

# The role of alliance in modern biotech industries in developing countries

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*Biotechnology holds enormous potential in both developed and developing countries. The technology component in the generation of goods and services is of highest significance in biotechnology. Regenerating raw materials, which are more abundantly available in developing countries, forms the source for different industrial activities, including biotech industries. Working on regenerating raw materials would provide cutting-edge advantage in the supply of such materials to industries that depend on them. It has been argued that developing countries need to intensify their research in specific areas, including regenerating materials to have a competitive edge. Developing countries would need competitive technologies to develop and upgrade their biotech industries. Various modes of alliances would aid in sourcing efficient technologies and some Indian companies have created such alliances. Enormous opportunities exist in several sectors for developing countries; these can be harnessed by creating appropriate R&D infrastructure and trained manpower in skills, specific to modern biotechnology industry. Alliance between partners of developing and developed countries would benefit both the partners.*

BIOTECHNOLOGY encompasses techniques applied to organisms or parts thereof to produce, identify or design substances, or to modify organisms for specific applications<sup>1</sup>. Cell-fusion techniques; hybridomas; recombinant DNA technology; whole genome cloning; protein engineering; structure-based molecular design; genomics and proteomics (including understanding the relationships mediated through proteins and/or nucleotides among nucleotide sequences and proteins or peptides on one hand, and relationships among carbohydrates, lipids and other bioactive molecules on the other); bio-informatics, including bio-chips and computational methods for understanding cellular processes; cell therapy, including transplantation of cells or tissues or organs, and creation of artificial cells are considered as modern biotechnology. After understanding the central dogma of life at the molecular level that DNA produces RNA, RNA produces proteins and proteins activate DNA into transcription, modern biotechnologists are venturing to understand the interactions in life processes at cellular, organic and composite structures, again at the molecular level. Gene-expression studies are indeed complex and the current tools are inadequate. More sensitive methods for measuring expression in different cell types will unveil the complexities of genomic functioning. Taken together, such ventures of acquiring knowledge will lead to several fallouts as products and services in the near future.

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; microbial cell culturing, including prokaryotes and eukaryotes; reproduction, artificial insemination and embryo transfer technology for animal breeding; methods for fish spawning induction and biotechnological intervention for faster growing of fingerlings; plant cell or tissue culture including production of somatic embryos; plant breeding for producing better seeds or plant cultivars; bio-fertilizers; bio-pesticides; plant growth stimulants; innovative methods of extraction and isolation of active principles from plants or animals or parts thereof, etc.

The process of globalization has necessitated networking of organizations in order to enhance their spectra of learning. Modern biotechnology is highly knowledge-intensive. It is multidisciplinary in nature. The full cycle of innovation from basic research to development of products and processes followed by setting up of manufacturing facility and marketing these products, which were often carried out earlier within the boundaries of one company, is hardly economically feasible anymore. It is almost impossible for one organization to keep pace with advancements in multiple spheres of specialization, which is required for dealing with complex biological processes that draw inputs from living organisms. Consequently, for strategic reasons and to economize, there

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would be teaming ups not only in the developed countries but also in developing countries among industries and institutions. Governments have also to create the necessary infrastructure and provide strong administrative and other support to enable firm rooting of alliances among willing partners. This article examines the need for and the possibilities of alliances in and among industries in developing countries, within and outside.

### Components of wealth creation in biotechnology industry

Entrepreneurs the world over create value-added goods and services by judiciously deploying mainly four factors of production, namely resources, organizational structure, infrastructure and technology. Every entrepreneur works in an environment which is created by the people, the societal structure, the political system, governments, etc. Among all these direct and indirect factors, entrepreneurs create maximum contribution to value addition from the technology component, in highly knowledge-based industries like biotechnology. The factors that enable entrepreneurs in value-addition in biotechnology, as conceived by the author, are schematically represented in Figure 1.

The net sales realization of goods and services by entrepreneurs after marketing these, minus the cost incurred in producing them, i.e.  $(j-a)$  is the surplus  $(k)$  generated by the entrepreneurs. Surplus is net realization minus the net costs. When better goods and services are produced, several intermediaries (stockists, distributors, retailers, etc.) get generated to share a pie and in this process the ultimate recipients of the products pay higher prices for the services offered by the intermediaries, in addition to the exchange value of the products fixed by the entrepreneurs. In a free world, the competitive environment that is going to become strongly reinforced in the years ahead, the quality and content of technology will be the main

contributor to the application of biotechnology in all relevant sectors. Among the factors for value addition, resources are meant for procured or purchased 'goods and services' that are directly required in creating value addition. These are common to all entrepreneurs and therefore are of relatively lesser importance when compared with other factors for value addition within a closed system. It can be seen from Figure 1 that the next input is the organizational structure. This plays an important role in wealth creation, next only to technology component. Talented people create the organization. Inculcating talent requires proper utilization of people in organizations, identifying challenging problems, cultivating people through work culture and assessing people through achievements. In such events only shall the technology be best utilized. The development path in developing countries in biotechnology, therefore, lies in inducting qualified people who are trained in business-management principles, professionalization of managerial skills, market networking, internationalization of the industry in order to source talents and broaden its markets for maximizing sale as well as for accessing more capital through the goodwill of the people and society. The organizational structure and the people of an enterprise handle all the resources of the organization under the broad directives of the entrepreneurs for creating value addition to the resources. The entrepreneur acts as Chief Executive upon whose vision and action the organization succeeds. The utilization of all the resources in the most productive manner depends upon the capabilities of the people of the organization, its organizational structure and the hierarchy. The intelligent way of using the resources creates increased value addition to the resources. The integral quotient of value addition resulting in the realization of maximum value for the goods and services generates more surpluses to an organization. Generation of surplus needs to be continued by creating loyal customers over a long period by satisfying and improving upon their unmet needs. When such surpluses are shared rationally among its people, the employees become prosperous; in the context of States, the people become richer and the country becomes developed. Surpluses are also judiciously utilized for newer technology development. Technology is the key resource for the generation of increased surpluses. Therefore, a successful entrepreneur would always set aside a part of the resources for research and development with a view to sharpen his knowledge resource, which in its utilizable form is designated as technology. Different entrepreneurs deploy different methods for possessing and developing technology resource, as has been discussed briefly later in the article. Ordinary entrepreneurs work in the market by leveraging on pricing, relationship-building, influencing opinion makers, etc. These strategies have limited resource-generating potential. On the other hand, entrepreneurs leveraging on technology, quality management, quality improvement, scientific publications, innovative developmental studies, etc.

