through company-to-company deals for early technologies will boost India's potential to develop technologies that are relevant to other developing economies, improve its in-licensing capabilities and enhance the ability to negotiate cross border technology transfer, as well as to instill better confidence regarding India's capability in the international community. Application of biotechnology to agriculture is complex and needs patience, persistence and a sense of proportion backed by a strong regulatory agency.

While there is no doubt that genomics research will increase our understanding of the fundamental basis of living organisms, its translational potential in terms of predictive and customized products is, as yet, uncertain. The potential of other cutting edge areas such as synthetic biology, systems biology and nanoscience have to be explored. Greater attention has to devoted be developing medical implants and devices. Today, almost 85% of these are sourced from outside the country. The DBT-Stanford biodesign programme, MIT's India HST initiative and, the Translational Health Science & Technology Institute and the Stem Cell institute are good examples of work well begun. Increasing environment concerns dictate that we pay greater attention to bio-based greener and cheaper manufacturing process and bioenergy. The new biofuel policy envisions gradual increase up to 20% in blending of biodiesel with conventional diesel by 2017. Hopefully, biotechnology together with other technologies will make this possible.

One could say that India is currently engaged in a phase of 'operation rational redesign' of its science enterprise. Indian biotechnology is committing firmly on the course of knowledge creation and application. Whether and how far it succeeds will depend on a number of factors including its scientific leadership, enactment of the right government policies, availability of adequate funding support for early and late stage development, an efficient science-based and transparent regulatory system and, above all, the ability to quickly adapt to new technological and social challenges. In the end, technologies have to be really affordable to attain widespread acceptance, and therein lies the challenge for India. Judging by recent developments, there is reason to believe that India will rise to the occasion.

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LIST OF ILLUSTRATIONS

FIGURE LEGENDS

Fig.1

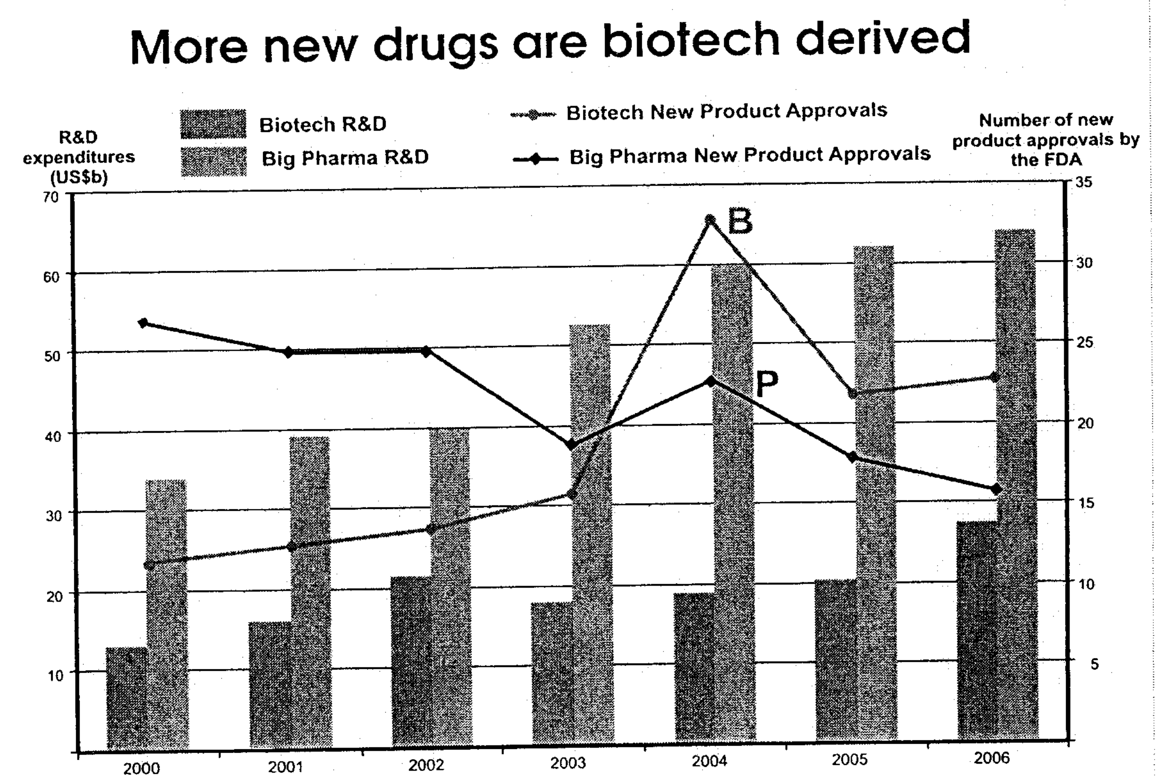
More new drugs are biotech derived
Biotech R&D
Big Pharma R&D
Biotech New Product Approvals
Big Pharma New Product Approvals
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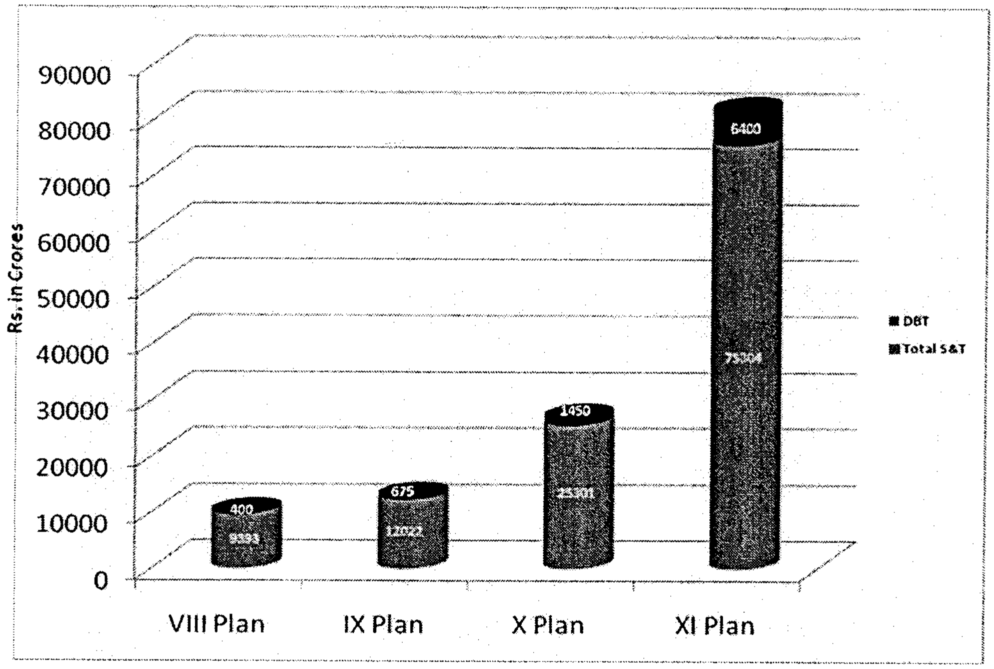
Fig 2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Total S&T
VIII Plan
IX Plan
X Plan
XI Plan