

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

S. Natesh* and M. K. Bhan

The establishment of an independent Department of Biotechnology within the Ministry of Science and Technology as early as 1986 helped in creating a scientific workforce, a large infrastructure network, and strong support to R&D in life sciences. The private sector with several home-grown companies, meanwhile, has done well 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. Clearly, it is time to take decisive steps towards discovery and innovation and yet in doing so, India faces several barriers. In September 2007, the government approved the National Biotechnology Development Strategy, which seeks to build coherence and connectivity between disciplines, bring together the variegated skills across sectors to enhance synergy and address a number of challenges. Many of the promises made in the strategy 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 the country will rise to the occasion.

Keywords: Barriers, Indian biotechnology sector, limitations, outlook, strengths.

BIOTECHNOLOGY is an umbrella term that covers a wide spectrum of scientific applications used in many sectors. It 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, healthcare and environmental sustainability. It has at the same time sparked-off a number of controversies. These range from seeking an optimal balance be-

tween 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, generation of employment, creation of intellectual wealth, expansion of entrepreneurial opportunities and augmenting industrial growth are a few 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 sciences companies generate a lion's share of over US\$ 500 billion in revenues², 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% (ref. 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

S. Natesh and M. K. Bhan are in the Department of Biotechnology, Ministry of Science and Technology, CGO Complex, Lodhi Road, New Delhi 110 003, India.

*For correspondence. (e-mail: natesh.dbt@nic.in)

as an essential investment³. The life sciences industry in the Asia Pacific (not including Japan) registered US\$ 103.59 billion in 2007, growing at 13% (ref. 2). Biotechnology industry continues to grow rapidly, with over 6000 companies engaged in activities related to discovery, consumables and equipment and the number is increasing at 6% annually³. It is noteworthy that in spite of much larger R&D investments in the pharma sector, more and more approvals granted by the US FDA are for bio-drugs (Figure 1).

The rate of adoption of GM/biotech crops is striking. From a mere 1.7 million hectare (m ha) in 1996, the cultivated area under biotech crops spread to 125 m ha in 2008 (ref. 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 established an independent Department of Biotechnology (DBT) in the Ministry of Science and Technology as early as 1986, much before 'biotechnology' became a buzzword. Government funding to the S&T sector in-

creased by eight times from the 8th Five-Year Plan to the 11th Five-Year Plan and support to the life sciences sector steadily increased by 16 times in the same period (Figure 2). As a result, a firmer 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 now. 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 and other organizations have proactively taken up a number of initiatives in creating trained human resource, institutional infrastructure (e.g. microbial culture collections, cell and 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 postgraduate teaching programme in biotechnology has currently expanded to about 70 academic institutions that train ~1000 students each year. There are doctoral and postdoctoral fellowships as well. The initial hype surrounding biotechnology led to misinformed private institutions starting specialized undergraduate (B Sc)

