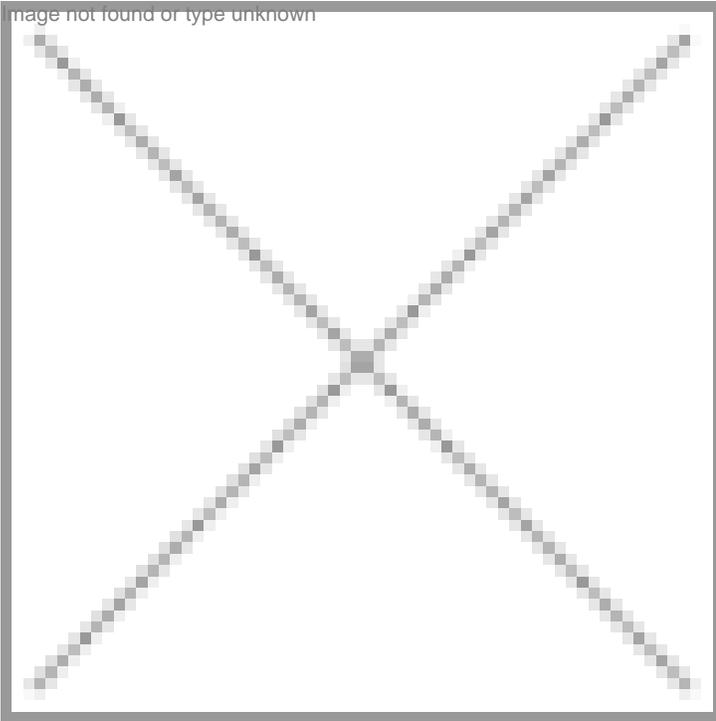


"Aim to be among the Top 5 BioClusters"

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India is showing the way to the rest of the world. It is not the volume of business or growth. India is a land of ideas and Dr RA Mashelkar would also like to see those ideas translate into products and technology. Dr Mashelkar in his vision talk at Bangalore Bio 2006 spoke on several things that we can and should do. BioSpectrum publishes those as a ready-reckoner for the industry in first person.

India has attracted much attention in the last two years. The interest in India is unbelievable.

People are looking at tapping the opportunities in India. In fact, there are new terminologies that are coming up. One is familiar with the history of science but now people are talking about the geography of science, the changing geography of science. People look at creation of a new atlas where the center of gravity of research and innovation is shifting to the Asia Pacific. India and China figure prominently in the discussions. People are so tired of talking about India and China that they call it Chindia. It is obvious as to why this excitement. It was in March 1995 that I gave a Thappar Memorial lecture. It was presided by the then finance minister and now the Prime Minister, Dr Manmohan Singh. The title of the talk was "India's emergence as a global R&D platform: Challenges and opportunities". And I had a very simple premise that I had built in that paper. That was skill-based competition. The real competition is going to be on the basis of skills and that the product is merely going to be a transient. A product is going to be one where the company will derive value by selling it in the market. But how will a company keep the product together will be determined on how one gets the best skills in the cheapest possible way, the smartest possible way, and in the shortest possible time. And based on that I thought India could assume an

important position. That was in 1995.

There are now close to 200 companies that have set up R&D centers. When the Jack Welch Center was inaugurated and when Jack Welch was asked why the center was set up in India, his response was simple- the highest intellectual capital per dollar. He was not talking just about cost, but cost cum competence. He was talking about competence as reflected in intellectual capital and cost as reflected in dollar. For a long time, I wondered how could that be valid. I did a simple analysis a year ago. Suppose one is looking at Science Cited Index (SCI) papers that are peer reviewed. I made a list based on the SCI Papers produced per GDP per capita. For a five-year period, India topped the list with (31) and was followed by China (27) and the US (7). This list was about the maximum scientific output per dollar invested. Clearly, this shows where the investments will go.

India is going to have good time in the future.

