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Biotechnology Industries in India: Investment Opportunities*

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INTRODUCTION

The term 'biotechnology' in India includes the application of scientific and engineering principles to the processing of materials by biological agents to provide products, processes and services. Application of modern biological methods, including tissue culture raised plants, production of high-yielding cell lines of hybrid vigour, artificial seeds, development of animals of high milk-producing capacity as well as robust draught animals by use of animal husbandry practices based on embryo transfer technology and artificial insemination, preservation of embryos and gametes for longer periods, increasing the production of fish and aquatic life forms by biological, engineering and other inputs, are listed in biotechnology practices. Control of pests by biological methods and production of biofertilisers are also included. Biotechnology covers utilisation of microbes and microbial technology for the large-scale production of useful products of food and pharmaceuticals and other bioproducts. Modern biotechnology implies an understanding of the molecular basis of biological cell function and the ability of mankind to alter the cell functions to make it produce products required by society. Separation of bioproducts from complex cell debris and other

*This paper expresses the personal views of the author and does not necessarily express the views of the Organisation to which the author belongs.

mixtures in pure forms, is indeed intricate and is infallibly associated with the success or otherwise of the application of modern biology. Consequently, the complex bioseparation processes, including the production and use of associated agents, such as special gels, modified polymers etc., are also included in the area of biotechnology.

India is burdened with an increased reproductive rate, high infant and child mortality rates and comparatively lower life expectancy rates at birth. Infectious diseases take a toll of many precious lives and society has not been able to provide simple and inexpensive ways of containing diseases. The food production is no doubt increasing. However, given the low production base, the need to accelerate the speed of production requires no special emphasis. For effectively attending to many such problems, the biotechnology industry is expected to play a major role in years to come.

Some facets of status of the biotechnology industry in India have recently been reviewed [1, 2]. However there is not yet adequate generation of basic data regarding the exhaustive list of products and technologies that the country should be looking for in an effort to set up biotech. industries in its vast spectra of applications, ranging from agriculture through human health to industrial bulk chemicals (alcohols, organic acids, amino acids etc.). The Dept. of Biotechnology along with other agencies has been taking several promotional steps, including creation of a strong R&D base, training of manpower in modern biology and establishment of finer and expensive infrastructures to ease the adoption, absorption and application of biotechnologies with a view to setting up industries. Several policy options have also been promulgated to attract investors and entrepreneurs; besides institutes are being encouraged to establish greater interaction with the industry to transfer and perfect in-country research into industrial products. All these have resulted in increased interest among the entrepreneurs to set up biotech. industries. However, the current industrial base using modern biology is still quite small and it will take some time to come to the stage of real take-off, especially in the areas of animal tissue culture, animal husbandry practices, increased production of fish and prawn by biotechnological methods, genetic engineering methods of production of bioactive molecules, intricate bioproducts separation etc.

It may be realised that biotechnology innovations are not simple; they require long lead time between scientific discoveries and marketing. Although the scientific work *per se* does not require very heavy investment, the total investment prior to commercialisation is expected to be greater and greater as one moves towards the goal of marketing a product. With the commercialisation and marketing of a product or a process, the benefits of investment accrue to the investor as well as to

society. An investor is always eager to have a fair return on the investments made in R&D at the earliest. The developments in this sector for the last couple of years, indicate that the returns of R&D will not be quicker. The R&D investors, be they Government, public or private bodies, will have to wait long periods before returns start accruing. To achieve quicker success, it is foreseen that pilot-level experimentation and demonstration, with a view to establishing large-scale validation will have to be meticulously worked out with the progresses monitored carefully and continuously to cut down the application time. This process again requires substantial investment. Ultimately, many expensive experiments will yield no returns. Yet, investors have to take such venture-risks now, as in future procurement costs of on-the-shelf technologies will be enormous and often the state-of-the-art technology will not be available for purchase.

Biotechnology propounders promise profound changes in society by projecting revolutionary developments in several areas, including human and animal health, agriculture, biomass and green cover, energy, environmental protection and other industrial applications. This paper identifies certain specific areas or products in the following sectors with reference to India, where enormous opportunity exists, with reasonable possibilities of achieving success, in the setting up of modern biotechnology industries:

- Human and Animal Health
- Animal Husbandry and Aquaculture
- Agriculture
- Other Industrial Areas

The description below narrates the existing scenario, certain investment opportunities and a profile of the current R&D status in the country, with a view to generating an initial interest in the readers towards the setting up of biotech. industries in specific areas.

HUMAN AND ANIMAL HEALTH

The following subareas hold enormous opportunities for the setting up of industries, based on modern approaches:

- Diagnostics
- Vaccines
- Antibiotics
- Bioactive molecules

Diagnostics

A large number of communicable and non-communicable diseases are creating enormous health problem in this country. While many of

the diseases can be diagnosed from the disease syndrome, many others cannot be detected easily. In this connection simple, easy-to-use, inexpensive kits for early diagnosis of diseases are very relevant tools in the hands of the clinicians and pathologists. Currently, however, most of the diagnostic kits other than clinical chemistry kits are imported from foreign suppliers. The current market (1989) in terms of sales was of the order of Rs. 320 million [3], of which nearly 47.5% was clinical chemistry, about 11.6% was infectious diseases testing kits, 25.3% was for testing non-infectious diseases and other physiological states of body fluids, and the remaining 15.6% devoted to haematology and blood banking. The clinical chemistry tests comprise the bulk of the market. The area is competitive and the prices are comparable among the competitors. A large number of indigenous producers of reagents and chemicals have also entered the market. However, the least developed is the market of rapid diagnosis by immunological approaches. In this category, the largest market currently belongs to early pregnancy; detection tests, followed by tests for rheumatoid factor, hepatitis-B, certain cancer markers and hormone estimation tests. At present, there are only about 20 major companies in the diagnostic business; several large companies, however, are showing an interest in the market. The basic facilities for production have been set up in the country by only about 14 companies. Thus the industrial infrastructure is not yet adequate to support and innovate new products in India.

Realising this and concerned about the expensive scientific infrastructure already created by the Government of India, the Department of Biotechnology (DBT) took up the work of development and promotion of an immunodiagnostic market in the country through indigenous research. The DBT is working on the following lines:

- Funding R&D Institutes to develop technologies for early detection of diseases relevant to India.
- Constantly reviewing the progress in the development of techniques in disease diagnosis at various Institutes.
- Liaising with the industry to transfer the techniques from institutes to industry.
- Arranging evaluation and extending premarket support wherever necessary.
- Inducting foreign technologies in areas where indigenous capabilities do not exist and where there is a pressing need.

Through the Government efforts, indigenous technologies for kits, such as early detection of pregnancy, filariasis, typhoid fever and amoebic liver abscess, have been transferred to the industry. A foreign company is also setting up a basic manufacturing facility for producing

several modern immunodiagnostic kits, including kits for detecting sero-positives for AIDS and hepatitis-B viruses.