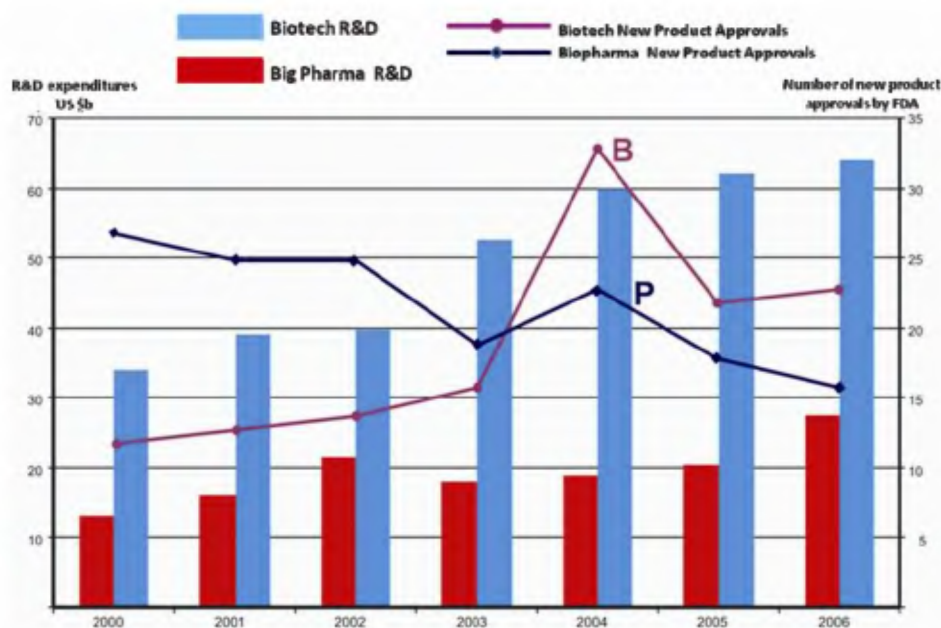


Figure 1. The innovation gap: biotech and big pharma R&D expenditures and new product approvals. More and more biotech drugs are getting FDA approvals¹.

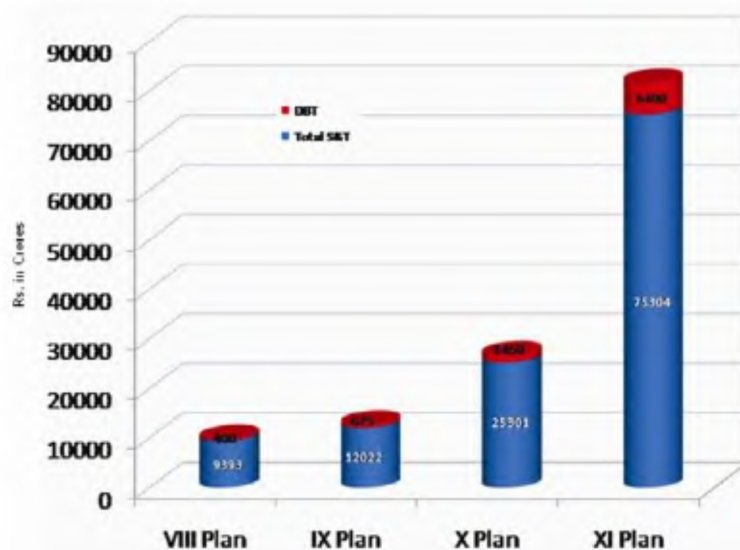


Figure 2. From the 8th Five-Year Plan to the 11th Five-Year Plan, government's total S&T budget increased by eight times and DBT's budget by 16 times.

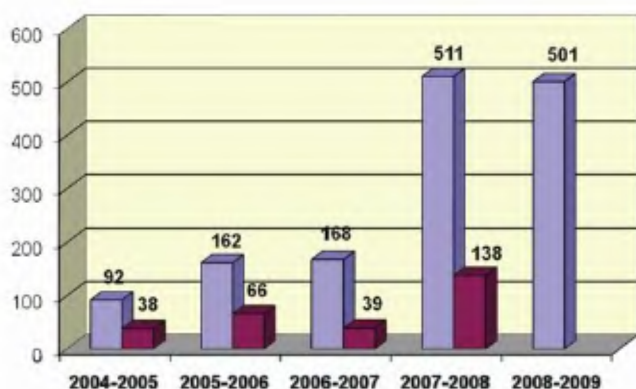


Figure 3. Number of biotech trainees selected and absorbed in industry finishing schools.

programmes in the discipline. 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. It did not find too many takers initially. However, 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 six-month training to 665 postgraduates and ~27% of these have been absorbed by the industry (Figure 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, has today more than 150 bioinformatics centres located across the country. This acts as a distributed database and network, and has become successful as a vehicle for the 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 (IIT), 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 segments. 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, Indian companies have done reasonably well and commercialized a number of products.