There are 3 Ds, which are responsible for innovation, creative thinking etc-Democracy, Diversity, and Demography (the largest number of young people). These will continue to be our key strengths in the next two to three decades. This window is open to us for some time.

Let me come to why one feels optimistic about India. There are many good reasons. India's future is IT (Indian Talent). The second thing is the growth of our economy. India is growing at over 8 percent and India can easily grow above 10 percent. If we are growing like that, we are expanding the internal markets. This is a big advantage with large countries.

These are generic advantages. But when we come to biotechnology in particular, there are many things that have happened. The best thing that has happened is Kiran Mazumdar-Shaw. What she has done is transforming her organization from an enzyme producing company to an integrated company. What she demonstrated is that it is not by trade alone that one can grow. One can grow by technology and innovation. Her journey has fuelled aspirations and inspiration. Her role as a visionary has sent strong signals to a lot of young people.

I have seen that states are investing in technology. Earlier, this was done mainly by the Centre. Many states are setting up technology parks. It is very encouraging. The industry today is very close to the \$1.5 billion mark. The numbers are achievable. But there is a story more than the numbers. Though the numbers are small at the moment, still these mean much more. It is about lilies in pond. They double up everyday. So let us say the pond is full on the 30th day. It is half full on 29th. It is quarter full on 28th. It is 1/8th full on 27th; 1/16th full on 26th (means 6.25 percent full). In other words, it is 94 percent empty till 26th. One would feel skeptical that what can be done but what people fail to realize is that the lilies double.

So the numbers will happen. But the question is, will these happen? What is the guarantee for growth? What are the factors that retard growth? We have come a long way. There is plenty of good news. What is important is the direction is right. What we require is direction and speed in making some of these things happen.

We need movements. We need to move from Biohype to Biohope. That hope will not happen if careers, entrepreneurs, and jobs are not created and if biofunding does not happen or bioregulations do not progress.

We need to move from bioactivism to biorationalism. The 21st Century is going to be the century of hope.

Dr Mashelkar's Mantras

- Top 5 club membership: If India has to gain respectability in biotech, it has to become a member of the big club. Two years ago, India was not there in the list of 17 countries, but now we are making an entry. Our vision should be that we have to be among the top 5 clusters.
- Resourceful: In order to do that we need to understand that biotechnology is both knowledge-intensive and capital-intensive. Since it is knowledge-intensive, we have to create human capital, which is not only people who understand bioinformatics, cellular or molecular biology, but also those who understand IPR, bioentrepreneurship, clinical trials, etc. It is going to be a big issue. Because it is capital-intensive, I believe the government-institutional partnerships and innovation are going to be important. And in a country which is short of resources, one can move forward by being resourceful like Japan. That will mean smart-policy level initiative.
- Techno-entrepreneurship: We have two goddesses. The Goddesses of Knowledge and Wealth. Normally they are

treated separately and kept together. But there is a route from the Goddess of Knowledge to the Goddess of Wealth. That was how Silicon Valley was created. Somehow we have not understood that. That is where we need to change. Take for example the UK. Prof. Robert May, the president of Royal Society, about 15 years ago in one of his speeches remarked that the UK is fantastic in science and in creating wealth through ideas-but not in the UK but elsewhere in the world. But look now, all that has changed. The temples of knowledge, Cambridge and Oxford, all have changed. About 10 percent of the European Unions' venture capital has been invested in Cambridge enterprise. And over 50,000 jobs have been created. Ten years ago, Oxford put up one start-up company in every four years. Now it spins out one start-up company every two months. In India, we have not got the dynamics of techno-entrepreneurship. There are a few examples like Dr Vijay Chandru of Strand Life Sciences or Dr Padmanabhan Babu of Bangalore (Sanmar) Genei or Dr Ashok Jhunjunwala of Tenet. What we need to focus on is how do we promote that and how do you make it a rule. This is our biggest challenge.

