INDUSTRIAL AND ENVIRONMENTAL APPLICATION OF BIOTECHNOLOGY

Developing Countries in a New Bioeconomy

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INTRODUCTION[1]

The promise of biotechnology, a set of revolutionary techniques, has been the subject of public policy aspirations for the last two decades. In a call tempered by realism and caution, Agenda 21, the work programme adopted by the 1992 United Nations Conference on Environment and Development, asserted that biotechnology “promises to make a significant contribution in enabling the development of, for example, better health care, enhanced food security through sustainable agricultural practices, improved supplies of potable water, more efficient industrial development processes for transforming raw materials, support for sustainable methods of aforestation and reforestation, and detoxification of hazardous wastes.”

At face value, it appears that biotechnology has not lived up to its earlier promises, and this perception is reinforced by current debates over the safety of genetically modified (GM) foods. But a careful examination reveals biotechnology inroads into nearly all the major fields of human endeavor.[2] The adoption pace witnessed in the fields of biotechnology is consistent with previous trends in other generic technologies. The rate of diffusion will be fastest where biotechnology creates new products that do not compete with existing applications. In the field of health, for example, new diagnostic methods for a wide range of biological and non-biological expressions could be such products. The pace will be slow and possibly controversial where biotechnology seeks to displace existing processes and products or enhances the competitiveness of certain products.

It is now a decade since world leaders signed onto Agenda 21. Since then, three major developments have occurred. First, the institutions of globalization that were being crafted at the time of the adoption of Agenda 21 are now in place, and their influence on the international trading system has become a subject of considerable debate. Second, biotechnology products have made their debut on the international market, and it is now possible to assess the performance of biotechnology in the global economy. Third, advances in biology (especially molecular biology) signal the prospect of a new generation of products and services that were not conceivable a decade ago. This background provides the basis against which the present report reviews the promise, prospects and challenges associated with the introduction of industrial and environmental biotechnology into the global economy.

More specifically, the paper is concerned with the ability of developing countries to play a significant role in what is clearly an emerging field, involving the wider application of modern biotechnologies in areas such as agriculture, medicine and industry. We refer to the confluence of modern biotechnologies and the market niches that they occupy as “the new bioeconomy”. This analysis is guided by heuristics from the influence of microprocessing on traditional industries—especially manufacturing—in the 1980s and 1990s. In this regard, we surmise that every industry that uses biological resources will be affected in one way or another by modern

1. We are indebted to Derya Honca and Karen Fang (Center for International Development at Harvard University) and Alexey Vikhlyaev (United Nations Conference on Trade and Development, Geneva) for their support, additional information and comments on an earlier version of this paper.
2. Pew Initiative on Food and Biotechnology (2001) *Harvest on the Horizon: Future Uses of Agricultural Biotechnology*. Washington, D.C.: Pew Initiative on Food and Biotechnology.

biotechnologies. New industrial structures are likely to emerge, driven by technological innovation. The new bioeconomy will benefit from advances in other fields, especially informatics, and it will take root in countries and regions that take deliberate steps to create an enabling environment for its adoption. The new bioeconomy will also be driven by considerations such as industrial sustainability.

The paper suggests that sustaining a new bioeconomy requires the adoption of a global governance regime for biotechnology that helps to bring a large number of developing countries into the global trading system. Failure to do so will create a "genetic divide" among countries and is likely to intensify public opposition to biotechnology.[3] Such opposition is likely to be fuelled by presumptions about possible market dislocation and apparent features of technological disparities between nations. The elements of such a governance system include improvements in market access, development of technological capabilities, access to technology, national regulation of biotechnology, and the management of risks and benefits associated with its use.

1. THE EMERGENCE OF A NEW BIOECONOMY

Advances in biotechnology-related fields such as genomics, genetic engineering, chemical engineering and cell technology are transforming the industrial and environmental process and management landscape. Microorganisms, enzymes or their products are replacing processes that heavily depended on chemicals, many of which are implicated in environmental damage. However, much discussion on biotechnology currently focuses on agricultural applications (and to some extent biomedical uses). The generic nature of biotechnology techniques makes it possible to create a new bioeconomy with greater prospects for the commercialization of new biotechnology products and wider participation of the developing countries.[4] This market inclusion model will differ from the current one in which technology is concentrated in a small number of countries and resistance to new products is widespread.[5]

Since its emergence, modern biotechnology has been associated with debates concerning benefits and risks. The ability to transform life itself to generate new products and services has been classified as a revolutionary technology with the same societal impacts as the information and communications revolution. With these high expectations have also come fears and concerns, which have captured public and policy attention worldwide. Concealed in the narrower debates about the impacts of biotechnology on human health and the environment are wider concerns about socio-economic considerations, which can be translated into market dislocations.

3. Juma, C. (Forthcoming) "The new genetic divide: biotechnology in a globalizing world", *International Journal of Biotechnology*.
4. Models of biotechnology commercialization in small economies may be of relevance to most developing countries. See, for example, Marsh, D. (2000) *Fostering Innovation in a Small Open Economy: The Case of the New Zealand Biotechnology Sector*. Manchester, UK: Eighth International Joseph A. Schumpeter Society Conference, 28 June.
5. This view also takes into account key dimensions of international politics. See for, example, Pownall, I.E. (2000) "An international political economy view of the biotechnology industry", *Electronic Journal of Biotechnology*, Vol. 3, No. 2, pp. 1-20.

Indeed, early concerns about agricultural biotechnology focused on the possible impacts of genetic engineering or shifting the locus of production of raw materials and its potential to reduce the participation of developing countries in the global economy. Little attention was paid to the ability of the developing countries to use the same technologies to diversify their produce and become players in the new bioeconomy. The debate over the distribution of biotechnological capabilities is evident in the field of agriculture, where only a handful of countries are producing GM crops. This narrow distribution of capabilities is also a major source of international concern and a key factor in the acceptance of GM foods worldwide. Similar trends are likely to develop in the fields of industrial and environmental biotechnology, unless the global governance of biotechnology is improved.

Although scientific advances in biotechnology appear to be concentrated in a smaller number of industrialized countries, there are various factors that would allow for the wider participation of developing countries in the new bioeconomy. The first factor is the growing recognition that the current patterns of globalization are untenable, if they do not increasingly include developing country products. These countries depend on industries that are based on natural resources and therefore can benefit from the use of modern biotechnology. Second, many of the techniques used in biotechnology research are becoming readily available because of scientific familiarity, and are therefore relatively easy to acquire through sustained capacity and enterprise development efforts. Thirdly, much of the initial R&D expenditures have already been borne by the industrialized countries and what is needed is effective international technology partnerships.

Taking advantage of these opportunities, however, will depend on the level of domestic technological capacity in the developing countries and the kind of global biotechnology governance system that emerges from the current policy debates. A global governance system that provides opportunities for market access will help to foster the commercialization of new technologies, especially those that threaten to alter the patterns and loci of production. In other words, resistance to new technologies is likely to be reduced by perceptions of access to the new technologies, as well as to their markets. This, indeed, has not been the case with agricultural biotechnology, which involves worldwide exports with the potential for product displacement, while leaving wide margins of uncertainty for technological followers.

