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PROSPECTS FOR BIOTECHNOLOGY IN INDIA

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Introduction

Biotechnology encompasses techniques applied to organisms or parts thereof to produce, identify or design substances, or to modify organisms for specific applications. Cell fusion techniques, hydridomas, recombinant DNA technology, protein engineering and structure based molecular design are considered as modern biotechnology. Emanating from the above, the structural and functional genomics complemented with computer-aided informatics are making fast inroads into the frontiers of modern biotechnology.

Conventional biotechnology includes fermentation or conversion of substrates into desired products by biological processes; downstream processing for recovery of metabolites; use of microbes or enzymes for producing value added products; sera, vaccines and diagnostics produced by conventional methods; reproduction, artificial insemination and embryo transfer technology for animal breeding; methods for fish spawning induction; plant cell or tissue culture; plant breeding for producing better seeds or plants cultivars; bio-fertilisers; biopesticides; plant growth stimulants; extraction and isolation of active principles from plants or animals or parts thereof etc.

Biotechnologists use molecular keys and biological tools to produce tangible and intangible wealth. The flowsheet (Fig 1) depicts the activities undertaken by the biotechnologists the world over to create wealth in different sectors such as health care products, agriculture, bio-industrial products and sustainable environment management practices. Right teaming up of biotechnologists skilful at least in molecular biology, immunology, chemistry and chemical engineering sciences is rare. But this combination holds the great potential of taking products of this powerful technology from laboratory to the market . In agriculture, the breeders must also be part of the team.

Consumption Scenario of Biotech Products in India:

^{*} The views expressed in the paper are those of the author and do not necessarily reflect the views of the organisation to which the author belongs.

India has been practising conventional biotechnology for several decades. Products manufactured by the use of genetic engineering, immunological techniques, cell culture methods and hybridoma technology are increasingly being used during the last 5 years and local research in these areas has been intensified. The following table-1 gives the current consumption and future demand of biotech products in value in India, as compiled and computed by the author.

In million US Dollars		1789	2186	4270
Total		86040 (100)	94000 (100)	233790 (100)
4. Other Biotech	Products	1040 (1.2)	1300 (01.4)	7940 (3.4)
3. Industrial Proc	lucts	27090 (31.5)	28500 (30.3)	53590 (22.9)
2. Agriculture (in	cluding seeds)	25670 (29.8)	28880 (30.7)	78720 (33.7)
1. Human & Ani Products	mal Health care	32240 (37.5)	35320 (37.6)	93540 (40.0)
		1999	2005	2010
Particulars of Biotech Sub-sectors		Actual Consumption	Future Consumption	Future Consumption
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Table 1 (Past Consumption of Biotech Products in India and Future Consumption Estimates)

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(Figures in brackets indicate contributions in % of the total)

It will be seen from the above that the health care products shall dominate the scene and may contribute to about 40% of the consumption market by 2010 from nearly 37.5% in 1999. Contribution of biotechnology in agriculture may also rise to nearly 33.7% from its share of 29.8% in 1999. Contributions in industrial products and other biotech materials may go down from the present 32.7% to about 26.3%, although in monetary terms the absolute contributions in these areas would also rise.

Modern biotechnology is rather new to India. There is little doubt however that the applications of modern biotechnology would increase very fast, as the products or processes hold great potential for providing much better solutions to improve the health of people or the quality of life, improve agricultural productivity significantly alongwith supplying more nutritious food, produce industrial bio-products at much cheaper prices and improve the quality of environment more effectively on a sustainable basis.

World leader-countries in Biotechnology during the next one decade:

World-wide USA would lead the people in modern biotechnology, but developments in other countries especially in Europe would also be significant. The countries such as UK, Germany, France, Sweden, Switzerland, Belgium, Denmark, Italy, Finland, Ireland, Russia, Hungary and Poland would make significant progress. Among the Asian countries Israel, Japan, China, India and South Korea shall have several modern biotech companies. India, China and South Korea are expected to emerge as major players towards providing the health care products at much cheaper prices than at what prices they are available to day. In agriculture, China may pioneer achieving major breakthrough among developing countries that are likely to inspire many poor countries to adopt modern biotechnology in their agriculture. Australian developments in certain sectors are also expected to be substantial. Besides, significant progress is foreseen from Canada, Brazil, Argentina, Mexico, Cuba and Columbia. Among the African countries maximum developments are expected from South Africa. Globally, main developments are expected in health care products followed by agriculture.