The sector crossed the US\$ 2.5 billion (Rs 10,273.70 crores) mark during 2007–08 (ref. 2). The past five years have witnessed a spectacular growth rate of more than 30% (Figure 4), although because of the global meltdown there was a slump to 20% in 2007–08. The biopharma segment continues to contribute the lion's share (67%), followed by bioservices (15%), agribiotech (12%), bioindustrial (4%) and bioinformatics (2%) segments. Exports

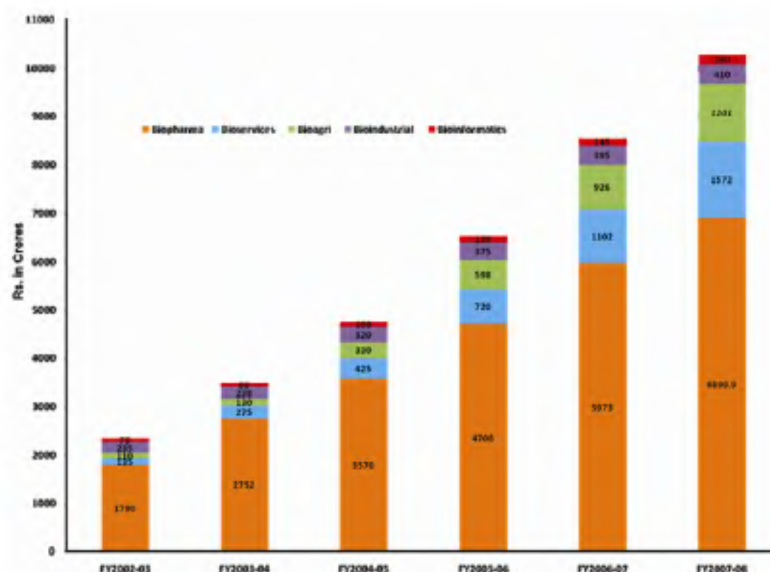


Figure 4. Biotech industry revenues during 2002–08. The sector grew at >30% during this period².

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 US\$ 13–16 billion in revenue (Figure 4). The top 25 biotech companies in India, ranked by revenue, are listed 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 services⁴. 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. Ltd, Hyderabad, Indian Immunologicals and Serum Institute of India, Pune, resulted in a 30-fold price reduction (from US\$ 15 to US\$ 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 the marketing of over 50 brands for 15 different vaccines. In 2006–07, vaccine business was worth Rs 3053 crores (US\$ 745 million) and registered 30.41% growth against Rs 1800 crores in the preceding fiscal. Human and animal vac-

cines 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 UNICEF in many countries. The Serum Institute of India is not only the largest supplier of vaccines to the Government of India's Expanded Programme of Immunization (EPI), but also the country's largest exporter of vaccines, with 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 Biotech, 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 (MVI), Bill & Melinda Gates Foundation (BMGF), Program for Appropriate Technologies in Health (PATH) and the Wellcome Trust.

There are other examples of process efficiency and cost-effective indigenous manufacture resulting in better affordability of biopharmaceuticals. Biogenics (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 biogenics pie. Biocon, Bangalore's development of a proprietary

Table 1. Top 25 biotech companies in India

Sl. no.	Company	Biotech revenues in crores of rupees			
		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 Immunologicals	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 serial nos 6, 7, 14, 17 and 20 are home-grown companies.

(b) The top three companies account for 25% share of the total biotech revenues of Rs 10,274 crores, with combined revenues of Rs 2576.98 crores. Source: Based on information in Anonymous².

process for manufacture of recombinant insulin (Insugen) forced international competitors to cut back their price by 40%, even before the product entered the 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 (~US\$ 6.5), substantially lower than the then imported product at Rs 1200 (US\$ 26). Other novel home-grown 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, New Delhi, Biological E, Hyderabad and Transgene Biotek, Medak); (c) vaccine against rotaviral diarrhoea (Bharat Biotech International); and (d) novel products such as bacteriophages as antibacterial agents against multi-drug resistant bacteria (GangaGen Biotechnologies, Bangalore) and lysostaphin, an anti-infective multidrug-resistant *Staphylococcus aureus* (Bharat Biotech International) (for more details, see Frew *et al.*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 building commercial capacities⁶. India is fast becoming one of the largest hubs for conducting global clinical trials. According to a new research report by RNCOS⁷, 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. The 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. The registration of clinical trials in India would allow implementation of quality assurance measures. International auditing of centres will also be helpful in promoting enforcement of ethical norms and good clinical practices.

