

## Biotechnology in India: The technology imperative

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*The government should de-emphasize basic research and instead provide infrastructure and technology channels for promotion of biotech sector. Facilities like technopark available to software industry if made available to the biotech industry can spur growth of this biotech sector. This will also facilitate proper technology licensing and transfer and promote growth. On a long-term basis, we should also focus on technology development especially for the diseases of the developing countries.*

### Global prospects for biotechnology industry

In a short span of 15 years, biotechnology has established itself as a significant factor in health-care industry. In USA it has already gained nearly 10% share of the total pharma market. The biotech industry is just coming out of its infancy (Table 1). Its potential is being tested, realized and used. The public awareness and acceptance will accelerate the process. This sector is expected to expand at least 2-fold by the end of the century and will soon match or surpass the computer industry in size, importance and growth. It holds good promise in a number of areas, specially those for which we have no current treatment. There is a tremendous potential for developing countries like India to apply biotechnology in health-care, agriculture and environmental resource management. In the earlier paper<sup>1</sup> I discussed the current status of biotechnology as an industry sector, in this paper I will discuss how India can best benefit from this new set of technologies.

### Biotechnology in India

India has a number of good academic institutions with expertise in basic sciences relevant to biotechnology. India also has a fair number of suppliers and stockists who market required reagents and supplies. There is also a surge in testing facilities, R&D institutions, small medical equipment fabricators, repackers and sellers of relevant imported materials.

India has a rapidly swelling population of upper-class and middle-class, needing

newer diagnostics and therapeutics. Moreover, proliferating private medical and hospital care has created a tremendous demand for biotech products. Proliferation of diagnostics is mostly met by imports, primarily because there is a general failure of locally developed diagnostics.

### Indian pharma industry

Indian pharmaceutical industry is strong and has the expertise for chemical drugs. It is competing well in bulk drug market, largely due to the more efficient nature of the processes and manufacturing costs. The same can hold true for the biological drugs, but at the moment it has little experience in biotech diagnostics and no experience in biotech therapeutics. India's economic liberalization and signing of GATT and Dunkel Draft clear the way and need for significant R&D activities by pharmaceutical industry. Impending changes in patent law will make it necessary to either develop our own technology or obtain proper licence from others. Globalization of economy and liberalization of our economy make this an appropriate time to seek outside licensing and technology transfer. The Western India (Gujarat, Maharashtra), with more than 50% of the registered pharmaceutical units, accounts for 90% of the pharmaceutical production. This region also accounts for more than 70% of import and export of the pharmaceuticals. The Indian pharmaceutical industry will sooner or later enter in manufacturing of biotechnology-based diagnostics and therapeutics. There is no government institution

or university in this region with expertise in this area to help the pharma industry.

### Diagnostics

Worldwide there are about 600 new biotechnology-based diagnostics in the market with a value of about \$ 20 billions. Many more are about to enter the market, the most prominent among these will be nuclear probe and PCR-based diagnostics. India relies on imports for many of the immunodiagnostics kits. Many of the locally developed diagnostics have failed, while the imported diagnostics are either unsuitable or expensive.

### Therapeutics

Expression of foreign genes in convenient prokaryotic cells and the large-scale production of gene products is now routine. These protein products could have applications as therapeutics, diagnostics, restriction enzymes or industrial enzymes. At present there are about 79 biotechnology-derived therapeutics approved for human use in USA. The total market value of these products is about \$ 50 billions. About 150 companies have 700 more products in various stages of clinical trials and development. With increasing acceptability of biotech products, there will be about 200 biotechnology-derived therapeutics available in the market by the turn of the century. In 1987 the number of new drugs (IND, Investigational New Drug) produced by biotechnology had overtaken IND produced by conventional means (chemical and antibiotic drugs). This is an indication of the trend that, in future, new therapeutics will be made by cellular factories using recombinant technologies. At present, there is no locally manufactured recombinant therapeutic product available in the market. Few imported biological therapeutic products are marketed in India, e.g. human insulin and streptokinase.