Wider participation in the bioeconomy will also foster greater interest in the harmonization of regulatory practices among countries. This view is based on the claim that regulatory practices evolve from the practical management of technology. In other words, those who have the capacity to use modern biotechnology are also the ones who would have the means and interest to develop regulatory systems for that technology. An alternative scenario involves a small number of biotechnology exporters and a large number of countries that are likely to consider restrictive regulatory practices. This seems to be a possible scenario in the field of GM foods.

The fears of technological exclusion are real. The skills and detailed knowledge, from biology to engineering, needed for countries to become players in modern biotechnology are diverse and in-depth. In addition, equipment sophistication and finance must be globally competitive.[6] Responses by developing countries to these requirements will vary considerably, depending on prior capabilities in relevant fields, existing strategies for enhancing national competitiveness in biotechnology and the degree of integration into global technological networks through joint ventures and strategic alliances. In the field of agriculture, for example, developing countries have been able to develop capabilities through international research networks such as the Consultative Group on International Agricultural Research (CGIAR). But this particular network represents a unique initiative that is rooted in the challenges of the Cold War and has not been replicated in other fields. Moreover, the CGIAR's future is currently uncertain, partly because of the declining interest in the industrialized countries to address technological challenges facing the developing world.

The new bioeconomy is characterized by the emergence of institutional structures, as well as rules, that demand alternative technology cooperation approaches. First, the new bioeconomy has emerged concurrently with international trading rules that reinforce the market dominance of leaders in particular technological fields. These rules are reinforced by greater emphasis on instruments such as the Agreement on Trade-related Intellectual Property (TRIPs) under the World Trade Organization (WTO), which reduce the prospects for technological spillovers to developing countries. Second, globalization has intensified interactions among firms in the developed world and contributed to technological convergence among firms in this region at the expense of linkages with firms in developing countries. Third, the new bioeconomy is driven largely by the private sector, with lesser participation of public sector enterprises. The growing role of the private sector in the industrialized countries demands a similar shift in the developing countries. This suggestion does not entail a reduction in the role of the public sector. However, it necessitates a review of the role of the public sector in a globalizing world. On the whole, a new technology governance regime is needed to foster technological cooperation, expand market opportunities for all major players, and expand the prospects for wider acceptance of biotechnology products.

2. GLOBAL TECHNOLOGY AND POLICY TRENDS

2.1 Technological innovation

The last century saw the replacement of plant-derived products with petroleum derivatives. These remarkable transformations helped humanity to overcome some of the natural limitations of relying on natural processes. The change was largely a result of advances in chemistry and allied fields. This century promises to open new avenues for increasing the use of renewable resources in the global economy. These trends will open up new opportunities for the participation of developing countries in the new bioeconomy. But as in previous technological revolutions, the promise and reality are different. In the case of agricultural biotechnology, for example, only a handful of developing countries have so far managed to

6. Visalakshi, S. (2001) "Manpower requirement in biotechnology and strategies to achieve them-international and Indian experiences", *International Journal of Biotechnology*, Vol. 3, pp. 199-216.

become players in the global economy. The rest have little hope of playing significant roles in the near future. As in other technological fields, participation in the new bioeconomy will be uneven and limited to those countries that make the necessary investments in technological development.

So far, much of the research on policy aspects of biotechnology has focused on agricultural and pharmaceutical biotechnology. The field of industrial and environmental biotechnology remains understudied. Industrial biotechnology covers two distinct areas. The first area is the use of renewable raw materials (biomass) to replace raw material derived from fossil fuels. The second is the use of biological systems such as cells or enzymes (used as reagents or catalysts) to replace conventional, non-biological methods.

Industrial application of biotechnology is emerging as a spin-off from developments in other fields such as the pharmaceutical sector. This is largely because industrial biotechnology has not received the same level of public policy attention as has biotechnology in other sectors. There are other structural factors that influence the diffusion of industrial biotechnology. These include the dominance of physical and chemical technology as a source of concepts for the design of industrial plants, which limits the scope for introducing biological processes.

One of the main advantages of industrial biotechnology is the prospect for the controlled production of biological catalysts. These biocatalysts are more specific and selective than their non-biological counterparts. As a result, they offer greater potential for cleaner industrial production. In other words, biocatalysts generate fewer by-products and can start with relatively less purified feedstocks. And because they are self-propagating, they can be used in applications such as waste treatment.[7] But despite these advantages, biocatalysts are generally fragile (requiring large amounts of water) and have low volumetric productivity. Over the years, however, incremental technological innovations and new bioreactor designs have helped to improve the industrial performance of biocatalysts. With incremental improvements in biocatalysts and the emergence of new design concepts, biotechnology's capacity to diffuse in the industrial sector will grow. This prospect is enhanced by the growth in the biological sciences, as well as complementary fields such as chemistry and informatics.

The use of biomass for energy and industrial uses has been on the agenda of many governments for nearly two decades. Much of the interest was triggered by the oil crises of the 1970s. Although the interest waned with the decline in energy prices, advances in the biological sciences have continued to enhance the prospects for technological improvement and wider application. In addition to energy, living plants can be used to produce chemicals such as citric acid, lysine and lactic acid. Genetic modification offers new possibilities for using plants as a source of raw materials for chemicals or even finished products. Monsanto, for example, has experimented with a genetically modified crest plant to produce a biodegradable plastic using a gene from a bacterium, *Ralstonia eutropha*. Similar experiments are underway in other chemical firms around the world. One of the most advanced efforts is an initiative by Cargill Dow Polymers (CDP) to construct a plant to produce 140,000 tons a year of polylactide (a biodegradable plastic) using lactic acid fermented from corn.

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7. OECD (1998). *Biotechnology for Clean Industrial Products and Processes: Towards Industrial Sustainability*. Paris: Organisation for Economic Cooperation and Development.

As enzyme technology improves, attention is shifting to other areas of bioprocessing by tapping the potential in the world's splendor of microbial life. Much of this world remains untapped largely because microorganisms have so far been poorly studied and documented. With the advent of DNA sequencing, microorganisms will become an important addition to industrial activities through scientists' discovery of new biocatalysts. The field of genomics is therefore likely to extend its influence from medicine and agriculture to industrial production. Methods such as forced evolution and rational design will increasingly be used to discover new enzymes for industrial use. In addition, methods such as gene shuffling are helping firms to optimize their bioprocessing activities.

It is expected that the genomes of major industrial microorganisms will be sequenced in the coming years, and this will add significantly to the library of industrial biotechnology. Prospecting for biological organisms of industrial value will increase as bioprocessing gains acceptance. The network of agreements between bioprospecting firms such as Diversa and biotechnology-related firms such as Dow, Aventis, Glaxo, and Syngenta illustrates the growing increase in this field. These technological developments will result in new generations of chemicals and polymers that will compete directly with bulk petro-chemical products.

These developments are improvements over a long history of efforts to use bioprocessing in industry. The mining sector, for example, has been using bioprocessing for a long time. Bioleaching is a natural process that helps in weathering of sulphide ores. Organisms have been harnessed successfully in zinc, copper, nickel and gold mining among others. Bioleaching is environmentally friendly, cheaper to build and cheaper to run than traditional leaching methods.[8] The use of *Thiobacillus ferrooxidans* to oxidize sulphide metal ores dates back several centuries. But it was not until 1986 that the world's first commercial bioleaching tank for gold-bearing sulphide was commissioned in South Africa by Gencor. The procedure now employs both mesophilic and thermophilic microoganisms.