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 features *Bt* genes sourced from Monsanto, but bred into local hybrids. From about 50,000 ha in the year of its introduction, the acreage reached 7.6 m ha in 2008 – an incredible 150-fold increase, occupying 82% of the 9.3 m ha under cotton in India⁴. In 2008, 30 seed companies were engaged in the production of 274 *Bt* cotton hybrids in nine states⁴. 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, Nagpur and the University of Agricultural Sciences, Dharwad – was approved in 2008 and will be planted in 2009. Since this is a variety and not a hybrid, 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 the 2008–09 season. Half of this is attributable to *Bt* cotton hybrids that have generated impressive economic gains for Indian farmers, halved the insecticide requirement and enabled India to emerge as a net exporter of cotton from being a net importer. The 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 tonnes (mt) in 2007–08, from 0.9 mt in 2006–07. According to the Solvent Extractor's Association of India, recovery of cotton-seed oil is higher from *Bt* cotton hybrids⁸, which has contributed towards increasing the production of cotton-seed oil. *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 the 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, chickpea, 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 Tuli *et al.*⁹ for a recent review). *Bt* rice is under field-testing. Other priorities include enhancement of nutritional quality (beta carotene in rice and mustard, micronutrients such as iron and zinc in rice, wheat and maize, and protein quality in potato through *amal* gene) and improvement of shelf life in fruits and vegetables, especially through delayed ripening. There is a strong pipeline of biotech crops in India (Table 3), but *Bt* brinjal may become the first transgenic food crop to be introduced in India¹⁰.

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 supply¹¹. 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 and 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 the biomass production system, promote the bio-refinery concept aiming at the integral use of biomass and maximizing the cost-effectiveness of the final product. Biotech interventions are being used to reengineer feed stock for enhanced ethanol recovery and microorganisms for increased productivity. DBT has established an Energy Biosciences Centre at the University Institute of Chemical Technology, Mumbai, to develop economically and ecologically sustainable technology for biofuel from biomass and provide a platform for evaluating bioenergy-related technologies.

International collaboration

In the knowledge-based 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 interna-

Table 2. Area, production and productivity of cotton in India, 2002–08

Year	Area (m ha)	Production (m bales; 1 bale = 170 kg)	Productivity (kg 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.