Based on the research leads in several Indian institutes, it is anticipated that kits for hepatitis-A, hepatitis-B, viral encephalitis, brucellosis, toxoplasmosis, malaria, leishmaniasis, tuberculosis, leprosy, cysticercosis, streptococcal infection and certain cancer markets will be available on the market during the next five years solely through the efforts of Indian Research.

The potentials of the immunodiagnostic market are anticipated to be very high based on the author's projection of the incidence of diseases and other physiological states of the body which require measurement and assessment. It is estimated that the current market (1989) for immunodiagnostic tests and nucleic acid probes (current market for the latter non-existent) of about Rs. 100-110 million could increase to about Rs. 1500-2000 million annually, if adequate promotion were undertaken. Substantial production based could also be sustained and gainfully employed. However, this issue is related to those industries making substantial investment in R&D. The research base, expected to be a blend of modern microbiology, immunology, hybridoma technology, genetic engineering, protein and oligonucleotide chemistry, polymer science, separation technology and others, has not yet been truly established by any industry in the country. The modern techniques of rapid diagnosis need a fairly sound research base to sustain a technology procured from elsewhere. For innovation and new product development, the base has to be even stronger. As such a research base is expensive to establish, several companies are expected to set up links with Government Institutes, as this would at least partly provide the initial adequate R&D support to the industry. This situation would perforce continue for sometime, until the market had grown and become appreciably larger enough to sustain an expensive R&D set-up.

With the above scenario in view, it is projected that another 10 to 20 new diagnostic companies could be formed and started up in India during the next five years. Investment requirements for individual projects would range from Rs. 5 million to Rs. 50 million depending upon the size of operation. Packages from simple clinical chemistry tests to rapid immunodiagnostic kits, nucleic acid probes, blood grouping sera, immunobiologicals, culture media etc. could be included. Dealing with sophisticated kits and reagents would invariably need the back-up of a strong R&D support, for which adequate investment options must be provided. As the Indian developments are just picking up, it would be wise to have initial tie-ups with proven technology companies, in addition to linkages with Indian R&D Institutions and Universities. As regards product selection for rapid diagnosis, detection devices for

diagnosing diseases such as streptococcal infection, typhoid fever, hepatitis-A and B, encephalitis, toxoplasmosis, rubella, chlamydiae, tuberculosis, leprosy, malaria, leishmaniasis, rheumatoid arthritis, AIDS, intestinal and hepatic amoebiasis, venereal diseases and rheumatic heart diseases could be included. The market for blood-grouping sera is also increasing fast. Similarly, demands for both prognostic and diagnostic devices for various cancer markers for cervix, breast, prostate and buccal cavity are also on the increase.

Vaccines

The country has been producing several vaccines required for treating childhood and other diseases, such as tetanus, diphtheria, pertussis (whooping cough), tuberculosis, rabies, cholera, typhoid fever, yellow fever etc. The vaccines against certain childhood diseases, such as polio, measles, mumps, rubella, viral influenza as well as other diseases, e.g. viral hepatitis etc., are not being produced in the country and the requirements are met through imports. For certain other diseases, such as leprosy, filariasis, malaria, diarrhoeal infections etc., no effective vaccines are available as yet in the world.

Taking into consideration the infrastructural set-up in the country and the steps taken by the Govt. to erect two modern vaccine plants at Bulandshahr (UP) and Gurgaon (Haryana) respectively for the production of enough polio, measles and rabies vaccines [2], there exists the need for a vaccine plant just to curtail Hepatitis-B infection, the feasibility of which is described here. To date no agency has attempted to set up facilities for the production of this vaccine in India despite the significant prevalence of this disease.

HEPATITIS-B

Hepatitis or inflammatory liver disease is a result of acute hepatocellular necrosis and is manifested in its full bloom version as jaundice, fever and other complications including hepatocellular carcinoma. There are several causative agents of hepatitis which include hepatitis A virus, hepatitis B virus, hepatitis non-A non-B causative agent, hepatic amoebiasis caused by *E. histolytica* etc. Of the various causative agents, hepatitis B viral infection is the most prevalent one. According to World Health Organisation figures published in 1985 [4], there are currently more than one billion infected people, more than 200 million carriers and nearly 2 million die every year due to this disease world over. In India according to the study of several groups, nearly 2-4% of the population are carriers. One group has estimated that at least 15 to 20 million people are carriers in India [5]; we estimate however that the numbers are larger and may be about 25 to 30 million. The prevalence of the carrier state is very high among the high-risk groups, including

the nurses, doctors, dentists, blood bank technicians and personnel engaged in blood dialysis, and could be 10 to 15%; this observation is based on limited data collected from certain hospitals in Delhi.

The modes of spread are blood and other body fluids including semen, saliva, sweat, vaginal secretion and tears. A major mode of transmission is contact with infected blood. Non-hospital spread is generally through intimate bodily contacts with carriers, use of infected needles by drug addicts and new borns acquiring from an infected mother. Post-transfusion hepatitis-B is still the major cause in hospital infection to patients, even though the blood is screened. The current screening methods are not foolproof and tested negative plasma only reduces the chance of infection but does not fully eliminate the risk. Hence the need to protect the individual *a priori* becomes more relevant.

The disease is preventable and at least two types of active immunisation products such as human-plasma-derived-vaccine as well as recombinant vaccine (expressed in yeast) are already available commercially. These products use the hepatitis-B surface antigen, a 22 nm spherical particle derived from the envelope protein of the virus and designated as HBsAg antigen, the immunising agent in humans. Merck Sharp and Dohme, USA; Pasteur Laboratory, France; and Smith Kline Beecham, Belgium are the major world suppliers of the vaccine. In India, the recombinant vaccine of Smith Kline Beecham, Belgium is consumed to the maximum extent. The current total consumption is low and could be placed at 150,000 vials (doses) annually. The future of the plasma-derived vaccine in India does not seem to be bright; therefore, only the recombinant vaccine is described here. The dose schedule is one each on the day 0, 30, 60, 365 and thereafter one between an 8 to 10-year interval throughout life or one each on day 0, 30, 180 and thereafter one after every 5 years throughout life. Based on current knowledge, three to four injections in the 1st year followed by 7 to 14 thereafter during the lifespan is expected to fully protect persons from this deadly infection. In the current context, the cost of the 1st year's treatment is more relevant and studies are in progress to decide on the actual number of doses required to be taken after one year of vaccination, following either of the above vaccination schedules.

Current single dose cost is over Rs. 300 and is considered expensive. Because of this, the annual total number of persons presently receiving injections in India is estimated at forty to fifty thousand. However, considering the prevalent incidence rate and having regard for the vulnerable population at large, the sale could be substantially increased to 1.5 to 2 million doses per annum. If the product could be made available at an affordable price range for its inclusion in the Expanded Immunisation Programme of the Government, the annual demand

could be pushed to 70 to 100 million doses per annum. The market potential is thus enormous.

