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Biotechnology, the Gene Revolution, and Proprietary Technology in Agriculture:

A Strategic Note for the World Bank

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Editorial Policy: The purpose of *IP Strategy Today* is to provide a forum to share creative, innovative and pragmatic analysis and ideas in intellectual property strategies and management issues, particularly as they affect the transfer of proprietary technologies to developing countries, developing countries access to proprietary technologies in agriculture, the environment and health, and the international exchange of genetic resources. Emphasis on the implications of biotechnology are specifically encouraged. Papers must have a problem solving orientation and demonstrate originality and innovation in thinking, analysis, methods or application. Issues related to research investments and management, bilateral and multilateral donor policies, extension, teaching, public-private partnerships are equally encouraged, as is interdisciplinary research with a significant IP and international development component. Manuscripts, review articles and working papers that offer a comprehensive and insightful survey of a relevant subject, consistent with the scope of *IP Strategy Today*, are welcome. All articles published, regardless of their nature, will be reviewed anonymously by members of the editorial board.

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The world economy experienced significant growth and transformation, with increases in productivity, product quality, and export base diversification in the 1990s. These advances were mainly driven by the growth of traditional agricultural and industrial sectors, including the natural resource-based sectors. This article outlines how application that New Science offers an opportunity for equitable growth that will assist in further poverty alleviation throughout the world. New Science will impact all poverty areas such as income, nutrition and environmental enhancement. The principal objective of this document was to provide a textual report on the topic of innovation in science and technology, and in particular the way that new science such as biotechnology and information technology serve as factors for increasing the competitiveness of developing nations in the global context. Interwoven into this subject matter the report provides clear positions to consider adopting in the critical areas of Intellectual Property Rights, Biotechnology Biosafety, Trade and Environmental Protection. The report addresses the following:

- analyze the major advances and trends in the field of biotechnology. This includes both the animal science and commodity sectors. It focuses on a science-based approach to agricultural development;
- present an analysis of the policy framework in terms of Intellectual Property Rights (IPR) and Regulatory frameworks that underpin this research agenda;
- review the current and potential legal liability issues that accompany the application of new science to research and development, including both health and environmental liabilities;
- examine the current evolving IPR framework and the impact this may have on international national agricultural research in the developing world, especially regarding World Trade Organization (WTO) matters and Trade-Related Aspects of Intellectual Property Rights (TRIPS) as it relates to trade and research;
- discuss the current and future trends in Public-Private partnerships and how these may play a role in enhancing technology development and availability;
- scrutinize the current debate on genetically modified organisms (GMOs) and suggest a position on science and technology that underpins the risk assessment process;

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- provide a preliminary analysis of the role of international development investors (e.g. The World Bank) in the development and deployment of International Public Goods;
- describe briefly how innovations in this field are likely to affect the competitiveness and growth opportunities of countries in various stages of development, particularly on trade related matters;
- illustrate succinctly how innovations in this field are likely to affect the competitiveness and growth opportunities, especially on international agricultural research;
- characterize tools to develop international best practices in the fields of biotechnology and IPR management; and
- draw conclusions to promote debate on the role of the public and private sectors in promoting innovations in biotechnology as factors for increasing competitiveness of developing countries.

This document also provides an assessment of the current impact of biotechnology and future potential to advancing agriculture, and the legal, environmental and economic implications, especially for the developing world. The document reviews the role of the private sector and how to strengthen its linkages with public, national and international research efforts. While addressing each of the selected topics, this document considers the evolution of research in agriculture, its accomplishments, and the potential role of biotechnology but not in isolation from other on-going research in agriculture. While reviewing the current status this article also considers how modern information technology or in other allied sciences are reshaping the framework of future of agricultural research and what new targets are being pursued. The document looks at the future with a clear view of past experiences in research and technology and makes a candid assessment of what should be realistically expected from biotechnology advances.

Summary of Recommendations

Section 2. Biotechnology and Agriculture

Further improvements in global agriculture require innovative science and the development of plant derived products with high returns. Given that this type of research is based on a highly skilled workforce and the assembly of multidisciplinary teams:

> The World Bank should continue to build bridges between available biotechnology tools and their application for the improvement of crops and livestock in developing countries. Competitive funding schemes encouraging research links between advanced research institutes, both in the North and the South, and with the Consultative Group on International Agricultural Research should be pursued.

Furthermore, in order to have a research and development process driven by product delivery:

> The competitive funding scheme should ensure the integration of biotechnology with classical breeding and other associated technical disciplines. The applicants must be encouraged to develop research proposals in the framework of a holistic approach with well-defined pathways for disseminating both the knowledge and technology produced from this investment.

Section 3. Biotechnology and Information Technology (or Bio-Informatics)

Given that bioinformatics databases are International Public Goods that make possible these new technologies and products:

The World Bank should provide support for bioinformatics efforts that optimize resources, avoid duplication, and promote a new attitude of sharing in the scientific community.

Given the current lack of technical skills in this area, particularly in the developing world:

The World Bank should support personnel training. Trained people in bio-informatics are a prerequisite for this technology to succeed. Institutional links between North and South will not have an effect without skilled personnel in developing countries that can absorb, adapt, and use the information made available to them.

In order to maintain public access and use of this data, particularly for the worlds staple food-crops that feed the poor:

The World Bank should encourage and provide "seed money" to establish a public facility or consortium for bio-informatics. This will require investments in human resources and computer equipment. A task force may be established, under the auspices of the World Bank, to develop an action plan for consolidation, centralization, and programmatic integration of bio-informatics teams working in this area. The CGIAR research centers should be a key part of this international public initiative.

Section 4. IPR on Research and Agriculture

Given the fundamental link between research investment and IPR:

The World Bank should actively engage in debate and professional exchange with the World Intellectual Property Organization (WIPO) to further study the impact of IP on research investment in the developing world.

Given the need for more persons with technical and legal skills in these areas:

The World Bank should foster more human resource development in the area of IP and particularly in entrepreneurship. The mix of technical and legal skills needed in the new economy is in short supply in developing countries.

In order to develop a set of paradigm models, and to learn while doing:

The World Bank should encourage well-researched, planned investment in global IP protection for inventions from developing countries.

However, given that not all crops, animals, and technologies lend themselves to proprietary protection and market approaches:

The World Bank can foster the development of International Public Goods for those technology platforms or commodities where no proprietary avenues exist or are appropriate.

Section 5. IPR and Trade

Given the critical policy and development implications for the developing world:

The World Bank should be a key player and actively advocate for the developing world in upcoming WTO discussions on trade and agricultural IP.

Given the evolving nature of these complex relationships:

The World Bank should continue to monitor the intimate relationship between trade, IP, and research investment in both the public and private sectors. Research is indispensable for maintaining competitiveness in the market; accordingly, the World Bank should continue to foster and enhance its activities in agricultural research, including the CGIAR centers.

Section 6. Genetic Engineering Technology: A Complement to Breeding

Because of concerns some sectors of the public have raised about genetic engineering technology:

> The World Bank should encourage and support public dialogue about the risks and benefits of transgenic technology used to improve agriculture in developing countries. This dialogue must ensure that the voices of the people in the developing world are heard and that their unique needs are considered.

Furthermore, given the tremendous potential of these techniques to impact the quality of life for the poor:

> The World Bank should provide support to innovative improvement programs that combine the best of conventional methods with emerging genetic engineering technology to improve both crops and livestock.

Section 7. Genetic Mapping Technology: Knowing Where the Genes Are

The new tools of applied genomics are rapidly increasing our knowledge of biological systems and the tools to manipulate these systems. The commercial implications of these developments are fueling unprecedented scientific progress but at the expense of free access.

> The World Bank should support initiatives in applied genomics to ensure that important advances will be made available to plant breeders in national programs and in small to medium-sized companies that are supporting the development of staple crops and livestock. As custodian of the world's genetic resources, the CGIAR (Consultative Group on International Agricultural Research) international system of agricultural research centers now has a major role to play in ensuring the equitable enhancement of the world's staple food crops.

Section 8. Molecular Breeding to Address Global Issues Such as Drought and Heat Stress

The rapid development of molecular breeding tools for complex traits will require research projects that bring together large-scale multi-locational field experiments with state-of-the-art high throughput marker screening technologies and strong capacities in biometrics and bioinformatics. Hence:

> The World Bank should support long-term initiatives to undertake molecular breeding of crop and livestock species important to feeding the developing world. In this respect those CGIAR centers with breeding programs will continue to have a major role to play because they possess in-house capacity in all essential elements.

Section 9. Changing Plant Architecture: New Plants for a New Future

Given the need to feed more people on the same land area using less water and nutrients:

> Through a competitive grant framework the World Bank should encourage and support innovative research (including multidisciplinary approaches) aimed at the development of specific locally adapted prototypes to maximize the yield potential of crops. This investment could be cost-effective by tapping the knowledge and information accumulated by the CGIAR and their diverse partners.

Section 10. Biosafety: How Safe are New Agricultural Technologies?

Given that a number of other international organizations are already actively working with developing countries in the area of biosafety:

The World Bank should support the development of appropriate biosafety guidelines in the developing world by collaborating with other organizations engaged in similar efforts.

Section 11. Food Safety: It Is Safe to Grow, but is It Safe to Eat?

Given public concerns and the government's fundamental role in setting food health policies:

The World Bank should encourage and ensure science-based debate and decision-making about food health matters. The benefits of technological change, the possible risks of this change, and the consequences of no change should be addressed.

Section 12. Bioethics

Given the concerns associated with the development and deployment of genetically engineered organisms:

The World Bank (both management and staff) should be aware and sensitive to the issues surrounding GMO's and other biotechnology applications. The World Bank should encourage scientific transparency; this will be the best tool to convince people about the advantages of transgenic crops and other biotechnology applications.

Section 13. The Public Sector and International Public Good

Given the tremendous opportunities that exist to leverage publicly available data:

The World Bank should increase spending on infrastructure and human capacity building in regards to database management and information sorting and dissemination.

Through support to the CGIAR, the World Bank can take steps to improve database management and ownership for many staple food commodities. The World Bank can foster a genome network for the developing world to access databases through the CGIAR and its partners.

Section 14. Public Sector/Private Sector Partnerships: The Need for their Visionary Expansion and Diversity

Given the globalization of agricultural research companies and the current shift in research resources from the public to the private sector:

The World Bank should develop additional fora that will bring together the public and private sector in an enabling environment that will allow for the building of mutual trust and a dialogue on research and regulatory issues.

The World Bank should continue to support programs to enhance the skills of scientists, lawyers, and policy makers in these new areas of science and law. Skills in science and negotiation are important components for fair partnership arrangements.

While proprietary technology will use market forces to drive license agreements in market economies and sectors, provision must be made for those sectors of society that are left behind. Therefore:

The World Bank should try to identify areas where private sector proprietary technology developed for one purpose may be able to play humanitarian purposes in other areas, such as orphan crops or diseases prevalent in the developing world.

Section 15. IPR and Animal Science

Given the important economic and nutritional roles that livestock play in rural communities:

The World Bank should support special international studies to review the human health implications of genetically modified animal products. Given the costs associated with these studies, harmonization and cross acceptance of data is very important.

