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American Patent Policy, Biotechnology, and African Agriculture:

The Case for Policy Change

Michael R. Taylor and Jerry Cayford

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Acknowledgements

We came to this topic as novices in patent law and policy, interested in taking a policy analyst's look at a specialist's field. Consequently, we have been dependent all along on the kind help of many professionals better versed than we are in the details of patents on biotechnology.

A large number of experts and stakeholders shared their knowledge and opinions with us in answering our survey. Their names are listed in Appendix C, and we thank them all. Along the way, early and late, we also received very helpful advice and comments from Prof. John R. (Jay) Thomas, Bruce Morrissey, Lila Feisee, and Ron Meeusen.

Midway through the project, a small group of experts and stakeholders attended a workshop that we convened jointly with Prof. Walter Falcon and the Center for Environmental Science and Policy at Stanford University. The workshop provided for more intensive discussions of the issues, as captured in the first draft of our paper. To this group and to that workshop we owe a large debt of gratitude for refining and deepening our understanding of the complex interplay of patenting and third world development. We would like to thank Carolyn Deere, Richard Johnson, Prof. Donald Kennedy, Robert Lettington, Rosamond Naylor, Carol Nottenburg, Peter Odell, Stephen Smith, Shawn Sullivan, and Robert Weissman for all their thoughtful contributions to that very successful and enlightening workshop. Some of the workshop participants gave us extra help in a wide variety of ways, including but not limited to commenting on the penultimate draft of this report, and we would like to thank especially Prof. John Barton, Dr. Jack Clough, Professor Falcon, Michael Gollin, Stephen Hansen, Dr. Robert Horsch, Silvia Salazar, and Susan Sechler. Professor Falcon in particular was an essential supporter of our interest in this subject and a steady source of good counsel and comment throughout.

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Executive Summary

Substantial improvement in agricultural productivity is essential for achieving sustainable food security and reducing chronic rural poverty in many developing countries, especially in sub-Saharan Africa. Modern biotechnology, along with other important tools, can help solve some of the basic productivity problems that plague the millions of small-scale and subsistence farmers who are the backbone of African agriculture. However, important components of the biotechnology tool kit—gene traits, plant transformation tools, and genetically improved germplasm—have been patented in the United States and elsewhere by companies that have little economic incentive to develop and disseminate the technology to meet the needs of these farmers. This report analyzes how U.S. patent policy affects the development and dissemination of biotechnology to improve agriculture and food security in Africa; and the report makes the case for policy change.

Patent policy is but one example of U.S. policies and government programs that affect food security and poverty reduction in developing countries and that deserve scrutiny. The United Nations' Millennium Development Goals aim to eradicate extreme poverty and hunger, and they recognize the importance of developing country agriculture in achieving that objective. The United States has embraced these goals, but many policies of the United States are not fully aligned with the goals or with the critical need to improve developing country agriculture. This includes U.S. policies concerning agricultural subsidies, trade barriers, development assistance, and food aid.

Nor does U.S. patent policy appear fully aligned with the goal of achieving global food security. The U.S. government is a strong promoter of biotechnology as a tool for improving food security, and the U.S. patent system has enthusiastically embraced plant biotechnology through the issuance of thousands of patents. The United States is also a proponent of strong patent protection worldwide. It is thus important to explore how the U.S. stance in these three connected areas—biotechnology, patent policy, and the need for progress in developing country agriculture—can be reconciled, and how food security and the broader international interests of the United States can be advanced through patent policy change.

To address these questions, we analyze in this report the U.S. patent system and patent policy as social constructs that are intended to benefit society by fostering useful innovation and whose performance is properly evaluated from the perspective of the social outcomes they achieve. Under this approach, change in patent policy is justified if it would improve dissemination of the tools of agricultural biotechnology for important social purposes, such as improving food security in Africa, without significantly undercutting incentives for the invention of such tools.

From this conceptual vantage point, we describe the origins of the "patent thicket" surrounding plant biotechnology, policies affecting access to patented technologies, and U.S. "foreign policy" on patents, including the U.S. stance on implementation of the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) and other efforts to harmonize patent policy internationally. We then analyze the impact of U.S. patent practices and policies on developing country access to biotechnology, present the case for change across a spectrum of domestic and foreign patent policies, and briefly analyze several possible policy changes.

This report will succeed if it stimulates thinking among policymakers and stakeholders about how U.S. patent policies affect the broader U.S. interest in poverty reduction and food security in Africa, and how patent policies might be changed to advance that interest. The authors are neither propatent nor antipatent. We assume that patents have played and will continue to play an important role in stimulating private investment in plant biotechnology, and any change in U.S. patent policy must take account of the patent system's goal of stimulating invention. We do not claim to have the final answer on the ideal mix of policies in this complex area, but we find the case for policy change convincing.

Food Security, Agricultural Productivity, and the Patenting of Biotechnology

A common reality in many developing and food-insecure countries is that a large majority of the people depends on agriculture for their livelihood, directly or indirectly. In sub-Saharan Africa, 70% of the people are rural and largely agriculture-dependent. Although industrialization has fueled growth and hunger reduction in some Asian economies, it is generally recognized among experts that the poor countries of sub-Saharan Africa must improve their agriculture and food systems to achieve economic growth and food security. Moreover, according to the World Bank, global food production will have to double by 2050 to meet rising demand.

The lack of effective and fair markets for surplus food production may be the greatest obstacle to improving agriculture and food security in developing countries. Access to local, national, and international markets is necessary to provide farmers the incentive they need to risk their labor and capital on expanded production. Effective markets require sound political, economic, and social institutions and policies, as well as transportation and other physical infrastructure, which are lacking in many developing countries. Effective markets in developing countries will also require change in the agricultural and trade policies of the United States and other industrialized countries that distort market prices for staple commodities and create obstacles to developing country exports.

Within this context, improving the productivity of farmers is not by itself the solution to food security. It is, however, an important part of the picture, especially in sub-Saharan Africa. African farmers often face difficult growing conditions, and better access to the basic Green Revolution tools of fertilizer, pesticides, improved seeds, and irrigation certainly can play an important role in improving their productivity. With the environmental lessons of the Green Revolution in mind, many agricultural experts also believe that the tools of modern biotechnology (including the use of recombinant DNA technology to produce genetically modified plants) can play a role in solving developing country agronomic problems and increasing productivity. By

building into the seed itself traits for drought and disease resistance, insect and other pest control, and improved yield under specific local growing conditions, biotechnology may enable farmers to increase their productivity without as much reliance on the external inputs that characterized the Green Revolution.

Biotechnology cannot benefit African farmers, however, if they and those who would develop the technology specifically for developing country purposes cannot gain access to it. This report focuses on the problem of access to biotechnology for developing country purposes that arises from the recent shift of investment in agricultural innovation from the public sector to the private and the use of the patent system by biotechnology companies to protect their investments. Research breakthroughs in the use of recombinant DNA techniques to modify plants, coupled with the 1980 U.S. Supreme Court decision in *Diamond v. Chakrabarty* that sanctioned the patenting of living organisms made by humans, have spawned substantial investment in biotechnology by large agricultural chemical companies and small biotech startup companies, primarily in the United States and Europe. Increased private investment in and patenting of biotechnology are producing significant changes in how agricultural innovation occurs, how it is paid for, and who controls it. For most of history, innovation in seed technology has been a freely shared or public good. Farmers developed higher yielding, better performing varieties and shared them with neighbors, and, in most developing countries, seed innovation remains largely a public good. Farmers produce, save, and share improved seed, and national and international agricultural research laboratories produce innovations in seed technology that are commonly distributed through public channels. With the advent of biotechnology and the availability of plant patents, the balance between the public and private sectors—in terms of research and control of technology—has shifted.