Indian capabilities in modern biotechnology:

Coming back to Indian developments, while there exists over 800 companies operating in all sectors of biotechnology, there are only about 25 companies that are working in modern biotech sectors. These include Shantha Biotech, Hyderabad; Bharat Biotech, Hyderabad; Wokhardt Biotech Ltd, Aurangabad; Panacea Biotech, Ropar; Torrent Biotech, Ahmedabad; SPIC, Chennai; Scheering India Ltd., Mumbai; Serum Institute, Pune; Sun Pharmaceuticals, Ahmedabad; Span Diagnostics, Surat; J. Mitra & Company, Delhi; Ranbaxy-Eli Lilly, Delhi; Dr. Reddy's Laboratory, Hyderabad; East India Pharmaceutical Works, Calcutta; Infar India Ltd., Calcutta; Cadila Health Care Ltd., Ahmedabad; Cadila Pharmaceuticals Ltd., Ahmedabad; Hindustan Antibiotics Ltd., Pune; A.S.C. Ltd., Baroda; Maharashtra Hybrid Seeds Company Ltd., Mumbai; Pro-Agro PGS, Gurgaon; Indo-American Hybrid Seeds, Bangalore; Rallies India Ltd., Bangalore; Monsanto India Ltd., Mumbai; Novartis India Ltd., Mumbai etc. None of the Indian companies have introduced any product of original research in Indian market that could be considered as unique, introduced for the first time in the world. But some have introduced known products that are tantamount to effective imports substitution. Some others have teamed up with foreign companies for sourcing technologies and are experimenting with new products produced by foreign technologies with a view to introduce them into the Indian market within the frame work of Indian laws. Certain companies are also introducing novel and effective but intellectually protected genes in to Indian germplasms to increase agricultural productivity or to reduce agricultural production costs. All these conditions and situations are satisfactory to

begin with, but the country has to go a long way to come up with innovative products that would be original and that would have cutting edge impact in the global context.

Developing a modern biotech product from scratch and testing its efficacy to be effective and safe within the framework of law in any country including in India is a time consuming process and an expensive affair. It is presently technologically difficult task too. Concerned people would have to have patience and would have to look for sufficient funds for creating the right kind of research and development environment. It is prudent in this context to turn our attention to the current government policies to understand in what directions these interventions are moving.

Indian Government intervention in the management of economy:

In India, the management of economy and industry is vested upon the Central Government, which promulgates from time to time the policies of planning, control of industrial capacities, regulation of locations of industrial undertakings, and approval of foreign collaborations.

India has believed in socialistic pattern of society. In early years from our independence upto late eighties, the policies followed by the government had major emphasis on creating interventions that work on the distribution of wealth, as it was thought that enough wealth was being created and was getting accumulated in a few hands only. Entrepreneurs create wealth by deploying capital, labour and technology. Wealth created by entrepreneurs' remains with them if adequate interventions are not exercised by the political system and by the government. In the early years upto late eighties, Indian government had put enormous intervention on private ownership of wealth with a view to move towards equitable distribution of wealth among people by taking such major steps as summarised below:

- a. Central planning to divert resources as per the visions of the Central government.
- b. Pronouncement of Industrial policy to boost the Public Sectors.
- c. Setting up of highly capital intensive Public Sector Undertakings.
- d. Nationalisation of major Private Banks and Insurance.
- e. Regulation of Private Sector Industries by introducing

-MRTP act -FERA -The Indian Patents Act 1970 -Price control -Control and distribution of essential communities -Concessions to the Small Scale Sectors

These conservative policies did create an impact on the phenomenon of wealth distribution and created a rise in the population of middle class, though interestingly very little impact was perceived on the real poor. The assumptions that planned development of industries dispersed regionally with manufacturing capacities created without attention to economy of scale, limited scope of further expansion of manufacturing capacities, price protection of communities to enable industries to recover cost plus margins for the goods and services produced by them from an non-competitive market place, and more such public/local-industry friendly measures would be beneficial to promote economic welfare could not hold any more beyond late eighties. Symptoms were manifested in terms of lowering of reserves of foreign exchange and insolvency in economy resulting primarily from inefficiencies from productivity in most of the industries but particularly in the public sector undertakings in most of the sectors of industries. Consequently, to correct the situation the Central Government from the Ministry of Industry substantially modified the previous developmental policies from July 1991 onwards. The licensing policy was enormously liberalised through the enactment of simpler policies successively over the years through the pronouncements of the Foreign Investment Promotion Board of the Union Ministry of Industry to attract large Foreign Investments. The present promotional policy of the Indian Government for the development of industries in all sectors including the biotech sector can be stated as follows:

-Industrial licensing policy has been liberalised for accommodating automatic registration.