The World Bank should continue to study the impact of biotechnology and of quarantines on the trade of animal products. There is a special need to study these impacts as they relate to tropical diseases in Africa.

1. Introduction: Agriculture, Biotechnology, Poverty Alleviation, and International Public Goods

A fifth of the world's population lives in absolute poverty (less than US$ 1 per day), and almost 50% of the total world's population lives on less than US$ 2 per day. Of this meager amount, 80% is spent on food. Extreme poverty and financial insolvency translate into despair and economic isolation, and it has been shown that food insecurity and poverty are significantly related with each other. Indeed, crises in public health and food production are distinctive features of Highly Indebted Poor Countries (HIPC). The statistics for these countries paint a grim picture. About 826 million people lack adequate food to eat, and 20% of the children in the world's poorest countries do not reach the age of five. Furthermore, one third of all children under five in HIPCs are malnourished and physically stunted, which will negatively affect the rest of their lives. Their diets are often deficient in vitamins, leading not only to malnutrition but also to disease, and in severe cases, to blindness. It seems that these number of poor people may remain unchanged within the next decade if slow growth remains and inequality increases. However, the number of poor people may decline by 40% in 2008 if countries adopt policies and interventions fostering inclusion and benefiting all equally. Surely in the 21st century, when new agricultural technologies are readily available to enhance the nutritional value of crops and to increase their yields, the poor citizens of this planet have a right to benefit from these new technologies and to better their own lives and those of their children.

Development investors and policy makers should act with all possible speed to bring modern science and technology to bear on the problems of public health, food insecurity, environmental degradation and demographic stress in HIPCs. Poverty reduction and economic development need a stable base of agricultural production, particularly since a high percentage of people in the developing world depend on agriculture for their livelihoods. In this regard, science-based agricultural improvements can play an important role. For example, recent developments and new breakthroughs in molecular and cell biology (often included under the umbrella of the word "biotechnology") provide more and new sophisticated tools for the genetic betterment of crops, livestock, and fish, thereby improving yield potential—even under stress or in marginal environments—as well as the nutritional value of their food. Accordingly, it has become critical for development investors, such as the World Bank, to review advances made in applied agricultural biotechnology and to analyze how these advances can benefit the poor.

An analysis of biotechnological crop improvement should take a holistic approach while recognizing at the same time the unique needs of HIPCs. It should consider the benefits to people working and living in the agro-ecosystem rather than just the plant species. The key issue here is feeding a growing population while protecting the environment. Poor people must meet basic needs, and biotechnology has a roll to play here. At the same time, it must be kept in mind that the poorest people in the developing world live in distinct agricultural and economic zones, face different health problems, and must overcome agronomic constraints that are not the same as those in the northern hemisphere (39 out of 42 HIPC are in tropical or desert (i.e., arid and semi-arid) environments and the other 3 in temperate zones). Futhermore, what is valuable biotechnology in the industrial world is not necessarily directly beneficial to the developing world, and vice-versa. This is one reason why biotechnology applications that benefit HIPCs have been only recently developed. A good example is vitamin A rice, or so-called "GoldenRice". This rice is genetically engineered to produce vitamin A, which gives the rice grains a light gold color. In many areas of the world where rice is a basic staple, thousands of poor people every year lose their eyesight because of vitamin A deficiency. This new rice variety could deliver vitamin A directly to the poor in their staple food. Vitamin A deficiency is not a problem in the industrial world, but it is obviously of great benefit Asia's rural poor.

Agricultural biotechnology should not, however, be perceived as a *panacea* but as an important option for enhancing sustainable agricultural productivity and ensuring food security. Agri-biotech can reduce poverty, especially in rural areas, where fragile environments can also be protected by the introduction of new eco-friendly technologies. In short, any strategy supported by development investors in regards to the deployment of agricultural biotechnology in the developing world must carefully determine how poverty issues will be addressed, keeping in mind that poverty alleviation requires an integrated solution because it is a multi-faceted problem.

Of course, the use of agricultural biotechnology in the developing world carries its own multi-faceted problems, and it is the burden of this document to map them and chart a path forward. Most recent advances in agricultural biotechnology, for example, have been developed by the private sector, which has not been especially effective in explaining the benefits of these technologies to the public. Public perceptions are affecting their adoption, especially in the industrialized world. A host of issues have arisen, all of which must be publicly addressed in both wealthy and poor countries, these include biosafety, food safety, and intellectual property rights, which govern not only the technology itself but also the methods through which it is invented and in some cases the living components of this technology.

The debate about agricultural biotechnology in industrialized countries has made one thing very clear: the public's voice must be heard and taken into consideration. Discussions need to be broadened to bring the public into the debate about the risks and benefits of using agricultural biotechnology to improve food crops. While this is an issue that remains sensitive, especially for some of the inhabitants of the industrialized world, it is a debate in which the developing world must likewise have its own voice. Its right to set its own standards must be accepted. After all, developing counties have far different economies, ecologies, and climates than those of northern nations. They must ensure that the new science serves their needs and aspirations.

A more proactive approach than the one taken so far by the private sector is needed to ensure equitable access to proprietary agricultural biotechnology tools. Only then will the benefits of the so called 'gene revolution' reach the poor, particularly in rural areas of the developing world. Furthermore, agricultural biotechnology products developed by the private sector must, of course, be deployed in a way that considers both environmental issues and human health.

Indeed, without the establishment and effective enforcement of acceptable principles for human and ecological safety, deals between the public and private sector cannot be brokered. As a first step, development investors, national agricultural research systems, private seed and agricultural biotechnology companies, as well as non-governmental organizations (NGOs) and other institutions in civil society must strive to better understand their respective agendas, especially in the framework of globalization. Such an exchange between the key players in agricultural development will help to determine whether they can work together—and perhaps even collaborate (e.g., a multi-partner venture)—to share innovative technology and resources that can be harnessed to develop public goods for the benefit of the poor in this era of globalization. Globalization is the future, and quixotic attempts to derail it will harm the world's poor more than any other group. Instead, we must carefully weigh its benefits and costs in the light of a more just, humane, and equitable vision of the future. If properly guided, globalization—under the on-going scrutiny of the public—could provide access to markets, capital, technology, and techniques that would assist the efforts of the developing world to achieve sustainable food security and to establish an economic base for further growth.

The massive increase in rice and wheat production spearheaded by the centers of the Consultative Group on International Agricultural Research (CGIAR)—the so-called "Green Revolution"—is one of the best examples of the use of genetic resources and conventional plant breeding to improve cereal crops (especially rice and wheat). Farmers widely adapted and adopted these varieties, increasing the aggregate food supply through productivity gains in agriculture, which made it possible for developing countries to avoid the specter of poverty: hunger. Thanks to the Green Revolution, especially in Asia and Latin America, by conservative estimates the lives of 400 million people were saved. That said, we cannot continue to rely on the "Green Revolution" for further productivity and income gains. We must accept that almost all-usable agricultural land is now under cultivation. Indeed, any significant increase in production must come through increased productivity on the same land area. Furthermore, the vast majority of new agricultural technologies are proprietary and cannot be easily distributed by national agricultural research centers.

The value of these new technologies, however, is much greater than those of the "Green Revolution." By incorporating resistance to pests into crops, for example, crop and yield quality improves without the high costs and environmental problems associated with pesticides. The profits of poor farmers are enhanced through eco-friendly technologies that can provide sustainable food security in HIPCs. In addition, high yielding crops provide job employments to poor people through the trade chain (from harvesting to processing). In short, higher and more stable yield potential and profitability permit poor farmers to invest in inputs to produce more food and income. This may in turn lead to reduced food prices for the urban and rural poor. Furthermore, enhanced productivity makes more food accessible and available for sale, and other crops may be included in the farming system, thereby increasing agrobiodiversity.

The World Bank and other development investors need to ensure that agricultural biotechnology will improve the livelihoods of the poor. They can do this by providing targeted support and especially by brokering agreements with the private sector, which owns most of the science. For rural areas of Africa and other locations by-passed by the "Green Revolution", such investments and agreements are crucial. The worlds' poor, who stand to benefit most from new agricultural technologies, cannot afford to miss the benefits of the "Gene Revolution." Yet for agricultural biotechnology to benefit the poor farmers and consumers of the developing world, it will need to focus on their problems and needs. Investments in agricultural biotechnology in developing countries, however, must be built upon those already made by the private sector. These countries do not have the resources to re-invent the technologies made possible by billions of dollars worth of research and development by the private sector. Creative partnerships are essential to success. Moreover, technology and genetic resources are only part of the solution—they will not alleviate poverty by themselves. Cooperation between the rich and poor nations of the world, institutional alliances, information and knowledge sharing, and the development of intellectual property rights management systems should all be part of integrated technology transfer packages for the benefit of the poor. Clearly, innovative partnerships are needed to provide long term and sustainable financing for producing the international public goods that will enhance the livelihood and prosperity of today's poor in HIPCs.

The World Bank should lead efforts to ensure that investments in agricultural biotechnology produce international public goods that benefit the world's poor. To this end, it should facilitate innovative arrangements with the owners of proprietary science and technology. To be effective, such arrangements must be flexible, efficient, and inclusive. They must respond coherently to the needs of the poor, especially in the rural developing world. The World Bank's institutional centrality gives it a unique position—and responsibility—to open high-level policy dialogues with all relevant parties. This approach will be very important because the World Bank's own investments are insufficient to meet the agricultural research needs of the developing world. Indeed, neither the World Bank nor developing countries should waste limited funds and precious time in re-inventing technologies developed and owned by the private sector. Partnerships are the solution, and by facilitating such international coordination, the World Bank will have taken a major forward step towards global equity.

Consider the possibilities of a Global Development Agenda that links up public and private investments in agricultural biotechnology to alleviate poverty. Improvements to the "orphan" crops of the world's subsistence farmers, such as chickpea, pigeon pea, sweet potato, cassava, yam, plantain, cowpea, and lentil, which the private sector has not included in its investment portfolio, will dramatically improve these farmers' lives. Their crops could benefit either from the transfer of agricultural biotechnology methods for their improvement (e.g., gene transfer through transgenics), or from knowledge obtained by researching a better-endowed crop that may be relevant for enhancing these "orphan" crops.

Let us now proceed to review the various critical components of this new science and the new policy environments that accompany them, and indicate what decisions are needed in each area in order to bring about an integrated science and policy framework that will bring the benefits of these new technologies to the world's poor farmers.

2. Biotechnology and Agriculture

2.1 Background and Prior Debate

In the last century, genetics became a key scientific discipline. Revolutionary discoveries rapidly followed one another: the identification of DNA as hereditary material, the elucidation of the double helix structure of the DNA molecule, the cracking of the genetic code, the ability to isolate genes, and the application of DNA recombinant techniques. These advances also shaped animal and plant breeding, whose respective methods changed dramatically throughout the 20th century. Today we understand the molecular basis of genetics, and new tools allow us to exploit that knowledge in very specific ways for crop and livestock improvement.

