

## €government should make it hassle-free biotech€?

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**Q. Biotechnology is now looked upon as the next savior of human race. Which are the areas where biotechnology will make maximum difference?**

**A.** Biotechnology has the potential to transform the lives of the people by impacting hugely on agriculture, animal husbandry, health, environmental protection, material transformation, etc. Take one example of health sector specifically. Thanks to our increasingly deeper understanding of the intricate biochemical interactions at the cellular and molecular levels, there are new paradigms in health care.

We have moved from preventive medicine (vaccines) and curative medicines (antibiotics) to predictive and corrective medicine, thanks to the unraveling of the mystery of the human genome. We can now identify not only the genes that cause a disease but also correct the defects through gene therapy. Recent breakthroughs in stem cell research have, for the first time, given the hope that we may be able to regenerate diseased organs, thus paving the way for regenerative medicine.

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**Q. What are the other opportunities in biotechnology?**

**A.** Bio-fuels will provide new sources of energy. Bio-pesticides will provide ecologically safe pest treatments. Bio-fertilizers will provide safer and ecologically friendly fertilizers. Bioremediation, rather than chemical treatment, can now convert hazardous wastes into useful products. Bioinformatics, with the confluence of information technology and

biotechnology, for the first time is opening up exciting new opportunities of unparalleled dimensions.

**Q. What impact will biotechnology have on agriculture?**

**A.** Agriculture contributes in a major way to our Gross National Product (GNP). The maximum impact of biotechnology will be felt in this sector. The Green Revolution transformed the country from one perennially beset with food shortages and resultant hunger to one where the silos are overflowing. In future, however, India will face the problem of producing more from less that is, more food from less arable land, less water per capital less polluting energy sources, etc.

New biotechnology holds the promise of finding a solution to this problem through creation of high-yielding and disease and drought resistant crops.

**Q. Now there is a clear race among various states to attract investments in biotechnology. Should states try to identify niche areas and selectively attract FDI and should they grab all investments?**

**A.** Each state should identify niche areas, since each one of them has something special to offer. For example, Kerala is already marketing itself as a healing state by emphasizing on traditional system of medicine. Madhya Pradesh is rich in medicinal aromatic plants and bio-diversity. Maharashtra can progress in both medical biotechnology as well as industrial biotechnology. Bangalore has the potential to grow as a major bio-informatics center due to its great strength in information technology and also the presence of outstanding life science institutions. Andhra Pradesh is already strong in bulk drug manufacture. It can grow into a leading biopharmaceutical R&D and manufacturing center.

**Q. Health is one area where biotechnology intensive products are making a major difference. What will be the impact of the current global interest on a strong IPR regime in health sector?**

**A.** The impact of intellectual property rules and practices on the health of poor people in developing countries has generated substantial controversy in recent years. Although these controversies predated TRIPS and featured prominently in the TRIPS negotiations, impetus has been added by the coming into force of TRIPS and the dramatic rise in the incidence of HIV/AIDS, particularly in developing countries. For such countries, a major concern is how the adoption of intellectual property regimes would affect their efforts to improve public health, and economic and technological development more generally, particularly if the effect of introducing patent protection is to increase the price and decrease the choice of sources of pharmaceuticals.

A strong IPR regime will have another impact. While patent protection provides an incentive for R&D, the patenting of intermediate technologies (particularly gene-based ones) required in the research process may actually create disincentives for researchers in terms of accessing, or unwittingly infringing patents impinge directly on what research done for people in the developing world, and there are implications for the type of patent regimes that developing countries adopt.

**Q. The venture funding sector is not well developed in the case of Biotechnology. Why?**

**A.** Venture capitalist must think in a manner where they truly venture or adventure. Nine out of 10 projects may fail, but the one that succeeds will generate revenues to fund 100 more. I am afraid this adventure is missing from our venture capital funding sector.

**Q. How are the lessons learnt from the turmeric patent issues being institutionalized to protect the vast database of traditional Indian knowledge?**

**A.** The patent on wound healing by turmeric that was granted by United States Patents & Trade-marks Office (USPTO) was fought by CSIR showing that this was ancient wisdom in India. In a landmark case, the patent was revoked. But a large number of US patents have been granted on the ancient wisdom in India. To prevent its repeated recurrence, a solution was found, which has reached an international acceptability now. The Indian Government has taken steps to create a Traditional Knowledge Digital Library (TKDL) which will lead to a Traditional Knowledge Resource Classification (TKRC). Linking this to internationally accepted International Patent Classification (IPC) System will mean building the bridge between the knowledge contained say in an old Sanskrit Shloka and the computer screen of a patent examiner in Washington! This will eliminate the problem of the grant of wrong patents, since the Indian rights to that knowledge will be known to the examiner. Hopefully, wrong patents on turmeric, neem, etc. will be the things of the past! This Indian initiative will help all the developing

world, which is seen in traditional knowledge.