- Indian diaspora advantage: India should make best use of the great strength that we have in the form of Indian diaspora. About 2 percent of Indians who are living outside India generate income that is almost equal to the GDP of India. We do not need remittance of the dollars, but what we need is remittance of knowledge. We need to put in place a mechanism that will help us leverage this.
- Inclusive strategy: It has to be recognized that BT is not an end. It's a means to end. The real end is for the welfare and wealth care. It is the welfare of everyone, by including the vast population. We require expansion of systems and maintaining highest quality and at the same time inclusion of the benefits to vast majority. I have been the vice chair of WHO's commission on IPR, innovation, and public health. Madame Dreifuss, former President of Switzerland, was the chairperson of the commission. We worked for two years together and recently submitted the report to the Assembly. We looked at the entire issue of making diagnostics, vaccines, and therapeutics available, affordable, and accessible to those who are deprived. And there I made an appeal and talked about creating a new global knowledge pool for global good, through global funding, and through new global understandings. New global understanding has to be on the basis of some principles, where we understand the interests of the inventor or the innovator and the interests of the society. That is where we are looking at new models. That is where one is looking at Public-Private-Partnerships (PPP). About 60 percent of the funding comes from the Bill Gates Foundation. It is where the participation of nations is important. That money should also be used for creating the knowledge.

Broad Concerns

Single window clearance, streamlined approval process

- A hassle-free and fast regulatory approval is the need of the hour. This could be achieved under a single regulatory authority with two units, one for health biotech products and another for agricultural products.
- Approval process needs to be streamlined in terms of both timelines and review.
- For example, a technical committee at the level of Drug Controller General of India (DCGI), for proper review of new products, is needed. This will actually decrease the time lag, which is now due to the referrals to ICMR. This is especially relevant to be considered in case of the novel products which are being worked on more in India now.
- Streamline the approval process to import and export of biologicals and the samples. A step in this direction has been initiated in the Mashelkar Committee recommendations, but it has to be further simplified in terms of many parallel clearances that the companies need to get.

Sector thrust
Clinical trials

Change in regulations to authorize DCGI to grant permission to conduct Phase-I and Phase-0 studies.

- Facilitate animal trials: Undue delays and interference by CPCSEA nominees (who many a times are activists) are bottlenecks and roadblocks in generating pre clinical data in animals. The government has to take more positive steps to resolve this issue.
- Allow commercial export and import of non-clinical trial related biological samples like blood, serum, and plasma for R&D use.
- Priority clearances at customs for clinical trial medicines since most of the clinical trial supplies are temperature sensitive.
- Single window clearance for all required approvals to be established.
- A clear stand by the regulatory bodies on the data exclusivity is essential for the growth of the biotechnology industry. A discussion between officials and experts regulatory bodies pharma/biotech industry and pharma associations could settle this issue.

BioAgri

Now that the concerns of the BioPharma sector are more or less addressed, the focus should be on setting things right for the BioAgri sector. On one hand there is a requirement to address the GM crops policy and on the other support is needed for the biofertilizers and biopesticide manufacturers and tissue culture companies.

- The involvement of multiple agencies and multi-tier committees often leads to unnecessary delays and duplication of efforts. For e.g., the testing of agronomic performance both in the Large Scale Trials (LST) and in the Indian Council of Agricultural Research (ICAR) trials is unnecessary duplication of efforts. It can even be argued that the regulatory testing should be limited to assessing the bio-safety and efficacy of the transgenic product. With increasing choices, it should be left to the farmer's wisdom to choose the variety that best suits his/her growing conditions.
- The formation of the proposed National Biotechnology Regulatory Authority (NBRA) as envisaged in the National Biotechnology Development Strategy document prepared by the Department of Biotechnology could be a single window agency to clear the commercialization of transgenic crops. Further, the implementation of certain policy changes in the regulatory process like gene/event based approval instead of the present variety/hybrid based approval will go a long way in avoiding unnecessary costs and generally in hastening the dissemination of approved technologies.
- We have many public institutions that have the competence to develop genetically altered crop varieties using all the modern tools that plant biology has to offer. However, very few useful products have been commercialized by these institutes over the years. While project funding needs to be increased, there must be an immediate review of the projects to bring about a focus on products or solutions to specific agricultural problems. There should also be a thrust on networking and meaningful collaborations between the public and private institutions.
- The biofertilizers and biopesticide manufacturers need support in terms of recognition as an independent industry under National Industrial Classification (NIC) 2004. Be treated as preferential industry and concessions be given.