Developing countries have been the center of origin for some of the bioleaching technologies. For example, the Biox process owned and developed in South Africa is now used in many other countries, while the success of the largest experimental solvent extraction electro-wining (SXEW) in Zambia has been used in 40 other mines in developed countries. Current efforts are focusing on identifying new organisms that are stable, multiply efficiently and are reliable. Other initiatives focus on identifying organisms for different processes such as reduction of iron and sulphates, as well those that can be used to dissolve toxic metals in mine waste discharge. Technology is also being developed to inhibit organisms that are involved in mine acid generation. Biofilters for sulphides are also under and represent an effective and cheap alternative to traditional filters.

The textile and leather industry is another sector that has used biotechnology for decades, especially through the use of enzymes. Many enzymatic products (amylases, lipases, cellulases, isomerases and extremophiles) are being marketed by firms such as Maps (India), Novozyme (Netherlands) and Genencor (USA). Genetic probes have been developed that could detect adulteration of the merchandise and deterioration of fiber. There is now a

8. It is suitable for production of up to 150, 000 tonnes per annum.

movement toward preparation of high quality fiber from microorganisms, plants and animals, using genetic engineering technology.

For developing countries, the demand for high quality leather and fibers is likely to increase. These countries could add value to their raw materials and meet the demands by adopting the new technologies in their processes. The leather and textile industry is faltering or dying in some countries, due to poor quality of products and increased costs of production. Biotechnology, if appropriately used, could lower the cost of production and improve the quality of leather and textile products.

The paper industry is another old technology that relies heavily on wood, energy, water and chemicals. New technologies have emerged that are changing the face of this industry. The pulp and paper industry was estimated in 2000 as the fastest growing market for industrial enzymes. Enzymes are quickly replacing traditional chemicals in pulping, in paper production and in de-inking recycled paper. Biopulping (using fungi) results in nearly 30% saving of electricity, while treatment with cellulase and hemicellulase reduces wood drying time considerably. Bioleaching of pulp reduces chemical requirements by 50%. The use of enzymes and fungi increases the physical properties of the fibers and the quality of paper. Many developing countries have lagged behind in technological developments in paper manufacturing and have become importers of paper, even when they have the potential to be exporters.

In addition to industrial applications, modern biotechnology also is likely to make major inroads into the field of environmental management. Using microorganisms or their constituents, environmental biotechnology involves processes that detoxify industrial waste, clean up industrial contaminants and enhance control of environmentally unfriendly practices. Environmental management is indeed a growing industry that will benefit from further advances in biotechnology. The use of sensors to detect pH, voltage, ionic strength, heat, light and smoke, among others, has been the basis of many analytical and home instruments. The selectivity of enzymes, other proteins, nucleic acids and carbohydrates has become the focus of research to identify noxious gases in mines and organisms in the environment.

2.2 Structure and evolution of the biotechnology industry

The structure of industrial biotechnology remains a complex network of corporate players, dominated by large firms with strong marketing capabilities and start-up firms that focus on research and development. Because of the cumulative nature of innovation, many of the technological advances in industrial and environmental biotechnology originate from leading biotechnology firms with strong backgrounds in chemical engineering. In this respect, the structure of the biotechnology industry has the same attributes as the conventional industry. The frontier technologies are concentrated in the hands of a few firms in the industrialized countries. Many of these are the same firms involved in other fields of biotechnology.

The biotechnology industry has in recent years undergone major changes associated with waves of mergers, acquisitions and spin-offs. For a while, the firms experimented with the model of “life science” industries seeking to bring together various applications in the fields of health, agriculture and industry under one umbrella enterprise and a common technology platform. This corporate model—represented by firms such as Monsanto—has yet to demonstrate its viability. Other firms, such as DuPont, continue to maintain their chemical competence as they expand their presence in biotechnology.

Fundamentally, the "life science" corporate model did not work as envisaged, because of differences in R&D approaches, regulatory pathways and markets in the health and agricultural sectors. Strategies for developing products in the two sectors differ considerably, and so do corporate R&D cultures. The promise of synergy provided by a common technology platform has been difficult to sustain. As a result, firms such as Monsanto, Novartis and AstraZeneca have had to scale back their expectations.

Alliance formation still remains a central feature in the development of industrial and environmental biotechnology. Cargill, specializing in polymer research, has formed an alliance with Dow Chemical, a respected name in plastics, to form CDP. In turn, CDP has formed alliances with polymer users and support industries (plastic molding firms). There are similar alliances between enzyme R&D centers, enzyme producers and enzyme users. These alliances share the risks and benefits of research, development and commercialization of innovations. Another major feature of these new developments is information sharing. The end users identify problems that are passed on to the developers or research centers. For example, detergent manufacturers have formed alliances with Genencor and Novozyme to develop enzymes that work at all the normal ranges of washing temperature, water hardness and salinity. The result should be tailor-made products that fit market requirements.

Such alliances and interactions have been concentrated in the industrialized countries, and as a result, they have played only a marginal role in bringing developing countries into the new bioeconomy. Extending, on a selective basis, the alliances and interactions to developing countries through appropriate institutional arrangements is an important element in promoting the wider application of industrial and environmental biotechnology.

2.3 International and national policy

International and national policies influencing biotechnology are still in the early stages of development and have not been consolidated into a body of governance. This is partly because the biotechnology industry is an outgrowth of other industrial operations, and as a result, many of the policies that govern the field are derived from governance of the wider industrial sector. There are, however, exceptional cases where clear policies are being developed to specifically address biotechnology. One of the earliest areas of policy development in biotechnology was the determination of research funding priorities. These broad funding decisions have given way to more specific and targeted approaches by various countries. In the United States, for example, funding for biofuels research is an example of such measures.
Other complementary areas of policy development include the extension of intellectual property rights to cover living forms. This is particularly significant, given the fact that historically, living organisms fell outside the scope of protection of most intellectual property systems. Industry has argued that the absence of intellectual property protection for living organisms undermined funding prospects for biotechnology. This intellectual property

standard has been incorporated into the TRIPs agreement.[9] Critics, however, have argued that such property rights are inconsistent with morality and have been too wide.[10] In other words, the extension of intellectual property rights to cover living organisms is seen in some sections of society as being against the public interest.[11] In response to these claims, patent offices around the world continue to review the scope of patentability to seek a balance between the demand for protecting inventions and the pressure to safeguard public interest.

Another major area of policy development is the emergence of new rules that seek to govern biological inventions on the basis of their presumed risks to human health and the environment.[12] These policy measures come under the general umbrella of “biosafety” and are the subject matter of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. Although the Cartagena Protocol has not come into force, it provides a set of policy guidelines that will have implications for the development of biotechnology.[13] One of the most significant features of the protocol is the promulgation of the precautionary principle as a tool for risk management in the face of uncertainty.[14] This is a contested field, because of the potential for the principle to be used as an instrument for market protection.[15] The critical policy issue here is how to establish an international standard for balancing between safety and international trade.