Several approaches are being worked upon worldwide for producing this vaccine by recombinant methods in *E. coli*, mammalian cells, hepatoma cell lines, vaccinia virus and SV-40 in mammalian cells. Production of synthetic antigen peptides is also being tried. There will be a breakthrough in years to come and progress in several places should be instrumental in a substantial price reduction. The current recombinant vaccine is a non-secreted protein produced in yeast. Recombinant yeast cells grown in controlled fermentation tanks are separated, the cells disintegrated by glass beads and the desired protein subjected to hydrophobic adsorption, ion-exchange chromatography and gel-filtration. Assuming the recovery of the desired protein from the disintegrated yeast cell soup at 30%, a rough estimate has been made on the project cost of a plant of a capacity of 2 million doses per annum. It is estimated that such a plant would cost around Rs. 80-150 million excluding the cost of know-how, and the cost of production per dose may be between Rs. 12 to Rs. 20. The project thus looks substantially profitable.

VACCINES FOR OTHER DISEASES [2]

Several other diseases, such as malaria, leprosy, filaria, tuberculosis, certain diarrhoeal disorders etc., are creating an enormous national problem. The research activities for these diseases and others indicated earlier have been intensified at many fronts and some progress has also been achieved. A genetically engineered vaccinia virus which imparts protection against rabies has been developed which has given one hundred per cent protection to dogs in one injection; further trials are in progress. Work is being done to control fertility in women by immunological approaches. An hCG vaccine for conferring infertility to women on a reversible basis has completed Phase-I clinical trials and Phase-II trials have been started. An FSH-Vaccine for conferring sterility in men is also being developed and the vaccine has shown good protection in primates. Phase-I clinical trials are being started in men on this product soon. Work is progressing satisfactorily on the development of leprosy vaccines in three institutes in the country; one of the leprosy vaccines under development has shown protection against tuberculosis also and could be tried extensively for examining its efficiency in protecting humans. rDNA vaccine expressed in vaccinia virus for protection against hepatitis-B has been developed and is being tested in primates. An animal birth-control injection called 'Talsur' has been developed for the sterilisation of male animals. The product has been found to induce complete sterility in bulls and dogs with or without

loss of libido. The products, after satisfactory final stage of evaluation, was cleared by the Drug Controller of India for its introduction into the market. The product shall be marketed by M/s. Karnataka Antibiotics & Pharmaceuticals Ltd., Bangalore soon.

POULTRY VACCINES

In the field of veterinary vaccines, at present there are 17 state-run production centres in addition to the Indian Veterinary Research Institutes and some private companies which are catering to the needs of the country. In this paper only the poultry area has been enumerated. The poultry population as of now and as expected by the end of 1994-95 is given in Table 1.

Table 1: Poultry population (million numbers)

Category	Current (1989-90)	At the end of 1994-95
Broilers	150	250
Layers	100	110
Breeders (Broilers)	1.6	2.5
Breeders (Layers)	1.4	1.5
Total	253	364

Several poultry diseases, such as the newcastle disease (ND), avian infectious bronchitis (IB) fowl pox, infectious bursal disease (IBD) also known as gumboro disease, infectious coryza, Marek's disease (MD), fowl cholera (FC) etc., create enormous economic loss to farm holders once an outbreak occurs. Large poultry farms cannot take chances and vaccinate the birds with the appropriate vaccines available for protection. For protection against Newcastle disease, live vaccine formulations based on LaSota as well as R2B strain are commercially available. Similarly, for protection against IB, MD, FC and IBD, live vaccine formulations using appropriate viral strains are being used; vaccines based on killed organisms are also available. For protection against coryza, inactive or killed organisms are used. A combination of some of three vaccines is also available commercially in live and/or inactive (killed) forms.

The common poultry vaccines currently used for maintaining a poultry industry with the existing requirements as well as those by 1994-95 are given in Table 2 [6].

Although these vaccines are being produced in the country, the indigenous availability is inadequate. Moreover, only a few companies are monopolising the market. It is felt that there is adequate scope for the setting up of a new plant with a total overall capacity of 1000 million

Table 2: Poultry vaccines (million doses)

Type	Existing requirement (1989-90)	Requirement by 1994-95
LaSota (L)	505	720
R2D strain	103	110
Combined (L + IB)	253	360
ND killed	103	110
Avian infectious bronchitis (IB)	103	360
IBD killed	103	110
Fowl pox	103	110
Marek's disease	253	360
Coryza killed	103	110
Fowl cholera	3	4
Total	1632	2354

Table 3: New plant economics

1. Capacity: 1000 million doses per annum.
2. Estimated investments: Rs. 80 million.
3. *Estimated value added:*
 - Turnover at 100% capacity utilisation with current retail rates of vaccines: Rs. 120 million.
 - Turnover, allowing a discount of 30% to distributors and retailers: Rs. 84 million.
 - *Bought-out inputs:*
 - Raw and packing Materials: Rs. 30 million
 - Utilities: Rs. 5 "
 - Total: Rs. 35 " Rs. 35 million
 - Value added: (on bought-out items):
 - (a) At current retail rate: 242%
 - (b) At estimated manufacturer's recovery rate: 140%

The retailers turnover has been calculated based on the existing selling prices of products.

doses, with product mix to be adjusted in accordance with the market requirement. A rough estimate of the economics of such a plant is given in Table 3.

It can be seen from Table 3 that the added value at the manufacturer's level is very high and is an indication of clear high profit, making an industrial proposition.

Antibiotics

In this area India already has a large production base. Currently, there are ten fermentation plants producing 12 antibiotics from the basic stage. The antibiotics produced through fermentation include potassium penicillin G/V, streptomycin, tetracycline, oxytetracycline, chlorotetracycline, demethyl chlorotetracycline, erythromycin, gentamicin, kanamycin, griseofulvin, hamycin and aureofungin.

In total, about 30 different antibiotic molecules are used for formulation purposes including the above; several of these are semi-synthetic betalactams derived from 6-APA and 7-ADCA, which are being produced within the country. Large quantities of rifamycin are also being produced from imported late intermediates, such as Rifa-S and 3-Formyl Rifamycin-SV.

The consumption and demand of the large volume or higher value bulk antibiotics during the recent past along with estimated current and future demands are given in Table 4 [2].

Table 4: Consumption/demand for bulk antibiotics

Antibiotics	Units	Consumption during		Estimated demand during	
		1986-87	1987-88	1990-91	1994-95
Penicillin by fermentation	MMU	715	1050	1880	3040
Tetracycline	MT	185	215	255	310
Oxytetracycline	MT	91	153	165	200
Gentamicin	Kg	2341	4365	6050	8860
Erythromycin	MT	42	43	75	100
Rifampicin	MT	100	120	180	300
Cephalexin	MT	25	30	80	140
Injectable cephalosporins	MT	6	10	15	25
Ampicillin (oral and injectable)	MT	326	429	480	840

Two of these products are discussed further with reference to future investment potentials.