- -100% foreign equity investment is possible in all sectors
- -74% foreign equity investment is automatic in drugs and pharmaceuticals sector, and over 74% is on case by case basis, provided basic manufacture is undertaken locally
- -Fast Tract Clearance route for Foreign Direct Investment
- -Rationalising of customs duties, central excise duties, special excise duties and value added tax
- -Central Government playing proactive role of development, in creating conditions for easing open field experiments with genetically modified organisms including plants for enabling industry/entrepreneurs to take products from lab to the market faster

-Creation of equal level playing ground for all sectors of entrepreneur: Indian public sector, Indian private sector or foreign entrepreneurs

- -Government investment over Rs 1000 crores in biotechnology for developing skilled manpower, creating R & D infrastructure and providing extramural R & D support to public funded institutions. Government attention to promote biotechnology is significant
- -100% rebate on own R & D expenditure, and 125% rebate if research is contracted in public funded R & D institutions
- -Over 50 R & D labs in public sector in place and over 20 conducting research in frontier areas of biotechnology: theses facilities can be used for teaming up by the entrepreneurs/industry; stand-alone research is often expensive and unproductive

-Joint R & D projects are promoted with special fiscal benefits accruing to such projects

The current liberalized policy implemented in right spirit has the ingredients of providing the necessary impetus to the entrepreneurs to set up sustainable and competitive local industrial units with the necessary support extended by and from the Government.

Indian commitments to globalisation:

India is a signatory to the World Trade Organisation (WTO) and the country is taking steps to enact the provision of WTO in letters and spirit. The objectives of WTO are presented in the form of a flow diagram (Fig 2)

In all the above areas, the Indian government is taking steps to fulfil the objectives of WTO. But such steps are taken commensurate with maintenance of a rationale that does not create an imbalance in the core competence of the country. No steps have been taken that create a virtual collapse in any industrial sector. All the steps taken by the government are within the broad framework of procedures and principles of the WTO.

Being also a signatory to the Convention on Biological Diversity (CBD), India is committed to protect its genetic biodiversity and concurrently it would consent to enabling access to people to its genetic diversity. The objectives of CBD are stated in a flow diagram (Fig. 3). As a signatory country to CBD, India would soon constitute its Biodiversity Authority and exact procedures for accessing Indian Genetic Biodiversity by the CBD member countries.

More regulatory dictums within the framework of international commitments of India to WTO and CBD are therefore in the offing. These include the creation of Plant Quarantine Authority of India, the Geographical Indications Act, the Biodiversity Protection Act etc. all of which cut across the interests of the biotech industries. The future years hold enormous inquisitiveness from the entrepreneurs on how the laws are going to be framed and how industry would be benefited from these.

Future trend of development of biotechnology in various sub-sectors:

India already has developed competence in selected areas that provide the entrepreneurs an edge over other countries to set up viable and competitive biotech industry in certain areas. Indian Government continues to play a significant role in the promotion of biotechnology in all its facets. These efforts have been instrumental to developing competence within the country. The areas of core competence in India in the context of biotechnology are as under:

-Capacity in handling sterile fermentation processes

-Skills in handling microbes and animal cells

-Skills in plant cell/tissue culture

- -Competence in chemical synthesis, proficiency in immunology and hands-on experience in microbiology
- -Capacity in downstream processing and isolation methods
- -Recent skills in cloning of desired organisms in relation to rDNA technology
- -Skills in extraction and isolation of plant and animal products
- -Competence in plant and animal breeding
- -Infrastructure and skills in fabricating bio-reactors and processing equipment of diverse kinds

With the above strengths in view and having regard to the market demand of products and processes in Indian context, the investment opportunities in various sub sectors of biotechnology is thought to be as under:

Human and animal health products:

The human and animal health care products would grow substantially. There would be increase in the production of more effective vaccines. There is immediate demand for cocktail vaccines of DPT with hepatitis B, Tetanus toxoids with hepatitis B, hepatitis A with B, influenza, vericella and meningitis vaccines; technical solutions exist in all these areas and can be gainfully exploited. There is need for increased availability of effective typhoid vaccines. There is an unmet demand for several animal and poultry vaccines. It is roughly estimated that investment to the tune of Rs. 300 to 400 million can come in vaccine area during the next five years if local opportunities are availed of. There are also opportunities for developing vaccine for protection against hepatitis C, hepatitis E, HIV, Malaria, Tuberculosis and Leishmaniasis; these developments are closely related with a long term planning on research. There are also opportunities for developing recombinant viral vector vaccines and DNA vaccines.

Disease diagnostic areas are growing fast although the country has kept investment opportunities for local production neglected. Most of the diagnostic products are imported and used although local skills could be sharpened and used as competitive global advantage. Diagnostics based on monoclonals, synthetic peptides and recombinant antigens or antibodies could be made locally, as skills exist; the requirement of membranes could be met from local sources by providing encouragement to the skilful local producers. The requirement of speciality plastics could also be met from local capabilities. The intervention in policies could play a vital role in developing this industry locally. With a little readjustment to provide for equal level playing grounds to the local producers compared to advantages available to the direct importers of certain products, it is possible to enable the deployment of investment to the tune of over Rs. 500 million in diagnostic business in next five years to create a globally competitive local industry. Opportunities exist for the setting up of facilities for developing diagnostics devices for detecting HIV, HCV, HEV, Papilloma, Malaria and Tuberculosis. Further, opportunities exists for quantitative estimation of hormones such as T3/T4/TSH, hCG, LH, FSH, Progesterone, Testosterone, Corticosteroids, Alpha fetoproetin and prostatic inhibin. Still further opportunities exist for setting up facilities for producing diverse biochemicals required in health care products like diagnostics such as Monoclonals, monoclonal antigens/antibodies, recombinant antigens/antibodies for various conditions, peptides, nucleotides, specialty plastics, membranes of different molecular weight cut off, polyclonal antisera, conjugates and specialty enzymes.

The area of production of therapeutic recombinant proteins is growing locally, but the speed of development is slow. Local skills can be sharpened by prioritising, the activities and with the removal of certain impediments it is possible to create a viable and globally competitive industry in the India, and investment to the tune of Rs. 0.8 to 1.00 billion could be attracted. Opportunities exists for taking up production facilities for Interferons, Insulin, Human

growth hormone, G-CSF, GM-CSF, Erythropoietin, Blood factors VIII and IX, Urokinase, Tissue Plasminogen activator, Streptokinase, Interleukins and Tissue necrosis factors.

In antibiotics area, opportunities for future investment is not presently bright, specially keeping in view the core competence of some Asian countries, and the policies adopted by such countries to push their products globally. However, in order to protect the local industry on scientific considerations such as maintenance of high quality standards effected by vigilant and authoritative monitoring, and introduction of stringent procedures for registration of products, it is possible to create environment for further growth of antibiotics industry locally. Without disturbing the terminal prices of formulations, it should be possible to readjust strategies within the core of the antibiotics production set-up, starting from the high investment bulk producers to the low investment formulators, to share certain cost elements rationally within the sector, such as the costs of electricity and the costs of capital servicing, with a view to improve the health of the core bulk production sector. If such considerations are brought into play, it should be possible to induct fresh investment to the tune of over Rs. 1 billion during the next five years, besides reassuring the survival of local antibiotics industry. This situation is considered to contribute to protecting and increasing the local skills developed over a long period of ardent perseverance starting from early fifties. In the long run, this will benefit the country economically.

There also exists opportunities for fresh investment in setting up facilities for the fractionation of blood and blood products into cellular and non-cellular components, and sensitised immunoglobulins. Separately, significant demand exists for the production of different monoclonals, peptides, hyaluranic acid and other animal products, besides effective biotechnological drug delivery systems. For all such opportunities to be availed of, over Rs. 1 billion could be invested for creating local production facilities.