The application of industrial biotechnology could be enhanced through the adoption of policies that promote the use of cleaner technologies. Such policies could derive their inspiration from international or domestic sustainability norms. Agenda 21 provides one of the most important sources of guidelines for promoting cleaner industrial production. Other international agreements dealing with reductions in chemical pollution, atmospheric pollution and hazardous waste provide policy frameworks for promoting the use of clean biotechnology. There have also been missed opportunities in the international arena. The Convention on Biological Diversity, for example, has devoted the last five years to developing rules for the safe use and handling of biotechnology. However, over that period little was done to explore areas that could benefit from the new safety rules. The convention’s provisions that call upon countries to cooperate in the field of biotechnology still remain dormant.

2.4 Biotechnology commercialization in developing countries

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9. Watal, J. (2000) “Intellectual property and biotechnology: trade interests of developing countries”, *International Journal of Biotechnology*, Vol. 2, No. 1/2/3, pp. 44-55.
10. Drahos, P. (1999) “Biotechnology patents, markets and morality”, *European Intellectual Property Review*, Vol. 21, No. 9, pp. 441-449.
11. Barton, J. (2000) “Rational limits on genomic patents”, *Nature Biotechnology*, Vol. 18, No. 8, p. 805.
12. Wolfenbarger, L. and P. Phifer. (2000). “The ecological risks and benefits of genetically engineered plants”, *Science*, Vol. 290, pp. 2088-2093.
13. Gupta, A. (2000) “Governing trade in genetically modified organisms: the Cartagena Protocol on Biosafety”, *Environment*, Vol. 42, No. 4, pp. 22-33.
14. Soule, E. (2000) “Assessing the precautionary principle”, *Public Affairs Quarterly*, Vol. 14, No. 4, pp. 309-328.
15. Hagen, P.E. and Weiner, J.B. (2000) “The Cartagena Protocol on Biosafety: new rules for international trade in living modified organisms”, *Georgetown International Law Journal*, Vol. 12, pp. 696-717.

There is no single characterization of the industrial and environmental biotechnology industry in developing countries. What is evident, though, is the growing importance of international partnerships and alliances in biotechnology's evolution in developing countries. Such alliances are likely to increase with time. These alliances also serve a larger function. They provide a basis for the kinds of partnerships that are essential for a market inclusion model to function. The absence of open markets for technology and products can lead to resistance to the adoption of new technologies. Such partnerships are thus essential for the effective commercialization of biotechnology products. A winner-take-all scenario that was tried in the field of agricultural biotechnology is slowly giving way to opportunities to explore new models of international cooperation. So far, much of the public debate on this issue has tended to focus on the importance of partnerships between the private and public sectors. While these linkages are important, they are not a substitute for international alliances, under which the private sector plays a critical role in the commercialization of new products.

The importance of international alliances is illustrated by the evolution of Biocon India. The company was established in 1978 in Bangalore as a joint venture between Biocon Biochemicals of Ireland and local interests. The company started with the production of simple fermentation products and later embarked on its own R&D program that saw it become a major player in the fields of modern biotechnology. The R&D efforts were inspired by the need to diversify the company's product portfolio. One of the first efforts was to develop a local alternative to Konji—a carefully fermented mass of cooked soybean meal and roasted wheat—imported from Japan. This is a good source of amylases and proteases, enzymes crucial in the hydrolysis of carbohydrates and enzymes.

The process was complicated and largely unknown outside Japan. But after three years Biocon India successfully mastered the techniques leading to new fermentation platforms and enzymes that matched those from Japan. These successes were also encouraged by Biocon Ireland, which bought products from the company. Biocon India became an owner of new fermentation technologies, and two manufacturing plants were commissioned to meet demand. Following these successes, Biocon India became a supplier of food enzymes to United States and European markets. In addition to enzyme production, the company also invested in the development of new production systems that incorporated the advantages of solid state and submerged fermentation. After five years of effort, the team developed Plafractor, a solid phase fermentation platform whose controls are automated and programmable, allowing reliability, repeatability and reproducibility. It is also a closed system which protects the operator and the environment from any toxic agents produced during fermentation. Further, it allows the quick and convenient recovery of fermentation products and saves space and labor. The patented bioreactor recently won the 2001 Biotechnology Product and Process Development Award from the Indian Department of Biotechnology in the Ministry of Science and Technology.

The story of Biocon India is an example of the importance of international partnerships. While Biocon India carried out innovations and production, Biocon Ireland provided the market for its products, enabling the newly formed firm to have a steady flow of income as well as eliminating marketing costs of products. In 1989, Biocon Ireland and its 30% share in Biocon India was acquired by Uniliver. Uniliver's financial muscle and global standing gave Biocon new linkages and access to funds. Biocon learned Uniliver's global operations, standards and financial methods.

Biocon India has expanded its operations and ventured into fields such as pharmaceutical research. It established Syngene, which in turn spun off Clinigene International as a wholly owned subsidiary. Syngene has close collaborations with AsraZeneca, Glaxo and BMS which contribute to its research efforts. Clinigene specializes in genomics and clinical studies to support the pharmaceutical section of the Biocon Group. Biocon has thus developed rapidly through strategic partnerships with end users of its products. Research, to a great extent, has been driven by the demand of its customers resulting in accumulation of proprietary technology and development of products and processes. This flow of information between producer and end user was an important input in R&D activities.

Market access was guaranteed in the initial stages by Biocon Ireland. However, the team went through a steep learning curve in global management, standards and negotiations. They exploited the chances that were presented to them, through association with global companies, to expand their markets and product range. All these lessons helped the company to consolidate its position, identify funding opportunities and take advantage of market availability. The creation of different units into individual companies spurred their expansion, depth of research, and product development. The autonomy enjoyed by the different units soon led to innovations that became the basis of new companies and new associations with other companies outside the group. Biocon India represents one model of biotechnology commercialization that depends largely on international partnerships and alliances. It carries with it the attributes of inclusion that should be encouraged in the development of industrial and environmental biotechnology.

The case of market inclusion through international alliances is also illustrated by Cuban experiences in biotechnology commercialization. Cuba's Centro Nacional de Investigaciones Cientificas (CENIC) was established in 1964 with a biochemistry research and training facility devoted to health sector needs. It was not until the early 1980s that Cuba started to focus policy attention on biotechnology as a source of pharmaceutical products. The initial focus of the government was to support the creation of research centers, starting with the Centro de Investigaciones Biológicos (CIB) in 1982. CIB was replaced in 1986 by the Centro de Ingenieria Genética y Biotecnologia (CIGB), which produced proteins and hormones for human and veterinary medicine, vaccines and diagnostic kits for diseases common in Cuba and other developing countries. It has facilities for immunology, enzyme preparation, pharmaceutical production, and conversion of biomass.

CIGB is estimated to employ 1200 scientists and technicians and has about 192 laboratories in total, equipped with the best instruments from countries such as Japan, Germany and Sweden. These facilities produce vaccines for meningitis B and hepatitis B. Vaccines for HIV, hemophilia and cholera are under development. In diagnostics, CIGB has produced analytic systems capable of detecting HIV, hepatitis B, herpes simplex, changás, leprosy and other diseases. It has also produced probes for plant diseases, about 50 enzymes (some of which are produced only in Cuba), and 160 medical and pharmaceutical products.