PENICILLIN

Table 4 clearly reveals that there is going to be substantial demand by 1994-95; this is going to increase further by 2000 AD. The four existing plants in the country have in total a capacity of 1080 MMU and produced about 745 MMU during 1989-90. There will be a gap of around

2000 MMU by 1994-95 and 5000 MMU by 2000 AD, if the existing units do not expand and new units do not come up. In this context, assuming three to four years as the gestation period for the setting up of a large plant, there is scope for the setting up of two to four new units, each of capacity 1000 MMU/a, taking into consideration the possibilities of substantial expansion of the current units. A rough estimate of the project cost of a 1000 MMU/a plant at current rates would be Rs. 900-1000 million and the profitability picture is expected to be given in Table 5.

Table 5: Estimated cost of a 1000 MMU/a plant

Assumptions:	Fermenter productivity: 125-130 BU per kilolitre of installed fermenter volume per month.
	Recovery efficiency: 85-88%
Estimated project cost:	Rs. 900-1000 million
Cost of production:	Rs. per BU
(100% capacity utilization):	
Raw materials	200
Utilities	150
Conversion cost	70
Dep. & interest costs	80
Cost of sales (Total)	500
Current selling price	723

Thus there are possibilities of good return on the investment. However, the landed cost of imported material is around Rs. 280 per BU. Indigenous plants are therefore to be price-protected against imported materials, which is already being done by the Govt.

RIFAMPICIN

Nearly 35% of the world consumption of this drug occurs in India [7], yet there is no basic production unit in India. A 100 TPA plant could be set up with the investment and profitability projections as given in Table 6.

The project would thus succeed if the indigenous costs are protected.

Some issues for new investments

The investment scenario for the setting up of antibiotic plants holds opportunities as well as risks mentioned below. While there is a firm fermentation culture and infrastructure in the country, most of the technologies in vogue are not yet internationally competitive nor are contemporary technologies available, as is evident from Tables 7 and 8. The figures have been calculated based on information in reference [2] and other information available with the author.

Table 6: Estimated cost of 100 TPA plant

Assumptions:	Productivity of strain 35-36 kgs of Rifamycin B per kilolitre of installed fermenter volume per month
	Recovery/Conversion (from Rifamycin B) efficiency of Rifampicin: 60%
Estimated project cost:	Rs. 650-700 million
Cost of production:	Rs. per kg
(100% capacity utilization):	
Raw materials	3400
Utilities	400
Conversion cost	250
Dep. & interest costs	950
Cost of sales (Total)	5000
Estd. selling price	5500
Current landed cost	3600

Table 7

Antibiotics	Net productivity (finished antibiotics produced in kgs per kilolitre of installed fermenter volume per month)	
	India	International
Penicillin G/V 1st Crystals	40-55	70-90
Tetracycline	35-45	55-60
Gentamicin	2-2.4	4-5.8
Erythromycin	8.5-10.3	15-17.5

Apart from lower productivity, the input materials and utilities are also expensive—the raw materials are about 2 to 3 times the international prices and the utilities are about 1.5-2.00 times more expensive. The cost of capital is also more in India. Besides, the indigenous plants are also comparatively smaller in size. Thus the costs of antibiotics produced in India are 2-2.5 times more than the international costs, as can be seen from Table 8.

Table 8

Bulk Antibiotics	Units	Indian price (US dollars)	International price (US dollars)	Ratio
Pot. Penicillin G/K	BU	40	15	2.67 : 1
Tetracycline HCl	Kg	53	25	2.12 : 1
Erythromycin stearate	Kg	120	50	2.40 : 1
Gentamicin sulphate	Kg	736	300	2.45 : 1

Against this background, one can imagine how much pressure an antibiotic fermentation industry is subjected to for mere survival against competition from border prices. The foreign suppliers impose constant pressure and threat to the very existence of this industry in India because of their comparatively competitive and lower prices. In India there is a Drugs Prices Control Order promulgated by the Government. So far the Government has been deliberately protecting the indigenous manufacturers by protecting their costs. Constant pressures have also been put by the Govt. simultaneously on the industry to be competitive, and this has been reflected in the fixation of prices by resorting to normated consumption coefficients of inputs and plant capacity utilisation based on the performance of efficient units. The situation of competitiveness has thus improved the efficiencies of technologies as well as performances to some extent in India; yet this situation is far from the international standards and Indian manufacturers have found no way to become internationally competitive in costs. The best technologies have also not flown into the country and Indians have had to be content with what was available. In this context, therefore, the following issues are most relevant to the new investors:

- Whether the investors are assured of adequate returns on their investment.
- Whether there would be adequate price protection to the Indian investors.
- Whether the imports would be restricted or regulated to the advantage of Indian companies.
- Whether new fiscal incentives would be worked out to promote investments in India.

Unless many of these issues are resolved to the advantage of the investors, it is doubtful whether adequate new and fast investment would take place in this sector, even though *prima facie* opportunities would exist for investment.

Need for strengthening R&D base

In this connection there is also an urgent need for strengthening the research base in this sector. It may be mentioned here that production of antibiotics is highly science-based, and all the units existing in the country have some infrastructure of research activities. In fact, by utilising in-house infrastructure, the strain potencies of penicillins were increased from about 2000 units per millilitre in the late 1950s to about 20,000-22,000 units per millilitre by the early 1980s. Similarly, the strain potency of tetracyclines was raised from 3,000 units per millilitre in the early 1960s to about 25,000-30,000 units per millilitre

by the late 1980s. The strain improvement work was achieved by employing conventional and mutational techniques. The Indian developments, however, remained behind in competition with the international companies who had, in the meantime, improved their productivities much more.

Gene-cloning techniques, especially in *Streptomyces*, have made encouraging achievements only recently [8]. This technique has made it possible to clone antibiotic biosynthetic pathways region or portion to other suitable hosts. By this process, genes are being characterised, resistance genes identified and new antibiotics or hybrid antibiotics are being created. Biosynthetic genes for individual antibiotic compounds produced by streptomycetes are clustered together [9]. There have been reports of extensive homology between the putative polyketide synthetase genes in the *Streptomyces* species [10]. The polyketides in extensive use are tetracyclines, erythromycin, rifampicin, anthracyclines etc. Research work on improving the strains by genetic engineering methods as a complement to traditional approaches has not yet started in this country. It is necessary that we eventually construct economically viable potent expression systems in *Streptomyces* or any other species so as to increase the various Indian industrial strains at least to the level of international productivity. With the infrastructures the country already has in the industry as well as in the institutes, this can easily be initiated now. Govt. of India from the Dept. of Biotechnology has, in fact, already initiated actions for strengthening the R&D base of two public sector undertakings (to start with) by funding substantial sums to undertake research in strain improvement as well as to improve the downstream recovery processes. Such initiatives are expected to motivate other companies in India to divert more funds for research activities.

Bioactive Molecules

Several bioactive molecules, especially those indicated below, will be consumed in large quantities in the country in the near future; some are already being consumed in notable quantities:

- Insulin
- Interferons
- Interleukins
- Human growth hormone
- Bovine growth hormone
- Human chorionic gonadotropin
- Erythropoietin
- Streptokinase
- Urokinase

- Tissue plasminogen activator
- Epidermal growth factor

Discussion here is limited to insulin only. Bulk insulin is produced in this country by M/s. Boots (India) Ltd., Bombay. The Company uses the pancreas of slaughtered animals. Usually bovine and porcine pancreases are used as the insulin source and almost the entire quantity is imported; about 1 to 5% is supplemented from indigenous slaughter houses from time to time.