Agriculture Biotechnology:

In agriculture, major contribution is anticipated from the local production of increased quantities of hybrid seeds and high-yielding varieties. Already core competence exists for developing varieties and hybrids; the cheap labour force available locally is of great advantage. Unfortunately this area has not grown because it has not been possible to bring home the great merits in the replacement of productive seeds every year, which presently stands at below 10%. Genetically modified plants/ seeds are expected to emerge in the coming years and would capture markets in specific sectors of seed industry. Already contained field experiments have been initiated to evaluate the environmental risks, taking also into consideration the risks to human health. Initial results have not shown any unmanageable risks either to the environment or to human health. Indeed the good news is that there has been significant rise in the agronomic benefits, besides reduction in the use of chemical pesticides for plants engineered for

resisting the attack of insect pests. There would also be increase in the usage of bio-pesticides including botanical pesticides. Formulations based on Bt, different viruses like NPV and GV as well as neem based pesticides would be increasingly used. The seeds industry alone holds possibilities of investing over Rs. 1.5 billion in another five years. Concomitantly opportunities exist for new investment in bio-fertilisers (over Rs. 200 million), bio-pesticides (about Rs. 300 million), pheromones, growth stimulants/ promoters (over Rs. 500 million) and botanical pesticides.(over Rs.600 million).

Industrial and other Biotech products:

The sector represented by industrial products will remain primarily based on conventional biotechnology although recombinant microbial strains are expected to contribute substantially to the production of bio-catalysts (useful for complex chemical reactions), industrial enzymes, food-grade enzymes, production of simple microbial metabolites such as organic acids and amino acids. There would be a rise in the production of speciality enzymes and oligo-nucleotides in molecular biology research, speciality materials including speciality plastics for specific uses, analytical materials and reagents for diverse use, and application of biological materials in electronic devices. Among the industrial products, new investment opportunities are foreseen in industrial enzymes (over Rs. 500 million) and in amino acids production where investment of over Rs 700 million can come up to meet not only local needs but to cater to the export needs also. Opportunities in investment in these areas are clearly linked with India's having sizeable quantities of sugar cane molasses, and also other cheap agricultural substrates like various grades of starches from tapioca, maize, potato etc; corn steep liquor (whose quality can be improved if adequate demand is created), sugar, pea /peanut /soybean meals, and various vegetable oils. In the area of bakers and brewers yeast, opportunities for production of fresh compressed yeast do not presently exist but production of value-added NAD/NADH and speciality enzymes could be explored by using the locally available compressed yeast. In addition to the above areas of investment, there exist reasonable scope for setting up facilities for the recovery of value-added products from wastes such as proteins from milk whey, bio-gas and composted fertilisers from municipal or agriculture wastes, better methods of recycling of organic wastes, production of speciality bio-chemicals and speciality plastics that are bio-degradable. Opportunities thoughtfully explored can provide avenues for investment of over Rs. 1 billion in these areas too.

Future consumption estimates of major biotech products in India

Table 2 gives the gist of the current (1997) consumption and the future requirements of a number of important biotech products in the country during the coming years.

Table - 2

(Demand estimates of selected biotech products)

Products category and Products with measuring units	Consumption 1997	Estimated consumption 2000	Estimated demand 2005
A. Animal & Health Care Products			
Vaccines (Million doses)			
1. DPT	110	114	124
2. DT	54	57	65
3. Tetanus toxoids	192	200	222
4. BCG	41	43	47
5. Oral Polio	110	160	225
6. Measles	25	32	45
7. Measles, Mumps, Rubella	7	8	10
8. Hepatitis B vaccine	/	18	45
9. Rables (Tissue culture based)	5 0.4	/	12
10. Typnoid (injectable)	0.4	0.8	2.5
<u>Diagnostics</u> (Million Tests)			
11. Early pregnancy	12	23	37
12. Ovulation	2	4	8
13. Estimation of T3, T4 & TSH	5	14	42
14. HIV infection	9	17	27
15. HBV infection	20	33	53
16. HCV infection	3	8	12
17. Rheumatoid diseases/disorders	0.4	0.5	1
18. Cancer (cervix, colon, prostate,	0.5	1	2
lungs, mouth etc.)			
19. Kidney function tests	34	52	104
20. Liver function tests	35	58	116
Therapeutic Recombinant			
Proteins	05	110	270
21. Human Insulin (kgs.)	95 1500	2000	270
22. Erythropoletin (gms.)	1300	2000	4000
23. Interferons (million doses)	0.2	0.3	2
24. Sueptokinase (minion doses)	0.3	1.5	5
<u>Antibiotics</u>			
25. Penicillin G and V Ist crystals (MMU)	4100	6300	6300
26. Rifampicin (tones)	260	300	380
27. Salinomycin (tones)	80	90	110
28. Tetracyclines (tones)	510	500	480
29. Erythromycin (tones)	120	150	220