The privatization of research affects the kinds of research done and products developed. Private companies have invested heavily in the technology and in the seed companies required to bring new products to market. To capture a return on this investment, they have focused their commercial efforts, including product development, on applications that have mass appeal to farmers who can afford the technology. This economic reality creates a problem, however, because private-sector holders of biotechnology patents have little or no economic incentive to use the laboratory tools or gene traits they own to develop solutions to developing country agricultural problems. The market infrastructure and opportunity required to earn rates of return that would be acceptable in Western financial markets simply do not exist in most developing countries. Consequently, the finite capital resources of biotechnology companies will, for the foreseeable future, continue to be focused on meeting the needs of farmers in Western industrialized countries and will not be deployed in substantial measure to meet the needs of developing country farmers.

If the benefits of cutting-edge advances in seed technology based on modern biotechnology are to reach the vast majority of African farmers, it will have to occur, for the foreseeable future, primarily through public and public-private cooperative channels. Starting from this premise, the core policy questions we address in this report are whether and how U.S. patent policies could be changed to foster the development of biotechnology for African farmers through these channels.

U.S. Foreign Policy on Patents

It is important to distinguish conceptually between "domestic" and "foreign" patent policies. Domestic patent policy includes the rules governing what gets patented in the United States and how non-patentholders might gain access to patented technology. It involves balancing competing interests (invention and dissemination, benefits and costs) within the United States. U.S. foreign policy on patents addresses primarily the rules and procedures through which patents are issued and access to patented technologies is obtained in other countries. It is better thought of as a species of U.S. foreign policy in the broader sense of the term, or, more specifically, as an element of U.S. trade and development policy. Plainly put, it involves the one-dimensional task of pursuing the economic interest that the United States and U.S. technology companies have in a strong, global patent system. The countervailing interests and costs fall largely within and upon other countries: U.S. inventors gain the benefit of patent protection in other countries, and the costs of that protection, such as higher prices and restricted access, are borne by individuals and businesses in the other country.

The ways in which U.S. patent policy affects developing countries are complex and multifaceted. They include domestic policies on what gets patented under U.S. patent law and the rules governing access to U.S.-patented technology. The effects of these policies are difficult to measure but, in the view of many well-informed stakeholders, they can be substantial. In the future, however, developing country access to biotechnology for food-security purposes may be affected even more substantially by patent-related policies the U.S. government pursues in the international arena. U.S. foreign policy on patents manifests itself in three main contexts: implementation of the TRIPs Agreement, international harmonization of patent laws through the World Intellectual Property Organization (WIPO), and use of bilateral trade relationships to strengthen patent protections.

The TRIPs Agreement explicitly recognizes the need of developing countries for maximum flexibility in implementing their patent laws in ways that enable them to create "a sound and viable technological base." It contains several provisions that give countries the flexibility to grant exceptions to patent rights under certain circumstances, including broad authority in Article 30 to grant exceptions when the interests of the patent holder will not be adversely affected and authority in Article 31 to provide for compulsory licenses, subject to some conditions, when the patent holder's interests are affected. Furthermore, Article 27.3(b) permits countries to exclude plants and animals from patentability altogether, provided an alternative *sui generis* system of protection is provided. This is important flexibility for countries that might judge it in their interest to adopt a system of plant variety protection that allows for the use of protected plants for breeding of new varieties and for farmers to save their seed for planting the next year. These provisions reflect the reality documented by expert commissions and commentators that the patent and other intellectual-property needs of developing countries vary and can be sharply different from the needs of industrialized countries.

Nevertheless, the United States and other Western industrialized nations are leading a concerted effort through WIPO to achieve international harmonization of patent law beyond that provided for in the TRIPs Agreement. The TRIPs Agreement only established minimum standards for adoption of patent systems by WTO members and left considerable flexibility to tailor the system to local needs. WIPO is focusing on a more standardized "one size fits all" approach

to patents that would support the move toward a single patent application that would establish patent rights to an invention worldwide. If successful, this approach to harmonization could hinder developing countries in adopting patent regimes tailored to their particular needs, including the need to foster dissemination of biotechnology for food-security purposes.

The Case and Opportunity for Policy Change

The United States cannot solve the world's technological and economic problems by itself, but the United States has a national security interest in reducing global poverty and hunger. It also has a duty, as the richest and most powerful country in the world, to avoid actions and policies that have unnecessary and avoidable adverse impacts on progress elsewhere. This includes patent policies that adversely affect food security in developing countries. If the United States believes biotechnology can help improve agriculture and food security in developing countries and if, as documented in this report, U.S. patent policy can impede such improvement, policy change should be considered. The case for policy change is well grounded in the fundamental social purpose of the patent system, which grants patents to serve society's interests in both the invention and dissemination of innovative technology. Patent policies should be changed if the changes will improve dissemination for food security or other important social purposes without significantly undercutting incentives for invention.

We outline below a set of possible changes in U.S. patent policy that appear to meet that test. They fall into three categories: changing U.S. law and policy to improve access to patented technologies; preserving the flexibility developing countries have in the current TRIPs Agreement to tailor their patent systems to their local needs; and more fully implementing Article 66.2 of TRIPs regarding support for technology transfer. Most of the changes to U.S. law that we consider are designed to improve access to patented technology specifically for developing country food security purposes. This narrow focus limits special access to cases in which that benefit is achieved without directly competing with the patent holder in the market (the United States) for which the patent was granted.

We limit ourselves here to a brief summary of each possible policy change, because our primary purpose is to make a simple point: if one accepts as a matter of principle that it is appropriate to consider access to biotechnology for developing country food-security purposes when formulating U.S. patent policy, there are a number of policy alternatives that appear to meet the threshold test of improving access without significantly undercutting invention incentives.

Improving Access to Patented Technologies

We outline five domestic patent policy alternatives that are worthy of consideration; they involve a research exemption, compulsory licensing, a working requirement, use of eminent domain authority, and placement of U.S. government-funded technology in the public domain. All involve expanding access to patented technologies, rather than changing what gets patented.

Create a Strong Research Exemption: Under this policy alternative, Congress would enact a statutory limitation on the scope of the patent monopoly such that the use of a patented tool of biotechnology in the research and development of new applications for developing country food-security purposes would not constitute infringement of the patent.

***Establish a Compulsory License Requirement for Agricultural Biotechnology*:** This policy alternative would add to U.S. patent law a procedure to grant nonexclusive licenses to any requesting party for the use of any patented tool of biotechnology for developing country food-security purposes. Royalties would be set at rates (including zero) that reflect the extent of the reasonably foreseeable value forgone by the patent holder, taking into account the likelihood of the patent holder's commercialization of the technology for the developing country purpose.

***Establish a "Working" Requirement for Agricultural Biotechnology Patents*:** A working requirement is a condition on the right to exclude others from using a patented invention: it limits the exclusion right to only those applications of the invention that the patent holder is actually working or exploiting. This policy alternative would add to U.S. patent law a working requirement for patented biotechnology: if, within three years of the patent's being issued, the patent holder has not worked the patent for a specific developing country purpose, or has not made it readily available by license to those who seek to use it for that purpose, any party could apply to a designated authority for a nonexclusive license authorizing use for such a purpose.

***Exercise U.S. Eminent Domain Authority*:** Under this policy alternative, the U.S. government would exercise its existing statutory eminent domain authority under 28 USC §1498 to authorize the use of patented tools of biotechnology for developing country food-security purposes. A designated authority within the U.S. government could establish an administrative mechanism under which a technology developer who wanted to use the patented technology could make application and then be deemed to be using the technology for the United States. The U.S. government, rather than the technology developer, would then be liable for any compensation to which the patent holder could prove itself entitled in court.

***Make Available U.S. Government-Funded or -Owned Biotechnology*:** This alternative would establish as a matter of policy that all tools of agricultural biotechnology developed by the U.S. Department of Agriculture and other U.S. government agencies, whether patented or not, would be made available by the government, without the need for a license or other permission, when used for developing country food-security purposes.