M/s. Boots (India) Ltd. convert their entire bulk into formulated insulin and sell it in the Indian market. Besides this company, M/s. Synbiotics Ltd., Baroda markets highly purified human insulin in the country, based on imported finished vials. M/s. M.J. Pharmaceuticals, Gujarat and M/s. Torrent Laboratories, Ahmedabad produce vialled insulin from imported bulk insulin.

The current consumptions and also the projected demand during 1994-95 is indicated in Table 9 [11].

Table 9

Year	Bulk Insulin (MU)	Bulk Insulin (equivalent kgs)
1986-87	2352	94
1987-88	3198	128
1990-91	4930	197
1994-95	7210	288

The projections in Table 9 are based on steady production rates during the last couple of years. However, when one looks at the rates of increase in the insulin-dependent diabetic population, stated to be increasing by 3-5% in the world every year and the incidence of which is placed at 3.5-4.0 per 1000 population in India, the real number of the insulin-dependent diabetic population could be placed at 2.8-3.2 million. Assuming a daily dose of 30 to 40 IU per patient per day, the requirement of bulk insulin works out between 1350 kgs to 2050 kgs. This indicates the potential real demand of this bulk drug in the country.

Formulated insulin is sold in the market in 10 ml vials, usually with a potency of 40 IU per millilitre as the major formulation although other potencies are also available. The prices of these commonly available vials are as given in Table 10.

Table 10 shows the wide difference in price of bovine/porcine insulin versus human insulin. It has been reported that long use of bovine/porcine insulin produces antibodies and it becomes inactive. Moreover, it produces allergic manifestations in some patients. The possibilities of such complications are less with human insulin.

Table 10

Type	Price per 10 ml vial (40 IU per millilitre)
Plain Human Bovine/Porcine Insulin	Rs. 16.85
Plain Human Insulin (rDNA)	Rs. 77.50
Lente Bovine/Porcine Insulin	Rs. 16.90
Lente Human Insulin (rDNA)	Rs. 79.50

Considering the actual demand for insulin in the near future, as indicated above, there is scope for setting up new units with capacities ranging between 100 to 300 kgs per annum. Setting up a bovine/porcine-based insulin factory has the following limitations:

- Adequately potent and properly preserved animal pancreas to be obtained in large quantities.
- A good technology to be procured.

Although India has the largest cattle population and several piggeries, the slaughterhouses are not adequately geared to collect the pancreas, which has to be isolated within half an hour after slaughter and preserved at subzero temperature in deep freezers. Moreover, as usually aged animals are slaughtered in India, often 10 to 15 years of age, the insulin content in the pancreas is exorbitantly low, of the order of 800 to 1200 IU per kg, compared to the pancreas obtained through imports at 5000 IU per kg and often as much as 10,000-12000 IU per kg. Obviously, the animals are slaughtered between 18 to 36 months of age. To set up a production unit, therefore, the unit would have to resort to imports of pancreas, which is not currently abundantly available. As regards procuring efficient technology for animal-pancreas-derived insulin production units, there are several international companies who would be willing to part with it on reasonable commercial terms. The problem is really the availability of enough potent pancreases.

In view of the problems associated with the procurement of animal pancreas and being aware of the side effects of animal insulin, companies should resort to exploring only the possibilities of procuring human insulin technology in India. Human insulin is being made internationally by two methods. A chemical transformation of porcine insulin, commonly known as transpeptidation reaction, leads to pure human insulin. This method again is dependent upon obtaining enough porcine pancreas as porcine insulin has to be produced first. A second method is production by recombinant DNA technology using either *E. coli* or yeast as the production organism. Currently, rDNA technology is known to be available in the hands of the following agencies only:

- Eli, Lily, USA
- Novo-Nordisk Industries, Denmark
- Hoechst, Germany
- National Antibiotic Research Institute (Moscow), Russia

Only two of the above, namely Eli Lily and Novo, have introduced their products in the market. They are not quite willing to part with their technology just now.

Under the circumstances, one option is to develop the technology in India, using published research results. Many agencies are at work but the success level is not yet known. The other approach is purely commercial and it is thought that this could be explored. India has a strong base of pharmaceuticals including injectables. The machinery, manpower, the raw and packing materials are available in abundance for these activities. An injectable insulin formulation unit built in India up to the FDA (USA) standards would be cheap and the unit cost of products would be internally competitive. A rough calculation for setting up an injectable formulation unit (using procured bulk insulin) with a capacity of consuming 200 kgs of bulk insulin annually, works out to about Rs. 80-100 million. If such a unit were set up in collaboration with either of the above producing units, initially for export market or for both export and internal markets, with the condition that eventually the basic production technology would be passed on to the Indian

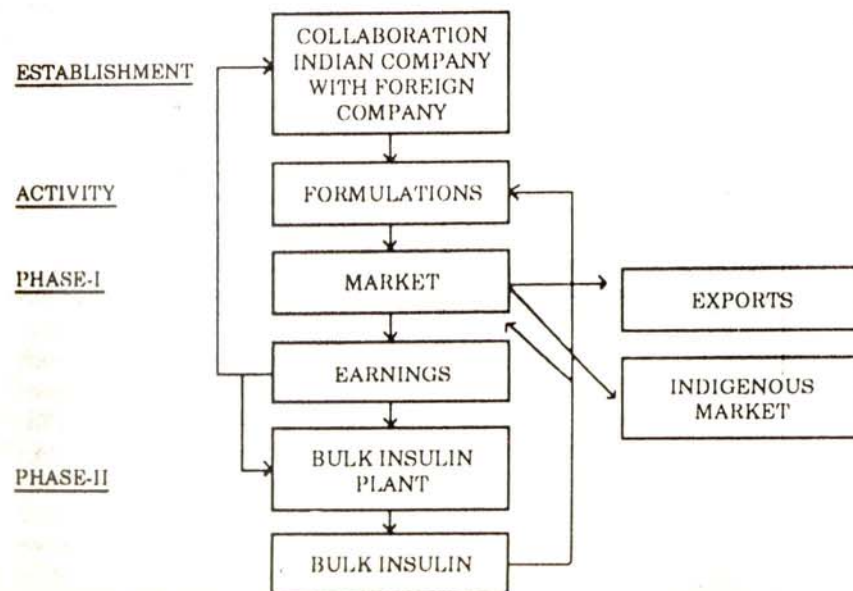


Fig. 1: Induction of insulin technology: a strategy.

company, this should work out well to all the parties concerned purely on commercial considerations. India has several advantages in creating an export market in certain countries and such markets are large. The proposal should therefore attract the foreign companies solely on business merits. The proposal is outlined in Fig. 1.

Given the fast world developments in rDNA technology in several countries, such technology should be in the possession of many others, either through their own developments or through transfer, within another 5 to 10 years. While induction of technologies through such developments is expected to take its time, it is felt that the above process could cut down substantially the time for India's possessing the basic technology, which is direly needed.