Table 3. Biotech crops in field trial in India, 2008

Crop	Organization	Transgene/event
Brinjal	Indian Agricultural Research Institute, New Delhi	<i>cry1Aabc</i>
	Sungro Seeds Ltd, New Delhi	<i>cry1Ac</i>
	Mahyco, Jalna	<i>cry1Ac</i>
	Tamil Nadu Agricultural University, Coimbatore	<i>cry1Ac</i>
	University of Agricultural Sciences, Dharwad	<i>cry1Ac</i>
	Bejo Sheetal, Jalna	<i>cry1Fa1</i>
Cabbage	Nunhems, Gurgaon	<i>cry1Ba</i> and <i>cry1Ca</i>
	Sungro Seeds Ltd, New Delhi	<i>cry1Ac</i>
Castor	Directorate of Oilseeds Research, Hyderabad	<i>cry1Aa</i> and <i>cry1Ec</i>
Cauliflower	Sungro Seeds Ltd, New Delhi	<i>cry1Ac</i>
	Nunhems, Gurgaon	<i>cry1Ac</i> , <i>cry1Ba</i> and <i>cry1Ca</i>
Corn	Monsanto, Mumbai	<i>Mon89034</i> , <i>NK603</i>
Groundnut	International Crops Research Institute for the Semi-Arid Tropics, Hyderabad	Rice chit and DREB
Okra	Mahyco, Mumbai	<i>cry1Ac</i>
	Sungro Seeds Ltd, New Delhi	<i>cry1Ac</i>
	Bejo Sheetal, Jalna	<i>cry1Ac</i>
	Arya Seeds, Gurgaon	<i>CP-AV1</i>
Potato	Central Potato Research Institute, Shimla	<i>RB</i>
	National Institute of Plant Genome Research, New Delhi	<i>ama1</i>
Rice	Indian Agricultural Research Institute, New Delhi	<i>cry1Aabc</i> , <i>DREB</i> , <i>GR-1</i> and <i>GR-2</i> (Golden rice)
	Tamil Nadu Agricultural University, Coimbatore	<i>Chi11</i>
	M. S. Swaminathan Research Foundation, Chennai	<i>MnSOD</i>
	Directorate of Rice Research, Hyderabad	<i>cry1Ac</i>
	Mahyco, Mumbai	<i>cry1Ac</i> , <i>cry2Ab</i>
	Bayer CropScience, Hyderabad	<i>cry1Ac</i> , <i>cry1Ab</i> , <i>bar</i>
	Avesthagen, Bangalore	<i>NAD9</i>
Tomato	Indian Agricultural Research Institute, New Delhi	Antisense replicase, <i>osmotin</i> , <i>DREB</i>
	Mahyco, Mumbai	<i>cry1Ac</i>
	Avesthagen, Bangalore	<i>NAD9</i>

Source: Indian GMO Research Information System (IGMORIS), 2008; Department of Biotechnology, 2008; James, 2008⁴.

tional 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 for joint IP generation, for harmonizing regulatory processes, smoothening trans-boundary movements of biologicals and to leverage better markets for biotech products and processes. Home-grown 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 (Table 4) in specific R&D areas with a few well-chosen countries and institutions^{12,13}. 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, health and well-being). Other notable partners include the Wellcome Trust, UK (see later); Stanford University, California for bringing to-

gether medical and engineering experts for the ‘bio-design’ programme for medical devices; Biotechnology and Biological Sciences Research Council, UK, for the Biotechnology Young Entrepreneurship Scheme (YES); University of Wisconsin, Madison for exchange of doctoral scholars; and PATH, BMGF 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 which 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, the 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 sciences training¹⁴. 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, where patient burden or extension activities take a heavy toll on research. Archaic rules on faculty hiring and promotions, and insufficient infrastructure further aggravate the problems. While technology institutions (IITs) have been traditionally strong in engineering and physical sciences, they do lag behind in biological research, although plans are now afoot to rectify this historic omission. In comparison, the research institutions (set up by the federal government) fare better in terms of good research projects, but do not train 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 in the research institutes, the number of faculty is relatively small¹⁵ and this needs urgent expansion with quality. Meanwhile, the brightest and 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^{15,16}. 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 (Ewing Marion Kauffman Foundation) reminds us, we live today not only in the information age, but also in the entrepreneurial age¹⁷. While the benefits of information age are well appreciated, the basic realities of the entrepreneurial age are not. It is no coincidence that the world GDP has grown more than ten-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 economies¹⁷. Now entrepreneurship is driving growth everywhere, including India and China. Yet, 'enterprise' is a term wholly lacking in discussions about higher education and research intensive universities. In spite of the current economic

downturn, the USA remains the guiding light of entrepreneurship¹⁸. The US universities have traditionally close relations with the 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 laboratories, 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 the 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, the 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&D spending, but until recently, direct investment in industry R&D was not available (Table 4). Even so, funding agencies will have to find creative ways of breaking the sociologic and behavioural stranglehold of the current competitive grant system that selects against risk taking. A recent survey of 424 home-grown Indian biotech and pharmaceutical companies revealed that till 31 December 2007 just 57 (<15% of the total) held US patents¹⁹. 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

Table 4. Perceived problem(s) and recent remedial measures taken* or proposed to be taken**[#]