Cuba moved into the commercialization of biotechnology products through the creation of a semi-private enterprise, Herber Biotech. By 1998, Herber Biotech was recording about

US$290 million in sales of hepatitis B vaccines and its pharmaceuticals in 34 countries. The company also had representatives in about 50 countries. Nationally, biotechnology was placed just behind tourism, nickel production and tobacco in terms of export earnings. The company is extending its partnerships with other developing countries. For example, in 2001, it established a joint venture with Kee Pharmaceuticals of India, in Haryana. This marketing venture is aimed at getting access to the Indian market through special pricing and technology transfer. The company's main product, a recombinant of streptokinase called cardiostrep, is owned by Herber Biotech, is used for the hydrolysis of coronary clots or prevention of heart attacks and has a potential market value of about US$11 million per year. The market value is expected to grow by 30% annually. Other products under the deal have included interferon and human transfer factor, also owned by Herber Biotech.

Cuba recognizes that participating in the global market involves forging alliances with a wide range of enterprises, especially those that have extensive marketing networks. For this reason, some of its biotechnology products, such as the meningitis B vaccine, are being marketed by Pfizer, a US-based multinational firm. Cuba's biotechnology industry is an example of the importance of political leadership on technological matters, domestic funding for research activities, creation of appropriate research institutions, and international alliances for product commercialization. The future of the Cuban biotechnology program will depend on the degree to which these elements are maintained, especially in the face of worsening economic conditions that might divert allocation of resources and political commitment to other sectors.

The field of genomics also offers opportunities for developing countries to commercialize specialized bioinformatics services. The data derived from genome sequencing activities needs to be analyzed to determine the functions, activity and regulations of genes and facilitate product development. Traditional methods of test tube analysis of each molecule's chemical, physical and biological properties are laborious and insufficient when faced with thousands of different molecules from various organisms. Firms devoted to bioinformatics are starting to emerge in developing countries. For example, in 1996 Electric Genetics was established in South Africa to commercialize innovations from the South African National Bioinformatics Institute (SANBI). Electric Genetics is housed at SANBI at the Western Cape University and is funded through an national innovation fund aimed at encouraging science, engineering and technology.

The company and its partners, SANBI and Silicon Graphics, have developed two software packages for clustering, alignment and recombination of sequence data. The first program is a management system for expression variation analysis and transcript reconstruction, while the second is a sequence tag alignment and consensus knowledge database. The programs have been used by leading genomics institutions such as Celera, The Institute for Genomics Research, Paracel, Paradigm Genetics and The German Cancer Research Center, among others. In 2000, Electric Genetics won the prestigious Technology Top 100 Award in its category from the South African Ministry of Trade and Industry. The award was a recognition of the company's excellence in development and research as well as its ability to commercialize its products internationally. International partnerships have played a key role in the development of the company.

3. INTERNATIONAL MARKET OPPORTUNITIES

3.1 Scope for trade

The evolution of market opportunities for industrial and environmental biotechnology is difficult to predict, partly because of the nascent nature of the industry, poor understanding of its structure, and a lack of concerted efforts to improve the policy environment for the diffusion of biotechnology products. What is likely to emerge, however, is a scenario dominated by niche markets in a wide range of sub-sectors. Furthermore, the blurring of boundaries between agriculture, health and industry makes it difficult to predict potential areas of market expansion. Even though the "life science"s industries model is currently being questioned, the generic nature of the technology suggests that firms that have established a lead in pharmaceutical or agricultural biotechnology are likely to become equally important players in industrial biotechnology.

However, it is clear that industrial biotechnology has a wide range of starting points, which should lead to expansion. For example, enzymes are estimated to hold a world market value of $1.6 billion, of which North America and Europe account for 35% and 31%, respectively. The share of the enzymes market in the textile and detergents sectors shrank, while that in animal feeds, specialty chemicals, and food applications increased at least five-fold, between 1992 and 1998.

Asia has the fastest growing market for feed additives, currently estimated to be over $6 billion globally, followed by Latin America. Amino acids and vitamins account for about $3 billion, digestive enhancers about $1.3 billion and disease-preventing agents $480 million. It is estimated that the amino acid and digestive enhancers market will continue to grow. The market for probiotics should continue to grow, following the introduction of legislation in Europe and other countries to prohibit the use of antibiotics in animal feed.

However, it is also important to note that a number of the current biotechnological products are more expensive than their traditional equivalents. Biopesticides are still lagging behind chemical pesticides due to target specificity (which is bad for business, but good for the environment), instability and batch (potency) variation. This makes the marketing and production of biopesticides difficult and their use by farmers, households and industry unattractive. They are estimated to be worth about US$380 million (or $74 million without Bt) out of an estimated US$8 billion pesticide market.[15]

Bioplastics and biofuels have been more expensive than traditional plastics and petroleum-derived equivalents in developed countries. Although the gains to the environment, made by the use of these products, are hard to determine, bioplastics and biofuels remain worthwhile areas for development, especially since costs of production are dropping. Bioplastics are now commonly used in hospitals and in home products and disposable_utensils. Further, the costs of petroleum products in developing and developed countries are different, which makes them attractive in the former. It is along these line that genetic engineering may increase the value, but reduce the cost of production of these products.

Table 1: ***Market estimates for industrial biotechnology***

Product	Current product (Examples)	Market($million)
Enzymes	Liquefying, proteolytic, maltogenic and isomeric enzymes	1,600
Biopesticides	Nematodes, pheromones, natural products and derivatives, and insects	380[#]
Bioplastics	Hospital fibers, straps, cutlery, straws, belts	135 million MT[x]
Nutraceuticals	Dietary supplements, foods (natural/organic/functional), phyto-pharmaceutical	86,000
Biofuels	Electricity, fuel additives, methanol, ethanol	2 billion gallons[*]
Bioreactors	Mining, enzymes	NA

1997; represents 1.4% of the pesticide industry
*The price range is $1-$2 with subsidies and represents only ethanol.

It can be seen from the previous summary that the influence or impact of biotechnology on industry is likely to increase over the next years, and it will spread from the farm to the manufacturing sector. As new materials with enhancer properties are discovered, so will be the need for better household, industrial and scientific products. Most of the products we touch, wear and see are already produced, in one way or another, using biotechnology-derived reagents. The development of modern tools (genetic engineering or recombinant DNA technology) will transfer many of these processes and products to higher levels of productivity not yet experienced.

3.2 Market structure

Biotechnology powerhouses in developed countries currently dominate the market. The major chemical, oil, agricultural and pharmaceutical firms are also major players in biotechnology which, in itself, is good for technological development through increased investments. However, if these firms have not been known to transfer technology to developing countries they are unlikely, this time around, to change their attitudes regarding R&D management. The market is heavily dominated by the US, which has invested heavily in biotechnology human capital and research activities, followed by Europe. Other important players include Canada, Japan, Australia, China, India and Cuba.

These countries have some of the leading R&D centers, producers and exporters of biotechnology products. It is possible to estimate where many players are located, by identifying the major producers and their major consumers, as well as the markets that they serve. Enzymes and plastics give an indication of biotechnology market shares. Most of the industrial enzymes are produced in Europe and the US, while most of the plastics are consumed in Asia, followed by North America and Europe. Biotechnology application in industry is following trends similar to those observed in agricultural and pharmaceutical sectors, where the major producers develop solutions that are tailored to meet the needs of their markets. This pattern is reinforced by alliances between technology developers and end users.