ANIMAL HUSBANDRY AND AQUACULTURE

Animal Husbandry

This area constitutes an important means of rural employment and income. Currently, this sector contributes around Rs. 21630 million annually, accounting for 24% of the gross agricultural output. About 70% of this income comes from milk and milk products, 8.8% from poultry and 7.8% from dung for fuel. The current level of products from livestock is estimated at 51.5 million tonnes of milk, 20 thousand million eggs, 43 million kgs of wool and about one million tonnes of meat. In addition, the value of draught power is estimated to be of order of Rs. 5000 crore annually [6].

As production of milk and draught power constitutes the major inputs of this sector and as demand of these are going to substantially rise (e.g. targeted milk production by the end of the 8th Plan is 63 million tonnes and by 2000 A.D. is 80 million tonnes), programmes have been drawn up to produce high milking cows and buffaloes by Embryo Transfer Technology (ETT) and Artificial Insemination (AI). The present average milk yield per lactation (305 days) per cow/buffalo of 400-800 litres is to be raised to nearly 2500 litres. In fact, the Holstein Friesian cow can produce 4500 to 8000 kgs per lactation if properly managed. This breed is making a significant impact as a donor for cross-breeding and an increasing number of farmers and institutions are using this breed or its crosses for commercial milk production.

ETT includes collection of fertilised eggs from the donor elite females and their transfer to the uterus of recipient females in 'heat'. Techniques for multiple ovulation of donor elite females have been near-perfected by sequential treatment of the animals with required doses FSH and LH followed by normalising the animals with LHRH after every cycle. Currently, to obtain about 50 embryos per donor cow per

year is a near reality in India. In buffaloes, however, so far only 25-30 embryos have been obtained per year per donor.

Before normalising the animals after superovulation, the embryos are fertilised within the animals by artificial insemination with sperm from the progeny-tested sires. Subsequently, the fertilised eggs are withdrawn by flushing the uterus with normal saline and preserved in deep freezers until used for inseminating the foster mothers in 'heat'.

The entire gamut of ETT and AI has not yet been fully perfected. The current advances have provided success up to about 30%. Indications are, however, that within a couple of years substantial perfection shall be achieved. It is estimated that to raise milk production to 80 lakh tonnes from the current level by ETT cows/buffaloes, nearly 48 million embryos would be needed to generate over 8 million female animals.

Success would generate two distinct kinds of industrial activities in the country. In one type, profitable commercial dairy farms would be set up with herds strengths of as small as 25 animals to as high as 500 or more animals. Small farms would be economically viable if properly managed and would cost around Rs. 3 lakh per set-up. Ten to fifteen thousand such small dairy farms could be profitably set up throughout the country during the next decade. In addition, another one thousand farms, each containing 500 animals, may also be needed to cope with the requirement of additional milk. The potential is thus enormous. Besides the setting up of dairy farms, other activities of generating elite embryo banks, elite cows and buffaloes, and inseminating foster mothers in 'heat' with elite fertilised embryos would also be prominent industrial activities. The country is gradually but steadily making R&D moves towards this direction. It is anticipated that several hundred crores of investment shall take place in these areas within a decade, although currently this activity for economic gains is non-existent.

Aquaculture

Field demonstration projects for increasing the production of carp from the current productivity of less than 5 tonnes per hectare per year to at least 10 tonnes per hectare per year, going up to 25 tonnes per hectare per year, has been taken up by the DBT. Once the technology package is perfected, it will be made available to the farmers. Similarly, demonstration projects for increasing the shrimp production from 0.5 tonne per hectare per year to 8-10 tonnes per hectare per year has been taken up at Nellore and the initial results are encouraging. Work is being pursued on feed development, production of hybrid high-yielding, disease-resistant varieties of carp by genetic selection and post-harvest processing of carp and shrimp. Technology packages are expected to be ready within a couple of years.

While good developmental work has been done on carp in India, semi-intensive or intensive shrimp farming is not yet established. The Dept. of Biotechnology therefore took up a field demonstration project in Nellore District of Andhra Pradesh in June 1990. This is a 3-year project being implemented by MPEDA. Based on the initial results of this project, the estimated cost and profitability of a small shrimp farm in an area of 5 hectares has been estimated as shown in Table 11.

Table 11

(a) Shrimp Farm area:	5 hectare
(b) Total Investment:	Rs. 35 lakhs
(c) Assumption:	— Yielding 9 MT of shrimp per hectare per year in two crops. — Ex-farm selling rate, Rs. 90,000 per MT.
(d) Total Output at full capacity:	Rs 40.5 lakhs.
(e) Cost of Sales:	Rs. Lakhs
	Seed Cost 4.50
	Feed Cost 14.00
	Fertilisers Cost 0.30
	Power and Fuel 1.00
	Salaries & Wages 2.50
	Repairs & Maintenance 1.50
	Overhead Cost 5.00
	Depreciation @ 10% of Capital Cost 3.00
	Interest Cost 4.45
	Harvesting & Marketing 0.70
	<hr/> 36.95
(f) Return on Investment	22%
(g) Net Profit on Ex-factory Sale	9.6%
(h) Tax Payable	NIL

If the project of the DBT is successfully demonstrated, it is anticipated that more than 150 hectares of semi-intensive shrimp farming capacity shall be set up during the next five years.

AGRICULTURE

Conventional as well as modern biotechnological methods have been applied by a number of agencies in India over the last one-and-a-half decades to increase agricultural production. The efforts cover field application as well as R&D. The Green Revolution of the 1970s was the most significant result of Indian agricultural sciences. The recently introduced areas of modern biotechnology include hyperproduction of

high-yielding oilseeds, tissue culture of elite plant materials, including fruit plants, forest plants, vegetable and other economically important plant materials, such as flowering plants, orchids etc.

Realising the dire edible oil shortage, an Oil Palm Demonstration Project has been taken up [12] to field-demonstrate the productivity of oil at 3-4 tonnes per hectare per year. Both elite seeds as well as tissue culture raised oil palm are being planted at three locations in Andhra Pradesh, Karnataka and Maharashtra. The net annual income per hectare of cultivated land under oil palm is expected to be between Rs. 25,000-35,000. Currently, oil palm is scarcely being cultivated in the country and the productivity is low. Once the field demonstration is successful and establishes higher productivity, it is expected that oil palm cultivation will be widely practised, which would reduce the edible oil shortage. The current productivity of edible oil using ground-nut, mustard and even sunflower/safflower seeds is not more than 1.0-1.5 tonnes per hectare per year and the general productivity is less than a tonne.

The cardamom yield in India is around 50-60 kgs per hectare per year although higher productivities of above 250 kgs have been obtained in some fields. Currently, high-yielding clones with a yield potential of 300-400 kgs per hectare, going up to 600 kgs per hectare per year are available. Using tissue culture techniques, high-yielding clones have been produced by a commercial company and are being field tested at several demonstration plots over an area of 100 hectares located in three states namely, Kerala, Karnataka and Tamil Nadu. The field demonstration results will be converted into cultivation packages and offered to individual cultivators.