Preserving Flexibility for Developing Countries

The key issue in U.S. foreign policy on patents is the degree to which the United States will support the preservation and use of the flexibility now built into the TRIPs Agreement for developing countries to fashion patent regimes that serve their local technology and development needs. The United States has been ambivalent at best on this question, supporting TRIPs in general and touting its flexibility in dealing with access to drugs for HIV/AIDS, while pursuing through WIPO and bilateral and regional trade negotiations a more stringent approach to harmonization. To help ensure access to biotechnology for developing country food-security purposes without undercutting invention incentives, the United States could support preservation and use of developing country flexibility in several ways.

Support Incorporating TRIPs Flexibility Provisions in Any New WIPO Agreement and in Any Bilateral or Regional Trade Agreements: The TRIPs Agreement provides significant flexibility for developing countries to devise patent regimes that serve their local technology and development needs. The United States could support the inclusion of these same general flexibil-

ity provisions in the draft WIPO Substantive Patent Law Treaty and oppose any efforts through the WIPO process to reduce the patent policy flexibility granted developing countries in the TRIPs Agreement. Similarly, it could accept the inclusion of these flexibility provisions in any trade agreements it negotiates with developing countries, reversing the trend against flexibility set in its recent agreements with Singapore and Chile. Perhaps more simply, the United States could refrain from incorporating any intellectual-property provisions at all in new trade agreements with developing countries already bound by TRIPs.

***Support Preserving the TRIPs Flexibility Provisions*:** The TRIPs Council is reviewing the TRIPs Agreement in the context of the Doha Round of WTO trade negotiations. The United States could make clear in this review that it supports maintaining the current flexibility provisions in the TRIPs Agreement. There are many such provisions, including: the broad authority in Article 30 to grant benign exceptions to patents; the Article 27.3(b) explicit right to exclude plants and animals from patentable subject matter; the implicit right to set patentability standards (novelty, inventive step, utility, disclosure) so as to maximize disclosure, minimize patenting of discoveries, and narrow patent breadth; and the right to grant compulsory licenses.

***Endorse Application of Articles 8 and 30 to Food Security Needs*:** By their terms, Articles 8 and 30, as well as potentially other flexibility provisions in TRIPs, are available to allow developing countries to devise intellectual property approaches to agricultural biotechnology that best serve local food-security needs. The United States could specifically endorse the use of these provisions for that purpose and support efforts to craft implementation schemes for these provisions that comply with TRIPs, meet the food-security need, and preserve invention incentives.

***Specifically Endorse Retention and Use of Article 27.3(b) in the TRIPs Agreement*:** Article 27.3(b) of TRIPs explicitly allows countries to exclude plants from patentability, provided they establish an effective alternative for protecting plant varieties. This flexibility is vital for countries that rely on publicly funded breeding programs and on the saving and reuse of seed by farmers to develop and disseminate new seed varieties. The United States could endorse retention of this provision and support its use in ways that meet developing country food-security needs without undercutting invention incentives.

Fully Implement Article 66.2 of the TRIPs Agreement

Article 66.2 of the TRIPs Agreement says:

Developed countries shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least developed country members in order to enable them to create a sound and viable technological base.

This provision speaks directly to the disparity in innovation capacity and access to technology between developed and developing countries. It was part of the quid pro quo in the TRIPs negotiations, in which developing countries were to be provided assistance with technology transfer in exchange for establishing the patent systems that developed countries were seeking to protect their intellectual property. The perception among many in developing countries is that,

while they are working to establish patent systems, the developed countries have not met their technology transfer obligations.

The United States has not taken steps targeted specifically at providing incentives to U.S. companies to transfer agricultural technologies to developing countries for food-security purposes. Nor has it taken any steps to provide incentives to U.S. companies to transfer patented technology, such as the tools of biotechnology. The United States could work to fulfill its obligation under Article 66.2 with respect to agricultural biotechnology and food security by providing incentives, perhaps in the form of tax credits or other economic subsidies, for companies to transfer the tools of biotechnology and other agricultural technologies to public and private sector researchers based in developing countries.

A model for the public-private channel is the newly founded, nonprofit African Agricultural Technology Foundation (AATF). With start-up funding from The Rockefeller Foundation and the U.S. Agency for International Development, the AATF was established specifically "to identify and facilitate the royalty-free transfer of proprietary technologies that meet the needs of resource-poor African farmers in ways that address and resolve the concerns of technology providers," including concerns related to intellectual property, protection of commercially important markets, and liability. The United States could develop an agenda of concrete actions to encourage and support the transfer of technology from U.S.-based technology owners to those who can make good use of it for developing country food-security purposes, through AATF and similar organizations.

Implementation of Article 66.2 in these focused ways would contribute directly to solving the technology access problem. It would complement the creation of a policy framework that reduces obstacles to access, but it is not an adequate substitute for policy change. Developing countries need the flexibility to develop intellectual-property systems that strike the right balance between inducing and rewarding invention and ensuring that inventions are put to practical uses that meet local needs. Full implementation of Article 66.2 can help, but, for purposes of gaining access to the tools they need to achieve basic food security, developing countries should not be dependent solely on decisions made in Washington or by biotechnology companies.

Conclusion

The countries of sub-Saharan Africa face daunting social, economic, and health challenges. Achieving basic food security is the central one for many countries and individuals in that region. If basic nutritional needs are not being met, the consequences are seen, certainly, in individual suffering, but also in the failure of societies to thrive socially and economically. Food security, economic development, and poverty reduction are thoroughly intertwined. So too are the interests of the United States and developing countries in Africa and elsewhere. In the post-September 11 environment, U.S. leaders increasingly recognize that the lack of food security outside the United States is related to our quest for physical security inside the United States.

There is also an increasing recognition in the U.S. media and policy circles that a wide range of U.S. policies affects the efforts of developing countries to address food security and other basic development problems. These include U.S. agricultural and trade policies, development as-

sistance and food aid policies, and the approaches the United States takes in the international arena to address trade and other development-related policy issues.

Patent policy is an important part of this picture. We document in this report the relationship between U.S. patents and patent policy and the opportunity of developing countries to access the latest technology to meet their food-security needs. Based on our analysis, there are changes the United States could make in both its domestic and foreign policies that would improve developing country access to the patented tools of biotechnology without significantly undercutting the core invention incentives of the patent system. These changes deserve consideration as the United States grapples with its heightened national interest in global food security and works to build a harmonized global patent system that embraces the needs of developed and developing countries alike.

■ ■ ■

CHAPTER ONE

Introduction

This report addresses the impact of American patent policy on access to modern biotechnology to improve agriculture in some of the world's least developed countries, many of which are in Africa. Substantial improvement in agricultural productivity is essential in many of these countries to achieving sustainable food security and reducing chronic rural poverty.[1] Modern biotechnology can, in the view of agricultural experts, help solve some of the basic productivity problems that plague small and subsistence farmers and impede the development of successful agricultural systems in sub-Saharan Africa. However, important components of the biotechnology tool kit—gene traits, plant transformation tools, and genetically improved germplasm—have been patented in the United States and elsewhere by companies that have little economic incentive to develop and disseminate the technology to meet the needs of small-scale farmers, who are the backbone of African agriculture. This report analyzes how U.S. patent policy affects the development and dissemination of biotechnology to improve African agriculture and makes the case for policy change.

Questions about U.S. patent policy are among the many that can be asked about policies and programs of the United States that affect agriculture and, in turn, food security in Africa and other developing regions. Senior officials of the current U.S. administration emphasize the importance of developing country agriculture in reducing poverty and achieving food security,[2] and the United States has embraced the United Nations' Millennium Development Goals, which have eradication of extreme poverty and hunger their first objective.[3] President Bush told a World Bank audience early in his term that a "world where some live in comfort and plenty, while half of the human race lives on less than $2 a day is neither just, nor stable,"[4] and Undersecretary of State Alan Larson recently declared that "[f]ood security is a serious foreign policy concern that profoundly threatens human health, economic prosperity and political stability."[5]

The policies the United States has in place, however, are not fully aligned with its interests in global food security. The portion of U.S. development assistance devoted to improving agriculture in developing countries remains small. Food aid, the largest single component of U.S. development assistance, tends to undermine agriculture in receiving countries. And the government's subsidy of agricultural overproduction in the United States, which was increased and extended in the 2002 Farm Bill, distorts global commodity markets and contributes to the creation of a nonlevel playing field—one on which many developing country farmers cannot afford

to compete.[6] Consequentially, it is important to examine the impact of U.S. policies and programs that affect agriculture in Africa, whether intentionally or unintentionally, and to consider whether they can be modified in ways that will help achieve the declared goals of reducing poverty and achieving food security through improvements in agriculture.