Potential market gains

Biofertilizers represent an affordable industry for many developing countries. In many African countries, the use of inorganic fertilizer has increased soil acidity, reducing the yield per ton of fertilizer. Biofertilizers are cheap to manufacture, suitable for small-scale farmers if produced locally (eliminating distribution costs), and the investment in technology is far lower than that of inorganic fertilizers. Biofertilizers have been produced, packaged and sold commercially in India, while in a number of African and Latin American countries, biofertilizers have been produced at national research centers. Most importantly, the demand for biofertilizers has outstripped production in almost all these countries. It is estimated that about $40,000 to $50,000 is required to build a 100-150 MT biofertilizer plant. Alternatively, $500,000 for 10 plants in different locations could produce up to 1000-1500 MT to meet the demand by rural farmers. With increased production capacity, biofertilizers have a market locally and possibly internationally.

The increasing urbanization of most developing countries has caused the emergence of problems often thought of as being “Western” (dental caries, diabetes, obesity, cancers and cardiac diseases). Demand for body and health products is rising. It is a rapidly expanding industry that offers growing prospects for both developed and developing countries. Nutraceuticals already have a big market in developed and developing countries. The demand for natural remedies is likely to increase and present a market for developing countries endowed with wide biodiversity.

The food industry has failed to expand in many developing countries, due to their continued use of chemical preservatives that many international market are unwilling to accept. The use of natural products to inhibit bacteria and fungal growth will improve the acceptability of products. Further, most of the enzymes involved are now easy to prepare in-house or could be obtained on the international market at a fair price from different sources. The products to be affected will include fruit and vegetable preparations, fish and meat products and fresh grains (e.g. corn) exports.

Textiles and leather are another sector where developing countries could expand their exports using biotechnology. Many of the newly industrialized countries in Asia have already registered a marked increased in textile exports. Biotechnology in these areas has been and continues to be used to increase product quality, reduce waste and save energy. With many of the biotechnology companies moving into developing countries in search of new markets, the use of biotechnology in leather and textiles should increase.

The mining sector is the mainstay of many developing countries and its contribution to the economy is often large. The technology currently on the market has focused on the large mining conglomerates that produce copper, gold, zinc, nickel and other bulky metals. The semi-precious mining sector (the small mining sector, as it is popularly called) has attracted very little attention from technology developers, despite its importance. For example, Ghana's small mining sector earned approximately $140 million in 1995.[16] This sector could increase its share of earning, if appropriate technology is developed.

In the future, industrial products such as enzymes, vaccines and some drugs will be produced by plants and animals and will require processing. Developing countries will need to acquire capacity, not only to produce, but also to process products. The international market for industrial enzymes and products is large. It presents an area of interest in which developing countries such as India and China are already involved. For example, Maps of India has registered growth of above 150% per year and is an exporter of industrial enzymes. It should be possible for other developing countries to develop their own industrial products that supply their home industries and compete on the international market.

Of great interest is integration of the many opportunities to maximize gains and share the risks and benefits of different products. It would be economical to have a milling plant to produce syrup, animal feed, oil, fuel, high protein supplements, flour and fertilizers, among others. The corn refiners in the US consume about a quarter of the $25 billion corn produce and turn it into syrup, gas (carbon dioxide), alcohol, feed additives and flour. They do not just add value to a product that often remains after exports, but they are a big market for corn. Most of the agricultural programs in developing countries are affected by lack of a market, and integration could be beneficial. The final products may have an export market.

Potential market losses

The gains outlined above will not occur automatically and evenly. Those firms that invest in biotechnology early enough are the ones that are likely to take advantage of these market opportunities. This prediction would also suggest that large enterprises with an edge in technological innovation stand the best opportunity to make inroads into the emerging markets. But such advances, especially in a world marked by growing industrial inequalities, could trigger market opposition and even resistance to biotechnology. It is therefore important to understand the market risks posed by the new technologies, in order to appreciate their potential for wider commercialization of biotechnology products.

Market losses are likely to occur in areas where biotechnology products replace conventional sources of raw materials or where chemical processes are replaced by bioprocesses. What is critical is the fact that product substitution is likely to occur. Indeed, the new innovations are expected to have an impact on the composition of products and processes. What is critical is to design mechanisms that allow for the wider distribution of benefits and risks. The participation of petro-chemical enterprises in the new technology is essential for the wider diffusion of biotechnology, mainly because perceptions of potential market losses are likely to be high in these sectors.

3.3 Opportunities for developing countries

16. United Nations (1996) *Developments in Small-scale Mining*. New York, USA: United Nations.

One of the challenges facing many developing countries now is to make the transition from raw material exports to processed products. Industrial biotechnology processes may be able to reduce the cost of investment and production, as well as growth of high-quality fibers. Africa exports 54%, Asia 16%, Latin America and the Caribbean 29%, and the USA 19% of the value of their cotton production. The high ratio of cotton exports from Africa reflects the lack of a strong African textile industry. Although Europe exported 80% of the value of its cotton production, it imported 360% of its production volume, while Africa imported only 15% of its production volume. This situation may remain until industrial inputs are, at least in part, produced locally or regionally.

Some of the existing trade arrangements between developing countries and the industrialized countries reinforce dependence on export of raw materials. Trade incentives such as the Africa Growth and Opportunity Act passed by the US in April 2000 should provide a basis for faciliting the transition towards industrial processing. Asia and Latin America have fast-growing and robust textile industries. The demand to meet market needs should force these countries, some with emerging and some with already growing markets, to look for alternative technologies. Industrial biotechnology is likely to play an important role.

Biofertilizers present developing countries with a unique opportunity to enhance their crop yields. Countries like Bangladesh, Brazil, Kenya, Tanzania, Zimbabwe and Zambia have had successful pilot plants for the production of biofertilizers, and demand has often exceeded production. If any of these countries built a production plant with local and regional markets in mind, they could be exporting their products. India has developed many biofertilizers that are currently on the market for gardeners and farmers. If these products are coupled with crop rotation and irrigation, it is possible to increase crop yields of legumes and cereals. Biopesticides, too, could help increase crop yield, reduce import bills, and increase export earnings. Taken together, they could provide an affordable source of agricultural inputs that would challenge chemical use in rural areas. Chemical fertilizer and pesticide imports and exports from developing countries are low, and production yields are very poor, especially in Africa. Biotechnology will depend on renewable raw materials, and agriculture should play a big role in developing countries' exports.

Biofuels, too, hold considerably more promise for developing countries than for developed countries. The cost of petroleum-based fuel in developed countries has been as low as \$1/gallon or \$0.22/liter. In many developing countries it is as high as \$4.5/gallon or \$1/liter. Even at their present prices, biofuels could compete with petroleum-based products in some developing countries. This means that many developing countries could reduce their petroleum import bill, add value to agricultural crops, help clean up the waste at a profit, and provide jobs for many unemployed people, all without subsidies.

Though biogas is part of biofuels, it presents many developing countries with a unique opportunity in the provision of lighting and heating energy. With a life span of about 50 years, low-cost lighting systems can be supplied in rural areas where conventional electricity is not profitable or unreliable.