Scientific advances in plant breeding led to the "Green Revolution", regarded as one of the most important agricultural achievements of mankind. This Revolution targeted staple cereal crops, particularly wheat, rice, and maize, with staggering results. Towards the end of the 20th century 370 kg of cereals per person were harvested versus 275 kg in the mid-20th century—more than a 33% per capita gain. Other crops have made gains of about 20% since the early 1960s. In simple terms, this prevented the starvation and malnutrition of almost 1 billion people. However, the "Green Revolution" appears to have been fully maximized, and other approaches are needed to continue to improve plants and livestock in the 21st century. The need is increasingly urgent because the per capita area to support food production will decline from 0.44 ha in 1961 to 0.15 in 2050. Again, in simple language, our growing population requires increased agricultural productivity to stave off mass famine outbreaks in the developing world.

Biotechnology complements classical breeding tools with new and better means to improve both crops and livestock. Most of the staple foods of the poor, which feed millions of people daily, have received little attention from the biotechnology industry because they are not regarded as cash commodities. Applying biotechnology in animal and plant breeding is nowhere more essential, however, because of the pressing challenge of providing food to the more than 1 billion hungry people in the developing world, more than 185 million of which are malnourished school children. Biotechnology offers new means to achieve a higher intensity of selection (e.g., through in vitro techniques) and more objective selection methods through genetic markers. Likewise, genetic engineering(so-called transgenic) can insert new genes into plants to enhance the quality of a new variety and enlarge the breeding pool. In what follows we offer some examples of the new biotechnology and indicate some of the value these new products have for the developing world.

2.2 Identification of Key Issues

The most common and successful application of biotechnology for crop and livestock improvements are in:

- **Cell and Tissue Culture** is a process of growing plant cells to produce uniform individuals or to shorten the number of years needed to produce and release new varieties. Tissue culture techniques have led to dramatic production increases in cassava, yams, bananas and plantains, palms, and potato to mention only a few. Tissue culture laboratories also employ highly skilled staff, mainly in the private sector in the developing world.

- **Genetic Engineering for pest and disease resistance**. There are now hundreds of millions of acres of genetically engineered crops grown throughout the industrial and developing world. To date the principal focus has been on crops that use large amounts of pesticides or herbicides, such as maize, cotton, potatoes, and soybeans.
- **DNA fingerprinting**, the same technology used in forensic science, provides better insights into pathogen diversity, which may make it possible to prevent the breakdown of host plant resistance to pests and diseases. Sources of genetic diversity are the building blocks from which new breeds and varieties are developed, and DNA fingerprinting makes it possible to use this diversity more effectively.
- **Molecular-aided analyses** can lead to better management of seed storage facilities, or so-called gene banks, and to greater knowledge of biodiversity. The more we know about this genetic diversity, the better we can apply it to produce higher yielding, more resistant materials.
- **DNA markers** allows scientists to locate genes with specific disease and pest tolerance. We may eventually be able to study resistance to more complex traits such as drought and heat stress. We have already witnessed what the human genome-sequencing program is starting to achieve, and we must apply the same tools to improve agriculture.
- **New testing tools** to detect pests, diseases, and dangerous food contaminants. These techniques will help us produce not only more food, but food that is more nutritious and safer to eat.

2.3 Future Trends

The speed of research in these fields is dramatic. The commercial company Celera-Genomics was able to sequence the entire human genome in less than one year. Within the next decade, research in crop improvement will target:

- Male sterility systems to allow genetic engineering for hybrid seed production, with its dramatic yield increases, in currently self-pollinating crops.
- Short-cycling populations for rapid improvement of forest and fruit trees.
- Converting annual into perennial crops for more sustainable agricultural systems.
- Farming in environmentally friendly systems with pest and disease resistant germplasm.
- Enhancing adaptation to environments affected by problems such as drought, salinity, extreme temperature, chemical toxicity and oxidative stress. Given future projections on global climate change, these long-term goals are vital to the developing world.
- Improvement of food quality (e.g., vitamin A content), to satisfy the needs for a balanced diet in poor rural areas as well as for new demands for varied diets in urban populations with more income. GoldenRice is a good start in this area. Research groups are already attempting to further improve GoldenRice by enhancing the quality of the rice protein to contain more essential amino acids.
- Improved plants and animals to fit into intensive peri-urban agriculture systems, which require specific plant architecture, tolerance to urban pollution, efficient nutrient uptake, and crop acclimatization.

2.4 Major Constraints and Opportunities

Biotechnology will be an important tool to ensure success in the above areas. In addition, biotechnology may also provide new methods to add value to raw agricultural products (e.g., growing edible portions of food crops in vitro or converting plants into producers of high value chemicals). "Pharming" (derived from Pharmaceutical) is the term that has been coined to refer to a new system in which medicine production capabilities are incorporated into a plant. A research group at The Boyce Thomson Institute at Cornell University has already engineered banana plants to produce vaccines

The new tools of molecular genetics enable researchers to understand better and faster the full potential of the genetic resources of crops, to preserve this genetic heritage, and to develop improved plant materials. The identification, isolation, and cloning of new genes controlling specific characteristics will also facilitate the development of a more stable, diversified germplasm with improved resistance to diseases and pests, stress tolerance, better food quality, and higher productivity. For example, genes allowing a reduced crop cycle or modified plant structure will provide pathways for new cropping systems. Nonetheless, conventional crossbreeding will be still required for appropriate testing and further transfer of these genes to the advanced breeding pools of the crop. Furthermore, seed delivery systems of improved genotypes will need to be in place to promote the utilization of new cultivars, which will enhance and stabilize agricultural production, farm income, and farm-family welfare. In brief, the new tools of biotechnology alone cannot provide the answer to genetic improvement, but they are facilitating and accelerating the pace of the development of new cultivars.

Some of the current achievements of biotechnology applications for improving agriculture are surpassing original expectations, and the outlook appears to be even more promising. The fulfillment and impact of biotechnology, however, does not depend only on the demonstrated research advances and technology ensuing from their applications but also on both favorable regulatory frameworks by national governments (or through regional agreements) and positive public acceptance.

2.5 Recommendations

Further improvements in global agriculture require innovative science and the development of plant derived products with high returns. Given that this type of research is based on a highly skilled workforce and the assembly of multidisciplinary teams:

The World Bank should continue to build bridges between available biotechnology tools and their application for the improvement of crops and livestock in developing countries. Competitive funding schemes encouraging research links between advanced research institutes, both in the North and the South, and with the Consultative Group on International Agricultural Research should be pursued.

Furthermore, in order to have a research and development process driven by product delivery:

The competitive funding scheme should ensure the integration of biotechnology with classical breeding and other associated technical disciplines. The applicants must be encouraged to develop research proposals in the framework of a holistic approach with well-defined pathways for disseminating both the knowledge and technology produced from this investment.

3. Biotechnology and Information Technology (or Bio-Informatics)

3.1 Background and Prior Debate

A relatively new field, bio-informatics is the scientific management and use of genetic information. In large laboratories sequencing and genetic mapping has led to massive databases of different types of genetic information. This data is valuable and can lead to further discoveries—but only if it is carefully managed. Indeed, the enormous amount of information to be tracked has made the computer an indispensable tool for genetic research. In fact, the breathtaking research speed of the human genome project would not have been possible if Celera Genomics had not built the largest non-military super computer in the world.

'Genomics' refers to the systematic use of genome information, in conjunction with new experimental data, to answer biological questions. The success or failure of genomic projects now depends on the availability and utility of their data to the scientific community. The best example of this is the "Human Genome Project." Conceived in the mid-1980s, sequencing of the human genome began in 1996 and was completed in early 2000, years ahead of the scheduled completion date. One reason for the speedy completion of this effort: large investments by the private sector, which had identified the Project's potential utility. These investments produced a number of technical innovations that greatly contributed to the success of the Human Genome Project. The sequencing and mapping components of the project, for example, relied heavily on advances made in the automation and robotics of the sequencer, allowing for the production of sequence data at an extraordinary rate. This in turn generated advances in information technology that led to the genesis of 'bio-informatics'—otherwise the Project would have "drowned in data."

Currently bioinformatics provides procedures for identifying, protecting, and sharing critical research information. Indeed, access to sequenced data is critical for continued advances. A major stimulus to new work in bioinformatics was the widespread availability of the Internet in the mid 1990s. The World Wide Web made it much easier to share and integrate databases, distribute software, and perform sophisticated analyses. Currently, there are at least 400 internet-accessible databases of biological information and about 20 software applications to analyze sequence data. This knowledge-based revolution can drive agricultural research for the benefit of all.

International efforts to create a plant-crop genome project similar to the Human Genome Project are already producing results. Japan,for example, is leading the International Rice Genome Sequencing Project (IRGP). Recently, Monsanto Company also agreed to share its rice genome data with researchers across the world. Developing countries are aware of these efforts and some of them have already invested in plant genomics.

3.2 Identification of Key Issues

Advances in genomics will require sharing databases. No one will succeed alone. Accordingly, international cooperation is essential. Current databases are already enormous and complex, and new information is constantly being added. Successful data mining and pattern determination—the first steps to diagnostics and/or remedies—will only be possible if acceptable structures and guidelines for database sharing are developed. This raises the following key issues:

- Users must recognize the need to share information
- Access to information must be obtainable, especially for countries that lack advance information infrastructures

- Investments in information and communication technologies to promote sharing and access to information must continue

3.3 Future Trends

Bioinformatics is a new way to handle genetic data and develop new products. There will be more and more sharing of data and information through the Internet, although this will raise concerns about the authenticity of such information. To ensure fairness and credibility a new code of ethics may have to be put in place. Furthermore, as we discuss later, this technology opens the door to the development of artificial chromosomes and to their accompanying ethical issues.

3.4 Major Constraints and Opportunities

The two major constraints to the effective use of these new technologies in developing countries are lack of access to the necessary information and lack of trained personnel to use it. Currently, the Information Technology industry is investing heavily into bio-informatics; both IBM and Compaq have recently invested hundreds of millions of dollars in bioinformatics ventures. The next step in bioinformatics will be to put the information it has generated to use in practical applications (e.g., using data obtained from genomics and bioinfomatics to develop diagnostics or therapies).

3.5 Recommendations

Given that bioinformatics databases are International Public Goods that make possible these new technologies and products:

The World Bank should provide support for bioinformatics efforts that optimize resources, avoid duplication, and promote a new attitude of sharing in the scientific community.

Given the current lack of technical skills in this area, particularly in the developing world:

The World Bank should support personnel training. Trained people in bio-informatics are a pre-requisite for this technology to succeed. Institutional links between North and South will not have an effect without skilled personnel in developing countries that can absorb, adapt, and use the information made available to them.

In order to maintain public access and use of this data, particularly for the worlds staple food-crops that feed the poor:

The World Bank should encourage and provide "seed money" to establish a public facility or consortium for bio-informatics. This will require investments in human resources and computer equipment. A task force may be established, under the auspices of the World Bank, to develop an action plan for consolidation, centralization, and programmatic integration of bio-informatics teams working in this area. The CGIAR research centers should be a key part of this international public initiative.

4. IPR on Research and Agriculture

4.1 Background and Prior Debate

Most legislation worldwide regards it reasonable for an inventor to have the right to exclude others from the sale or use of an invention for a limited time in return for a full public disclosure of how the invention is performed. On the one hand, this right of exclusivity allows the inventor to recuperate his research investments by not allowing his competitors to use his intellectual property for free. On the other hand, the public disclosure of the invention allows competitors to improve upon or work around the patent.