The U.S. government's stances on biotechnology and patents invite such an inquiry. U.S.-based companies and researchers generate much of the world's innovation in plant biotechnology, and the U.S. government is a strong advocate for biotechnology, as applied to the needs of U.S. farmers and as potentially applied to the needs of farmers in developing countries.[7] The U.S. patent system has enthusiastically embraced plant biotechnology through the issuance of thousands of patents, and the United States generally is a proponent of strong patent protection worldwide, ideally harmonized with the U.S. model. It is thus important to explore how the U.S. positions on biotechnology, patents, and the need for progress in developing country agriculture can be reconciled, and how food security and the broad interests of the United States can be advanced through patent policy change. It is particularly important and timely to address these questions as the "development round" of trade negotiations launched by the World Trade Organization (WTO) at Doha unfolds, with its heavy emphasis on agriculture, and as the international debate heats up about the role of intellectual property in development.[8]

Modern biotechnology, along with other important tools, can help solve some of the basic productivity problems that plague the millions of small-scale and subsistence farmers who are the backbone of African agriculture.

This subject requires covering a lot of intellectual territory. We begin the next chapter by describing the potential role of biotechnology in improving agriculture in Africa and, in turn, contributing to poverty reduction and sustainable food security. This includes discussion of the factors that affect the success of agriculture and food security in Africa, the trend toward privatization of agricultural research and innovation, and the continuing need in Africa for a strong public research sector and for public-private collaborations to improve agriculture. Chapter 3 provides an overview of the theory underlying the U.S. patent system as background for comparing the actual impact of the system with the system's innovation and technology dissemination goals. Chapter 4 describes how the patent system's practices and policies have been applied to the patenting of plant biotechnology. This includes discussion of the so-called "patent thicket" surrounding plant biotechnology, policies affecting access to patented technologies, and U.S. foreign policy on patents, including the U.S. stance on implementation of the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) and other efforts to harmonize patent policy internationally. Chapter 5 analyzes the impact of U.S. patenting practices and policies on developing country access to biotechnology, considering both the current impact of the patent thicket and the potential future impact of U.S. efforts to harmonize patent policy globally. Chapter 5 also presents and analyzes the case for considering change by the United States across a spectrum of domestic and foreign patent policies as a means of advancing the U.S. interest in improving agriculture and achieving food security in Africa. In Chapter 6, we outline a framework for analyzing proposed policy changes, taking into account both the innova-

tion and dissemination objectives of the patent system and the goals of poverty reduction and food security in Africa; with this framework in mind, we identify and briefly analyze ideas for policy change.

Information Sources

This report draws extensively on a review of the existing literature to establish a base understanding of the U.S. patent system, how it is being implemented with respect to agricultural biotechnology, its effect on developing country access to biotechnology, and the lively international debate on the role of patent policy in development. We supplemented this literature review by interacting with a broad cross-section of experts and stakeholders in the arenas of patent policy, biotechnology, developing country agriculture, and food security. This included interviews with a core group of experts and stakeholders, and an informal written survey of a broader group of experts and stakeholders.

Based on this research, we produced a discussion paper that: outlined the theory and social objectives of the U.S. patent system; described how those objectives are being pursued in practice in the implementation of the patent law generally and with respect to agricultural biotechnology particularly; proposed a normative and analytical framework for evaluating whether specific policy changes would improve access to biotechnology for developing country food security purposes without jeopardizing the patent system's incentives; and briefly identified several specific policy changes as candidates for evaluation within this framework.[9] This paper was circulated in draft to a broad group to stimulate comment, discussion, and further development of the policy change ideas; and it served as the basis for a workshop of invited experts the authors convened in October 2002 in collaboration with Professor Walter Falcon of the Center for Environmental Science and Policy at Stanford University. A list of workshop participants is provided in an appendix. We draw heavily on our previous discussion paper and on the results of the Stanford workshop in this report.

U.S. policies on such matters as patents, agricultural subsidies, trade, and food aid have spillover effects beyond their original intent.

Our interactions with a diverse spectrum of experts and stakeholders have had a significant impact on our analysis and conclusions. The initial focus of this project was on U.S. patenting practices and features of U.S. law that directly affect access to patented technologies. We learned, however, how difficult it is to isolate U.S. patenting practices and legal rules from the many other factors affecting developing country access to biotechnology and how important U.S. patent policy in the international arena will be to the future of technological innovation in developing countries, including the patent laws developing countries adopt. We have thus expanded our focus to include the efforts of the U.S. government to influence those laws through the WTO and the World Intellectual Property Organization's (WIPO) program to harmonize patent law and policy internationally.

Though we have benefited from the input of many in the development of this report, the authors bear sole responsibility for the analysis and conclusions presented here, and for any errors of fact or interpretation.

Goal and Perspective of the Report

This report will succeed if it stimulates thinking among policymakers and stakeholders about how U.S. policies involving patents and the international patent system affect the U.S. interest in poverty reduction and food security in Africa, and how those policies might usefully be changed to advance that interest. The authors are neither propatent nor antipatent. We assume that patents have played and will continue to play an important role in stimulating private investment in plant biotechnology, and any change in U.S. patent policy must take account of the patent system's goal of stimulating invention. We do not claim to have the final answer on the ideal mix of policies in this complex area.

We are convinced, however, of one thing. U.S. policies on such matters as patents, agricultural subsidies, trade, and food aid—all of which are grounded in their own set of policy goals and political interests—have unintended spillover effects. This includes impacts on the poorest farmers in the world and on important U.S. interests, beyond the original intent of the policies, including the national interest in reducing poverty and achieving food security in Africa and other developing regions. In today's interconnected world, the United States cannot afford to develop and maintain these important policies without considering their broader impacts and attempting to reconcile them with the nation's broader interests. With regard to patent policy and the goals of food security and economic development in Africa, we believe there is a strong case for policy change.[10]

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CHAPTER TWO

Food Security, Biotechnology, and Agricultural Innovation in Africa

In 1996, at the World Food Summit in Rome, 186 countries, including the United States, pledged their efforts to achieve "food security for all... with an immediate view to reducing the number of undernourished people to half their present level no later than 2015."[11] The Food and Agriculture Organization (FAO) of the United Nations estimates that 800 million people in the world experience chronic hunger and so lack food security at an individual level. Millions of people, many of them children, die annually from hunger-related causes.[12]

Food insecurity is closely linked to poverty and concentrated in the developing countries of South Asia, Africa, and Latin America.[13] It is, however, an extraordinarily complex social, economic, and political problem whose causes and solutions vary from country to country.[14] In India and some other Asian countries, great strides have been made through the Green Revolution in increasing the productivity of agriculture, albeit with well-recognized costs to the environment.[15] These countries produce enough food to feed their populations and in some cases have become food exporters, but people are hungry because they lack the economic means to purchase or produce the food they need for themselves and their families. In many African countries, poverty and social instability are obstacles to food security, but, in addition, the basic problem of poor agricultural productivity has not been solved. The Green Revolution largely bypassed sub-Saharan Africa, and areas in that region have soil, water, climate, and plant pest conditions that make productivity gains hard to achieve and sustain.[16]

There is no single solution to the problem of hunger in Africa or other developing regions. A common reality in many developing and food-insecure countries, however, is that a large majority of the people depends on agriculture for their livelihood, directly or indirectly. In sub-Saharan Africa, 70% of the people are rural and largely agriculture-dependent.[17] Although industrialization has fueled growth and hunger reduction in some Asian economies, it is generally recognized among experts that the poor countries of sub-Saharan Africa must improve their agriculture and food systems to achieve economic growth and food security.[18] Moreover, according to the World Bank, global food production will have to double by 2050 to meet rising demand.[19] By improving agricultural productivity and local food processing and distribution systems, developing countries can increase locally available food stocks to feed their people and also generate income to purchase food in the marketplace, as needed to supplement local production. Improvement in developing country agricultural and food systems is critical to meeting the

world's long-term food needs. But in sub-Saharan Africa especially, any solution to food insecurity will require increased agricultural productivity, to which biotechnology can contribute.