Table 1. Ten years history of the biotechnology therapeutics in USA

	1985	1990	1995
Sales (\$ in billions)	1.1	2.9	9.3
Revenues (\$ in billions)	2.2	4.7	12.7
R&D expenditure (\$ in billions)	1.7	2.6	7.7
Number of companies	850	1,107	1,308
Employees	40,000	66,000	108,000

**Factors influencing biotech growth**

Table 2 shows various factors influencing growth in a particular segment of economy. For example, in USA the growth is driven by innovation while in Germany it is driven by capital investment and proper technology management. In Thailand (and India?) the factors like cheap labour or availability of raw materials, etc. can spur growth. In India and China, sudden growth is evidenced owing to the rapid opening of huge consumer markets. Thus, India is poised to enter the biotechnology market. Infusion of foreign technologies and collaboration has already taken place in other sectors of economy. It is now time for Biotech/Pharma sector to seek proven technologies from outside. The government should provide proper channel and infrastructure to the pharma industry. This will lead to value-added better stable, tested and validated products in the market. Other governments, including Germany has government-supported agencies for technology identification and import. The SIDCs (state industrial development corporations) should get serious about this sector. In addition, the problems of developing countries (malaria, tuberculosis, etc.) have remained untouched by biotechnology either in India or overseas. These problems will need innovative approaches.

*Development of new technologies*

India has a good number of government institutions and universities involved in the creation and development of new relevant technologies. We have a chain of CSIR institutions and other places like CCMB, IMTECH, NIPER, NII, IISc, etc. engaged in research and development that may help health-care sector. In spite of this modest but consistent support from the central government, we have not utilized our resources and infrastructure to

the fullest. I believe primarily it is the academic nature of these institutions which lack appreciation of industry and the market place, resulting in their inability to help industry.

*Commercialization of new technologies*

There are a few instances where a usable technology has been developed in an academic institution, primarily for diagnostics. However, in most of these cases technologies failed in development stages or even after marketing. This is another example where academia and industry show lack of understanding and appreciation of each other. Our pharma industry is by and large without significant R&D activities because of lower profit margin. Because academia cannot really do development of technologies, and because the industry is either burnt out by academia or unable to appreciate or afford development of technologies, some useful technologies go undeveloped. The net result is that we in India develop far fewer technologies than what our capabilities are and our demands require. Even fewer technologies are actually commercialized. Therefore, we depend on import of products from abroad to meet our growing needs. This hold true for most of the biotech diagnostics and therapeutics.

*Academic-industry relationship*

In India the academia-industry relationship has worked quite well for chemical industry and other engineering-based industries, primarily because of IITs. As far as biotechnology is concerned, academic-industry relationship is non-existent or ineffective. By and large each side has a lack of understanding or appreciation of other. At times it translates into outright apprehension (see *Curr. Sci.*, 1991, 60, 524-528).

*Technology absorption and transfer*

Since we do not invent and develop technologies, we rely on import of either products or the technologies. Proper licensing and transfer of proven technologies is not that common in India. The process patent policy helped us to 'improvize' processes and it was not needed to go for proper technology licensing. At the same time, very few government institutions worked to facilitate the absorption of technologies. A noted exception is BRIT, a DAE agency which developed indigenous radioimmunoassay kits and made it so user-friendly for Indian conditions that now about 20 diagnostic radioimmunoassay kits are developed and marketed by BRIT. There are about 200 diagnostic centres throughout India where BRIT-trained technicians operate these diagnostics.

*Biotech generic market*

In the international market, biotechnology drugs are very expensive. For example, Genetech's tPA is priced at about \$ 2000 per injection and streptokinase is marketed at about \$ 200 per injection. A genetically engineered Factor VIII used in the treatment of hemophiliacs costs \$ 25,000 a year. Imported therapeutics traded in India are exorbitantly priced (Rs 300 per dose of human insulin compared to Rs 65 per dose of traditional insulin) and about Rs 4000 per dose of streptokinase. What will be our strategy when in three years there will be over 200 therapeutics and vaccines available? Shall we still rely on imports? The next generation of these products will have to be less expensive and more effective. We can provide inexpensive manufacturing base for Indian as well as export market. We should go for proper technology transfer and develop the manufacturing base. In addition, many of the biotech products will be off-patent

**Table 2.** Driving forces influencing industrial growth

Driving force	Precondition	Strategy	Example
Factor	Factor advantage	Low tech sectors	Thailand, India??
Investment	Mature user industry	Investment in getting foreign technology, joint government and private ventures	Germany
Innovation	Developed science base, mature industry base, venture capital	New companies led development	USA
Market base	Sudden opening of large consumer market	Careful import and promotion of proven technologies	India, China, Eastern Europe, Former Soviet countries

in a few years. Priority could be to manufacture these off-patent products. India with proper technology transfer can develop its niche in off-patent biotech 'generic' market.