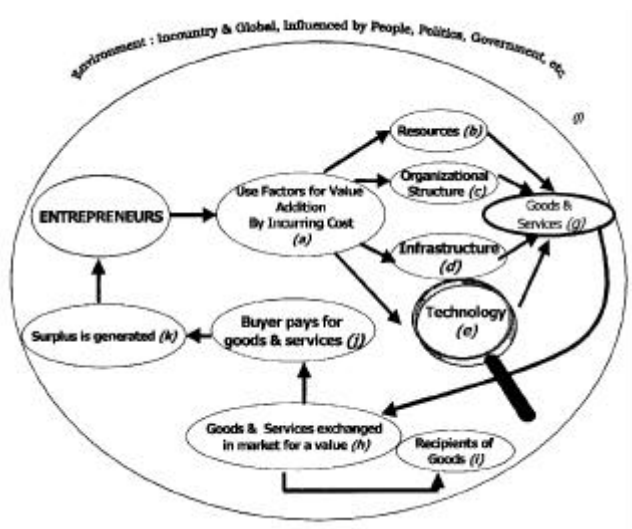


Figure 1. Wealth creation model (qualitative).

that hover around creating newer knowledge resources, are often more successful. Taken together, though the technology component is the main factor to value addition in the modern biotech industry, successful entrepreneurs would be those who would most effectively manoeuvre all the factors of production efficiently.

Till the time the net surplus is equal to or less than the costs, entrepreneurs are under severe stress; minimization of this period is the aim of every entrepreneur. If the potentials of the biotech business are such that the net surpluses are only up to 10% of the net costs of goods and services, such business classes are either mediocre or are subjected to severe competition. If the surplus is more than 10% and may be up to 100% of the net costs, it may be rated as good to very good. High-tech business structures accrue net surpluses of more than 100% and can sustain even up to 2500% for a considerable period! Sale of proprietary biological substances not available abundantly from natural sources or new products that are produced by recombinant DNA technology, such as erythropoietic factors (like erythropoietin), growth factors (human growth hormone, granulocyte-colony stimulating factors, granulocyte macrophage-colony stimulating factors, etc.), cytokines (interferons and interleukins), metabolic regulators (insulin, etc.), thrombolytic agents (tissue-plasminogen activator, urokinase, streptokinase, etc.), mono-

clonal antibodies (OTK – 3, herceptin, etc.) and recombinant vaccines (like Hepatitis B surface antigens, etc.) is a lasting testimony to the sustainable higher returns/profits-generating business. Accrual of high surpluses is the domain of the modern biotech industry<sup>2</sup>.

Modern biotechnology industry has enormous potential. Biotechnologists the world over work on understanding and exploring the value of molecular and biological keys and tools. In four major segments of applications, namely in health-care products, agriculture, environment management issues and industrial products sector, some of the potentials of modern biotechnology are already visible. Many developments are expected in biotech research platforms such as in proteomics, genomics, bioinformatics and understanding the relationship as well as roles of carbohydrates and lipids to proteins and nucleotides at molecular level in eliciting the life process. Developments in agriculture are expected to percolate more into developing countries. The canvas of basic and application-linked biotechnologists is depicted in Figure 2.

A synergy between basic scientists and application-oriented technologists would only enable fructification of biotech products and services effectively and economically in any country. On a broad canvas, clearly some groups of people would be concentrating on small and medium molecules, while a sizeable group would be work-