It has been clearly demonstrated that intellectual property (IP) protection has served to foster research and development. A frequently cited example of the power of IP protection to stimulate research investment and innovation is biotechnology. The landmark United States Supreme Court decision in Chakrabharty allowing patents on living organisms resulted in huge investments in biotechnology because companies could realistically expect to recuperate their investments.

This investment boom in biotechnology and information science continued throughout the 1990's and into the new millennium. The US Patent & Trademark Office now has more patents pending than it has issued in its entire 200+year history, and most of these are in the fields of biotechnology and information technology.

Another fundamental component to IP protection and research is the so-called "research exemption". This statutory provision provides for a person to use a patented invention where the intention is to use the patented technology for further research. This exemption is important as it permits "academic" researchers to add to the body of knowledge. Care should be exercised in the use of this exception as it is viewed narrowly and only relates to 'academia' not 'applied' research.

One of the challenges that public research organizations worldwide face is to determine whether they should seek proprietary protection of their research in order to obtain funds or recoup costs. In the United States, the Bayh/Dole Act (1980) allows public research organizations to hold the title to their inventions if invented using Federal research dollars. Although this can potentially serve as a source of funding for public institutions, also blurs the lines of comparative advantage between the public and private sectors

4.2 Identification of Key Issues

One key issue is to determine whether agricultural research is in some way "special" as it relates to IP and research. After all, human well being depends on food, the enhanced production of which will depend on the timeframes of research processes and on free global access to genetic resources. As such, agricultural research may deserve "special" status.

Some of the critical questions in this area that policy makers at the international, national and institutional levels need to address are given below. We also offer our viewpoint as to the answers to these questions:

1. Does IP protection truly stimulate research investment in agriculture? We believe the answer is clearly yes. Since the ruling of the US Supreme Court allowed for patent protection on living organisms there has been a massive investment in life sciences research. Billions of private sector dollars have been invested in biotechnology applications for health, food and environmental remediation.
2. Can proprietary research help fund developing country research? Again, our viewpoint is yes. There is no reason to believe that innovative research is less valuable because of geography. The growth of the software development industry in India and other parts of Asia is a good example. Several

multinational seed companies are already investing heavily in new research infrastructure in the developing world. More can and should be done.

3. Should governments or institutions see this as a revenue source or only as cost recovery? The minimum here is cost recovery, but as with not-for-profit research foundations in the industrial world, any "profit" could be reinvested into these organizations to further the development of more research output. Egypt's Agricultural Genetic Engineering Research Institute (AGERI) has set up a foundation that funnels the benefits of its license agreements with Pioneer back into more research.
4. Is there a role for truly "public" goods, both nationally and internationally? Clearly Yes. Producing animals and plants with resistance to certain pests and diseases, scourges that pay no heed to national boundaries, is a regional or international public good. Enhanced nutrition to alleviate human diseases associated with poverty is an international public good, and breeding for resistance to climate variation is also an international public good.
5. Does publishing play a key role in the public domain? Clearly Yes. If an organization wishes all its research output to be public goods then it should publish. Published research is so-called "prior art" and will serve to bar others from claiming such invention. The published article identifies the "inventor" and serves as a defensive publication. No one can now patent the invention as they are not the inventor and the publication identifies the true inventor.

4.3 Future Trends

Modern research is increasingly complex and involves significant interdisciplinary activities. These interactions across a range of disciplines will continue to grow and expand, thus adding to the complexity and cost of research.

The present growth of proprietary science will continue to grow because of the private sector's massive research investments. Projects such as the Human Genome Project will spawn new related ventures in a variety of areas. Celera Genomics, the company that first completed the human genome sequence, is already building the world's largest protein sequencing and engineering facility.

The globalization of research will continue, and the developing world will perform more of it because of a range of comparative advantages. What has already begun in the software industry will continue to develop in environmental science and agriculture. This growth will be coupled with increasing changes in the globalization of IP laws and the relationships of trade in a global economy.

4.4 Major Constraints and Opportunities

Constraints:

There is the potential for a backlash against IP protection in the area of living organisms and in food production. If it occurs, negative public perceptions of the technology will be the reason. These may be due to fundamental ethical or religious beliefs, or because of misunderstandings about the nature of the technology.

The drive to produce global technologies for a global market, with all the associated regulatory frameworks, may also push small companies, if not countries, out of the market. The IP portfolio of the small will be eaten by the big. Some even doubt that current anti-trust laws can adequately deal with these problems.

Opportunities:

There are opportunities to harmonize and simplify the current IP system to level the playing field for the smaller entities that wish to seek global protection. IP statutes could be amended to more equitably reward invention, including those who work through non-conventional channels.

When good quality science is performed in the public sector and when adequate and effective protection is established, budget allocations for public research can be increased. More efficiency and more creativity are already appearing, and the public sector can use IP tools to generate new revenue for more investment in research.

4.5 Recommendations

Given the fundamental link between research investment and IPR:

The World Bank should actively engage in debate and professional exchange with the World Intellectual Property Organization (WIPO) to further study the impact of IP on research investment in the developing world.

Given the need for more persons with technical and legal skills in these areas:

The World Bank should foster more human resource development in the area of IP and particularly in entrepreneurship. The mix of technical and legal skills needed in the new economy is in short supply in developing countries.

In order to develop a set of paradigm models, and to learn while doing:

The World Bank should encourage well-researched, planned investment in global IP protection for inventions from developing countries.

However, given that not all crops, animals, and technologies lend themselves to proprietary protection and market approaches:

The World Bank can foster the development of International Public Goods for those technology platforms or commodities where no proprietary avenues exist or are appropriate.

5. IPR and Trade

5.1 Background and Prior Debate

The spectacular bull run of the U.S. stock market and the globalization of trade dominated economic changes over the last two decades. Heated debates, sometimes literally bursting into flames, have fueled the development of regional and international trade pacts. We have seen the growth of trade-related legislation and organizing bodies such as the Asia Pacific Economic Community (APEC) and the North America Free Trade Association (NAFTA). We also witnessed the formation of the World Trade Organization (WTO) as a forum for reaching agreements about these matters.

As part of the globalization of the world economy and the massive increase in global trade, rules and regulations relating to intellectual property have been developed. The so-called TRIPS [Trade-Related Aspects of Intellectual Property Rigths (General Agreement on Tariff and Trade -(GATT/WTO)] provisions have brought IP protection front and center in trade matters.

In many cases, trade related IP matters involve agricultural products. In some cases arguments have even broken out between nations who hardly even produce the materials (e.g., the banana wars between the USA and Europe).

The formation of a global trading system and regional trading pacts has transformed what were previously national jurisdictional IP issues into international issues. IP has become a global, trade related practice through international conventions that regulate its use, and the lines that clearly demarcated patents as national rights have been substantially blurred in recent years.

5.2 Identification of Key Issues

IP protection is still in the process of being formalized, and the upcoming rounds of debate at the WTO on Agriculture will keep it in the policy spotlight. A number of critical issues face policy makers in coming years, including:

1. WTO Agriculture Round Negotiations.
2. Continued Globalization of Agricultural Trade.
3. The issue of non-tariff IP matters, such as the release of genetically modified foods or organisms (GMOs).
4. Globalization of IP protection and concurrent transactional costs.

5.3 Future Trends

Despite protests from some sectors of the public, more trade pacts and global alliances are in the pipeline. Many of them seek to distinguish between governmental trade pacts and the globalization of the private sector. There are also discussions of how a global regulatory framework, such as a global SEC, could review the antitrust potential of international mergers and acquisitions. The non-tariff elements of trade will continue to grow in coming years, both on good and bad faith grounds, and the new electronic economy will also likely have a very dramatic and somewhat unpredictable impact on the global trade of commodities, goods, and services.

5.4 Major Constraints and Opportunities

Constraints:

Both policy makers and the general public lack information about the pros and cons of IP and trade matters. This knowledge deficit allows special interest groups to take the limelight and spread their own "message" without accountability. A balanced, well-informed, and transparent debate is urgently needed.

The existing system also has to deal with an unprecedented rate of change. Current regulatory structures and existing national legislation are often unable to deal with the speed and nature of ongoing trade related changes. Furthermore, global litigation of trade matters, although necessary in the current framework, is slow and costly and therefore favors big entities over small ones. More efficient mechanisms for resolving disputes must be devised.

Opportunities:

New technologies and new trading relationships offer tremendous opportunities for new growth, especially the rapid expansion of markets to developing countries.

Global trade allows each country and entity to more effectively focus on its comparative advantages and thus maximize return on investments or research.

New markets create greater diversification and increased output, generating more and better employment opportunities. Opening markets creates internal competitive pressures that in a positive environment can be translated into increased efficiency and higher productivity.

5.5 Recommendations

Given the critical policy and development implications for the developing world:

The World Bank should be a key player and actively advocate for the developing world in upcoming WTO discussions on trade and agricultural IP.

Given the evolving nature of these complex relationships:

The World Bank should continue to monitor the intimate relationship between trade, IP, and research investment in both the public and private sectors. Research is indispensable for maintaining competitiveness in the market; accordingly, the World Bank should continue to foster and enhance its activities in agricultural research, including the CGIAR centers.

6. Genetic Engineering Technology: A Complement to Breeding

6.1 Background and Prior Debate

Conventional plant breeding and improved agricultural practices produced impressive gains in crop productivity in the 20th century. But human and livestock population pressures continue to increase, and conventional plant breeding can no longer deliver significant gains in productivity because of limited gene pools and the restricted range of organisms between which genes can be transferred. There is also limited scope for increasing the amount of land available to cultivate food crops without seriously impacting the environment. New techniques that supplement conventional plant breeding are needed to boost crop yields, particularly for staple food crops in developing countries. Genetic transformation, a form of genetic engineering, now provides a complementary means to enhance field crops. Genes can be accessed from exotic sources—plant, animal, bacteria, and even viruses—and introduced into crops.