Biotechnology and Food Security

Successful agricultural systems require a combination of natural resources, productive farming methods, and market outlets for surplus production. No element is sufficient by itself, but all are necessary. Natural resources—soil, water, and climate—are the least malleable, but successful agricultural systems have been created all over the world in diverse soil, water, and climatic conditions.[20]

In developing countries, the lack of effective and fair markets for surplus food production may be the greatest obstacle. Access to local, national, and international markets provides farmers the incentive they need to risk their labor and capital on expanded production. Without workable markets, the best natural resources and farming techniques are not enough to produce successful food systems. Effective markets require sound political, economic, and social institutions and policies, as well as transportation systems and other physical infrastructure, which are lacking in many developing countries. Effective markets in developing countries will also require change in the agricultural and trade policies of the United States and other industrialized countries that distort market prices for staple commodities and create obstacles to developing country exports.

The Green Revolution largely bypassed sub-Saharan Africa, where 70% of the people are rural and largely agriculture-dependent.

Within this context, we recognize that improving the productivity of farmers is not by itself the solution to food security. Improved productivity is, however, an important part of the picture, especially in sub-Saharan Africa. African farmers often face difficult growing conditions, and better access to the basic Green Revolution tools of fertilizer, pesticides, improved seeds, and irrigation certainly can play an important role in improving their productivity. With the environmental lessons of the Green Revolution in mind, many agricultural experts also believe that the tools of modern biotechnology (including the use of recombinant DNA technology to produce genetically modified plants) can play a role in solving developing country agronomic problems and increasing productivity.[21] By building into the seed itself traits for drought and disease resistance, insect and other pest control, and improved yield under specific local growing conditions, biotechnology may enable farmers to increase their productivity without as much reliance on the external inputs that characterized the Green Revolution.

Mindful of these potential benefits, researchers in national and international agricultural research organizations are experimenting with biotechnology and working to produce genetically modified plants that could be useful to developing country farmers.[22] In an informal survey of experts familiar with this field, conducted for this study by the authors, 79% of respondents (37 of 47) rated as "very high" or "high" (60% and 19% of respondents, respectively) the importance of access to the tools of biotechnology by researchers working on developing country agricultural problems.[23] Biotechnology companies also promote the potential of biotechnology to improve developing country agriculture and food security.[24]

There is debate about the ultimate value of biotechnology for developing country farmers, and the issues of food safety and environmental and social impacts of the technology should be addressed prior to its adoption. This report does not address these issues, which are discussed abundantly elsewhere.[25] This report takes as its starting point the interest in access to biotechnology among researchers working to improve developing country agriculture and the potential of biotechnology to improve agricultural productivity and thereby contribute to sustainable food security. This report focuses on the specific problem of access to biotechnology for developing country purposes, as affected by U.S. patents and patent policy.

The Privatization and Patenting of Agricultural Innovation

The access problem addressed in this report arises from the recent shift of investment in agricultural innovation from the public sector to the private and the use of the patent system by biotechnology companies to protect their investments. These developments are well described elsewhere.[26] In short, research breakthroughs in the use of recombinant DNA techniques to modify plants, coupled with the 1980 Supreme Court decision in *Diamond v. Chakrabarty*,[27] have spawned substantial investment in biotechnology by large agricultural chemical companies and small biotech startup companies, primarily in the United States and Europe. This shift has resulted in rapid development of the technological tools required to genetically transform plants; discovery of some specific, agronomically useful gene traits; and application of these traits in commercially significant food crops. Another result has been the extensive patenting of the tools of modern biotechnology and of the plants that result from their application.[28]

Technological developments and patent law are producing significant changes in how agricultural innovation occurs, how it is paid for, and who controls it.

These developments are producing significant changes in how agricultural innovation occurs, how it is paid for, and who controls it. For most of history, innovation in seed technology has been a freely shared or public good. For centuries, farmers developed higher-yielding, better-performing varieties and shared them with neighbors. From its founding in 1862, the U.S. Department of Agriculture (USDA) has invested in research to develop improved seed. Until 1925, USDA's largest budget item was a program that provided the latest seed free to farmers.[29] Only in the years following World War II did a large-scale private-sector seed industry develop in the United States and other industrialized countries based on hybridization technology.

In most developing countries seed innovation remains largely a public good. Farmers produce, save, and share improved seed, and national and international agricultural research laboratories produce innovations in seed technology that are commonly distributed through public channels. Internationally, the Consultative Group on International Agricultural Research (CGIAR), which is sponsored by the World Bank and funded largely by donor countries in the industrialized world, has played a leading role in seed innovation, and many of its laboratories are exploring the use of modern biotechnology to solve developing country agronomic problems.[30] There are fledgling seed industries in developing countries that are marketing privately developed hybrids and serving as distribution channels for publicly developed seed innovation,[31]

but in many areas, such as sub-Saharan Africa, innovation remains largely a public enterprise and a public good.

With the advent of biotechnology and the availability of plant patents, the balance between the public and private sectors—in terms of research and control of technology—has shifted. In the United States, most of the investment in research to produce improved seeds is now financed and conducted privately, much of it by biotechnology companies.[32] And innovation in seed technology is commonly patented. This includes the tools used in the laboratory to transfer DNA and produce genetically modified plants—such as transformation vectors and systems, gene-expression promoters, and transformation marker systems—as well as specific gene traits that perform some useful agronomic function and the plants that contain these traits. Gregory Graff has compiled a database of 2,428 patents related to agricultural biotechnology that were issued from 1975 to 1998.[33] Of these, 76% are assigned to private individuals or corporations, with the remainder assigned to universities or public institutions. The top four patenting organizations, with a combined 26% of the patents, are Pioneer Hi-Bred International, Mycogen, USDA, and Monsanto Company. Of the top 30 patent holders, 22 are U.S. or European corporations, which together hold 50% of the patents.[34]

Private-sector holders of biotechnology patents have little or no economic incentive to use the laboratory tools or gene traits they own to find solutions to developing country agricultural problems.

The dominance of the private sector may be even greater than these numbers reveal. Since the Bayh-Dole Act of 1980, public and university research institutions have been allowed and encouraged to patent their results and to enter into public-private partnerships. These cooperative agreements often include an option for the private partner to receive an exclusive license to any resulting patents filed by the public institution or university. Consequently, not only are the majority of biotechnology patents in private hands, but some important patents remaining in public hands, or developed by university researchers with public money, are exclusively licensed to private corporations. Furthermore, the ability to patent has given public institutions and universities the incentive to treat their patents—exclusively licensed or not—less as a public good than as a source of institutional revenue. Their incentive is to behave like the private sector.[35]

The ability to patent the laboratory tools and marketable products of modern biotechnology is cited by the biotechnology industry as a crucial incentive for their investment in the technology, and many observers see this incentive as the catalyst for important innovation in seed technology.[36] The role of the patent system in fostering innovation will be discussed later in this report. One clear consequence of the widespread patenting of biotechnology, however, is that the technology is to a large extent in private hands or in the hands of universities or public institutions that have a new interest and ability to control access to the technology.