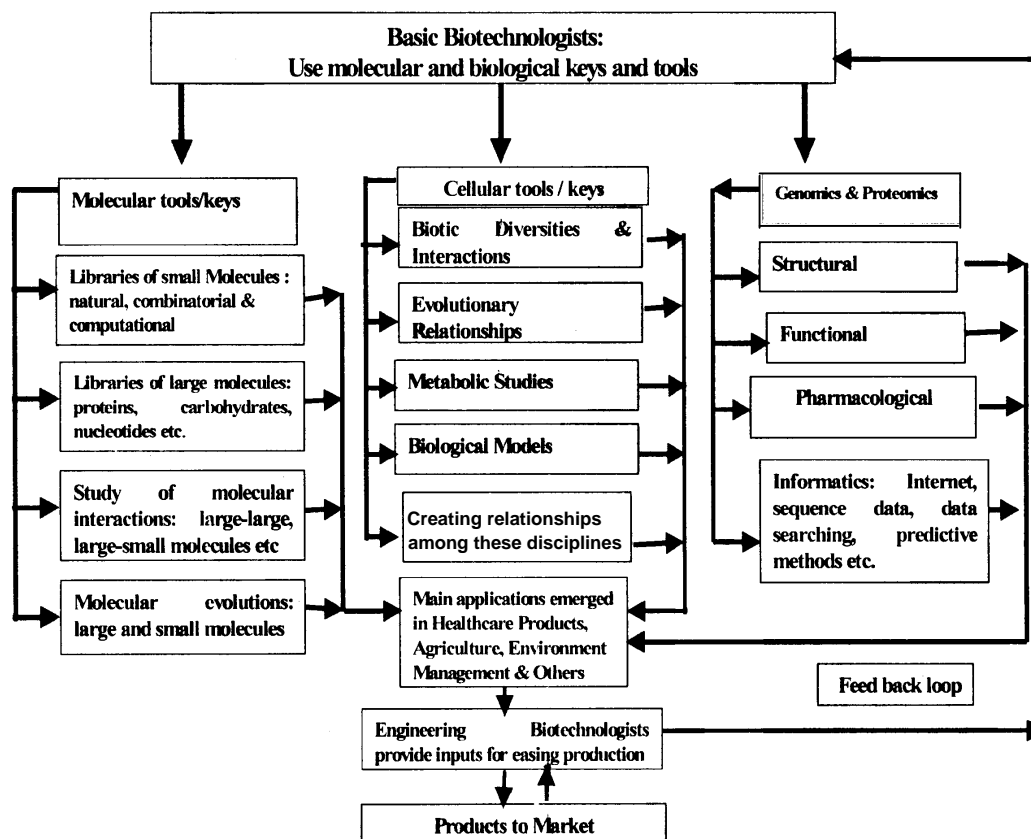


Figure 2. Schematic representation of domain of biotechnologists.

ing on large molecules and interactions among them, including proteins, nucleic acids, carbohydrates and lipids. Yet another group would be concentrating on cellular components, encompassing properties of single cells as well as their multiples in the form of tissues and organs. The groups that would try to understand relationships among different classes of molecules and their interactions on cells and tissues, would only be able to have an insight into the complex process of living organisms. Indeed, the full gamut of biotechnology would take many years to have a reasonably firm grasp on some of the life processes. In this context, the present understanding of the life process and the path ahead are depicted schematically in Figure 3.

As indicated earlier, human and animal healthcare, agriculture, industrial products and other areas, including environment management issues would be the four central areas of innovation in biotechnology.

Stages of development of drugs are indeed lengthy and complex. Most of the efforts have been to use biotechnologies to develop newer drugs. In brief, the exploration strategies are classified to pass five major stages, as described schematically in Figure 4.

The complexities involved and the large quantum of resources required for achieving success in this endeavour can be easily appreciated. Unless a concerted but determined effort is made on a narrow canvas, it would hardly be possible for developing countries to make a visible impact in this area on a global context. This is to suggest that with limited resources, developing countries may

like to concentrate on doable drugs-developmental plans that have fair chances of success. Creating alliances with developed countries in this context seem to be a viable option, the successful accomplishment of which would require sound diplomatic skills, besides attitudes towards the conduct of experiments on animals and human subjects. Further, areas of research could be such that protection of intellectual properties by patenting is not significantly important because of high rate of obsolescence (where 20 years protection cannot be exploited); skills can be guarded through trade secrets and therefore the intellectual properties shall not require adequate disclosures such as in production of diagnostic devices, or the market condition of the therapeutics that has a status close to orphan drugs in the developed countries, but may be important for developing countries, e.g. products required to combat such microbial diseases that are related to poor hygiene, malnutrition and poverty. This is not to suggest that centres of excellence need not be created; on the contrary, excellence in setting standards for known modern biotech drugs needs to be created either in public-funded institutions or in the joint sector where public money and private resources are jointly deployed to ease increased application potential. There are imminent needs for doing so in order to take advantage of producing and utilizing the so-called bio-generics for the developing countries. The emphasis is to suggest that developing countries should be careful to allocate resources for discovering new biotech drugs.

On the other hand, materials like cereals, meat, milk, fats and oils, sugar, cotton and other fibres, cellulosic pulp,

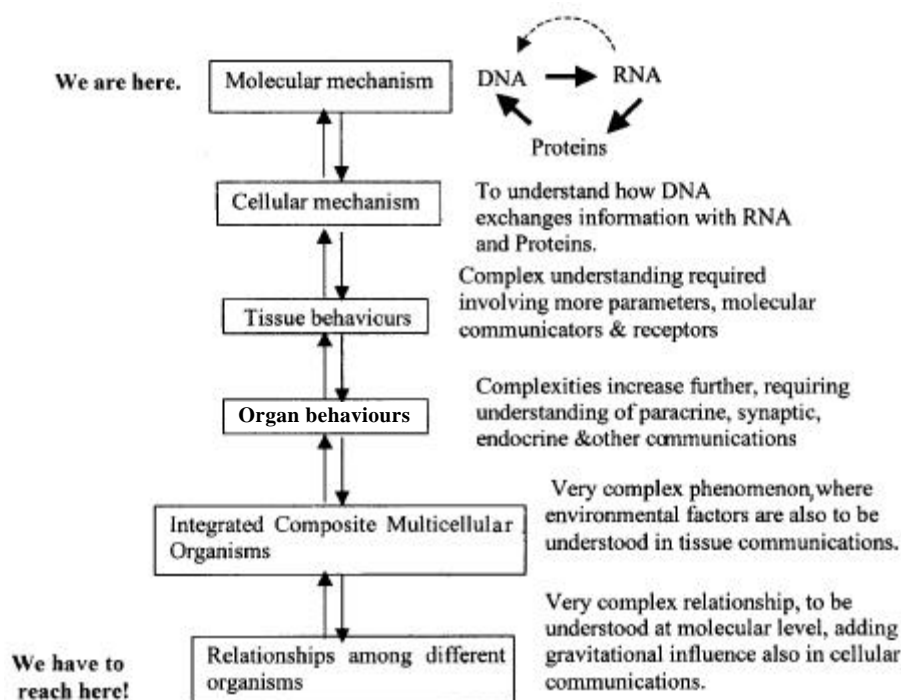


Figure 3. Our journey to understanding life.

lignocellulosic materials, egg albumin, leather, biogas and other large volume-regenerating materials would be required in increased quantities in future. Industries depending upon such regenerating raw materials would require these at attractive prices. The occupation of majority of people in the developing world presently is agriculture, e.g. about 60% in India compared to 3% in USA. This situation would not change in the coming several decades, though there would be relative changes in percentage of population distribution between rural and urban areas. Application of genetic engineering techniques in diverse areas as above, holds the potential of improving production and productivities of regenerating materials, which would be both rural and urban-based, but would be from developing countries, as these materials would be consumed in bulk and would have relatively less value addition. Research in specific areas of these relevant to different developing countries must therefore be intensified. Such research would no doubt be planned on a precautionary principle, having regard to the risks from genetically modified organisms (GMOs) to the environment and human safety<sup>3</sup>.