People-centred

Research-intensive universities

- 5 new Indian Institutes of Science Education & Research (MHRD); one National Institute of Science Education & Research (Department of Atomic Energy)*
- DBT–University redesign programme and programme support (DBT)*
- IITs to start life sciences programmes**
- 4 new National Institutes of Pharmaceutical Education and Research (Ministry of Chemicals & Fertilizers)*

Attracting students to science

- One million scholarships through INSPIRE (DST)* (<http://dst.gov.in/scientific-programme/inspire/ser-inspire.htm>)

Postdoctoral fellowship programme

- DBT–Wellcome Trust Fellowships (Early, Intermediate and Senior category postdocs)* (www.wellcomedbt.org)
- Ramalingaswami Fellowships (DBT)* (<http://dbtindia.nic.in/research/researchfmain.html>)
- Ramanujan Fellowships (DST)* (http://dst.gov.in/whats_new/ramanujan_fellowship.pdf)
- Single window information and placement facilitation in life sciences-related areas, Centre for DNA Fingerprinting and Diagnostics (CDFD), Hyderabad**
- Biotechnology Postdoctoral Niche Associateship Programme (DBT)*
- Rapid Grant for Young Investigators (DBT)*

Fellowships for innovators and entrepreneurs

- Tata Innovation Fellowships (DBT)* (www.dbtindia.nic.in)
- R&D Fellowships for industry (DBT)**
- Innovative Young Biotechnologist Award (DBT)* (www.dbtindia.nic.in)
- DBT–Stanford Biodesign Programme (DBT)*
- MIT Health Science and Technology Programme (THSTI)*
- DBT–BBSRC Biotechnology YES Programme (DBT)*
- Biotechnology Entrepreneurship Student Teams (BEST; DBT)* (www.ableindia.org/best/index.htm)
- DBT–University of Wisconsin Khorana Fellowship Programme*

R&D resources for innovation

- Centres of Excellence and Innovation in Biotechnology (DBT)* (www.dbtindia.nic.in)

Biotech parks and incubators

- Technology Business Incubators (DST)* (www.nstedb.com)
- ICICI Knowledge Park, Hyderabad*
- S&T Park, Bangalore*
- TICEL Park, Chennai*
- Agri-food Biotech Park, Mohali**
- Biotechnology Incubation Centre, Genome Valley, Hyderabad*
- Agri-Incubator, University of Agricultural Sciences, Dharwad*
- Agri Business Incubator, International Crops Research Institute for the Semi-Arid Tropics (ICRISAT), Hyderabad (DST)*

Resource centres

- Biomolecular Characterization Centre, Bangalore**
- Genomics and proteomics technology platforms DUSC, IARI (DBT)*
- Nanotechnology platform (DST)**
- Molecular and chemical libraries**
- International Depository Authority for microorganisms, IMTECH, Chandigarh (DBT/CSIR)* and NCCS, Pune (DBT)**
- National Development Service Agency to provide cost-effective pre-clinical and clinical services to small and medium sector enterprises (THSTI)**
- Knock-out animal facility, NCBS, Bangalore*
- Detection of genetically modified food and food products (CDFD, Hyderabad; National Bureau of Plant Genetic Resources (NBPGR), New Delhi; Industrial Toxicology Research Centre, Lucknow; National Institute of Nutrition, Hyderabad; and Central Food Technological Research Institute, Mysore) (DBT)*
- National Containment-cum-Quarantine Facility for Transgenic Planting Material, NBPGR, New Delhi (DBT)*
- National Certification Facility for Tissue Culture Plants (Several institutions) (DBT)*
- Facility for Transgenic Crops Trials, ICRISAT, Hyderabad (DBT)*

New institutions designed for basic and applied research

DBT

- Translational Health Science and Technology Institute, Faridabad (Under establishment)*
- Regional Centre for Biotechnology Training and Education, Faridabad (Under establishment)*
- National Agri-food Biotechnology Institute, Mohali (Under establishment)*
- Food Bioprocessing Unit, Mohali (Under establishment)*
- Institute of Stem Cell Science and Regenerative Medicine, Bangalore (Under establishment)*
- National Institute of Biomedical Genomics, Kalyani (Recently approved)**
- National Institute of Silk and Biomaterials**
- National Institute of Animal Biotechnology**
- National Institute of Marine Biotechnology**
- 3 Molecular Medicine Centres**

(Contd.)