Vitamins

30. Vitamins B-12 (kgs.)31. Vitamins C (tones)	570 1200	660 1600	850 2500
B. Agriculture			
High yielding hybrids (HYV)/ Varieties (VAR) / Genetically modified seeds (GMS) (in 1000 tones)			
32. Wheat	207(VAR)	220(VAR) 2(HYV)	250(VAR) 5(HYV)
33. Rice	155(VAR)	165(VAR) 1.6(HYV)	191(VAR) 2(HYV)
34. Sorghum	21(HYV) 21(VAR)	22.3(HYV) 22.3(VAR)	26(HYV) 26(VAR)
35. Pearl Millet	20(VAR)	21.2(VAR)	24.6(VAR)
36. Maize/Corn	5.2(HYV) 10.4(VAR)	5.5(HYV) 11.0(VAR)	5.0(HYV) 12.(VAR) 2.0(GMS)
37. Pulses (mainly peas and grams)	42.5(VAR)	45.1(VAR)	51(VAR)
38. Groundnut	78(VAR)	82.8(VAR)	95.6(VAR)
39. Mustard/Rapeseed	8.3(VAR)	8.8(VAR)	10(VAR) 2(GMS)
40. Soybean	31(VAR)	32.9(VAR)	38(VAR) 2(GMS)
41. Sunflower	6.2(VAR)	6.6(VAR)	7.7(VAR)
42. Cotton	12.4(HYV) 13.5(VAR)	13.2(HYV) 14.3(VAR)	7.5(HYV) 14(VAR) 10(GMS)

<u>Bio-fertilizers</u> (Tonnes)

43. Rhizobium	5000	5500	6700
44. Azospirillum	3470	3500	5800
45. Azotobacter	2000	2200	2400
<u>Bio-pesticides</u>			
46. Bacillus thuringiensis (tones)	40	120	200
Growth promoters/stimulants			
47. Gibberillic acid (kgs.)	7000	15000	30000
C. Industrial products			
Enzymes			
48. Industrial Enzymes(million rupees)	600	800	1300
Organic acids/Amino acids			
49 Lactic acids	1000	1160	1500
50. Citric acids	11000	13000	16000
51. Sodium Glutamate	1500	1700	2200
52. L-lysine	1000	1200	1500
<u>Yeast/Yeast products</u>			
53. Bakers & Brewers Yeast (tonnes of compressed fresh yeast)	22000	32000	45000

Note: VAR =*Varieties; HY V*= *Hybrid high yielding seeds; GMS* =*Genetically modified seeds.*

Estimated investment opportunities in biotechnology in the near future

It can be stated from the above that over the next five years, possibilities could be created for fresh investment of Rs. 7 to 8 billion in India that hold the promise of changing the biotech production scenario considerably. Such quantum of fresh investment if materialised, would hold the potential of providing turnover of Rs. 9 to 10 billion during the next 5 to 7 years, that could contribute towards import substitution, augmentation of local production and introduction of some new products in the global market.

Concluding Remarks

India is expected to emerge as a strong player in the consumption market of biotech products in the coming years. By 2005 AD, the comparative contributions of consumption from health care products are expected to the about 40% from the present 37.5% (1999), while agriculture may rise from 29.8% to nearly 33.7%. The other products would however get reduced from 32.7% to about 26.3%, although in monetary terms, there would be substantial rise in the consumption in these products as well. By adopting appropriate government interventions it should be possible to attract sizeable investment in this sector in near future to create competitive global industry locally. Wisdom lies in taking proactive steps within the provisions of the WTO and other international laws that are in place to develop a competitive local industry than to create demand for a consumption market that is fed by products from abroad.



Fig 1: Flowsheet depicting activities of biotechnologists

Fig 2: Flow-sheet depicting objectives of CBD





Fig. 3 Flow sheet depicting the Objectives of WTO