Development of core competence in biotechnology with the potentials of creating key ground-breaking R&D capabilities of world-class reputation in any segment of biotechnology requires besides human skill, abundant availability of sophisticated infrastructure and support of chemicals and reagents of high magnitude. The risks of such a developmental path are also high, as success cannot be guaranteed. All developmental segments require strong support services. In pharmaceutical product development, for example, critical support services include capabilities in product development, pilot-scale manufactures, clinical research (including testing and trials), formulation development, product and process validation, pharmaco-economic studies, etc. It is doubtful if developing countries would be able to create such stand-alone infrastructures in multiple numbers. It is also doubtful if adequate resources could be allocated for intensively studying a whole range of biotech product avenues. Tak-

ing into consideration the resource limitations that exist in developing countries, it is anticipated that developing countries would have to narrow down their developmental activities in specific areas in order to intensify work on key national problems that could be addressed through biotechnology. Concentrating on regenerating materials would be one such choice. Similarly, in the health-care segment, a few selected areas of disease or disorder for therapy and diagnosis could be chosen.

Regenerating raw materials can be more efficiently raised in developing countries, as these have greater land and mineral mass and biodiversity (that could be used as source materials for different kinds of novel genes and nucleotide sequences). Human skill and scientific infrastructure, when raised, would contribute to new developments. Developed countries would never be able to match the supply of most of the regenerating raw materials at economic prices to meet the needs of the industry. Industries utilizing these raw materials are, however, stronger in developed countries and therefore, they would bargain for confirmed supply of these primary raw materials from different sources at most advantageous terms. This is where alliances between developed and developing countries would be forged. Selected segments or areas in pharmaceutical product development could also provide an edge.

For obtaining better negotiating terms, developing countries must have a technological edge. In achieving the cutting edge, developing countries may like to consider the following strategies on a long-term basis:

- (a) To intensify research in regenerating materials, including plants, animals, microorganisms and substances that contributes to biomass increase.
- (b) To select such regenerating materials that are advantageous to multiply in regions, sub-regions or specific areas where there are natural advantages of climate.
- (c) To select a few diseases or disorders in human, animals and plants of national relevance that can be addressed through biotechnology.

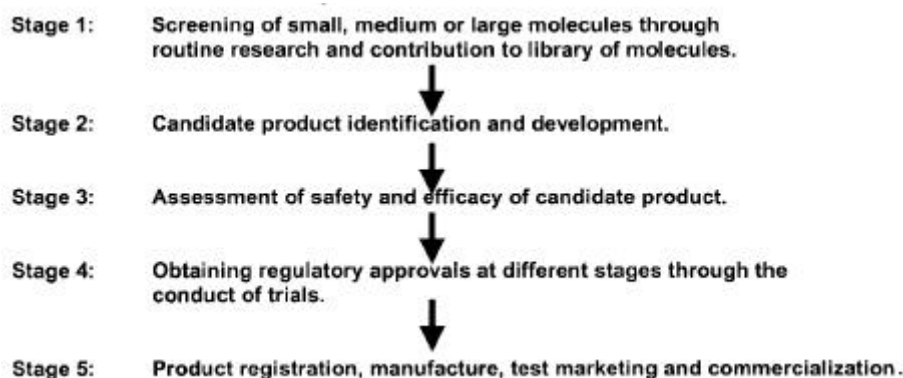


Figure 4. Biotech drug development stages.

(d) To take measures that promote academia and industry to participate in the projects.

In all the areas of regenerating raw materials, novel genes would be isolated and put to use. In many cases, the entire genome would be plucked from the nuclear compartment and inserted into able cellular machinery devoid of its genome and the new composites shall be reared in foster hosts to enable the blooming of the material into full-grown animals, as in the case of Dolly the sheep<sup>4</sup>. For discovery of new genes, the general strategies adopted would be as outlined in Figure 5.

Novel animals produced by nuclear transfer would move through the broad steps<sup>4,5</sup> depicted in Figure 6.

In all the above areas, new products and technologies would emerge. Countries that have higher capabilities in the understanding and practicing of intricate sciences would only be able to make significant discoveries. Others would have to play the role of recipients. However, since the present world has polarized itself into knowledge-rich and knowledge-deficient societies and since the population in the latter is undoubtedly larger, there would be flow of hi-tech products from the former to the latter. Alliance would therefore be necessary more in the interest of knowledge-deficient countries than the knowledge-rich ones, though for generating increased surpluses the latter may look for alliances to create larger markets in the territories of the former.

### Opportunities that exist for developing countries in biotech sectors

In the healthcare sector, recombinant DNA products, vaccines, monoclonals and targetted drug delivery in several

facets are already available from developed countries. Some of these are now produced in a handful of developing countries. Presently, more than 40 recombinant DNA products and 15 potent vaccines, including recombinant ones effective against infectious and communicable diseases, a large number of monoclonal antibodies to treat certain cancers, rheumatoid arthritis and cardiovascular conditions are available globally<sup>6</sup>. More than 700 new biotech drugs are under different stages of development the world over. There is yet no freely available published literature on the protected products that are patented in developed countries. There is also little interest in the developing countries on information about how many new products are under development. Such information needs to be continuously generated and extensively studied by industries in the developing countries in order to narrow down product selection, taking into consideration local strengths, capabilities and strategic advantages where applicable.