GENERAL ARTICLES

Table 4. (Contd.)

Others
<ul style="list-style-type: none">• 30 new Central Universities (MHRD)**• 8 new Indian Institutes of Technology (MHRD)**• Nanoscience Centre, Punjab Knowledge City, Mohali (DST)**
Increasing applications and commercialization of science outputs
Direct grants and soft loans
<ul style="list-style-type: none">• Small Business Innovation and Research Initiative (for early stage) (DBT)* (www.dbtindia.nic.in/sbiri)• Biotechnology Industry Partnership Programme (DBT)* (http://dbtindia.nic.in/AboutBIPP.pdf)• Ignition Grants for pre-proof of concept research (DBT)**
Indirect support
<ul style="list-style-type: none">• Fiscal exemptions for custom duty, excise duty, service tax, income tax, etc.
Improving knowledge transfer from academic institutions to industry
<ul style="list-style-type: none">• Biotechnology Industry Research Assistance Programme (DBT)* (http://dbtindia.nic.in/uniquepage.asp?ID_PK=680)• Technology Transfer Centres in universities (DBT)**
Modernizing S&T Management
<ul style="list-style-type: none">• Expansion of DBT**• Centre for Science, Technology & Education in Life Sciences, CDFD (DBT)**
Promoting new technology ventures
Training courses
<ul style="list-style-type: none">• New biotechnology entrepreneurship, management courses (DBT)**
Public institutions with special laboratory facilities accessible to industry
<ul style="list-style-type: none">• National Institute of Immunology, New Delhi* (www.nii.res.in)• Other DBT institutions**
Building biotechnology clusters
<ul style="list-style-type: none">• National Capital Region Biotechnology Cluster at Faridabad (DBT)**• Biotechnology Cluster, University of Agricultural Sciences, Bangalore (DBT)**• Agri-food Biotech Cluster, Punjab Knowledge City, Mohali (DBT)**• Biotechnology Cluster, University of Hyderabad, Hyderabad (DBT)**?
Creative international collaborations and partnerships in biotechnology through DBT
Countries
<ul style="list-style-type: none">• Australia – Agri- and food biotechnology; vaccines, diagnostics, implants and devices; stem cells; bioremediation• Canada – Plants for health and wellness, human health care and bioenergy• Denmark – Food, feed and energy• European commission – Functional foods and nutraceuticals, valorization of foods• Finland – Medical biotechnology, diagnostics; environmental biotechnology• Germany – Microbial biotechnology• Japan – Bioinformatics, computational biology• Norway – Human and animal vaccines, adjuvants• Switzerland – Plant, agri-biotechnology; bioremediation• Sweden – Tuberculosis• UK – Plant biotechnology, Biotechnology YES Programme, cancer• USA – Vaccines, contraceptive and reproductive health, vision research, agri-biotech
Institutions
<ul style="list-style-type: none">• International Centre for Genetic Engineering and Biotechnology, New Delhi – several areas• ICRISAT, Hyderabad – translational research• Malaria Vaccine Initiative, USA – Malaria vaccine• Massachusetts Institute of Technology, USA – Health Science and Technology Initiative• Bill & Melinda Gates Foundation, USA – Vaccines• Programme for Appropriate Technologies in Health, USA – Vaccines, nutrition• Stanford University, USA – Bidesign programme• University of Wisconsin, USA – Khorana Fellowship programme• Wellcome Trust, UK – Fellowships for high end biomedical research
New legislation
<ul style="list-style-type: none">• Public Funded R&D (Protection, Utilization and Regulation of Intellectual Property) Bill, 2007 (DBT)**• DNA Profiling Bill, 2007 (DBT)**
Reinforcing the regulatory framework
<ul style="list-style-type: none">• Establishment of National Biotechnology Regulatory Authority (DBT)**

*These include recent remedial measures taken or proposed by Department of Biotechnology (DBT) as a follow-up of promises made in the National Biotechnology Development Strategy; measures taken by other organizations such as Council of Scientific and Industrial Research, DST and MHRD are also indicated.