As described above, other industries such as mining are already benefiting from biotechnology. Bioleaching is a common technology in developing countries' mines. The small mining sector, often targeting small mineral deposits, could use bioleaching technology to improve the quality of the final products and reduce waste associated with mechanical cracking. In other cases, amethyst, agate, diamond and gold mining still use harmful chemicals. Finding biotechnological solutions will increase the value and earnings from this sector, as well as reduce environmental degradation.

The leather and textiles industries have been among the major environmental polluting industries. The use of enzymes, as discussed already, will reduce industrial discharge through recycling of water, cut down the electrical and water bills and improve the quality of the final products. Plants need not be rebuilt, but simple adjustments and replacement of harsh chemicals with biological systems are sufficient. With minor additions, enzymes and microbes could easily be produced in-house. With a reduced cleanup bill, increased earnings and turnover, the industry will be set to become competitive.

Paper production plants in some developing countries have either been closed or are uncompetitive. However, biotechnology presents this sector with many advantages that were never available before. The use of microbes and enzymes could replace chemicals, resulting in water and heat savings and improved quality of paper. Genetic engineering may produce designer wood that will grow faster and, when processed, require few steps, resulting in extra savings and improved quality of paper. Many of the paper manufacturing plants that are currently uncompetitive could soon become exporters of paper.

The most promising areas for many developing countries will lie in approaches that add more value to their raw materials. For example, technologies that will convert cassava into export products (e.g. plastics, sweeteners or fibers) will empower many poor farmers who currently do not have an international market for their products. These fibers or polymers will be used to generate bags, plates and other utensils that have a higher value than the raw materials. Biotechnology could present a means by which to indirectly market products that are currently difficult to sell. With a market for tubers, their production could exceed that of cereals in no time, in many developing countries.

A second promising application for developing countries will be the conversion of waste into useful products. Specifically, food waste may break down into amino acids, fuels and fertilizers which would benefit the rural and urban poor. Unlike the pharmaceutical industry, many developing countries could easily enter this market. The use of microbes and enzymes will be key in this revolution, and developing countries need to rise and seize the opportunities.

With appropriate investment and political commitment, developing countries could become players in the international biotechnology market. The case of Cuba, which has developed more than 50 different enzymes, 150 therapeutic agents and several vaccines demonstrates that developing countries could exploit technology just as efficiently as developed nations. Brazil has more than 10 biotechnology incubator projects that are about to be spun off as companies, while India has emerged as a center for enzyme production and drug development. Clearly, the investments required to build biotechnology competence are well below those of traditional industries (e.g., pharmaceuticals), but the returns are higher. Many developing countries see this as the area that presents real opportunities.

4. GLOBAL GOVERNANCE OF BIOTECHNOLOGY

The wider application of industrial and environmental biotechnology under current globalization trends will depend on the creation of an appropriate governance system for the new bioeconomy. For developing countries to participate effectively in the new bioeconomy, at least five key areas of the governance system will need to be adjusted: market access; international biotechnology alliances; intellectual property protection; regulation; and risk management. This section outlines some of the key recommendations that pertain to these areas of global governance.

4.1 Improving market access

Limited market access represents the greatest hurdle to international trade and consequently to technology access and acceptance. Although liberalization of markets has increased over the last 50 years following the numerous trade negotiations and integration of economies, many barriers to trade still exist, especially in labor-intensive sectors that are of interest to developing countries. The two major barriers are high tariffs and standards (sanitary and phytosanitary requirements). Agricultural products and industrial product exports to developed countries suffer most from tariff peaks.[17] The EU and Japan have the highest number of tariff peak products for agricultural imports, while the US and Japan have the high number for industrial and electronic products imports. These products represent about 15% of the exports of least developed countries to the developed countries.

Other than tariff peaks, these products also suffer from tariff escalation. For example, exports of finished textile and clothing products to Canada attracts 16 times the tariff on raw materials for the same industry. Other products that suffer from incremental applied tariffs by stage production include leather, rubber, metal, wood and paper. These are all products where developing countries have particular interest.

Taken together, tariff peaks and escalations reduce the desire in developing countries to export finished products, thereby reducing diversification and skill accumulation. Because of high levels of subsidies to agriculture and export products in developed countries, most developing countries continue to be marginalized in international trade.[18] In the absence of open markets, it is not surprising that developing countries do not invest heavily in export industries linked to the processing of raw materials.

Table 2: ***Tariff escalation for developing country exports to industrial countries***

	Imports (US$ billion)	Share of each stage %

17. Peak tariffs are tariffs of 15% or higher, or three times the tariff in developed countries. Tariff escalation refers to increasing tariff with level of downstream processing.
18. The OECD support to agriculture is estimated at $1 billion per day.

Natural resource-based		
Raw materials	14.6	44
Semi-processed	13.3	40
Finished products	5.5	17
All Industrial products		
Raw materials	36.7	22
Semi-processed	36.5	21
Finished products	96.5	57

Sources: World Bank and International Monetary Fund, Washington, DC.

Non-tariff restrictions such as quota allocation, voluntary export restraints and non-automatic licensing continue to affect exports from developing countries. Products affected by these measures include textile, sugar, rubber, minerals, machinery and precious stones in both developing and developed country markets. There are also fears that once these measures are phased out, they are likely to be substituted by other measures such as anti-dumping or other technical barriers.

The requirement for exporters to meet product standards similar to those found in the importing countries is a critical element in international trade. However, if the exporter's home market standards are different from that of the export market, then extra cost has to be incurred to meet the demands. Many developing countries do not have sufficient facilities and personnel to conform to industrial market demands. Developing countries often import products that are banned in developed countries, while developed countries are more restrictive when it comes from imports from developing countries. The implications of these restrictive measures and other trade inhibitory mechanisms such as countervailing duties, safeguards, customs and administrative red tape on industrial and environmental biotechnology are potentially large. These measures will affect fields such as polymers, fuels, paints, lubricants, fertilizers, plastics, and many other products.

Market access is an essential element of market liberalization, and special efforts need to create better trading opportunities for developing countries. In the absence of such improvements, trust in global markets will remain low, and the mistrust is likely to hinder the wider application of emerging technologies.

Efforts to promote the wider use of industrial and environmental biotechnologies should involve measures aimed at reducing barriers to market entry for products originating from developing countries. This should be done in the context of measures aimed at fostering the emergence of the new bioeconomy.

4.2 Forging international biotechnology alliances

One of the most significant developments in the structure of the global biotechnology industry is networks involving partnering activities.[19] These networks are products of complex

19. Mytelka, L. (1999) "New trends in biotechnology networking", *International Journal of Biotechnology*,

interlinkages between a wide range of enterprises, links which are designed to reduce the risks associated with the development of new products, as well as to facilitate information exchange. More specifically, these partnering arrangements help to provide sources of financing through licensing and upfront fees for R&D expenses, reimbursement of expenses for partnered products and services, royalties, profits and other “success fees” associated with the achievement of certain milestones. Such arrangements are particularly important in areas with limited access to other forms of financing, such as venture capital. Even where venture capital is available, these arrangements still serve an important risk-reducing function.