Gene therapy, cell therapy, organ transplantations, effective immunomodulators at molecular level, genomics, proteomics and bioinformatics are at a developmental stage the world over, including in the developed countries. Opportunities could be created in developing countries for conducting research in some selected areas only by taking advantage of the local skills where available and by creating alliance with technology and resource-rich developed countries/industries. Diplomatic skills and long-term planning are necessary for creating such alliances.

In agriculture, transgenic plants are emerging at a fast speed the world over. The spectra include transgenic crop plants that are resistant to pests, herbicides, various

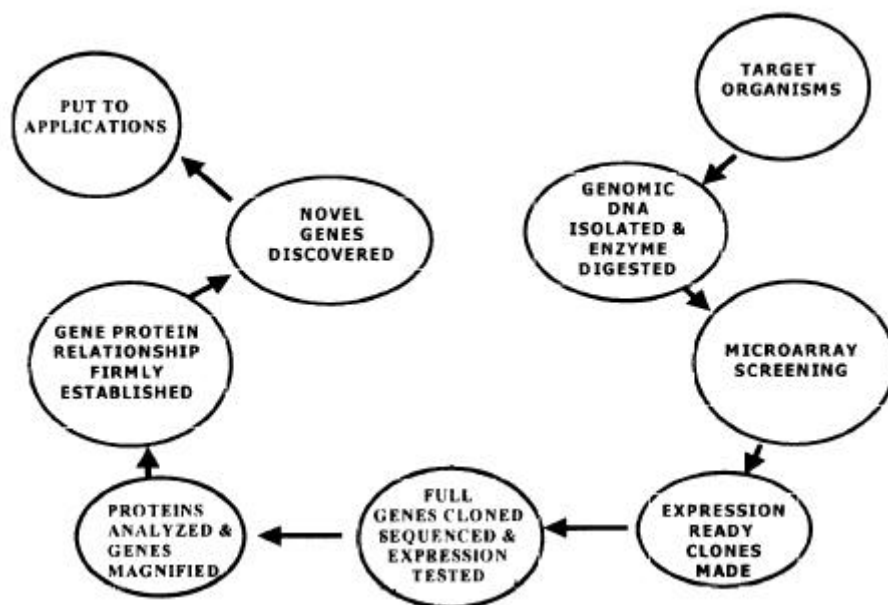


Figure 5. Broad steps in discovery of novel genes.

microbial diseases, abiotic stresses like salt tolerance, drought or excess water tolerance, etc. Some nutritional quality improvement programmes are also under development. Several disease-resistant transgenic forest plants are under experimentation. Some plants have been made to bear fruits that are used as vaccines against infectious diseases. All these developments in modern biotechnology are in the hands of a few international companies, although the application of these technologies would require the use of germplasms and local cultivars that are largely in the possession of developing countries. Therefore, in congruence with the Convention on Biological Diversity<sup>7</sup>, alliances would be created among the technology possessors and the germplasm holders for creating a win-win situation among all the participating partners.

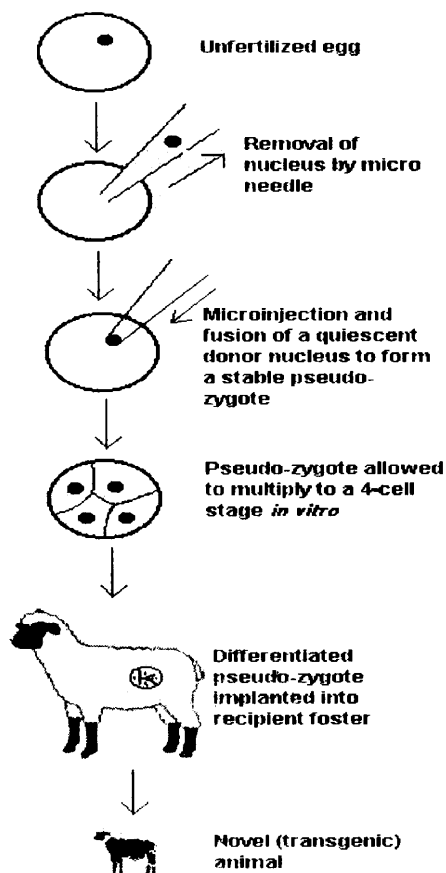
Forest development through biotechnology is another area of relevance. The selection and development of trees resistant to abiotic and biotic stresses, the choice of microbes for creating healthy plants, the choice of recipes for the upgradation of degraded lands are some of the thrust areas that could be pursued.

Other biotech products used for the management of environment include transgenic microbes for cleaning of oil

spills and toxic organic wastes, etc. Transgenic plants for accumulating toxic heavy metals from contaminated soils or water bodies are under development in certain developed countries. Applications of these technologies could be extended in developing countries. In the industrial sector, transgenic microbes for the production of enzymes used for treating textiles, leather, paper, etc. are also under development. Several food-processing enzymes are in use, which are produced by recombinant DNA technologies. In these areas also, the need for collaboration from developing countries is enormous, although technological capabilities are yet not adequate in them. All these products and technologies are required for adding value to the primary regenerating raw materials.