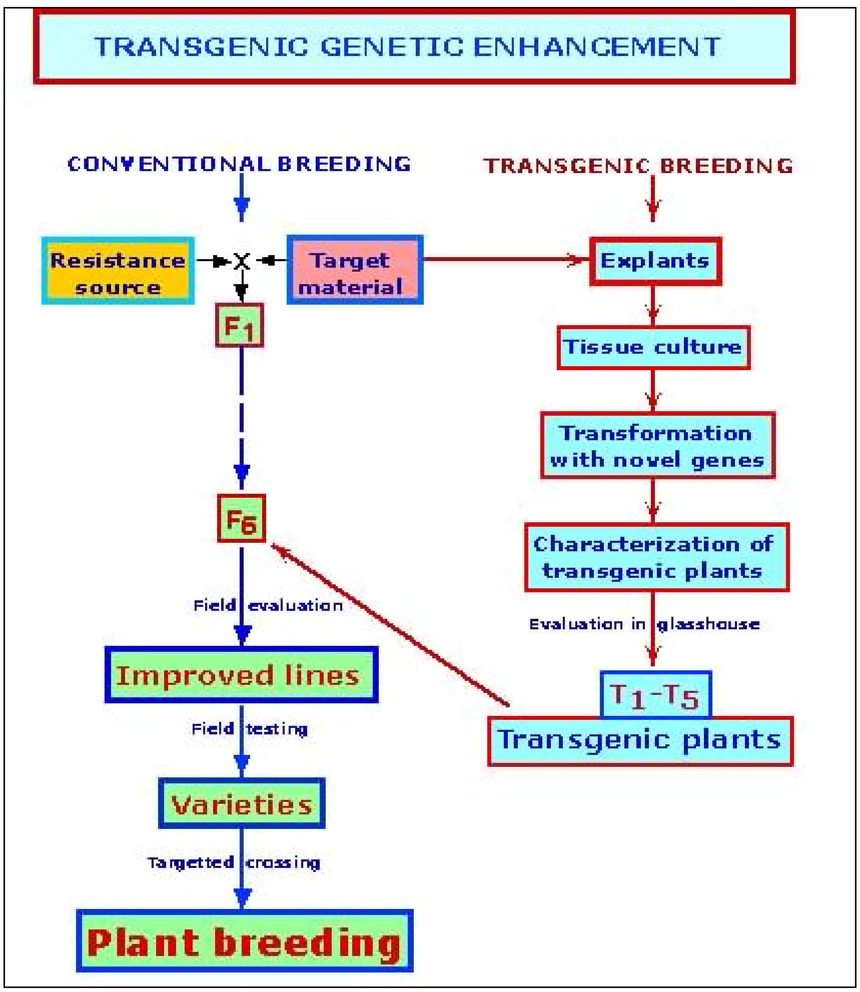
6.2 Identification of Key Issues

Over the past two decades, scientists have made significant progress in introducing foreign genes into plants, and this has made it possible to modify crops to increase yields, impart resistance to biotic and abiotic stresses, and improve nutritional quality. Among the examples of this are vitamin A rice, pest resistant maize, cotton, and potato, and a wide range of plants resistant to virus diseases. Millions of acres of these genetically engineered crops are now grown throughout the world. The flow diagram presented in Figure 1 describes how transgenic technology has been integrated into conventional plant breeding to enhance crop plants.

6.3 Future Trends

1. Modern agricultural biotechnology is one of the most promising developments in modern science, and research in agricultural biotechnology the potential to make major impacts on rural poverty. Eventually, improving agriculture through biotechnology could generate social, economic, and environmental benefits targeted at specific needs, especially the needs of the poorest. Again, the ability to produce more nutritious crops, or crops that need less fertilizer and water are good examples.
2. The indisputable core issue is the need to mobilize every instrument of agricultural transformation in our efforts to feed the hungry, help the poor, and protect the environment.
3. Regulations need to be harmonized and regulatory mechanisms simplified in the future. Much progress has been made in this area in the protocol talks under the Convention on Biological Diversity.
4. Agricultural biotechnology research must produce applications that are relevant to the needs of farmers in developing countries, and the benefits of that research must be transmitted to small-scale farmers and consumers in those countries at affordable prices. Yet again vitamin A rice is a good example. Other ongoing work on protein enhancement technologies and other nutritional enhancements is of vital importance to the world's hungriest.

Figure 1: The Integration of Transformation Technology with Plant Breeding



6.4 Major Constraints and Opportunities

Despite significant advances over the past decade, the lack of efficient transformation methods can still be a substantial barrier to applying recombinant technologies in some crop plants. For successful genetic transformation in the routine generation of transgenic plants, several key factors play important roles. These include the development of reliable tissue culture and plant regeneration systems, preparation of gene constructs and transformation with suitable vectors, efficient transformation techniques for the introduction of genes into the crop plants, recovery and multiplication of transgenic plants, molecular and genetic characterization of transgenic plants for stable and efficient gene expression, transfer of genes into elite cultivars by conventional plant breeding methods if required, and evaluation of transgenic plants for their effectiveness in alleviating biotic and abiotic stresses without causing environmental risks. A major limitation to the practical transformation of many plant species is the low frequency of tissue culture regeneration, which leads to very low genetic transformation success rates.

These technologies are now well established in the North, and in the developing world the focus is turning to studies that will apply these powerful tools to solve national and regional needs. In the human health area, many diseases that are unique to the developing world can be addressed through these techniques. Celera has already projected that a malaria vaccine will be available within two years. The ability to produce plants that are more productive in marginal lands where water and often nutrients are scarce will also have a huge impact. Nutritional improvements in vitamins, micronutrients, and protein quantity and quality are all technically within our grasp. The key is to set priorities and invest so that these dreams become reality.

6.5 Recommendations

Because of concerns some sectors of the public have raised about genetic engineering technology:

The World Bank should encourage and support public dialogue about the risks and benefits of transgenic technology used to improve agriculture in developing countries. This dialogue must ensure that the voices of the people in the developing world are heard and that their unique needs are considered.

Furthermore, given the tremendous potential of these techniques to impact the quality of life for the poor:

The World Bank should provide support to innovative improvement programs that combine the best of conventional methods with emerging genetic engineering technology to improve both crops and livestock.

7. Genetic Mapping Technology: Knowing Where the Genes Are

7.1 Background and Prior Debate

All genetic maps (and markers for specific traits) rely on theory developed over 80 years ago using morphological markers in plants and the fruit fly *Drosophila*. Although morphological markers were convenient for early studies, because they are relatively infrequent and interact with the environment they are now rarely used. Molecular markers, however, have no phenotypic effect, are not affected by the presence or absence of other genes and a large number of markers can be detected in most breeding populations.

Developed in the 1980s with reference to the human genome, genetic maps are constructed using molecular genetic markers. Such molecular approaches quickly proved to be powerful tools for studying the organization and behavior of plant genomes. Molecular biology has already revolutionized research in the life sciences, and DNA marker technology now promises to dramatically enhance the efficiency of plant and livestock breeding. Advances in automated technology are providing the convenience, speed, and level of throughput that will make it possible to offer stunning improvements to modern breeding programs. Meanwhile, advances in the allied fields of sequencing and bioinformatics have come together to form the rapidly progressing field of functional genomics, which provides information not only about the location of genes but also about what they do and how they work.

The theoretical basis for molecular marker-assisted breeding is well established and is now being rapidly refined, with a wide array of published examples covering most crops and animals of major economic or academic importance. Meanwhile, dramatic advances are being made in functional genomics, which will undoubtedly fuel the development of knowledge based breeding schemes.

The primary resource of breeding programs is the genetic variability of species. Successful crop and livestock improvement programs must efficiently tap this variability, but traditional breeding techniques rely on physically identifying traits to select for (phenotypic selection). In many instances, DNA marker technologies offer breeders the potential of making genetic progress more cheaply, quickly, and precisely. In simple language, breeders can determine what traits a plant has by looking at its genes instead of spending all the time and money needed to grow varieties by the field full.

7.2 Identification of Key Issues

Commercial plant breeding companies are moving fast to adopt these new technologies. They are investing heavily in molecular breeding because they see that it will reduce costs, increase precision, and make it possible to achieve new goals. In many cases, companies report returns on these investments within the first or second year of implementation. They are also able to make better use of their resources, which adds further value. Traditionally, conventional breeders have been reluctant to use exotic germplasm through backcross breeding because of complex, long-term, and unpredictable outcomes, particularly in crops where quality traits are important market criteria. But DNA marker assisted approaches provide breeders with cost effective tools to rapidly unleash the vast resources held in germplasm collections.

Commercial breeding companies know the value of time. Shortening crop breeding cycles can generate tens of millions of dollars within individual country markets. Likewise, public breeding programs, increasingly driven by product-focused national government and development investor projects, are seeking to maximize their product release times. Absolute cost savings, however, are not the only criteria that defines plant breeding strategies; increased time-efficiency throughout the breeding program may also be very valuable by increasing the program's overall productivity.

DNA marker analyses may be warranted in order to precisely fingerprint new lines for plant variety protection. In many countries, plant breeders' rights and essential derivation clauses of patents require specific levels of distinctness from new varieties entered for registration.

7.3 Future Trends

Applied genomics will revolutionize the existing paradigms of plant breeding through the power of DNA markers. Complementary approaches that combine traditional and molecular approaches within unique breeding systems will be developed that will harness the capacity of a range of marker assay types, utilizing their unique comparative advantages at different stages in the breeding system.

Accurate germplasm diversity analysis is an intensive multi-component endeavor, one best carried out by the international institutions designated to act as the custodians of global germplasm collections. These same institutions may also be the ones that can most effectively develop complex genetic stocks (e.g., those that combine many different resistance genes). After their development, these breeding lines and their respective DNA markers should then be placed in the public domain as an integrated package. This will allow national breeders to rapidly and efficiently use this material in their breeding programs. This approach has been effectively adopted for breeding resistance to bacterial blight by national programs within the Asian Rice Biotechnology Network.

Molecular breeding is a truly multidisciplinary endeavor where it will be increasingly difficult and expensive to generate appropriate critical mass in all the essential elements required to build a functional team. Consequently, public-private partnerships and consortiums will be vital. Furthermore, as DNA marker-assisted approaches become more widely integrated into plant breeding programs, their impact will compound and the associated capital and operational costs will decrease—while the need for experienced personnel will increase. Of course, traditional approaches will remain cost effective for many traits, and replicated multilocational evaluation will always be a necessary precursor to varietal release.

7.4 Constraints and Opportunities

In the future, molecular breeding will likely rely on sequence-based markers. The large-scale development of this marker-type is highly demanding on human and capital resources. Thus, public sector institutes are best placed to carryout marker development activities. For species where there is a considerable amount of public domain sequence data, bioinformatics groups can cost effectively and rapidly identify suitable sequences for microsatellite marker development.

Automated marker screening systems have dramatically increased data generation, which can now be deployed on the scale needed for modern breeding programs. In many cases, it is simply cheaper to contract out this type of work and use urgently needed resources elsewhere. Indeed, at least during the initial phase of adopting these new techniques, contracting out DNA marker screening is a cost-effective option for most small to medium-sized breeding programs.

7.5 Recommendation

The new tools of applied genomics are rapidly increasing our knowledge of biological systems and the tools to manipulate these systems. The commercial implications of these developments are fueling unprecedented scientific progress but at the expense of free access.

The World Bank should support initiatives in applied genomics to ensure that important advances will be made available to plant breeders in national programs and in small to medium-sized companies that are supporting the development of staple crops and livestock. As custodian of the world's genetic resources, the CGIAR (Consultative Group on International Agricultural Research) international system of agricultural research centers now has a major role to play in ensuring the equitable enhancement of the world's staple food crops.

8. Molecular Breeding to Address Global Issues Such as Drought and Heat Stress

8.1 Background and Prior Debate

Breeders see the greatest potential for molecular markers in the area of complex traits, particularly those that are highly sensitive to environmental conditions. These characters are the most difficult to work with using phenotypic selection, and developing effective marker assisted selection systems has also been the most difficult for these traits. This is due to the large number of genes involved and the effects of genotype-by-environment (GxE).

The principles governing the genetic basis of quantitative traits were outlined over 80 years ago; both quantitative and biometrical genetics evolved in the 1940s and 1950s. Since that time scientists have made great strides towards developing biometrical methods to assist breeders in effectively selecting complex traits through phenotypic evaluation. But to objectively determine how many genes influence a quantitative trait or what their influences are on phenotypic and genetic variation required the advent of DNA markers in the 1980s. Scientists were optimistic about the capacity of these new tools to simplify this complicated endeavor, and quantitative genetics has delivered. A new scientific heyday has been triggered by these recent advances in molecular biology.