Partnering activities are naturally more concentrated in the industrialized countries, but these arrangements are being extended to developing countries, especially in agricultural biotechnology. Similar arrangements could be considered in industrial and environmental biotechnology. In addition to the risk-reducing benefits outlined above, partnering arrangements could also play a key role in the development of technological capabilities in the firms and institutions in developing countries. Such capacity would be specialized and related to specific products and services. Furthermore, such partnering would also be useful in promoting the adoption of good management as industrial production standards in developing countries.

> *It is therefore recommended that partnering models that are relevant to developing countries be identified and promoted as part of the expansion of the new bioeconomy.*

4.3 Crafting flexible intellectual property systems

Emerging technologies are associated with strong regimes of intellectual property protection. Biotechnology is a particularly interesting area for two reasons. First, the patenting of living forms is a recent development that is specifically linked to policy measures to foster the establishment of the biotechnology industry. There are differences of opinion on the exact impact of patent protection on the evolution of the biotechnology industry. What is evident, though, is that complementary institutions such as venture capital would not have evolved to the extent that they did, without the existence of an intellectual property regime that provides comfort to investors and inventors alike.

In this regard, intellectual property protection has co-evolved with the biotechnology industry and is one if its key institutional attributes. There are, of course, many areas of industrial and environmental biotechnology in developing countries that have developed through the use of public domain technology and have therefore not been affected by increased intellectual protection barriers. This, however, is going to change as more countries are brought under the auspices of the TRIPs agreement, its successor arrangements and extra-juridical measures.

Trends in agricultural biotechnology suggest that the impact of intellectual property rights on the ability of developing countries to participate in the new bioeconomy varies considerably, depending on the nature of the research, level of technological development and enterprise size. Public sector research programs remain particularly vulnerable to changes in the

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intellectual property regime because of their traditional dependence on public domain technologies and lack of knowledge of intellectual property practices. Although this situation is starting to change, many developing countries are still far from mastering the details of inventive activity. It is paradoxical that for these countries to participate in the new bioeconomy, they will need to establish a certain level of familiarity and compliance with the emerging intellectual property rules. Ironically, however, these same rules might affect their ability to be players in the new bioeconomy.

Furthermore, most developing countries are still in the early stages of technological learning where access to patented technologies is essential for industrial development. The more advanced developing countries need to balance between their interest to have access to protected technologies now, while preserving the possibility that any of their future inventions will be protected. There are no general models that would enable countries to reflect these various balances in one strategy. However, there are specific areas that require policy attention.

> *First, developing countries will need to ensure that they meet the minimum requirements for intellectual property protection and create suitable environments for inventive activity. In turn, developed countries should help increase the level of trust in the intellectual property system by seeking to balance strong intellectual property protection with the need to broaden the base for technological partnerships with developing countries. Agricultural biotechnology firms are exploring ways of sharing their patented technologies with developing countries under special institutional arrangements, including flexible licensing arrangements. Similar measures may be needed in the field of industrial and environmental biotechnology.*

4.4 Creating enabling regulatory environments

There are two types of regulatory issue that deserve attention under the new bioeconomy. The first set is related to international trade in living modified organisms. The second set of regulatory issues involves measures that are designed to facilitate the adoption of industrial and environmental biotechnology. Industrial biotechnology regulations will be similar to those in agricultural or pharmaceutical industries, depending on the products, but have so far remained and will remain less controversial, for at least two reasons. Firstly, biotechnology products used in process management (e.g. enzymes in textile and leather processing) do not become part of the final product (cloth or shoes). Secondly, the enzymes do not have any ability to transfer the gene sequence from which they were produced to any other life forms. Industry is likely to recycle or bake the waste prior to discharge. Therefore, the main issue will be batch contamination and the quality of the discharge.

The potential environmental benefits of industrial biotechnology makes it attractive to those who are interested in promoting the transition towards sustainability. Incremental innovations as way new design concepts will help to make these technologies competitive with their conventional counterparts. Such cost reduction is important, especially with biofuels and bioplastics that are not yet competitive with petroleum-derived equivalents. However, the use of transgenic organisms in food processing, biofertilizers and waste treatment will be more controversial than in bioplastics and biofuels. The kinds of concerns expressed in agricultural biotechnology may arise here and should be treated in the same way.

Evidence from the implementation of the Cartagena Protocol on Biosafety shows that building regulatory capacity for biotechnology is a complex process requiring considerable external assistance for most developing countries. Those countries that have capacity in biotechnology research are also in a better position to design and implement regulatory systems. This view suggests that the growth of regulatory capabilities in developing countries will remain uneven and will be sensitive to cost factors. There are numerous models for reducing regulatory costs, including regional centers, mutual recognition arrangements, as well as cost-sharing agreements between government and industry.

Another area that might require special attention is the use of environmental regulation to promote industrial sustainability. This regulatory field is relatively new, but it offers opportunities for expanding the adoption of environmentally sound biotechnologies. The main limiting factor is the low level of use of environmental regulations to promote the adoption of alternative technologies in developing countries. Also related to this are measures that seek to reduce the consumption of non-renewable raw materials and replace them with bioproducts.

> *In order to promote the use of environmentally sound biotechnology, governments will need to specify areas where such technologies could result in specific benefits. But such specification may need to be done under the framework of a broader policy initiative aimed at promoting industrial sustainability.*

4.5 Managing economic risks and benefits

Much of the discussion about the risks of biotechnology deals with environmental and health issues. Equally important is the failure to manage these risks and benefits effectively is one of the main sources of resistance to the adoption of new technologies. There are institutions that deal with some aspects of risk and benefit management, such as anti-trust legislation. But these do not address the seemingly benign cases of product displacement. Generally, such adjustments are considered to be part of the evolution of markets. However, the pace and scale at which they happen could become a threat to the diffusion of the very technology that brings about new benefits. The use of pest-resistant crops, for example, could be seen as offering a wide range of economic and health benefits. But those who rely on the chemical industry for their livelihoods are likely to be direct and indirect sources of resistance to the new technology.

Early efforts to identify potential winners and losers is an important part of the technology development strategy. With this identification, it should be possible to manage both the risks and the benefits in a way that allows for relatively smooth technological transitions. Managing technological transition is not easy, partly because of the competitive nature of market behavior and the dominant view of losses as part of the institution of free markets. However, in the absence of measures that reduce radical market impacts, resistance to new technologies in likely to emerge and undermine the potential benefits to society.

Intra-industry and inter-industry consultations are an essential element of such a technological transition strategy. Such consultation should lead to measures that promote market inclusion insofar as they do not unduly interfere with the functioning of the market. And in doing this, particular attention should be given to potential impacts on developing country enterprises.

CONCLUSION

This paper has outlined some of the salient features of the emergence of industrial and environmental biotechnology as a growing segment of the new bioeconomy. The wider adoption of these technologies will depend largely on the extent to which global economic governance provides adequate space for the emerging technologies. Of particular relevance is the ability of developing countries to participate in the new bioeconomy. The paper has stressed the importance of a more open market access system, flexible enforcement of intellectual property rights in industrialized countries and adherence to minimum protection standards in developing countries, wider technology partnerships through corporate alliances, enabling regulatory environments, especially those that promote the transition towards industrial sustainability, and more effective systems for managing the economic risks and benefits associated with the introduction of new technologies.