### Creation of infrastructure for specialized skills for biotech industry development

In developing countries, companies would require acquiring skills in molecular biology and cloning of microorganisms, including bacteria, fungi, yeast and certain mammalian cell lines. Skill in fermentation, biochemical engineering, biochemistry, microbiology and molecular immunology would also be necessary. For medical products, expertise in conducting clinical trials, regulatory approval procedure and documentation would also be needed. The developing countries could take advantage of research results in certain areas, such as conducting research with human embryos or foetal or adult human stem cells by creating conditions that are application-worthy, as these materials are available in plenty. In agriculture, besides expertise in molecular biology and cloning capabilities, hands-on experience in conducting contained greenhouse and field trial experiments, especially when dealing with genetically engineered organisms, would also be advantageous. Environmental risk assessment and risk management capabilities have to be at the national level and companies should have capabilities to generate information in accordance with a country's regulations. Transboundary movement of GMOs would also require the creation of strong infrastructure and knowledge about handling such products safely. Besides, food safety assessment capabilities would also have to be developed for crops, for which, appropriate upgraded laboratories with animal houses should be in place. In plants, more experimentation is expected to upgrade the core competence besides improving the level of confidence; this will bring down the application time of economically beneficial food crops as well as forest plants that are empowered to withstand more unfavourable condition. The IPR issues would assume tremendous significance and the IPR laws of countries should at least have to be consistent with the provisions of WTO. In fact, public-friendly IPR laws within the provision of WTO would be more useful to the needs of developing countries<sup>8</sup>.



**Figure 6.** Schematic representation of whole genome cloning: novel animals by nuclear transfer.

## Developing countries would seek alliance for technologies

Industries in developing countries would enormously depend upon access to technologies. Strategy for access to modern biotechnology could be through various routes depicted in Figure 7.

External environment can have significant influence on in-country development of modern technologies in developing countries, which are resource-poor and multi-focused in developmental efforts. Modern technology development is a collective endeavour of skillful people in different disciplines. Individuals alone, however skillful they may be, cannot achieve this. While industries in developing countries would be conducting some in-house R&D and may also be involved in sponsored research in public institutions by co-financing public institutions with governments, they would primarily be dependant upon acquisition of value-added technologies from a relatively small number of foreign companies. Such technology-providing companies would also be the relatively small players in the international context. Products from modern biotechnology being highly skill-based and also being extremely science-intensive, those who possess such technologies would not be ready to part with them, unless they are small companies or there are other compelling reasons. Powerful companies would usually be ready only to offer value-added products and services at exorbitantly high prices till competitors emerge on the scene and make the availability, driven by market competition. Consequently, under the prevailing circumstances, strong in-house capabilities would have to be created not only to develop novel products but also to acquire skills to absorb the procured high-class technologies, so that further developments could be initiated for remaining competitive in the times ahead.

Between the events of setting up production infrastructure and commercialization of biotech products, there is

an event called marketing (not shown in Figure 7). Biotech product marketing is a more complex issue than marketing of the commodities, including a pharmaceutical formulation. The intermediate players who affect actual sales, like doctors for pharma products, pathologists for diagnostic products or vocal public and farmers for agricultural products, need to be effectively informed. A strong line of active communicators needs to be developed and kept vibrant in place with a team of specially trained personnel in order to obtain success in sales. Biotech products introduced in the market by a group of generalists are anticipated to be aborted sooner than surmised from the market, if specialists do not continuously support them.

## Factors that would govern success for promoting alliance

Biotechnology industry is characterized by fierce competition. Only those countries would be able to take advantage that have created adequate infrastructure and have put concerted efforts to develop biotechnology through multi-disciplinary alliance. The success would include a well-defined product portfolio, early entry into market, acquisition of technical skills for process development and capability for rapid commercialization, emphasizing on application-oriented R&D, concentrating on off-patent drugs and teaming up with transnational corporations.

Strong alliance can be forged only between strong partners. Strength comes from skills and complimentary competence. Countries with abundant genetic resources are considered to be with gifted advantage. With leadership and determination, skills can be acquired. Cuba is a glaring example of acquired skills in biotechnology. The need is to have a long-term strategy.

In the Indian context, about forty companies are presently involved in marketing of biotech products. Most of them have alliance with transnational corporations for

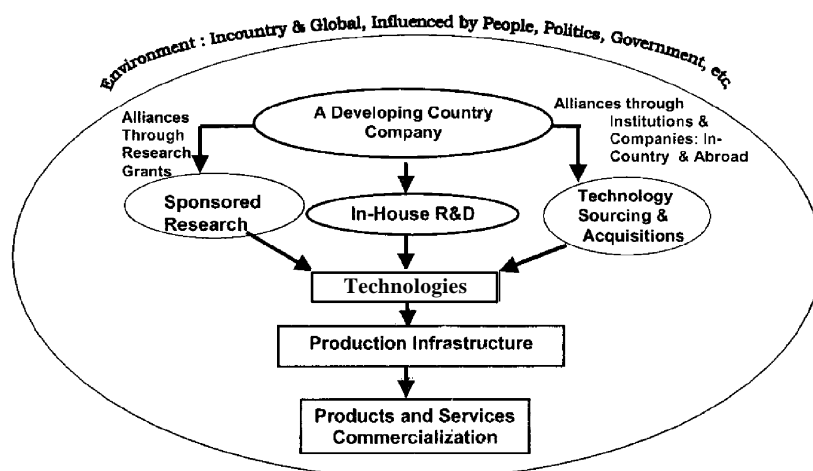


Figure 7. Strategies for technology development in industries of developing country.



product marketing. Others have gone further and have or are in the process of setting up manufacturing facility locally, again with some alliances. The companies in manufacture have sourced either the genetic materials or laboratory-proven technologies and have created infrastructure for further development and production. The products include a dozen of recombinant DNA biopharmaceuticals (three of which are in production and others are in the stage of near production), diagnostics, food enzymes, industrial enzymes and transgenic seeds for improving agricultural productivity. Table 1 shows the major Indian companies that have created alliances with different institutions and industries. The alliances include mainly product marketing rights; some have teamed up for product development with local institutes and only a few have taken steps for product manufacture (unpublished data).