For faster development of modern agriculture and for inducting foreign technology, activities related to production on hybrid seeds and tissue culture propagation of plants were classified as industrial activity in December, 1986 [13]. This resulted in a flow of foreign technologies. Currently, licences have been obtained by about a dozen companies for the production of hybrid high-yielding seeds as well as tissue culture propagation of elites in various areas of agriculture.

With this background of developments in agricultural biotechnology, one important area is being highlighted, namely floriculture. It is anticipated that there is ample scope for fresh investments. According to published information, the annual floriculture trade [14] worldwide during 1986 was as shown in Table 12.

The business mentioned relates to (a) creation of facilities for mass production of tissue culture raised flowering plant materials and

Table 12: Annual trade in floriculture (1986)

Country	Million US \$
Netherlands	1900
Colombia	420
Thailand	300
Others	380
Total	3000
India's share:	Less than 1 million US \$

(b) setting up of flower farms by using elite genetic materials. The objectives of such activities could be as under:

- Mass production of true-to-type, disease-free flowering plants and ornamentals.
- Increase in the productivity of high-quality plants in fields.
- Export of planting materials and flowers.
- Development of Indian Floriculture Industry.

Highly productive disease-free plants have recently been imported into the country with the following CIF prices per plant (Table 13). The table also indicates the plant density per hectare and the estimated cost of plantation in a hectare [15].

Table 13: Selected varieties of flowering plants, CIF prices and plantation cost per hectare

Flowering plants	CIF prices* per plant (Rs.)	Plant density per hectare (in 000 nos.)	Cost of plantation per hectare (Rs. million)
Alstroemeria	80.00	60	5.66
Anthurium	80.00	60	5.66
Carnation	40.25	230	10.92
Chrysanthemum	1.95	300	6.90
Freesia	4.00	960	4.53
Gerbera	22.00	70	1.82
Gladiolus	3.00	230	0.81
Rose	37.00	70	3.06

* In addition 15% customs duty and some clearing charges are leviable.

Table 13 indicates a very heavy initial investment for the setting up of a flower-producing farm. Such initial investment would make the flowering farm proposal economically unattractive. However, if such plants were raised in India, they would be much cheaper, of the order of Rs. 1 to 4 per plant depending upon the species, with adequate profit margins to the plant raisers (in the field).

A tissue culture laboratory with a capacity of 5 million plants per annum would have the following investment and profitability picture (Table 14).

Table 14

Plant capacity:	5 million nos./annum
Project cost: (excluding know-how cost)	Rs. 20-22 million
Profitability picture: (@ Rs. 4/-per plant & 80% capacity utilisation)	
<i>Particulars</i>	<i>Rs. million/annum</i>
Raw materials	1.60
Utilities	1.20
Salary and wages	1.20
Overheads	1.00
Depreciation & interest charges	3.00
Selling expenses	2.00
Cost of sales (Total)	10.00
Estd. sales realisation	16.00
Gross profit before tax	6.00
Tax	Nil

There are several collaborators in Europe who are looking for Indian partners, as the variable production costs in Europe are becoming exorbitant, especially because of increased wage costs. It should be possible to identify collaborators with 100% buy-back arrangements at least for the initial 3 to 5 years. If this could be clinched, excellent business propositions could be worked out and a dozen of factories could be set up in different parts of India. Even if initial tie-ups for export sale do not materialise, the prospects of such projects should not be belittled as the opportunity for exports is going to be brighter during the next decade.

As regards the setting up of farm houses for producing cut flowers, a rough estimate of profitability for the setting up of a one-hectare rose plantation has been made. Assuming planting density of 70,000 per hectare with the rate of Rs. 4 per plant, the fixed investment of the farm may work out to around Rs. 13-15 lakhs. This includes the cost of land (with land developments and fencing charges), farm buildings, farm house implements and the stocks of rose plants. The annual running cost, including interest and depreciation, is estimated at Rs. 10-10.5 lakhs. The return on investment is expected to be over 30% and the net profit after providing for interest and depreciation is expected to be over Rs. 3 lakhs annually at full capacity utilisation. As and when the tissue-culture facilities come up in the country, it is anticipated that 1000-1500 nos. of small and medium cut-flower farms shall come up in India during another 10 years' time.

OTHER INDUSTRIAL AREAS

In this sector only the areas of industrial enzymes are discussed. Enzymes have been extensively used throughout the world in various sectors; major industrial areas are listed below:

- Detergents industry
- Starch: liquefaction saccharification and isomerisation
- Cheese making
- Processed fruit juice
- Desizing in textiles
- Processed protein food
- Tannery; batting, soaking and unhairing
- Oils and fats
- Alcohol and brewing
- Pharmaceuticals

All the areas in India have some application of enzymes except the first one, namely the detergents industry. This area is therefore discussed here.

Production of detergents in India during the last three years and the estimated demand for 1994-95 are given in Table 15 [16].

Table 15

Category	Production ('000 MT) during			Demand for 1994-95
	1987	1988	1989	('000 MT)
Powder/Cake/Liquid	800	950	1050	1420
The prices per kg of common detergent powders sold in the market are as under:				
Name	Price per kg			
Nirma	10.00			
Wheel	10.50			
Fena	11.50			
Surf	31.00			
Det	29.00			
Key	20.50			
None of these contains enzymes.				

Detergents containing enzymes have been in use elsewhere since around 1966. Typically detergents contain 0.5 to 1.0% of certain enzymes. Four different types of enzymes listed below are in use:-

- Proteases
- Amylases

- Lipases
- Cellulases

Usually, the first two enzyme types are in maximum use. The enzymated detergents work efficiently even at lower washing temperatures. The overall performance, however, depends upon the detergent composition, enzyme content, pH, temperature of washing, washing time, types of textiles and nature of soiling. Everything being equal, enzymated detergents show much better results than the enzyme-free ones.

Currently, nearly 85% of the detergents used in Europe contain enzymes, 70% in Japan and 50% in the USA. There is some use in Latin American countries and the Middle East.

As regards the Indian scenario, considering the current per kg price of detergents and taking note of the fact that washing machines are being increasingly used, especially in cities, if a new detergent-enzyme formulation could be introduced with a price tag between Rs. 12 to 20 per kg, it is anticipated that such a formulation would capture substantial portions of the current enzyme-free detergent formulation market.

INDUSTRIAL CLIMATE

Industrialists have become aware of the commercial potential of biotechnology. Several multinational companies have teamed up with Indian companies/counterparts to set up industries. Currently, however, emphasis is on developing the market by selling imported products. In a few areas, such as plant tissue culture, production of vaccines, diagnostics, antibiotics, enzymes, drug delivery system etc., basic technologies are coming to the country.

The Government of India accepts foreign investments in high-tech. Areas of biotechnology to acquire advanced current technologies. Collaborations, joint ventures and other commercial relationships are welcomed. The FERA, 1973 allows foreign equity up to 40% which can even be raised in deserving cases.