The privatization of research affects the kinds of research done and products developed.[37] Private companies have invested heavily in the technology and in the seed companies required to bring new products to market. To capture a return on this investment, they have focused their commercial efforts, including product development, on applications that have mass appeal to farmers who can afford the technology. Thus, commercialization of agricultural biotechnology to date has consisted almost entirely of instilling two traits in cotton, corn, or soybeans for sale

to farmers in the United States and a few other countries: insect control based on the Bt toxin, and resistance to the herbicide glyphosate. This focus on commercially valuable traits and large-scale farming and markets is economically rational and, perhaps, the only thing that could reasonably be expected of companies working within our market system.

This economic reality creates a problem, however. The private-sector holders of biotechnology patents have little or no economic incentive to use the laboratory tools or gene traits they own to find solutions to developing country agricultural problems. The market infrastructure and opportunity required to earn rates of return that would be acceptable in Western financial markets simply do not exist in most developing countries, where agriculture is carried out largely by small-scale and subsistence farmers. As a result, the finite capital resources of biotechnology companies will, for the foreseeable future, continue to be focused on meeting the needs of farmers in Western industrialized countries and will not be deployed in substantial measure to meet the needs of developing country farmers.

Channels for Agricultural Innovation in Africa

With the foregoing trends in mind, the ultimate concern of this report is how innovative seed technology derived from patented tools of biotechnology can be developed and disseminated for the benefit of small-scale and subsistence African farmers, whose success is most vital to food security and poverty reduction. In order to analyze how U.S. patent policy and related technology-transfer policies can affect this process, it is important to state our assumption about the primary channels through which innovation in seed technology is likely to reach these farmers in the foreseeable future. We recognize that both development and dissemination of locally appropriate technologies are important, but we focus in this report on the research and development (R&D) stage of the process, which is most directly affected by the patent and technology-transfer policies we are examining.

We find it useful to posit three possible channels through which innovative seed technology based on modern biotechnology could be developed for the benefit of small-scale and subsistence farmers in Africa: the *private commercial channel*, which relies on private R&D investment to develop the needed traits and incorporate them in local germplasm; the *public channel*, which relies on government and other publicly funded R&D to produce the needed innovation, and the *public-private cooperative channel*, which involves making privately owned tools and traits available to public-sector researchers for the benefit of small-scale and subsistence farmers.

For the foreseeable future, the development of biotechnology for the use of small-scale and subsistence farmers in Africa will proceed largely through the public and public-private cooperative channels.

We assume that for the foreseeable future—the next two decades at least—the development of biotechnology for the use of small-scale and subsistence farmers in Africa will proceed largely through the public and public-private cooperative channels. This assumption is based on two factors. One is the current reality that most agricultural research for Africa is conducted in public institutions.[38] The other is the situation articulated in the previous subsection: that large, private biotechnology companies lack adequate economic incentives to invest their

R&D dollars in products to improve the local crops and germplasm that are important to small-scale and subsistence farmers.[39]

This does not mean that there will be no commercial development of biotechnology in Africa[40] and that larger-scale commercial agriculture will not grow and be important to the future of Africa. Such growth is desirable, and it is likely to occur, especially if the recent new interest in agriculture among development-assistance donors grows, and if progress is made through the WTO and bilateral trade agreements to reduce subsidies and generally level the playing field for African agricultural exports. The development of commercially viable private enterprises to distribute seed and other inputs is also desirable, and is not excluded by our assumption about the primacy of public and public-private channels of innovation.

The premise of this report, however, is that if the benefits of cutting-edge advances in seed technology based on modern biotechnology are to reach the vast majority of African farmers, it will have to occur for the foreseeable future primarily through public and public-private cooperative channels. Starting from this premise, the core policy questions we address in this report are whether and how U.S. patent policies could be changed to foster the development of biotechnology for African farmers through these nonprivate channels.

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CHAPTER THREE

The Theory and Social Objectives of the U.S. Patent System

We begin our analysis with an understanding of the objectives and theoretical underpinnings of the U.S. patent system because they both underlie the case for policy change and can help shape the analysis and choice of policy alternatives. We will describe here the patent system generally, and then, in the next section, its application to the field of agricultural biotechnology.

While our focus in this report is on patents and patent policy, it is important to emphasize that patent law is part of a broader set of social arrangements and policies that might be grouped under the heading "innovation policy." Broadly speaking, innovation policy addresses the question of how a society obtains the technology required to meet its needs. It addresses not only how intellectual property (IP) is defined and protected legally, but also such matters as the allocation of innovation roles and responsibilities between the public and private sectors; the extent and focus of publicly funded R&D; public policy incentives for private-sector R&D and innovation, such as tax incentives, subsidies, and regulatory streamlining; and preferences for generating innovation internally versus transferring it from external sources. The innovation policy of any country should appropriately reflect its current state of technological development and capacity for innovation and its particular technological needs. Because these circumstances vary so widely among countries, optimal innovation policies will vary among countries.[41]

Another component of innovation policy, besides patent policy, is technology-transfer policy, which addresses the arrangements for disseminating innovation to the places in the economy where it can meet a need and contribute to social welfare. Patent policy and technology-transfer policy are closely related, as the following discussion will make clear.

Patent policy cannot be meaningfully understood or effectively improved for developing country food security purposes in isolation from these broader policy contexts. We begin, however, with the foundation for our analysis of the case for patent-policy change: the theory and objectives of the U.S. patent system.

The Utilitarian Purpose of the Patent System

The Constitution of the United States establishes the mandate and states the broad objective of the U.S. patent and trademark system: "The Congress shall have Power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the

exclusive right to their respective Writings and Discoveries."[42] On its face, the constitutional objective of the U.S. patent system is a social one: to promote progress in science and the "useful Arts." It embodies a utilitarian conception of patents that has been in the mainstream of patent theory since ancient Greece, as reported by the patent scholar Robert Merges:

The belief in innovation that made Hippodamus a celebrated architect led him to propose a legal instrument to encourage innovation. And this proposal contains the seeds of a practical utilitarianism: honor the creator of a useful thing, and society will get more useful things. This proposal, this mode of thought, is the core of all patent systems, ancient as well as modern.[43]

Under the utilitarian or "instrumental"[44] conception of patents, the patent system is successful to the extent that it results in getting more useful things for society.

The countertheory for patents is the "natural rights" view that patents are a form of property to which inventors have a natural right by virtue of their inventive efforts. This perspective and other nonutilitarian perspectives on patents continue to surface in scholarly writings[45] and in policy debates,[46] but they continue to be rebutted eloquently by the famous statement made in 1813 by a noted American inventor and the first patent administrator, Thomas Jefferson:

It has been pretended by some . . . that inventors have a natural and exclusive right to their inventions . . . . If nature has made any one thing less susceptible than all others of exclusive property, it is the action of a thinking power called an idea . . . . Its peculiar character, too, is that no one possesses the less, because every other possesses the whole of it. He who receives an idea from me, receives instruction himself without lessening mine; as he who lights his taper at mine receives light without darkening me. That ideas should freely spread from one to another over the globe, for the moral and mutual instruction of man, and improvement of his condition, seems to have been peculiarly and benevolently designed by nature . . . . Inventions then cannot, in nature, be a subject of property. Society may give an exclusive right to the profits arising from them, as an encouragement to men to pursue ideas which may produce utility, but this may or may not be done, according to the will and convenience of society, without claim or complaint from anybody.[47]

Jefferson's understanding of patents as a benefit granted by society on terms designed to achieve social policy goals is central to our case for considering policy change. It is also embedded in U.S. patent law, which sets out the basic terms of what amounts to a contract between the inventor and society. Through operation of the patent law, society gives the inventor a time-limited monopoly right to exploit the invention for economic gain. In exchange, the inventor gives society new knowledge, the invention.

The requirements and conditions for granting patents reflect the terms of the deal between the inventor and society.

The requirements and conditions for granting patents reflect the terms of the deal between the inventor and society. They ensure that the inventor's contribution to society has value. Hence, there is a utility requirement,[48] so society will receive a useful invention. There is a novelty requirement,[49] so inventors cannot offer something that society already has. There is a nonobviousness requirement,[50] so inventors cannot offer what society would likely soon have in any case. And there is a disclosure or specification requirement,[51] so that society actually receives the invention, in the sense that it becomes part of the common knowledge, usable by others.

