

## Biotech success in India

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### a)Genetic Engineering:

Unfortunately, we haven't, totally on our own, produced a single genetically modified organism of commercial value, even though we have had enormous capabilities to do so. We have increasingly done well in the last decade in the direction of producing useful protein drugs using genetically engineered microorganisms grown under highly confined conditions. The first product to be produced in this manner was Hepatitis B vaccine, Shanvac-B, by Hyderabad based Shantha Biotechnics Pvt. Ltd. The product came in the market in 1997. Shantha Biotech invested Rs 16.5 crore for bringing out its first product Shanvac-B. It now has a pipeline of products on the anvil. In fact, Shanferon (Interferon alpha 2b), its second product is already in the market, and another product, Human Insulin, should be in the market by next summer. Other producers of Hepatitis B vaccine, such as Bharat Biotech and Wockhardt have followed Shantha Biotech. Wockhardt, on the other hand, is now also producing Erythropoietin through genetic engineering. In the area of protein drugs produced through genetically engineered microorganisms, we are poised to witness an exponential growth in the country based totally on our own expertise with new players constantly joining in the run. What one would like to see in the area, in national interest, is the new players producing products that are not so far produced (or not planned to be produced in the immediate future) by the existing players.

### b)Enzyme technologies:

We have done well in the enzyme technologies. The leadership is being provided by Biocon of Bangalore under the stewardship of Dr Kiran Mazumdar Shaw, and Bangalore Genii, a pioneering and highly successful company set up by Dr P

Babu, who left a successful and lucrative career in Molecular Biology to do so.

### c)DNA technologies:

Amongst various DNA technologies, India has provided outstanding leadership in the field of DNA fingerprinting. This is probably the most publicized technology in the area of modern biology developed in the country. I will, therefore, not say anything more about it except that the credit for the development of this technology that has already brought immeasurable social benefit to the country, goes to Dr Lalji Singh, the present director of the Center for Cellular and Molecular Biology (CCMB) at Hyderabad (Shantha Biotechnics Hepatitis B vaccine was also developed at the CCMB). Today in India, we also have a large number of laboratories (both in the public and private sector) with facilities for high throughput sequencing which would allow us to sequence genomes.

Pushpa M. Bhargava, one of India's most brilliant scientists, has founded and directed the Centre for Cellular and Molecular Biology (CCMB), Hyderabad. His scientific contributions include the preparation and characterization of primary liver cell suspensions, identification of proteins from the seminal plasma and extensive characterization of one of these proteins and seminalplasmin. He has been awarded with Padma Bhushan, the Legion d' Honneur, the Wattumul Memorial Prize and Goyal Prize.

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Companies such as Avesthagen set up by Dr Viloo Morawala-Patell in Bangalore, also have a high level of expertise in the development of new molecular markers for plant identification and characterization for commercial purposes. DNA-based probes for diagnosis of certain inherited disorders are already being used in the country, though there is no organization yet that would produce these probes commercially.

### d)Assisted Reproductive Technologies (ART):

Over the last ten years, there has been a mushrooming of infertility clinics which claim to have the required facilities for artificial insemination using husbands' or donors' semen, in vitro fertilization, intra-cytoplasmic sperm injection, and techniques involving egg donation and surrogate motherhood. This explosion of infertility clinics in the country has led to an immense variation in the quality of service provided, from outstanding to extremely poor. This situation led the Indian Council of Medical Research to prepare guidelines for accreditation and supervision of infertility clinics in the country. These guidelines have been debated around the country and now await appropriate legislation by the Government of India that would make the finalized guidelines mandatory. What is satisfying is that India is, by and large, at par with the rest of the world regarding ART.

### e)New drug delivery system:

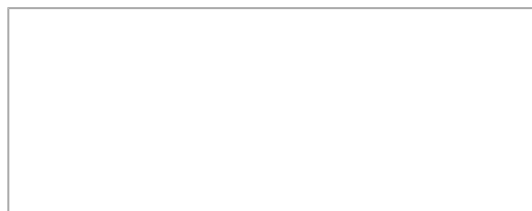
Some of the leading drug companies in India such as Sun Pharma and Shantha Biotech have been actively involved in developing and marketing new formulations which would make the intake of the drug more convenient and effective.