#### *Need for licensing and transfer of technologies*

We have witnessed that indigenously developed diagnostics have shown less than satisfactory performance in the market. The imported diagnostics are not suitable because they are expensive, not against local pathogenic strains, and with little or no quality and stability controls. In addition, the Indian pharmaceutical industry has little or no experience in modern diagnostics or biological therapeutics. Their approach of process improvization that worked well for chemical drugs will not work in biotechnology-based diagnostics or therapeutics. In addition, the number of newer diagnostics in the international market every year is burgeoning. Therefore, the national interest is better served by systematic approach in identifying, licensing and transferring of appropriate proven technologies.

#### *Need for technology development*

There are a few diagnostics developed in the country but overall performance has been dismal. There seems to be a gap of culture, communication or something between the academic and corporate worlds as a net result of which the internally developed technologies have not been designed or developed properly. The products do not reach the market or fail in the market. For a long-term interest of the nation there is a need for local development of technologies, especially against conditions like tuberculosis and malaria rampant in India.

#### *What the government can do?*

The growth of biotech sector in USA is innovation-based while in other Western countries it is based on technology transfer and capital investment. We ought to realize that every country cannot have innovation-based sector growth (see Table 2). In fact, in biotechnology it is only USA which has witnessed growth of the biotech sector based on innovation. Rest of the countries, including the Western Europe and Japan, have only minor contribution in innovation-based growth. Therefore, it will be futile for India to

pour its valuable resources only in research and hope that we too can have innovation-based biotech sector growth. The government can promote biotech sector by the following two approaches. (i) Provide a good infrastructure including a Biotech Park with the state of art common facilities including laboratory and pilot plant equipment. Contrary to belief, these infrastructure facilities can be made financially self-supportive. Benefits in terms of promoting industry are numerous. Many countries including Taiwan, Korea, Japan, European countries, and even Brazil have Biotech Parks to cater to and promote this sector. In India too there are several technoparks to cater to the computer industry. (ii) Establish technology transfer office where entrepreneurs can approach for available proven technology for licensing. This office can shop throughout the world for availability of proven technology, can advise and help entrepreneurs through the negotiation process, and can help industry to get the best deal on import and licencing of proven technologies. At the moment, only the large companies can afford to do their technology shopping on their own. Medium and small scale industry have no such help in identifying and obtaining proven technology. The emphasis is on *proven* technology, one that is successfully used elsewhere. It is a foregone conclusion that technology import or licensing is a must for the near future. It is also evident that small- and medium-scale industry has not been tapped for biotech sector. It has been observed that many entrepreneurs with good investment capacity but who are not trained in biotech would like to diversify in biotech provided they have some reliable technology sources. It has also been observed that many entrepreneurs who were ignorant of technology transfer ended up losing money in attempts to arrange for the technology transfer on their own. Both these groups of entrepreneurs could be helped by the proposed technology centre.

In summary, the government should de-emphasize basic research and instead provide infrastructure and technology channels for promotion of biotech sector.

#### *Potential concerns for technology transfer*

It may be perceived to be an expensive

proposition to go for proper technology transfer. However, we do not have any other option. Proper tech transfer adds only a small percentage to the final retail price. Depending on the expected volume, it may cost between 5% and 10% more to the final retail price. Considering the time and expenses saved, this small price is negligible.

Another apprehension is that we will not get a good technology, primarily because of our reputation as technology thieves. In some cases, individual companies have gotten into agreements which were not designed to their advantage. This is mainly due to our inexperience in evaluation of technology potential and negotiation process. And as we enter international business deals, we will have to face and rectify the reputation we might have. Changing our patent laws will be a step in this direction. Another pitfall is that we only look at USA for the technology source. Companies from many other countries have useful technologies while the market in their own countries is limited. These companies are eager to enter markets like India for its local consumers as well as regional export.

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