Better infrastructure

- The government may consider setting up state-of-the-art animal house facility to make available experimental animals

including non-human primates, specific transgenic animals, specific pathogen free animals etc. to the industry.

- cGMP/GLP pilot scale facilities for peptide and recombinant proteins would help to initiate faster pre clinical development of biotech products. These facilities should be made available to the industry, specially the start-ups. Facility for genomic and amino acid sequencing and facility for making available molecular biology reagents at an affordable cost would provide flip to the Indian biotech industry. These facilities could be set up in Biotech Parks. All these facilities could be made available to industry on payment basis.
- Facilitate clusters on the basis of strengths in a region.
- Availability of strains of pathogens/antibodies.
- It is difficult if not impossible to get strains of the pathogens that are available in the government supported research centers. It is even more difficult to obtain strains from "strain banks" established with the support of government funding. The appropriate mechanisms should be put in place where industry can get microbial strains from the "strain banks". The government may consider establishing such microbial strains banks and also reagents banks.

Human talent

- Since Biotechnology is knowledge-based discipline, a clear-cut policy and friendly facilitating system along with incentives to industry and university may be put into place. There may be a need to change clauses in UGC Act so that universities may be permitted to participate in establishing facilities along with industries. This would encourage public and private partnership.
- Improvement in course curriculum for Masters degree program in Biotechnology so as to have trained manpower relating to molecular pharmacology, molecular biochemistry, molecular immunology, molecular medicine, bio-computational tool, genomic and biotechnologists with the global expertise on information technology and vice versa. Such manpower is essentially needed for the "modern biotechnology industry" and the essential for the growth of this sector. There is dire deficiency in the availability of biotechnologists who are well trained in using cutting edge technologies.

Fiscal support

- Central and state governments may consider setting up venture funds for biotech industries.
- A dedicated fund by DBT or other agencies meant for establishing startup companies would usher in new biotech industry.
- The scientists located in the R&D units of the industry should be eligible to obtain research grant from government agencies in a fashion, similar to the scientists who are conducting R&D in government supported research centre(s). Most of the programs of NIH/PHS, USA are open both to industry and academia centre in identical fashion. A similar model could be adopted by funding agencies.
- Expenditure on R&D and filing of patent needs to be exempted from income tax. This would stimulate new patentable products/processes that are "must" for survival of biotechnology industry.
- The custom and excise duties on the import of biotech especially on life saving products have been slashed and a

further reduction in duties would augment availabilities of biotech products for unmet needs. Similarly, customs and excise duties on the import of reagents required for molecular biology tools including recombinant technology, monoclonal antibodies, etc. need to be slashed at a level equal to import duties for the biotech finish products.

- There is a need to give more incentives like rebate on the cost of land, concession in stamp duty and in registration charges, exemptions on stamp duty for biotech incubators, and more friendly power tariffs. The incentives like exemptions on payments from entry tax on capital goods, purchase tax, sales tax and work contract tax and availability of uninterrupted power supply, more friendly labor laws and friendly Pollution control regulation are essential for creating good infrastructure for knowledge based industry.
- The funding agencies may consider devising appropriate mechanisms to safe guard the confidentiality of the innovative research programs submitted by industry for grant/soft loans. The non-existing confidentiality mechanism discourages many biopharma/biotech to apply for grant or for soft loan.