8.2 Identification of Key Issues

The molecular mapping of simple traits is now a routine procedure, and attention has now shifted to the more practical aspects of applying these markers. In contrast, the methodology for mapping complex traits is still developing. Since the early 1990s, however, simulation studies have fueled rapid developments in methods for mapping complex traits (i.e., quantitative trait loci, or QTL).

Precise phenotypic evaluation in several locations and seasons is important for measuring the effects of component QTL and estimating their relative contributions and stability. But developing robust QTL markers will likely require populations much larger than those currently used. Indeed, new high throughput DNA marker screening technologies will be essential for empirically testing new approaches to QTL mapping and for the subsequent application of marker-assisted selection systems for these traits.

8.3 Future Trends

Rapid developments are taking place in the model crop systems fueled by automated technologies, advanced biometrics, and functional genomics. A new knowledge based breeding paradigm is evolving in these systems that will facilitate advances in allied but less studied crop systems. The impact molecular breeding has had on maize in the past decade provides an indication of the future for all crops. At the beginning of the 1990's there had been a six-fold increase in maize yields during the preceding 60 years, but little was known about the actual genetic basis of these improvements. Today, scientists have not only mapped and dissected many of these underlying characters, they are also already reporting the manipulation of these components through the knowledge gained by the new molecular technologies.

Modern plant breeding is a high technology business that is becoming even more complex and multifaceted. In this new era, successful plant breeding programs will be characterized by dynamic, holistic approaches led by functional multidisciplinary teams. A high level of synergy between team members will be vital for successful product-led innovation and problem solving.

8.4 Constraints and Opportunities

Many important agronomic and economic traits exhibit continuous variation (e.g., heat stress, drought resistance, and yield). The rate-limiting factor for developing effective marker-assisted selections systems for these characters remains the confounding effects of genotype-by-environment interaction. An array of computational methods aimed at addressing this issue is rapidly evolving, and there are many publications in this area using simulation studies, but not all of them are well analyzed. Improved maps and more powerful computing systems may allow us to select plants that are better adapted to these complex situations.

8.5 Recommendation

The rapid development of molecular breeding tools for complex traits will require research projects that bring together large-scale multi-locational field experiments with state-of-the-art high throughput marker screening technologies and strong capacities in biometrics and bioinformatics. Hence:

The World Bank should support long-term initiatives to undertake molecular breeding of crop and livestock species important to feeding the developing world. In this respect those CGIAR centers with breeding programs will continue to have a major role to play because they possess in-house capacity in all essential elements.

9. Changing Plant Architecture: New Plants for a New Future

9.1 Background and Prior Debate

Humans have made tools for more than a million years, but their crop plants have evolved under the influence of their powers of observation, selection, and imagination for only about ten thousand years. Crops and humans have evolved together in a kind of symbiosis. The transformation of humans from hunter-gatherers to settlers led to the domestication of about 200 plants. While gathering, humans perhaps used about 3000 plants as food. Today five major cereals, three tuber crops, plantains/bananas, and several legumes plus sugar cane and beet provide most of the dietary needs. While this narrow focus and intensification has helped to feed six billion people, it comes at a genetic cost.

Domestication, for example, has included selection against seed spread so as to enable easy gathering. The survival of crop plants now depends on humans. This change, one of the earliest and most marked differences between cultivated and wild progenitors, formed the basis of agriculture. Along with reduced dissemination, seed size often considerably increased. Plants with larger seeds can be harvested more quickly and agricultural man may have selected for them. Not only the form, but also the composition of harvested organs has changed greatly. Toxic components prevalent in wild progenitors (e.g., yam) were eliminated and selection for other components of special interest increased or improved (e.g., sugar content or oil). In addition to dealing with above ground components, research will be further enhanced to address root issues such as nutrient absorption, water uptake, and production capability for root crops such as sweet potato.

9.2 Identification of Key Issues

The world's amount of sustainable, cultivable land has reached its limit. Irrigating more land is a difficult option because of the ever-increasing demand for water from other sectors (domestic, industry). We must therefore improve the yield of cultivated crops to feed the world's constantly growing population. In other words, we must get more crop per drop.

Plant architecture refers to the number, size, shape, structure, arrangement, and display of particular plant parts. Plant architecture *per se*, however, has no relation to yield except as it is associated with or leads to improved physiological functions. Productivity is the sum product of the photosynthetic rate and the leaf area (machinery). The photosynthetic rate, which is the plant's ability to convert solar energy into stored energy, was once considered an avenue to increase plant productivity. But past efforts in this area discovered that although wild progenitors (e.g., in wheat) have high photosynthetic rates, this did not translate into increased stored metabolites because the other component—leaf area—became the limiting factor,.

The other physiological functions that directly contribute to higher biomass are water use efficiency (i.e., unit of dry matter produced per unit of water used by the plant) and nutrient use efficiency. Genetic variation for water use efficiency does exist within species but it is more pronounced between species (e.g., millet vs. alfalfa) and between cultivated and wild varieties.

9.3 Future Trends

In the last 20 years only a few major genes have been used to improve yields, especially for cereal crops. These genes mainly control plant height and photoperiod sensitivity, both of which affect the harvest index.

Biotechnology could be used to transfer some of these genes, which may be available in wild species that have eluded physiologists, into genotypes with high leaf area and the appropriate architecture to further increase yields. Furthermore, crop modeling, with data accumulated from plant physiology and crop protection research, may help to define ideotypes (genotypes, designed to exhibit specific characters) that can assist work of plant breeders. The characteristics required to develop improved plant prototypes from such a 'virtual breeding' approach may be available in the gene banks for these crops or in those of other associated (wild) species. Otherwise, breeders could obtain novel transgenes to develop the required ideotype. In other words, we need to begin to design new plants in the same way we design new cars or planes, by going back to the drawing board and making bold changes in overall design and architecture.

9.4 Major Constraints and Opportunities

The question remains as to whether the genes that control complex physiological characters (e.g., for higher photosynthetic rates) can be successfully isolated and transferred between species, especially from wild to cultivated gene pools. Interspecific crosses have been used in many crop species to obtain interesting genotypes for further improvement by breeders (e.g., in potato, banana/plantain, barley, tomato, and other crops). Biotechnology, however, can overcome any reproductive barriers and enhance the procedure in a more targeted manner with predictable results.[2] Such "precision breeding" can be used to efficiently develop new plant types for new markets or climates.

Of course, both water and nutrient use efficiency can be more effectively addressed by combining management options (i.e., irrigation methods, tillage, crop rotation, etc.) with a genetic approach. The effect of the environment is often so profound that the genetic gains are masked its influence. Because the need for more water and nutrient efficient plants will be so great over the coming decades, both genetic and improved management approaches must be fully explored.

9.5 Recommendation

Given the need to feed more people on the same land area using less water and nutrients:

Through a competitive grant framework the World Bank should encourage and support innovative research (including multidisciplinary approaches) aimed at the development of specific locally adapted prototypes to maximize the yield potential of crops. This investment could be cost-effective by tapping the knowledge and information accumulated by the CGIAR and their diverse partners.

10. Biosafety: How Safe are New Agricultural Technologies?

10.1 Background and Prior Debate

Given the types of issues raised in debates about the safety of genetically modified organisms, it appears that for many people the real problem with transgenic plants is that the risks associated with their use are not well investigated or known. But it is easier to predict gene expression in genetically modified organisms than in those developed through conventional breeding methods, and transgenes are not conceptually different than native genes or organisms modified by conventional technologies. Conventional plant breeding has never been able to foresee or control the physiological impact of new genes. Much greater efforts, however, have been made to determine these impacts in regards to transgenics. Carefully considered procedures and regulations have been developed to evaluate the biosafety of these crops. The need and extent of safety evaluation, for example, can be based on a comparison of a new food and an analogous food. The interaction of the new gene with the environment also needs to be investigated because of the potential for recombinant technologies to have a greater impact on the environment than is possible with conventional technologies. The management, interpretation, and utilization of information will be an important component of risk assessment, and will be key to determining the effectiveness and reliability of this technology.

10.2 Identification of Key Issues

Biosafety evaluation requires that risks, benefits, and needs be given a balanced assessment. In 1998, over 40 million acres of transgenic crops were grown around the globe. As these products are traded and pass from one country to the other, domestic regulatory regimes must be in place to ensure their safe use. What is safe in one country may not be safe in another because of genetic background of the flora. A genetically engineered potato, for example, has different safety issues in Idaho than in the highlands of the Andes where its wild relatives are found. Many initiatives are underway to work with developing countries on biosafety matters, these include efforts by the CGIAR Centers and by United Nations (UN) organizations such as the Food and Agricultural Organization (FAO) and the United Nations Industrial Organization (UNIDO). Other biotechnology providers such as the International Service for the Acquisition of Agri-Biotech Applications (ISAAA), the Agricultural Biotechnology for Sustainable Productivity (ABSP), and others are also providing training in this area.

10.3 Future Trends

As with any new and evolving technology, due caution must be exercised until the products of the technology are proven safe and are deregulated. Transgenic technology is like any other technology in this respect, and the emphasis of biosafety regulations should therefore be on the product rather than on the process.

Under the auspices of National Academy of Sciences of the USA, a working group of policy makers and scientists from six countries has recommended that a careful analysis of safety issues is required before the development of a commercial product using biotechnology—as is the case, they note, with the development of any new technology. Specifically, it must be shown that if the potential impact of a transgenic plant is not neutral or innocuous, it is preferable to the impact of the conventional agricultural technologies that it is designed to replace.

10.4 Major Constraints and Opportunities

As is the case with conventional plant breeding, research on transgenic crops aims to selectively alter and add or remove a character of choice in a crop plant with reference to regional needs and opportunities. Biotechnology offers the knowledge and tools to breed crops faster, with more precision, and with more genetic sources, but the promise of this technology to sustainably increase crop yields and productivity has been dimmed by concerns about the safety of transgenic organisms and their impact on the environment.. In some developed countries, public interest and environmental groups have raised concerns about the possible effects—conceived of in the broadest of terms—that transgenic crops could have on non-target organisms. In the developing world, such concerns have given rise to fear because of a lack of information. In response to these concerns, a biosafety working group has been formed by FAO, United Nations Environment Program (UNEP), UNIDO, and WHO, and guidelines for the handling and release of genetically modified organisms have been published.

10.5 Recommendation

Given that a number of other international organizations are already actively working with developing countries in the area of biosafety:

The World Bank should support the development of appropriate biosafety guidelines in the developing world by collaborating with other organizations engaged in similar efforts.

11. Food Safety: It Is Safe to Grow, but is It Safe to Eat?

11.1 Background and Prior Debate

Genetically improved foods are not intrinsically good or bad for humans. Their health effects depend on their specific content. Thus the risks and opportunities associated with genetically improved foods should be integrated into a country's general food safety regulations. Regulatory systems are also needed to govern food safety and assess any environmental risks, monitor compliance, and enforce regulations. Regulatory arrangements should be country-specific and reflect relevant risk factors. It may also be necessary to label transgenic foods, not only for cultural and religious reasons but also because consumers may want to know what their food contains and how it was produced. The public sector must design and enforce safety standards; it is one of the fundamental roles and responsibilities of governments.

