Biotechnology: "India The Global Competitor"

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Introduction

The Life Sciences & Biotechnology industry is among the fast growing knowledge based and highly knowledge-intensive industry that has evolved to a stage where it needs financial partners who have the requisite understanding and risk appetite to support its growth through structured financial and advisory solutions. This sector is expected to play a key role in the new economy, thus it is aptly described as the “technology of hope”. India has many comparative advantages in terms of knowledge, skills, R&D facilities and costs in the sector. The institutional infrastructure in the country provides the basic foundation for these strengths to translate into business opportunities.

India has a promising potential to be a global visibility and is being tracked for emerging investment opportunities in the arena of Biotechnology. India has a large pool of accomplished and cost competitive manpower, well established and integrated scientific infrastructure, highly developed chemical fusion technologies, manufacturing practices, diverse biological resources and, being globally recognized as a producer of low cost, high quality bulk drugs and formulations.

Degree of Importance

Biotechnology is a knowledge-driven technology, which needs to be driven by a flow of new ideas and concepts in the development of new tools for research, new processes for manufacturing and innovative business models. Rapid responses are needed to meet the challenges as they unfold and there is a requirement for specialized personnel and centers of excellence for R&D.

The policy goal for the next decade is to facilitate the availability of scientific and technical human resource in all disciplines relevant to the life science and biotechnology sector. In order to build a successful biotechnology sector, large talent pools are required in multiple scientific disciplines such as molecular and cell biology, chemistry, physics, engineering, bioinformatics, medicine, agriculture, microbiology, technology transfer & commercialization, bioentreprise & biofinancing and intellectual property rights management. Product and process development are inter-disciplinary in nature and deficiencies in specific areas may weaken the whole sector. The key issue is the manner in which to create an effective interface across disciplines.

Steps for improvisation

The emergence of India as a global player in the biotech sector requires government to play the role of a champion and foster an international competitive environment for investment and enterprise development. India's strategy must be to get more value from its R&D investment and from IPR generation. The Biotech industry being capital intensive in nature has historically relied on venture capital from public and private sources. India needs to provide active support through incubator funds, seed funds and provision of various incentives in order to develop the biotech sector.

In a highly competitive and fast moving business environment, innovative capacity is an important determinant of the ability to create a continuing pipeline of new products and processes. Innovation covers knowledge creation (R&D), knowledge diffusion (education and training) and knowledge application (commercialization). Innovation is not a one-time event; instead, it has to continuously respond to changing circumstances for creating sustainable growth. Clear government policies for promotion of innovation and commercialization of knowledge will propel the growth of the biotechnology sector.

Biotechnology and its sectors

i. Biotechnology & Agriculture

Biotechnology is necessary to maintain our agriculture competitive and remunerative and to achieve nutrition security in the face of major challenges such as declining per capita availability of arable land; lower productivity of crops, livestock and fisheries, heavy production losses due to biotic (insects pests, weeds) and abiotic (salinity, drought, alkalinity) stresses; heavy post-harvest crop damage and declining availability of water as an agricultural input. Investment in agricultural related biotechnology has resulted in significantly enhanced R&D capability and institutional building over the years. However, progress has been rather slow in converting the research leads into usable products.

Uncertainties regarding IPR management and regulatory requirements, poor understanding of risk assessment and lack of effective management and commercialization strategies have been significant impediments.

The spectrum of biotechnology application in agriculture is very wide and includes generation of improved crops, animals, plants of agro forestry importance; microbes; use of molecular markers to tag genes of interest; accelerating of breeding through marker – assisted selection; fingerprinting of cultivars, land raises, germplasm stocks; DNA based diagnostics for pests / pathogens of crops, farm animals and fish; assessment and monitoring of bio diversity; in vitro mass multiplication of elite planting material; embryo transfer technology for animal breeding; food and feed biotechnology.

ii. Aquaculture and marine biotechnology

Application of biotechnology would be crucial in disease resistance, enhanced productivity, fertility and reproductive growth, use of aquatic species as bioreactors for production of industrial products, value added products from sea weeds and other marine taxes and biosensors for pollution monitoring. Species of priority in fisheries would be carps, tiger shrimps and fresh water prawns. It is proposed to set up under the auspices of DBT and autonomous centre for marine biotechnology.