Alliances are not new concepts to industries in developed countries. Large biotech companies like Eli Lilly, Roche, Glaxo, Ciba-Geigy have each more than a dozen of collaborations at a time with different institutes<sup>9-11</sup>.

Indian companies have been comfortable for teaming up for co-marketing rather than equity participation or setting up manufacturing units with foreign partners; the moves were rare for conducting contract or joint R&D. Indian Institute of Science (IISc), Bangalore started a landmark experiment of providing space to companies so as to forge strong basic as well as application-oriented research within the premises of IISc. It was perhaps assumed that the complementing basic research capabilities would emanate from IISc and the companies at the space licensed by IISc would carry out the developmental R&D. This conceptually sound endeavour kicked-off well with Monsanto Inc. taking the lead followed by Cadila Pharmaceuticals and Lupin, but the myopic views of the institute and the researchers to obtain a lion's share of the grants from such collaboration along with the equally stronger short-sightedness of the licensee companies to invest less in R&D, did not result in any great success. The antagonists to the concept added fuel to fire by viewing such a concept as commercializing institutes of learning into corporate cultures for profits and surpluses. The concept is getting weaker day by day. There is a need to revisit the concept and to make changes in the policies at the national level that will enable the birth of economy – uplifting industrial endeavour from such befitting conceptions.

In developing countries alliances would not come about without a push from the top. Governments must push alliances as a necessity. They should not view these as obstacles to progress. Alliances happen among mature partners with complementing capabilities. Few partners ideally exist in developing countries for such tenures. Money spent by governments is thinly spread, as governments have to deal with all kinds of social factors, necessitating diversion of scarce funds in several low-

priority areas on the plea of equity or justice. If, however, alliances exist among public-funded institutions with industry and if such alliances are rated to be beneficial to the overall economic development, more public funds could be diverted to such institutions. This would not only make research-based, public-funded institutions more focused and reasonably effective, but it would also move towards fruition to application, as the industrial partner would impose directions on the collaborating partners. Industry cannot live without R&D results getting returns. It is believed that the governments can set the grounds for alliances in developing countries and can concurrently play key roles in forging and maintaining alliance. Innovative structures like 'hybrid firms' which emerged in the developed world<sup>12</sup> in science-based industries embedded in institutions of government research institutions and universities, should be encouraged to come up in India to further the process of commercialization of new developments in biotechnology like cloning, biochips, structure-based molecular design, protein engineering, contract research, etc.

### Alliance can also benefit developed countries

Alliance can be forged only among able partners. Ability arises either from the possession of complementing technological skills or from complementing synergies of supply-consumption needs. Some developing countries have a large pool of low-cost skilled manpower. They also have large potential markets. R&D cost for developing is usually much lower in developing nations. Cost of clinical trials for pharmaceuticals is substantially lower in developing countries. There are advantages of access to large germplasms, genetic materials, cheap agricultural raw materials and low-cost infrastructure.

Biotech research in future years would depend upon access to exotic genetic materials. The provisions of the Convention on Biological Diversity promote access to genetic materials through mutually agreed terms between the recipient and the supplier countries. As developing countries have greater access to such materials, alliances can also be forged between industries of developed countries and governments of developing countries for mutual benefits within the provisions of law and accepted cultural practices. Alliance in this area is expected to be gradually evolving.

### Concluding remarks

Developing countries and industries therein would be benefited from alliance with industries in developed country in various ways. While there would be an opportunity to have access to modern biotech products, they would also learn the intricacies of handling such products, which are often fragile and require careful handling under cold chain conditions when they are pharmaceuticals. These properties of bio-pharmaceuticals necessitate