**Q. Will TKDL serve a bigger purpose rather than just protection?**

**A.** Eventually the creation of TKDL could serve a bigger purpose in providing and enhancing our innovation capacity. It could integrate widely scattered and distributed references on the traditional knowledge systems in a retrievable form. It could act as a bridge between the traditional and modern knowledge systems. Availability of this knowledge in a retrievable form in many languages will give a major impetus to modern research in the developing world, as it itself can then get involved in innovative research on adding further value to this traditional knowledge; an example being the development of an allopathic medicine based on a traditional plant based therapeutic. Sustained efforts on the modernization of the traditional knowledge systems of the developing world will create higher awareness at national and international level and will establish a scientific approach that will ensure higher acceptability of these systems by practitioners of modern systems and public at large.

**Q. You have been speaking about creating special niches in the health sector for India. What are these?**

**A.** It is only by fusing the ancient wisdom and modern science that India can create world class products, because new products cannot compete with products which have only tradition and empirical observation as the knowledge base. The knowledge to be integrated into the traditional products has to emerge from modern science, especially modern biology and chemistry. Such fusion will lead to better definition of existing products, improved understanding of the mechanism of their action, modified compositions at molecular level, and better understanding of interactions amongst various molecules.

**Q. What is CSIR's special effort to put this great idea into practice?**

**A.** There is a 20-lab networked programme on discovery of bioactive molecules for their use as drugs and therapeutics. Our research is based on the clues that we get from our vast plant based traditional medicine systems including Ayurveda. For the first time, CSIR forged relationships with Indian traditional systems of medicine, namely Ayurvedic and Siddha systems. I still remember that when CSIR signed the MOU with Arya Vaidyashala in Kottakal, Prof. Valiathan, who brought both the partners together, said that is a holy place where two rivers are meeting; the river of traditional knowledge and ancient wisdom represented by Arya Vaidyashala and the river of modern knowledge represented by CSIR. This meeting of new knowledge systems is leading to exciting leads as 500 of our scientists and also our universities, which are part of our programme, drive the programme forward.

**Q. 'Asmon', which cures Asthma, is already in the market and is being received very well. How many more Asmon type products are in the pipeline from the CSIR system?**

**A.** We have several leads on Malaria, TB, Cancer, Diabetes, etc. We hope at least some of them will be winners as much as Asmon has been.

**Q. Is there some way to correct the asymmetry in the investments made in modern biotech research by public and private sector research system? Is there a danger of private sector companies developing a stranglehold over the agriculture and pharma sectors through huge R&D investments?**

**A.** So far about 80 percent of trials of transgenic crops have occurred in developed countries, where three quarters of the world's GM crops are grown. The breeding strategies of the multinationals have been naturally oriented to the needs of developed world markets, and the commercial sectors of middle income developing countries (for example, Brazil, Argentina or China). The development of genetic traits such as herbicide tolerance has been determined principally by the search for commercial advantage, rather than for characteristics useful to poor farmers in developing countries. But companies are introducing GM varieties which are considered by some developing countries to be of potential benefit to them (for example, the Bt gene which confers insect resistance). Bt Cotton or Bt maize is now grown in at least five developing countries, and other countries may be interested if they can resolve environmental concerns. For instance, India has recently approved the planting of Bt Cotton.

**Q. How will we make sure that the needs of the poor are taken care of?**

**A.** We need a new understanding on IPR and its sharing. Companies have also donated technologies of relevance to developing countries (for example, through royalty free licences), including those related to vitamin A enriched rice (Golden Rice) and cassava. Thus there is a potential for agricultural technologies developed by the private sector to spill over to the benefit of the commercial sectors in developing countries. More public sector research specifically oriented to poor farmers will continue to be a priority. In 1998, the CGIAR system which is the main provider of public sector knowledge pool spent

\$25 million on such research compared to the \$1.26 billion invested by Monsanto. We must increase CGIAR budgets.

**Q. Do you foresee India's biotechnology sector making rapid strides similar to the software export industry in five years? What could be the roadblocks in the path of this sector taking its rightful place in the global biotech sweepstakes?**

**A.** We need to understand that the only raw materials that were needed for software were "grey matter" and "the bandwidth". In biotechnology sector, government will have to play a crucial role. We have seen that the chain of "mind" to "marketplace" in biotechnology involves the government. Animal experimentations, custom clearances, regulatory approval delays and so on have been major bottlenecks so far. If the government does not create a "hassle free" environment, then biotechnology in India will not succeed, let even grow. But if we do so, then we have a huge chance. India's rich human, plant, and animal genetic diversity, its rich resource of human capital in life sciences, its tremendous cost advantage, and availability of large local markets in all diverse sectors can be leveraged to make India the rightful leader. What is most important is to see that hundreds of "bioenterprenurs" emerge in this sector who understand the route of Laxmi through Saraswati, just as our IT sector did. Then India can really fly.

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