Licensing arrangements allow royalty levels up to 5-8% for 5-7 years on ex-factory sales in deserving cases, besides allowing lump-sum payment of technology fees.

In December 1986, manufacturing activities involving tissue culture propagation of elites as well as production of hybrid seeds were considered as Appendix-1 activity under the I (D&R) Act, 1951 [13]. This boosted the flow of foreign technology in these areas in the country. This concept needs to be extended to animal husbandry and aquaculture so that latest technologies in these areas could also flow into the country through industrial activities. These would also enable large companies

to enter into these businesses and thus large managerial, financial as well as research inputs would flow into the system.

Besides these, in order to catalyse the transformation of institutional knowledge into products, processes and technologies usable by the industry, the Government from the Department of Biotechnology is trying to institutionalise a concept of bringing together the entrepreneurs, academia, industry, financial institutions and the other Government bodies together in the form of a Consortium, which is currently being commonly termed as the Science-Industry Consortium in Biotechnology. The following, *inter alia*, are the main objectives of the Consortium:

- To catalyse the interaction among the R&D institutes, academia, financial institutions, NRI scientists and Government department with the objective of developing product concepts and furthering such concepts into goods and services through industry.
- To develop one-to-one tie-ups with the industries, entrepreneurs and R&D institutes along with financial institutions.
- To enable leasing and renting of national facilities for product and process development.
- To produce Pre-Feasibility Reports (PFRs) and Detailed Project Reports (DPRs).
- To become economically self-supporting at least in certain areas of priority within a time-frame.

A number of institutions, such as NRDC, and the venture capital 'windows' of several financial institutions, such as IDBI, TDICI, RCTC and others that seek to facilitate the transfer of technology, do not really have the specially interactive cohesive partnership of the scientific institutions, universities, industry, financial institutions and the Government Departments. Consequently, the existing structure of institutional technology transfer to the industry does not force through prompt solutions to the various difficult problems that are encountered in the interactive chain of research, market studies, technology development, testing, certification and finally forging commercial success. The Consortium is expected to bring about quicker solutions to many stumbling problems that would obstruct the transformation of research into products. The Consortium would be specially active in reinforcing the links among the entrepreneurs/industry and research institutions would be involved in the preparation of PFRs and DPRs and would thus minimise the risks of substantial investment at every crucial stage of development of a project. The Consortium incorporated under the name M/s. Biotech. Consortium Indian Ltd., New Delhi, has been promoted by

the financial institutions and the industry, and has been supported by the Government, especially by the DBT.

CONCLUSION

So far promotion of modern biotechnology in India has mainly centred around the creation of an R&D based and infrastructure as well as manpower development. These were done to ease the application of modern biology and biotechnology.

Awareness has been created, mainly by the Government agencies, among the people as well as industrialists regarding the importance of biotechnology in India. This has resulted in definite interests of the industrialists to go in for modern biotechnology industries. Industrialists have perceived the potentials and are steadily envisioning the areas of immediate relevance and returns. These include hybrid high-yielding seeds, tissue-culture plant materials, diagnostics and vaccines, new antibiotics, bioactive molecules etc. The industrial climate is indeed conducive and encouraging as all-round supports are provided both from the Govt. as well as from the financial institutions to nurture new ventures in this sector. There is an enormous potential market for consumption of finished products. The labour is cheap and a large number of trained manpower is available. It is anticipated that this climate will be utilised by a large sector of industrialists to culminate the transformation of India into a leading biotechnology country in the near future.

The industry is expected to be established on import-intensiveness. Indian developments in technology have not adequately advanced. The academia as well as the scientific researchers have not yet developed a flare for industry-culture, nor does society look at such contours with adequate enthusiasm. Moreover, although very good science is being practised in biotechnology, the supporting facilities, including testing, validation and packaging of scientific research into technology are inadequate. Such support services are evolving but transformation of in-country institutional research into industrial products and processes would necessarily be slow. Hence the efforts of DBT and other agencies to field-test in-country products and processes would no doubt be received with enthusiasm. Such efforts would engender confidence and throw open the prospects of such products as viable business propositions. However, the packages that would evolve might require substantial perfection in engineering, product packaging, documentation and quality testing. Many open-ended questions might require substantial time for settlement. Indian businessmen believe in the establishment of units based on procured, proven technologies. They are not motivated to spend on R&D unless compelled to do so. Import-intensity will thus

be on the rise for some year in the pattern of biotechnology industrial growth in this country. While during the initial years this should be encouraged, eventually, industries must be coerced into investment in R&D as on the strength of innovativeness only can be adopted, adsorbed and assimilated imported technologies evolve enriching discoveries in the field of biotechnology.

REFERENCES

1. Ghosh, P.K. (1990). In: *Microbial Gene Technology* (H. Polasa, ed.), pp. 1-16. South Asian Pub., New Delhi.
2. Ghosh, P.K. (1990). *Proc. Nat'l. Biotech. Congress*, Osmania Univ. (in press)
3. Ghosh, P.K. A study of the diagnostics market in India—Opportunities and strengths. Paper submitted to National Institute of Science Technology and Development Studies, New Delhi.
4. WHO. (1985). *WHO Bull.*, 63 (1): 57-61.
5. Roy, S. and Vyas, G.N. (1989). In: *Progress in Vaccinology* (G.P. Talwar, ed.), vol. 2, pp. 67-81. Springer-Verlag, New York.
6. Natarajan, C. National Project Co-ordinator, Ministry of Agriculture, New Delhi. (Personal communication)
7. Ghosh, P.K. (1985). *Drugs & Pharmaceuticals—Industry Highlights*, 8(8): 335-346.
8. Chater, K.F. (1990). *Biotechnology*, 8: 115-120.
9. Hunter, I.S. and Baumberg, S. (1989). In: *Microbial Products: New Approaches* (S. Baumberg, I.S. Hunter and P.M. Rhodes, eds.), pp. 121-162. Cambridge Univ. Press, Cambridge.
10. Malpartida, F., Hallam, S.E., Kieser, H.M., Motamedi, H., Hutchinson, C.R., Butler, M.J., Sugden, D.A., Warren, M., Killop, C. Me., Bailey, C.R., Humphreys and Hopwood, D.A. (1987). *Nature*, 325: 818-821.
11. GOI (Ministry of Industry). (1990). Report Working Group Drugs & Pharmaceuticals for Eighth Five-Year Plan.
12. GOI (1991). Annual Report Deptt. Biotechnology, 1989-1990.
13. Jain, Rajiv. (1988-89). *Guide to Industries: Policies and Procedures*, p. 199. India Investment Publications, New Delhi, 3rd ed. Also see: Press Note no. 14 (1986), GOI, Min. Ind., Deptt. Ind. Dev., New Delhi.
14. United Nations. (1988). UN Trade Centre Study Reports for 1985 and 1986. UN, Geneva.
15. Sikder, B.P. M/s. Krud Consultancy Services Pvt. Ltd., New Delhi. (Personal communication)
16. Directorate General Technical Development, GOI, New Delhi.