Recent studies conducted by the National Academy of Sciences of USA on the safety of genetically modified organisms concluded that “crops modified by molecular and cellular methods should pose risks no different from those modified by classical genetic methods for similar traits.” The focus of science based analyses should be on the product and not the process, and so the steps used to conduct a risk assessment should be the same whether the risk assessment is performed by a government regulatory agency, an institutional variety release committee, or a private organization. Furthermore, both the safety assessment process and its conclusions should be public.

Several traditional detection methods have been proposed to detect recombinant allergens in transgenic foods. These methods are well established, specific, sensitive, and reproducible. They have already been effectively used to investigate recombinant food proteins in transgenic food products for their potential allergenicity.

A good example of the importance and effectiveness of such regulatory mechanisms was the detection of an allergen in a transgenic soybean. The allergen originated from Brazil nuts, some of the genes of which were expressed in soybeans to increase their sulfur content. But the modified soybeans also bound IgE from Brazil nut-sensitive individuals and were identified as a major Brazil nut allergen. This demonstrated that testing for allergens in new products when proteins are transferred from sources that contain known allergenic material will work. It also indicates that a safer approach would be to avoid the transfer of genes encoding for known food allergens. Genes transferred from sources known to be allergenic should be assumed to encode for an allergen, until proven otherwise.

11.3 Future Trends

Some discussions on transgenic crops place undue stress on risk assessment at the expense of any consideration of their potential advantages. Furthermore, although food allergies are a high priority in industrial countries, in countries with emerging economies they are a lower priority than nutrition. In any case, the increased productivity benefits of genetically modified foods may far outweigh any potential risk of allergic reactions. With reasonable biosafety regulations, this can be done with little or no risk to human health and the environment.

If they are not made accountable to the findings of science, the unnecessary escalation of increasingly stringent biosafety regulations regarding transgenic plants or food—in the absence of any scientifically proven generic risk—may prevent the application of transgenic research to sustainable staple food production or poverty alleviation. The global community must keep its sights set on the goal of assuring food for all. We cannot afford to be elitist luddites about any aspect of a possible solution, including agricultural biotechnology.

11.4 Major Constraints and Opportunities

Allergies to foods are generally a significant public health concern throughout the world. About 2% of adults and 4% to 6% of children suffer from food allergies, defined as adverse immunologically mediated reactions to antigenic molecules present in foods. Moreover, in the case of transgenic plants, since the transgenes code for proteins that ordinarily may not be present in the particular non-transgenic plants, there is particular concern about the potential allerginicity or toxicity of these new varieties to both human and livestock health.

Of course, genetic engineering approaches can be used to combat food allergies. Agricultural biotechnology has so far been used to transfer such traits as insect and virus resistance, herbicide tolerance, and changes in composition or nutritional content. The amount of protein expressed by the introduced genes is usually small and, in some cases, inactivation of a native gene results in the absence of a specific protein yields the desired trait (e.g., the tomato genetically engineered to delay ripening). This technology has the potential to reduce or eliminate the expression of major allergens.

11.5 Recommendation

Given public concerns and the government's fundamental role in setting food health policies:

The World Bank should encourage and ensure science-based debate and decision-making about food health matters. The benefits of technological change, the possible risks of this change, and the consequences of no change should be addressed.

12. Bioethics

12.1 Background and Prior Debate

Irrespective of the advances in plant biotechnology and its potential for crop improvement, the ethical dilemmas associated with the incorporation of transgenic crops into farming systems have divided both public and private researchers worldwide. This was not unexpected because the adoption of any new technology has rightly always been accompanied by careful scrutiny. An outright ban of transgenic crops, however, is neither a scientifically or economically sound option because their potential benefits (e.g., resistant or tolerant crops to abiotic and biotic stresses) also need to be carefully analyzed. The value of such traits should not be arbitrarily withheld from the public, especially the poor citizens of developing countries.

12.2 Identification of Key Issues

Banning biotechnology, particularly genetically modified organisms (GMOs), is a short sighted, narrow approach to a consideration of the technology's potential benefits—particularly in regards to the environment. Crops that eliminate or reduce the amount of polluting agro-chemicals in farming systems must be welcome by farmers and consumers. Indeed, the general public should see biotechnology as a tool for scientific crop improvement that is safer than many technologies already in use.

In the ongoing debate on globalibation and privatization, some groups see the protection of plant varieties and the use of contract mechanisms on the international scale as "ethical" agenda items.

The private sector wants to use biotechnology to accelerate its growth. Its search for profit, as in any other business, attracts investment in the industry, which also looks for new ways of protecting these investments through intellectual property rights, especially if biotechnology applications are used for accelerating the genetic enhancement of crops.

The private seed sector has shown that plant variety protection (PVP) encourages and ensures a return on research investments. PVP, as indicated by agri-business managers, helps to facilitate the transfer of technology and knowledge, providing encouragement and assurance for plant breeders to introduce their best varieties for production and propagation. In short, the private seed sector holds that any kind of plant variety protection would attract new and improved genetic material and technology, thereby enhancing the quality and yield of breeding materials. As a consequence of the introduction of intellectual property protection, material transfer agreement (MTA) has become a routine document for exchange of genetic material.

12.3 Future Trends

Public awareness and education about how biotechnology can improve crops may foster a proper discussion of its risks and benefits for farming systems and for biodiversity. The debate about crop biotechnology currently suffers from the loud exponents of non-scientific partisan views, a general lack of reference to scientific data, an exclusive focus on the uncertainty of potential risks, and ignorance about the basic contexts and processes of the technology. The public needs to hear the words of Nobel Peace Prize winner Norman Borlaug, who in a recent letter to a British newspaper describes the genetic modification of crops as a "progressive harnessing of the forces of nature to the benefit of feeding the human race. It is not a replacement to conventional breeding but rather a complementary research tool to identify desirable traits from remotely related taxonomic groups and transfer them more quickly and precisely into high yielding, high quality crop species."

The issue of releasing genetically modified plants (GMP) into the farming system has become particularly sensitive in Europe despite the widespread cultivation of such crops in North America and elsewhere. Scientists must realize that the general public is concerned that an un-cautious approach to the manipulation and cultivation of transgenic crops may affect biodiversity and its sustainable utilization in the farming system, (e.g., loss of variability and viability). They should make efforts to show how transgenic crops contribute to the protection of the environment, particularly the fostering of biodiversity.

12.4 Major Constraints and Opportunities

Collective approval may lead to new partnerships, cooperation, or joint ventures in research and development between scientists in the public and private sectors that will benefit farmers and consumers with profits and high quality products, respectively. Any potential risk in human development associated with biotechnology applications in agriculture should be resolved in a transparent, rational, and democratic fashion. The public needs to be able to trust the balanced, science-based safety regulations arrived at by lawmakers after listening to the views of scientists, producers, and consumers.

12.5 Recommendations

Given the concerns associated with the development and deployment of genetically engineered organisms:

The World Bank (both management and staff) should be aware and sensitive to the issues surrounding GMO's and other biotechnology applications. The World Bank should encourage scientific transparency; this will be the best tool to convince people about the advantages of transgenic crops and other biotechnology applications.

13. The Public Sector and International Public Good

13.1 Background and Prior Debate

The bulk of scientific knowledge is in the public domain and forms a body of International Public Goods. It should be remembered that after the limited exclusionary period, proprietary technology enters the public domain. Furthermore, although the content of a patent is "owned" by the inventor it is fully disclosed as a condition of granting the patent.

At the end of a patent's statutory life, the exclusive right is gone and the material is public knowledge. This approach in the pharmaceutical area has led to the growth of the so-called "generics" market. Products whose patent has expired are then manufactured by a variety of companies for direct sale in the marketplace.

In the case of agriculture, up until the last decade most information and materials were in the public domain. The Green Revolution was based in large part on materials and knowledge flowing from Universities and governmental research and breeding programs straight to farmers around the world. This was possible because before the 1980 Bayh/Dole act all such information was in the public domain.

Over the last decade, however, a substantial shift has occurred in the ability of public organizations to seek proprietary protection. Indeed, most governmental research laboratories and large universities in the industrial world now have their own IP offices to patent inventions from their research, including that sponsored by governmental agencies.

This "privatization" of public sector research has blurred the line between international bodies that are accessing research materials and multinational corporations. It is essentially no different to negotiate a license agreement with a major university than with a multinational.

13.2 Identification of Key Issues

Of all the areas under consideration in this report none is so complex or sensitive as determining the ownership of ideas and materials. There are strong opposing schools of thought on these matters, both of which offer rational and convincing arguments. A number of questions need to be addressed; our position on these matters is as follows:

1. Is the current "privatization" of public goods healthy? In general terms YES, so long as private ownership is balanced with access rights for scientists to continue further research. This temporary ownership also serves as a substantial stimulus to private research investment. The result of such investment has been powerful in information technology and pharmaceuticals; we would like to see the same growth in agricultural research. There are also usually public use provisions when the research has been done through public funds.
2. Are we looking at the availability of information, or its ownership? These are different, but related matters. To the scientist, the important issue is access to information; for product development, ownership is critical. In those crops where market forces are not directly applicable, other more innovative license agreements or waivers will be needed.
3. Is the privatization of these systems economic? In simple terms, if it is not economic then it will fail under privatization. The question then is whether the government still attaches sufficient strategic priority that it wishes to keep funding it from internal revenues.
4. How much is the trend driven by a desire to gain bargaining power? To some extent, owning some technology allows you to "trade" your IP for their IP. However, care should be exercised to ensure that there is truly something of value to trade. It is a viable alternative to truly keep all public inventions in the public domain and then seek access to alternative mechanisms.
5. How much is public access rather than ownership the issue? To the scientist, very much so. The ability to use the information for research purposes is critical to the progress of any research agenda. Ownership becomes an issue when the technology is deployed or commercialized. The ISAAA freedom to operate study on GoldenRice is a good example of the challenges that can be faced in moving from the research phase to potential product deployment.
6. Are international public goods something unique? Clearly YES. There are technologies, problems, and opportunities that spread beyond national boundaries. The whole set of issues surrounding ge-

netic resources, global warming effects, and many disease and pest control matters are truly international in scope and need concerted international efforts.

7. Is agriculture a unique circumstance that can be afforded some exemption? This is a truly difficult question to answer. While our existence on the planet depends on agricultural production, the same arguments can be made in other sectors such as health and energy.It could legitimately be argued, however, that staple food crops in the developing world are worthy of special treatment; likewise, crops and livestock with strong local but little international commodity focus should be treated somewhat differently. One way to resolve this may be to allow inventions a shorter time period in the proprietary domain before becoming public goods.

13.3 Future Trends

If the human genome program is the model for future research, then clearly more and more discoveries will by privately owned. The drive to obtain returns on massive private investments will likely mean that research will proceed more rapidly in the private than in the public sector. The human genome project, it will be recalled, began as a public research plan scheduled to take 10 to 15 years, yet a private sector effort, headed in large part by ex-public research employees, did it in 2 years with only 10% of the staffing. This has allowed 10+ years of research dollars in the public sector to be redirected to other areas.