Those conditions reflect the utilitarian and instrumental character of the patent system. A central assumption underlying the system is that society will benefit from new technology if inventors have the incentive and reward of a patent to induce their investment in the creative act, and the patent is awarded to achieve that social objective, not to reward inventors for the sake of rewarding inventors.

Specific Objectives of the Patent System

To assess whether or not the patent system is working to achieve its social objectives, we should be more specific about what those objectives are. Drawing on the work of Mazzoleni and Nelson,[52] we identify four: (1) increasing the amount of invention; (2) disseminating knowledge about inventions; (3) regulating the orderly investigation of new research areas; and (4) facilitating the practical use, including the production, application, and commercialization, of inventions.[53]

The first two objectives—increasing invention and disseminating information about inventions—are self-evident from the face of the patent law and the most common understanding of why we grant patents.[54] They reflect and are well satisfied by the simple paradigm of the lone inventor who is induced to invest effort in making the invention by the promise of a temporary monopoly on commercialization. With the inducement of the patent monopoly, it is reasonable to expect more rather than less inventive effort. With the disclosure requirement, there is at least some dissemination of knowledge, more certainly than if inventors sought to protect their commercial prospects by keeping their inventions secret.

Practical applications of biotechnology rarely occur through the efforts of the lone inventor, but rather through the creative efforts of many.

The third objective—regulating the orderly investigation of new research areas—is relevant mainly in complex fields like agricultural biotechnology. Practical applications of biotechnology rarely occur through the efforts of the lone inventor, but rather through the creative efforts of many. They typically require the use of transformation tools, marker systems, and other enabling technologies, as well as specific gene traits. Biotechnology is analogous in this respect to computer and information technology, which has advanced through the assembly of multiple technological building blocks from multiple sources. Patent scholars have theorized that the issuance of patents in such areas can, in principle, bring order to the research process and thereby help foster innovation.[55] By disclosing the invention, the patent enables others to learn from and build upon the invention and, at the same time, directs them away from research that might wastefully duplicate the now-proprietary work of the patent holder. Moreover, with control of a patented technology safely in hand, inventors can negotiate for financial backing and can offer investors protection from surprise competition.[56] With ownership clear, inventors can also license their inventions, so that development of practical, innovative applications proceeds cooperatively instead of in wasteful races.

The fourth objective—facilitating practical use—flows directly from the broad utilitarian purpose of the patent system. More invention and more information do not help society unless they result in more practical progress in the useful arts. This may require, for example, more than one invention, and it certainly requires that the invention be in the hands of a party

that has the interest and practical wherewithal to make use of the invention for a worthwhile purpose.

The objective of fostering practical innovation, not just new invention, is more than just an academic construct—it has been reflected in patent policy and policy debates. In Europe, Japan, and most of the rest of the world, patent law requires that patent holders "work" their patents (that is, put them to practical use) or else lose the right to exclude others from working them. The U.S. patent law does not include such a requirement. Recognition of facilitating practical development as an objective of the patent system is, however, embedded in the rationale for the Bayh-Dole Act,[57] which was enacted by the U.S. Congress in 1980 to authorize and encourage the patenting of inventions made by universities and other institutions with federal funding. The first two objectives of the patent system—more inventions and more dissemination of information about inventions—would not by themselves justify Bayh-Dole. After all, the incentives of public institutions to invest public money in research are not materially affected by the prospect of monopoly rewards. Public researchers also have no incentive to keep their results secret, but, quite the opposite, have every incentive to publish.[58]

Bayh-Dole was enacted for a different purpose: to increase the likelihood that publicly funded inventions would get into the hands of parties who would have the incentive to develop them commercially and thus turn inventions into useful products.[59] The idea was that companies would not be willing to invest in commercial development unless they could do so under patent protection. Consequently, publicly funded inventors were encouraged to patent their inventions so that they could transfer technology, through license or sale, with the benefit of patent protection. This is a clear instance of U.S. patent policy intending to facilitate not merely invention and information dissemination, but also practical use through commercialization.[60]

Complications in Achieving the Patent System's Goals

These are the objectives the patent system is meant to pursue, but it is not obvious what policies should be employed in pursuing them. The third and fourth objectives especially require a nuanced appreciation of the complications that arise when inventions are the products of many researchers building on one another's work. Especially in that case, patent policy must balance competing considerations, because the objectives of the patent system can be at cross purposes. Incentives for one step in a complex process of developing innovative technology can become disincentives for further steps required to achieve useful application of the technology. For example, a patent on something that contributes early in a technology development process (such as an enabling technology for genetic transformation of plants) but does not itself produce a useful commercial application (such as an improved plant variety) promotes dissemination of information and gives others the chance to move development forward. It may, however, give them less reason to do so if the patent on the early contribution blocks development and commercial use of the finished product.

Similarly, when patents are very broad in their scope or cover tools that are widely applicable to the work of researchers studying diverse problems, they can have a significant blocking effect on innovation.[61] Researchers, including those in public or other nonprofit research settings, must obtain permission from the patent holder or risk an infringement claim if they de-

velop a useful new product using a patented invention. Such "blocking patents" have come under critical scrutiny by patent scholars:

[H]ighly basic patents that preempt a large area of research are unlikely to be beneficial. The application of the basic technology is unpredictable so that restriction of a relatively basic research tool to a small number of researchers is likely to cost more in improvement research and lost insight to other research teams than it contributes to incentive and funding potential for the favored research team. This is the clear implication of the Merges and Nelson study of patent scope in a variety of sectors; its examples show that overly broad patents can particularly slow innovation in a highly scientific sector such as biotechnology.[62]

So, whether the initial patent facilitates practical innovation and orderly investigation or stifles them depends on the circumstances. Sound patent policies need to consider these effects.

According to one commentator (writing about biotechnology patents in the pharmaceutical field), "with cumulative innovation and multiple blocking patents, stronger patent rights can have the perverse effect of stifling, not encouraging, innovation."[63] The danger of too many or too broad or too early patents has been described by Heller and Eisenberg as an "anticommons,"[64] wherein too many actors have the ability to prevent others from development and marketing and no one has an effective ability to use and disseminate inventions.

When patents are very broad in their scope or cover tools that are widely applicable to researchers studying diverse problems, they can have a significant blocking effect on innovation.

The objective of facilitating practical use of inventions—which might be called technology transfer—is at the heart of the problem we address in this report. Since the existence of patents can sometimes hinder the application of patented technologies for their full range of socially beneficial uses, it is legitimate, as a matter of sound patent theory and policy, to ask how policies might be changed to reduce obstacles to such uses. First, however, we examine how the U.S. patent system has been implemented with respect to plant biotechnology and how this, coupled with U.S. patent policy in the international arena, affects access to the technology to meet agricultural needs in Africa and other developing regions.

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CHAPTER FOUR

Patent Proliferation and U.S. Patent Policy

Much has been written about the U.S. patent system and its application to agricultural (especially plant) biotechnology.[65] We will not summarize that literature, but we will sketch key elements of how the U.S. patent system and patent policy operate in this area to explain how access to biotechnology for developing country purposes has been and could in the future be affected by U.S. patent policy. We first describe how the patenting practices of the U.S. Patent and Trademark Office (PTO) have created what some call a "patent thicket" around biotechnology and how the PTO's propatent culture affects the proliferation of patents. We then identify policies affecting access to patented technology and U.S. foreign policy on patents, which we believe may, in the long run, have more impact on developing country access to biotechnology than the PTO's domestic patenting practices.

In this discussion, we will address the activities of the PTO in its roles both as the decisionmaker on whether to grant a patent and as an important contributor to the making of U.S. patent policy. The PTO is part of a patent policymaking system that begins with the Constitution but is directed by Congress through statute.[66] The system is heavily influenced by the courts, including the U.S. Supreme Court and the Court of Appeals for the Federal Circuit (CAFC).[67] The following discussion suggests, however, why the primary locus for policy change to address developing country concerns will lie not with the courts but with the Congress, the PTO, and the executive branch agencies responsible for managing trade and international affairs.