iii. Food and nutrition

R&D would be focused on: development of biotechnology tools for evaluating food safety, development of rapid diagnostic kits for detection of various food borne pathogens; development of analogical methods for detection of genetically modified foods and products derived there from; development of nutraceuticals / health food supplements/ functional foods for holistic health; development of pre-cooked, ready-to-eat, nutritionally fortified food for school going children; development of suitable pro-biotics for therapeutic purposes and development of bio food additives.

iv. Biofertilizers and biopesticides

Priorities would include screening of elite strains of micros-organisms and / or productions of super-strains, better understanding of the dynamics of symbiotic nitrogen fixation, process optimization for fermentor – based technologies, improved shelf life, better quality standards, setting up accredited quality control laboratories and standardization of GMP guidelines. Integrated nutrient management system would be further strengthened.

v. Industrial Biotechnology

At present, a third wave of biotechnology – industrial biotechnology – is strongly developing. Industrial biotechnology (also referred to as white biotechnology) uses biological systems for the production of useful chemical entities. This technology is mainly based on biocatalysis and fermentation technology in combination with recent breakthroughs in the forefront of molecular genetics and metabolic engineering. This new technology has developed into a main contributor to the so-called green chemistry, in which renewable resources such as sugars or vegetable oils are converted into a wide variety of chemical substances such as fine and bulk chemicals, pharmaceuticals, bio-colorants, solvents, bio-plastics, vitamins, food additives, bio-pesticides and bio-fuels such as bio-ethanol and bio-diesel.

The application of industrial biotechnology offers significant ecological advantages. Agricultural crops are used starting raw materials, instead of using fossil resources such as crude oil and gas. This technology

consequently has a beneficial effect on greenhouse gas emissions and at the same time supports the agricultural sector producing these raw materials. Industrial biotechnology frequently shows significant performance benefits compared to conventional chemical technology.

vi. Preventive & Therapeutic Medical Biotechnology

A healthy population is essential for economic development. Important contributors to the total disease burden are infections like HIV-AIDS, tuberculosis, malaria, respiratory infections and chronic diseases affecting the heart and blood vessels, neuro-psychiatric disorders, diabetes and cancer. It is important to synchronize the technology and products with the local needs of the health system and to facilitate technology diffusion into health practice.

Increasing knowledge about pathogen genomes and subtypes, host responses to infectious challenges, molecular determinants of virulence and protective immunity and novel understanding mechanisms underlying escaped immunity and ways to develop novel immunogens will guide development of vaccines against infectious diseases. Translational research and ability to rapidly evaluate multiple candidates in clinical trials can help accelerate the pace of vaccine development.

New directions in manufacturing and delivery are emerging. Major opportunities to control costs are the more efficient processes for manufacturing of new pharmaceuticals, more efficient systems for production of therapeutic proteins and biomaterials and development of drug delivery systems that release drugs at a target site. A shift from parenteral to oral or transcutaneous administration of drugs and vaccine holds the promise of simplifying delivery in health systems.

Medical biotechnology offers a significant possibility for Indian industry to establish a strong pharmacy sector, a growing number of small and medium biotechnology companies, a large network of universities, research institutes, and medical schools and low cost of product evaluation. The medical biotechnology sector annually contributes over 2/3rd of the biotechnology industry turnover. The Indian vaccine industry has highlighted India's potential by emerging as an important source of low cost vaccine for the entire developing world. Further, economic opportunities through contract research and manufacturing through global partnerships are large if supported by enabling government policies and incentives.

The policy goal is to accord high priority to basic and applied research, to strengthen capacity in pre-clinical and clinical product evaluation technologies relevant to all aspects of health and medical care-predictive, preventive, therapeutic and restorative

will be supported. Innovation will be supported through new granting mechanisms to support interdisciplinary networks and public private partnerships.

vii. Regenerative & Genomic Medicine

The first wave of real healthy life extension therapies seems likely to result from research stem cells and regenerative medicine which helps natural healing processes to work faster, or uses special materials to regrow missing or damaged tissue. Doctors use regenerative medicine to speed up healing, and to help heal injuries that cannot heal on their own. Regenerative therapies have been demonstrated (in trials or the laboratory) to heal broken bones, bad burns, blindness, deafness, heart damage, nerve damage, Parkinson's and other conditions. Regenerative medicine will result in extended healthy lifespan; we will be able to repair some of the damage caused by aging, organ by organ. The first crop of simple stem cell therapies for regenerative medicine might be only a few years away from widespread availability.