### f)Marine biotechnology:

The first company in the country totally devoted to marine biotechnology is Shantha Marine. The company is in the production of its first marine biotech product, Beta-carotene made by using marine algae. The product is already in the market. The expertise in this area in the country is of a very high order and, perhaps, comparable with the best anywhere.

### g)Rational drug design:

Dr Reddy's Laboratories in Hyderabad discovered a new anti-diabetic drug for the first time in the country using the rational drug design approach. The drug is now under clinical trials. There are other major pharma companies (Such as Ranbaxy and Sun Pharma) in the country that are engaged in new drug discovery using rational drug design based on advances in biotechnology and modern biology.



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#### **h)Probiotics:**

There are several companies in the country making probiotics, such as Actobacilli, as Over-the-Counter (OTC) drugs. One of them, Microbax, located in Hyderabad, is exclusively devoted to the production of such probiotics.

#### **i)Bioinformatics:**

There has been a great upsurge of activity in the area of bioinformatics in the country, in the research going on in both educational institutions and in industry. The bioinformatics group of an information technology major in the country has already identified a promising target for the development of a new drug against a most common disease in India.

Let us finally, look at the emerging areas in biotechnology, which have not yet been commercialized, and see what our country is doing in these areas.

#### **(1)Stem-cell research:**

Fortunately several major basic research laboratories in the country as well as commercial organizations are investing substantial time, energy, effort and resources in stem-cell research area. The ultimate objective of this area is being able to grow the desired organs in vitro to take care of the organ transplantation needs of the people. Some of these institutions are the CCMB in Hyderabad, the National Center for Biological Sciences in Bangalore, and the National Center for Cell Science in Pune. Reliance Life Sciences, it is believed, is also investing heavily in this area.

#### **(2)Increasing Photosynthesis efficiency:**

Unfortunately, virtually no significant work is being done in this area in the country.

#### **(3)Certain DNA technologies:**

We have not so far made any investment whatsoever in the development of DNA- based computers, the foundation of which was laid in 1994, when the well-known travelling salesman problem was solved using DNA computing. Since then, an enormous amount of effort has been put in, in this area of several countries, including Israel. We also do not have any investment today in developing antisense technologies.

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#### **(4)Use of phenomenon like circadian rhythms in developing individualized medicine:**

Although there has been at least one group—that of Dr MK Chandrashekar at Madurai (now in Bangalore) that has done outstanding work on circadian rhythms in certain animals. There has been, however, very little work done on circadian rhythms in human beings that will allow us to design individual-specific drug delivery protocols. Similarly, there is very little investment in the country in looking at certain promising new drug delivery systems such as electrical patches.

#### **(5)Vaccination using DNA:**

There is, fortunately, at least one group- at the Indian Institute of Science, Bangalore- that has been working in this area but we need expansion of research and development in this very promising field.

**(6)Nanobiotechnology:**

We haven't really made a beginning so far in this area which has immense promise in developing new and viable protocols for drug delivery, enzyme immobilization and DNA transformation.

What I have said in this and the preceding article is that we are trying to be there; we have enormous assets but we have to expand our activities in a focussed manner and use all the assets we haveâ€”human, infrastructural, natural, and financialâ€”to the best of our advantage. For this we would need to set up systems of cooperation between the various playersâ€”biotech industries in both the public and the private sector, the financial institutions and the venture capitalists, the national laboratories under the various agencies and the departments concerned of the Government. Each member of these various sectors will need to learn, to speak and interact with each other to optimize their collective output in their interest and in national interest. As of today, virtually all the efforts are in the private sector with little dialogue between the various players in this sector. There is no public sector biotechnology company in the country, even though the Department of Biotechnology was set up in 1986 precisely for this purpose. We need to have investments in biotechnology in the public sector, for what a public sector company in biotechnology can do, a private sector company cannot, and vice-versa. We should remember that the status of industry in the country in the private sector would not have been what it is, had it not been for the investment by the government in the core sectors. Certain areas in biotechnology must be regarded as belonging to such core sectors.

PM Bhargava