**Table 1.** Alliances of major Indian companies with different institutions and industries

Major Indian companies	Collaborating institutions/industries	Nature of collaboration
Shantha Biotechnics, Hyderabad	Osmania University, Hyderabad, Centre for Cellular and Molecular Biology (CCMB) Hyderabad; Indian Institute of Science (IISc), Bangalore; Jawaharlal Nehru University (JNU), Delhi; Pfizer India, Mumbai	Biotech process development, technology transfer and product sale
Bharat Biotech Ltd, Hyderabad	IISc; Center for Biochemical Technology (CBT) now renamed as Institute of Genomics and Integrative Biotechnology (IGIB), Delhi	Diagnostic kits development, Hepatitis B vaccine technology, Epidermal growth factor
Serum Institute, Pune	Serono International S.A., Switzerland	Marketing of reproductive hormones, growth hormones
Bhat Biotech, Bangalore	IISc	Biotech process development and diagnostics
Panacea Biotech, Punjab	JNU; Heber Biotech SA, Cuba	Vaccine development, including recombinant Hepatitis B and rabies, technology transfer and biotech product development
Hindustan Antibiotics Ltd, Pune	National Chemical Laboratories (NCL), Pune	Enzyme process development
Indian Immunologicals, Hyderabad	Welcome Foundation, UK	Veterinary viral vaccine against foot and mouth disease, process and technology transfer
National Dairy Development Board, Anand	Delhi University (DU), Delhi	Transgenic plant development, including mustard
Ranbaxy Laboratories, New Delhi	National Institute of Immunology (NII), Delhi; Central Drugs Research Institute (CDRI) UP and several transnational companies	Diagnostic kits development, procurement of kits and their sale
Span Diagnostics, Surat	CDRI; Path, USA; ICN Pharma; US Associates of Cape Cod Inc., USA; Remel Inc., USA; Hitachi Chemicals Inc., USA; Biopool Inc., USA; General Biometrics Inc., USA; Nihon Kohden Corp., Japan; Intergen Co, USA; Corgenix, UK; Biotechnica Instruments, Italy; KPL, USA	Diagnostic kits technology development, procurement, marketing rights, sale
Dabur India, UP	NII; DU	Biotech process development and technology transfer, including nanotechnology, especially targeting cancer
Cadila Pharma, Ahmedabad	DU; IISc; Institute of Microbial Technology, Chandigarh; The Energy Research Institute, Delhi; Indian Agricultural Research Institute, Delhi; International Centre for Genetic Engineering and Biotechnology, Trieste, Italy	Biotech process development, technology transfer and diagnostic kits development for viral diseases
Zydus Cadila, Ahmedabad	Schering AG, Germany; Boehringer Ingelheim, Germany; Baxter, USA; Berna Biotech, Germany	Biotech process development and technology transfer for human vaccines, oncology and bioactive therapeutics
Wockhardt Ltd, Mumbai	Rheine Biotech, Germany	Biotech process development and technology transfer Hepatitis B vaccine, insulin, cytokines
Nath Seeds, Aurangabad	Biocentury Transgene Company, China	Genetically modified cotton seeds and technology transfer
Maharashtra Hybrid Seeds (Mahyco), Mumbai	Monsanto, US	Equity participation and technology transfer for genetically modified seeds
Ankur Seeds, Aurangabad	Mahyco–Monsanto, India	Technology licensing for genetically modified seeds
Rasi Seeds, Tamil Nadu	Mahyco–Monsanto, India	Technology licensing for genetically modified seeds
Xyton, Bangalore	IISc; ICGEB	Diagnostic kits development and sale
J. Mitra and Co, New Delhi	Cancer Research Institute, Mumbai and several transnational companies	Diagnostic kits development and sale
Infar India Ltd, Kolkata	Organon Teknik, Holland	Product marketing
Concord Biotech, (Concord), Ahmedabad	America Type Culture Collection and Institute for Fermentation, Osaka, Japan	Procured primary microbial strains for producing antilipidic drugs like Lovastatin, Simvastatin
Biocon Limited, Bangalore	Concord, CIMAB, Cuba	Granulocyte colony-stimulating factor (G-CSF), erythropoietin (EPO), microbial strains for antilipidic drugs
Intas Pharmaceuticals, Ahmedabad	Indian Institute of Technology, Mumbai; Avestha Gengraine Technologies Pvt Ltd, Bangalore; Eurosequence, Netherlands	Analytical support for conducting structural analysis, amino acids sequencing, nucleotide sequencing of recombinant proteins like EPO, G-CSF
Shreya Lifesciences Pvt Ltd, Mumbai	SciTech, USA and SciGen Inc., Singapore	Technology tie-up for insulin, Hepatitis B vaccine, growth hormone and interferon
East India Pharmaceuticals, Kolkata	Cleveland Research Institute, USA	Biotech products and process development
Advanced Biochemical Limited, Thane	Pacific Corporation, South Korea	Technology and process development for industrial enzymes
Nicholas Piramal, Mumbai	IGIB	Research in bioinformatics and genomics

acquaintance in product documentation, registration and approval procedure. Such products also require specialized marketing networks, where documentation and supply cannot follow the usual routes of non-biotech pharmaceuticals. Qualified people need to handle such products, even for marketing. Use of such products also requires the setting up of sophisticated regulatory laboratories that could assess the quality of such products. In transgenic foods, agriculture capacities to identify such substances also assume importance as the products are new and the governments need to assure the public about their safety for which both identification and assessment of safety infrastructure needs to be upgraded. Alliances between private parties in these areas for product marketing would require upgradation of the regulatory infrastructure of a country that overseas safety as well as efficacy.

Internationally reputed companies that possess biotech products seek to invest and team up with those countries and companies where they are assured of protected use of their products, ensured about adequate returns and encouraged by the government to invest. However, an ideal environment does not exist. Consequently, within the prevailing environment, investment decisions are to be taken. Generally, developing countries form large potential markets that are growing fast as well. Besides, certain countries have surplus skilled manpower; adequate R&D infrastructure and government policies are supportive to collaborations. Teaming up, therefore, brings additional bonus points.

As biotechnology is highly science-based and heavily skill-intensive, several products and services could be created in small laboratories and could be in the possession of public or private funded institutions. Such products and services are protected through IPR and are often not available in the ready-to-use form. Considerable subsequent developmental work is necessary. Products and services at such stages are cheaper to procure and can be used by industries, if they have adequate infrastructure and capabilities. Creation of alliances and effecting technology transfer between such partners is foreseen as a strong possibility for biotech product development in many developing countries, where certain baseline capabilities exist. The provisions of IPR in WTO are reasonably compatible to the needs of developing countries. Many industries in developing countries are taking advantage of such situations for creating alliances for technology transfer from developed countries. Moreover, the provisions of IPR in many developing countries are more public-friendly than inventor-friendly, even though they comply with WTO. Such a situation in IPR shall continue to stay, as the opinion makers in the world, irrespective of their country of origin, shall favour more public-friendly IPR than inventor-friendly ones. IPR holders in healthcare products that address mainly the needs of developing countries as also products that address the food needs of poor people that are derived from

GMOs may have to recognize these signals and become generous while imposing their IPR rights. Strong alliances are forged in situations between industries in developing countries and institutes or small industries in developed countries, where partners have a compromising attitude; appropriately created alliances in such situations would complement the needs of both.

It can be stated that products and technologies in the biotech industry provide great advantage to the users. They are more effective and efficacious. People will therefore use them for their benefit. Use cannot be prevented through imposition of legal or other restrictions. If this is understood, all countries, strong or weak, developed or developing, should endeavour to encourage global networking through industries and other avenues within the framework of societal norms, cultural practices and political compulsions so as to maximize the use of biotech products for the benefit of mankind. Wisdom lies in creation of intelligent alliances and networking, rather than in installing inhibitions.

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