There are major scientific and ethical challenges and safety concerns that must be overcome in taking stem cell based technology for bench to bedside. As it is rapidly evolving field, the existing national (ICMR) guidelines need to be updated and supported by clear articulated procedures. India must consider the potential medical applications of stem cell research. We must reassure end users on the safety and quality by ensuring regulation on stem lines having stable characterizations so that safety risks are predictable. We must reassure suppliers by regulation from lab to market.

viii. Bio-informatics and IT - enabled Biotechnology

Bioinformatics has proved to be a powerful tool for advanced research and development in the field of biotechnology. Bioinformatics holds out strong expectations of reducing the cost and time of development of new products such as new drugs and vaccines, plants with specific properties and resistance to pests and diseases, new protein molecules and biological materials and properties. As the full genome sequences, data from micros arrays, proteomics as well as species data at the taxonomic level became available, integration of these databases require sophisticated bioinformatics tools. Organizing these data into suitable databases and developing appropriate software tools for analyzing the same are going to be major challenges. India has the potential to develop such resources at an affordable cost.

Bioinformatics in India can be used effectively for promoting research in biology; prospecting; conservation and management of bioresources; evaluation of products, processes and raw materials, managing complex data required to plan and monitor major national programs; and meeting the growing need of contract services and business outsourcing in pharma and

biotechnology sectors. One of the major challenges in optimum exploitation of bioinformatics for solving life science issues is the formulation of appropriate computational biology problems that can be addressed through IT tools. This requires adequate appreciation of the scope and strength of bioinformatics by the biologists and basic understanding of the biological sciences by the information scientists. The solution lies in having adequate leaders with expertise in both life sciences and information technology and strong institutional / program tie-up between specialists from both the fields.

Intellectual Property & Patent Law

The development of capabilities for the effective management of Intellectual Property (IP) is an important element in securing the benefits of public and private sector research in biotechnology. In this context, filings of patents both in India and aboard are critical to the growth of the Indian biotech Sector.

The expenses for filing patents especially outside India are prohibitive and a major barrier to effective Intellectual Property Management within the country.

The Patent Act, 1970, is widely believed to have helped the Indian pharmaceutical industry to develop its process innovation capabilities that is now recognized worldwide. India amended the Patents Act 1970 to provide for exclusive marketing rights (EMRs), as per her obligation under the provisions of the WTO/TRIPS agreement in 1999. EMR allows foreign firms to market their products on which they have obtained patents in any WTO member country. According to the WTO agreement, EMRs are to be provided in those countries where product patent is yet to be adopted as a practice for legal protection of intellectual property. In any case all the member countries would have to adopt product patents by 2005. Now when the government has already decided in favor of EMR it must ensure a speedy adoption of the product patent regime with a clear guideline on establishment of the 'mail box' for receiving the product patent applications. EMRs can only be given until 2005 and that too in cases where the patent application has been granted in or after 1995.

Whilst expenses incurred with respect to filing of patents in India is eligible for weighted deduction, similar benefit is not provided for expenses incurred with regard to filing patents outside India. As Intellectual Property Right (IPR)* creation is a pre-requisite for exports to the regulated markets, it is recommended that expenditure incurred with regard to filing patents outside India be also eligible for weighted deduction U/S 35 (2AB). This is also imperative in the new WTO-TRIPS regime, which has taken effect on 1st January 2005.

Conclusion

The National Science and Technology Policy of the Government and the Vision Statement on Biotechnology issued by the

Department of Biotechnology have directed notable interventions in the public and private sectors to foster life sciences and biotechnology. There has been substantial progress in terms of support for R&D, human resource generation and infrastructure development over the past decade. With the introduction of the product patent regime it is imperative to achieve higher levels of innovation in order to be globally competitive. The challenge now is to join the global biotech league. The issue of access to the products arising from biotechnology research in both medicine and agriculture is of paramount importance. Therefore, there should be adequate support for public good research designed to reach the unreached in terms of technology empowerment. Both "public good" and "for profit" research should become mutually reinforcing. Public institutions and industry both have an important role in the process. It is envisaged that clearly thought-out strategies will provide direction and enable action by various stakeholders to achieve the full potential of this exciting field for the social and economic well being of the nation.