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 pursue pure research with the intention of marketing products 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 ‘catching up with technology’. 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, entrepreneur and 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.

Lack of ignition grant system

In India no agency provides ignition grants to young graduates, academics or working professionals to help turn incipient ideas into viable inventions and ‘explore’ the business potential of a scientific idea. A very good example is the ignition grant mechanism of the Deshpande Centre at MIT. It enables the faculty of MIT – together with students, post-docs, and staff – to take risks and explore uncharted concepts, before they have developed proof of concept or gathered any data. DBT is in the process of developing a new scheme of ignition grants to young innovators (Table 4).

Streamlining the regulatory process

Lastly, research and application of 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 are given 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, which was approved by the Government of India in November 2007. The key elements of the strategy are displayed on DBT’s official website²⁰. 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 has been published²¹.

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 crosstalk as well as the seamless flow of knowledge, technology and consultation between the public and private sectors. The Indian Government has recently taken several bold and decisive steps on a hitherto unprecedented scale. The Ministry of Human Resource Development (MHRD) has recently set up five new Indian Institutes of Science Education and Research (IISERs) and two new IITs, and is in the process of establishing 30 new federal universities (Table 4). The primary goal of IISERs is to integrate high-quality interdisciplinary 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 assist undergraduate education through upgradation of knowledge and skills of teachers, improvement of infrastructure and exposure to platform technologies. The Department of Science and Technology (DST)’s latest initiative through the ambitious INSPIRE (Innovation in Science Pursuit for Inspired

Research) programme aims to provide one million scholarships at various levels to attract bright students to pursue a career in science²².

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 postgraduate training. Lured by the attraction of working in a foreign laboratory and using it as a stepping stone for jobs overseas, most of the good graduate students left for Europe or the 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 postdoctoral research in good Indian laboratories through three-tiered fellowships (Early Career, Intermediate and Senior categories). Each year, 70 fellowships will be awarded. The other example is the newly created Ramalingaswami Re-entry Fellowship scheme – available in all areas of biotechnology – which has already gained popularity, with all the selected 25 applicants in the last two years accepting to relocate to India.

Equally important is 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 (Table 4) to address areas 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 which 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 Faridabad, Mohali and Bangalore are currently under active design by DBT²³ (Table 4); more will be added to the list.

By far, the more far-reaching initiatives are industry-oriented. In the past, while the government has been indirectly supporting industry through fiscal concessions and tax rebates, 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 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 Department of Scientific and Industrial Research (DSIR) 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'. Soon, BIRAP is expected to be elevated to the status of a council (BIRAC). The Public-funded R&D (Protection, Utilization and Regulation of Intellectual Property) Bill, 2007 currently tabled in the Indian Parliament will address the challenges of transfer and management of 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 useful genes. Here is an opportunity for a country that boasts of being the tenth richest in terms of biodiversity to launch a strategic programme for the 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 sectors 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 has to be explored. Greater attention has to be devoted to developing medical implants and devices. Today, almost 85% of these are sourced from outside the country. A new enthusiasm is discernible in industry and research institutions to work together to address the problems. The DBT–Stanford biodesign programme, and the partnership of the Translational Science and Technology Institute with the Division of Health Sciences and Technology of MIT and Harvard, as well as the establishment of the Stem Cell Institute are good examples of work well begun. Measures are afoot to improve product standardization, evaluation and registration. Increasing environmental 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.

The last decade was focused on building capacity for good quality biological science. The agenda for this decade is to concentrate on the expansion and consolidation of this competence by strategically linking biological sciences with other scientific and engineering disciplines and enhancing India's strengths in innovation and science-based entrepreneurship. In this sense, 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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