There is also a trend towards data overload. The volume of information and its management will be a major issue. As an example of this the US Patent & Trademark Office is reviewing how it can maintain its patent sequence databases given the explosive growth of patent filings in this area. As the human genome project also revealed, there will be a trend to license DATA rather than materials. The capital of tomorrow will be data not goods—after all, we are in a knowledge economy.

13.4 Major Constraints and Opportunities

Constraints:

A major constraint for developing counties will be a lack of expertise about the computing and database skills and infrastructure needed to access the huge amount of public data that will be available.

Furthermore, as more data becomes proprietary, the skills needed to negotiate equitable license agreements--both with the private sector and with the new public sector—will be very important. In general, developing countries do have such experience in negotiating license agreements.

Opportunities:

New technology offers developing countries access to information in a revolutionary way. The poorly stocked libraries of the developing world can be upgraded to the highest possible standards with minimal investments in databases and infrastructure. In short books are gone, all countries have equal access to data. What an opportunity! Investments in essential library technologies will have enormous returns and should be given a high priority.

13.5 Recommendations

Given the tremendous opportunities that exist to leverage publicly available data:

The World Bank should increase spending on infrastructure and human capacity building in regards to database management and information sorting and dissemination.

Through support to the CGIAR, the World Bank can take steps to improve database management and ownership for many staple food commodities. The World Bank can foster a genome network for the developing world to access databases through the CGIAR and its partners.

14. Public Sector/Private Sector Partnerships: The Need for their Visionary Expansion and Diversity

14.1 Background and Prior Debate

Over the last decade a number of interesting models have enhanced and fostered interaction and cooperation between the public and the private sectors. Each sector brings a unique set of advantages to the relationship, creating a powerful synergy based upon their complementary strengths. The basis for the success of these relationships is complex, involving trust, mutual understanding, respect for goals and aims, and a clear set of institutional objectives. The issues of trust and understanding cannot be underestimated.

In the international agricultural biotechnology area, several programs have been active over the last decade in promoting public/private interactions, these include ABSP, a USAID funded program, ISAAA, a not-for-profit program hosted by Cornell University, and the Intermediary Biotechnology Service (IBS), managed at the International Service for National Agricultural Research (ISNAR), one of the CGIAR research centers. The common thread linking these organizations is the integrated nature of their programs, which include not only research but also regulatory and IP matters. This integration of science, policy, and regulatory affairs allows for maximum utilization of the comparative advantages of the public and private sectors.

14.2 Identification of Key Issues

As indicated above, building productive relationships between these sectors is complex and takes time. Given the sovereignty issues in regards to IP law and regulations, there are additional complications to these arrangements at the international level. Indeed, the key issues that underpin these agreements will need to be continually reviewed and improved. Yet as the examples below indicate, progress is already being made:

1. How to build mutual trust and confidence, particularly in regards to confidential information? This is a lengthy process. As a result of a workshop held by USAID in Washington, the ABSP project was started, which brings together the public and private sectors in agricultural partnerships. It has brokered a wide range of partnerships with small and large companies, universities, and governmental research organizations in both the US and various developing countries. These partnerships include:
    a. DNAP, a New Jersey small cap research company, and private sector producers in Indonesia and Costa Rica.
    b. The Egyptian Agricultural Genetic Engineering Research Institute and Pioneer Seeds.
    c. Monsanto Company and the Kenyan Agricultural Research Institute.
    d. Zeneca Seeds and the Indonesian Food Crops Research Institute.

2. Liability concerns are an increasing concern. When a company donates its technology to a development project it foregoes income but is not absolved of liability. If companies are to be encouraged to "donate" technologies then there must be a mechanism to deal with their liability exposure.
3. There is a need to identify common processes and methods. To make all of these arrangements on a one-on-one basis is inefficient and stifles expansion. We believe that the World Bank, working with and through other organizations, can do much to create a framework and universal templates for these types of technology transfer processes.
4. The issue of confidentiality is critical to the building of the trust and confidence. This is true not only for IP but also in regulatory matters. There is a need for greater understanding of the importance of confidentiality to the private sector. Clearly, if information is allwed to leak through poor stewardship then the owner will be damaged and will lack the confidence to share additional new confidential information.

14.3 Future Trends

Globalization of trade and research will also result in more examples of multinationals linking up with host governmental organizations. The regulatory environment will also evolve as the harmonization of health and environmental standards continues through the process of trade globalization.

14.4 Major Constraints and Opportunities

Constraints:

There still exists the possibility of public backlash against the privatization and globalization of research, particularly in relation to health and safety concerns. Developing countries have the right, however, to set their own risk and benefit parameters.

Anti-trust actions now common in the software industry may begin to become issues in agriculture and health, particularly in relation to biotechnology.

Opportunities:

Knowledge is the lifeblood of research, whether in the public or the private sector. The potential benefits to all sectors of society from greater knowledge sharing are tremendous. The human genome project is a good example of how it is possible to take ownership rights while still broadly sharing the information for research. More efforts are needed in this area.

The opportunities to create powerfully synergistic partnerships are abundant; they require only our careful planning and commitment. Their potential benefits are particularly evident in cases where private sector technology has impacted a major commodity or disease which can then be used by the public sector for orphan crops or for diseases where the private sector is unable to see returns from a purely economic standpoint.

The public sector, however, is still the primary producer of the raw material of innovation: skilled people! The role that education plays in terms of building scientific, legal, and entrepreneurial skills cannot and should not be underestimated.

14.5 Recommendations

Given the globalization of agricultural research companies and the current shift in research resources from the public to the private sector:

The World Bank should develop additional fora that will bring together the public and private sector in an enabling environment that will allow for the building of mutual trust and a dialogue on research and regulatory issues.

The World Bank should continue to support programs to enhance the skills of scientists, lawyers, and policy makers in these new areas of science and law. Skills in science and negotiation are important components for fair partnership arrangements.

While proprietary technology will use market forces to drive license agreements in market economies and sectors, provision must be made for those sectors of society that are left behind. Therefore:

The World Bank should try to identify areas where private sector proprietary technology developed for one purpose may be able to play humanitarian purposes in other areas, such as orphan crops or diseases prevalent in the developing world.

15. IPR and Animal Science

15.1 Background and Prior Debate

The impact of biotechnology on the public has been dramatic in the area of animal science. The cloned sheep "Dolly" propelled debate on a wide range of technological, ethical, and religious matters, and further research—which has now led to research level cloned production of pigs and cattle—will certainly keep this debate front and center.

Animal biotechnology research has the benefit of gaining substantial knowledge from overspill in the human genomics and health area, which has the disadvantage of competing for research talent and investments in those areas. There is clearly a huge degree of genetic similarity between humans and other animal species. The identification of disease resistance genes in one species will greatly assist the search for disease resistance in other species.

The human genome project has led to the production of a wealth of information that clearly will have added value in the areas of animal science. Likewise, development of vaccines and other treatments for diseases will benefit animal science researchers.

Animal science is also having difficult times in regards to public relations and perceptions in recent years. "Mad cow disease" has swayed public perception in animal science away from high technology, particularly the application of biotechnology, towards organic production mechanisms. The use of the growth hormone BST in milk production has raised human health questions. The potential tragedy of the PR scenario is that while increased milk production may be an economic problem for some industrial countries it is potentially a major benefit for many developing countries. The use of BST to increase milk has tremendous potential benefit to the growing population of the developing world, where milk is in scarce supply but is an excellent nutritional source, particularly for women and children. Biotechnology also has tremendous potential to produce effective vaccines against a wide range of animal diseases, many of which are important in the tropics.

15.2 Identification of Key Issues

Some of the issues in animal science are common with to their counterparts in the plant sciences, but some are unique. The critical issues and some examples of how to address them are:

1. How to build on the human genome project for animal science? In the short term, this is where the most rapid advances in genomics research may be made. The International Livestock Research Institute (ILRI) of the CGIAR is already working with the Institute of Genomic Research (a not-for-profit entity related to Celera Genomics) to sequence animal parasite genomes. This will lead to the production of new vaccines to address tropical animal diseases. Again, a critical component here will be access by research scientists to publicly available databanks. As a provider of international public goods, the CGIAR has a unique role to play, especially in disease control, where parasites and pests hold no respect for international geographic boundaries.
2. What about the ethical issues related to animal cloning? Of course, this is worthy of an entire treatise in its own rights. If pork genes are put into chicken can Muslims eat it? If animal genes are put into plants can vegetarians eat them? If a chromosome is made synthetically and inserted into an animal is this ethical? There are no simple answers to these questions. The answers to these religious and ethical dilemmas must come from those skilled in those areas. The key technical issue, in the view of these authors, is the public's right to know and choose. The mechanism for this may be through labeling schemes, but more support to resolve these matters is needed.
3. What about the biosafety aspects of animal science? Clearly there are animal diseases that can be passed to humans. Again, the concerns on mad cow disease underline this matter. The biosafety issues in relation to research studies and the use of research containment for animal science again are highly complex. More research is needed in this area, especially where there is any perception that the disease can be transmitted to humans. ILRI is a unique organization to guide and advise in this area.
4. Which animals and diseases should take priority? This is a national priority setting exercise. It should balance technical capabilities against needs and economic realities. There is some rationale for first studying those pests and diseases that cross-national barriers and cause regional health problems.

15.3 Future Trends

The human genome infrastructure will soon seek new target organisms to sequence, and animal science is the next logical field. The same issues discussed above will arise again: what will be the impact not only on database and knowledge development? Who will own this information?

Vaccine development will grow rapidly as new recombinant technologies allow custom design of vaccines against major pests and diseases. The heat stability of these vaccines should also be a major plus for the developing world.

Greater understanding of animal pathogens should also greatly increase the impact that biotechnology will have on animal health and productivity.

15.4 Major Constraints and Opportunities

Constraints:

The ethical issues associated with animal science are more complex and more culturally linked than is the case with plant technologies.

The economic impact of diseases has global importance. The costs of vaccine production and distribution can be recuperated for high value farming systems, but how are these techniques to be economically applied to resource poor small farmers? The arguments here are very similar to those for human tropical diseases. We have not solved this for malaria, so when will we tackle animal disease? We believe, however, that there is some light at the end of this tunnel. The Institute of Genomics Research (TIGR) is discussing a malaria vaccine trial for 2002.

The biosafety and human health aspects of recombinant animal technologies are complex and costly. Can we find effective, low cost methods and regulatory frameworks that will allow the potential benefits of this technology to flow? These authors believe Yes. The potential impact on milk and animal meat production in the developing world is to great for us not to act.

Opportunities:

The revolution in human genomics can and is revolutionizing animal science. The synergy between human research and animal science offers unique opportunities for common platforms and reduced cost. Once we identify genes in the human genome with specific characteristics, we can almost certainly apply the same knowledge in animal science.

Increased economic development usually leads to higher consumption of animal proteins. This increased economic growth should spill over into increased investment in animal science research and development.

15.5 Recommendations

Given the important economic and nutritional roles that livestock play in rural communities:

The World Bank should support special international studies to review the human health implications of genetically modified animal products. Given the costs associated with these studies, harmonization and cross acceptance of data is very important.

The World Bank should continue to study the impact of biotechnology and of quarantines on the trade of animal products. There is a special need to study these impacts as they relate to tropical diseases in Africa.

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