Background on Biotechnology Patenting

The history of agricultural biotechnology patenting is generally considered to have started in 1980 with the famous and controversial five-to-four Supreme Court decision in *Diamond v. Chakrabarty*.[68] Chakrabarty had applied for a patent on a genetically engineered bacterium that could break down crude oil. The Supreme Court allowed the issuance of a patent, concluding that the patent law extends to living creatures, such as this bacterium, as long as they are not naturally occurring but made by humans. In 1985, in *Ex parte Hibberd*,[69] the PTO expanded the scope of what it considered patentable biotechnologies from microorganisms to genetically modified plants.[70]

These decisions affect directly only the subcategory of biotechnology that involves a living organism—the genetically modified plants themselves. Laboratory tools required to transform

plants were not directly affected and would have been considered patentable—consistent with the statutory criteria of novelty, utility, and nonobviousness—without the *Chakrabarty* and *Hibberd* rulings. Moreover, plants themselves had long been subject to limited patent or patent-like protection under the Plant Patent Act of 1930[71] and the Plant Variety Protection Act of 1970.[72] The Plant Patent Act, administered by the PTO, covers asexually reproduced plants (i.e., not produced from seed) and provides protection against the sale by others of novel varieties produced in this fashion.[73] The Plant Variety Protection Act, administered by USDA, provides similar protection for novel plant varieties that are sexually reproduced. In contrast to the core patent statute, no showing of utility is required under these two plant-specific laws, but they confer considerably more limited rights on inventors than standard (or "utility") patents. In particular, they do not include the right to control what people do with derivatives of the plant in question, which means, among other things, that researchers are free to use plants patented under the Plant Patent Act in the course of further developing and commercializing new plants. The Plant Variety Protection Act explicitly contains both a farmer's exemption (allowing farmers to save and reuse seed from a protected variety) and a research exemption.[74]

Without utility patents, farmers would be free to save the seed from their genetically modified crops and use them the next year and thereafter, which would mean that most return on investment would have to come from one-time sales.

The practical impact of *Chakrabarty* and *Hibberd* was far-reaching.[75] The ability to patent genetically modified plants solved one of the major problems developers of biotechnology had faced in devising an effective model for commercial exploitation of the advances they were making in the laboratory. Without utility patents, farmers would be free to save the seed from their genetically modified crops and use them the next year and thereafter, which meant that most return on investment for technology developers would have to come from one-time sales. Given the size of the investment required to develop commercially viable varieties of genetically modified plants, developers prefer (and investors may require) the more sizable income that can be derived from annual sales over the life of the patent. With a utility patent on the plant, reuse of the seed would constitute patent infringement and could on that basis be prevented through strict license agreements with growers and litigation to enforce the licenses and patents, as needed.[76]

Utility patents thus changed fundamentally the incentives for investment and invention in the field of agricultural biotechnology.[77] By providing the basis for earning a return on genetically modified plants, they stimulated investment in the development and marketing of commercial varieties, such as the genetically modified corn, soybeans, and cotton that have captured large shares of the U.S. market.[78] The ability to patent and control the use of such plants made them more valuable, which in turn provided an economic incentive to discover and develop the functional gene traits and improved transformation tools required to pursue other commercially valuable genetic modifications of food crops. Under the basic utility patent law, these traits and tools are themselves patentable and have been patented in large numbers.

The Number and Pattern of Biotechnology Patents

Graff has compiled a unique dataset of agricultural plant biology patents,[79] on which we rely extensively for our analysis of the number and pattern of biotechnology patents. The bulk of

our analysis is in Appendix A, and we are only summarizing it here. Graff's data, coupled with data reported by the PTO and others, document the following points: a large number of biotechnology-related patents have been issued; they are being issued at an increasing rate; and; the majority of the patents are in private hands. (The appendix gives additional detail on both the numbers and kinds of technology being patented.)

Many biotechnology patents have already been issued. Considering only biotechnology specifically applicable to agriculture and focusing on specific genetic traits, plant germplasm, and tools to modify the genome of plants, we calculate that about 2,247 inventions were patented between 1975 and 1998. Beyond just the overall number of patents, the rate at which biotechnology patents are being issued is increasing. Data on this were not available specifically for agriculturally applied biotechnology, but in scientific areas closely related to plant biotechnology, PTO data show that the number of patents issued per year increased almost nine-fold between 1981 and 2001.[80] In the same time, overall utility patents per year slightly more than doubled. In agricultural biotechnology specifically, we can get an idea of the trend from a study of patents issued to universities. Barham et al. found that the number of agricultural biotechnology patents issued to universities in the four years from 1996 through 1999 (481) greatly exceeded the cumulative total of such patents issued in the previous 20 years (314).[81] We assume that the trend is similar for patents assigned to private individuals and corporations, though we have not found an analysis of that trend in the literature.

Graff's data also show how agricultural biotechnology patents are distributed among three groups of patent holders: universities or other public institutions, individuals and small or start-up firms, and large corporations. Of the 2,247 inventions covered by agricultural biotechnology patents that were issued from 1975 to 1998, 525 were patented by universities or public institutions, 812 by small firms or individuals, and 970 by corporations. (The sum of the patent holders exceeds 2,247 because a single patent can be granted to multiple assignees.) These data confirm that most of the agricultural biotechnology patents (79%) are in private hands.

The Breadth of Biotechnology Patents

In considering the impact of patents on access to biotechnology for developing country purposes (or for any purpose), it is important to consider not only the number but also the sort of patents being issued. The use of modern biotechnology to develop a genetically improved crop requires use of multiple tools, including gene traits, transformation tools, and germplasm, all of which may be patented. Some biotechnology patents are so broad in their scope or cover tools that are so widely applicable that they can have the blocking effect on innovation described earlier.

For example, in 1992, Agracetus (now a subsidiary of Monsanto Company) was granted a U.S. patent covering all genetically engineered cotton plants.[82] In 1994, Agracetus was granted a European patent on all transgenic soybeans, though it was later denied in the United States. In 1999, Monsanto filed patent applications in 81 countries on soybeans with enhanced yield derived by using a marker-assisted selection (MAS) technique. It covers "any cultivated soybeans containing certain genes or segments of DNA from 'wild' or 'exotic' soybeans identified through MAS."[83] The MAS technique, which allows plant breeders to "tag" genes that may contribute to increased yield or other positive attributes, is relatively simple and holds promise for crop improvements by public-sector researchers. Yet private companies are able to use their patents to

make tagged genes proprietary and thereby undercut the utility of the MAS technique for public purposes. [84]

Monsanto has patents on other critical tools used to genetically transform plants. These include a recently issued U.S. patent (No. 6,174,724) that covers "all practical methods of making modified plant cells that employ antibiotic-resistance markers," a widely used technique[85]; the widely applicable *Agrobacterium tumefaciens* vector system for transforming cotton plants, which Agracetus patented in the United States in 1991[86]; and the CaMV 35S promoter.

According to Gary Toenniessen of the Rockefeller Foundation, the Monsanto antibiotic-resistance marker patent "appears to be just another nail in the coffin of public-sector researchers' ability to produce transgenic plants with freedom to operate."[87] Such consequences are feared because some transformation tools, such as the *Agrobacterium* vector system, have very wide appeal and utility to researchers and thus can be a "must have" tool in many situations. The holders of such patents have the ability to exclude others not only from using the tools for purposes that compete directly with the use to which the patent holder is putting the patented invention, but also from other uses far removed. Under this circumstance, the transformation tools, which could be thought of (and may originally have been developed) as research aids, take on significant economic value and become more jealously guarded. Developers of new plant varieties that might require such patented traits and transformation tools, including researchers in public or other nonprofit research settings, must obtain permission from the patent holder and may have to pay royalties or agree to "reach-through" restrictions on the dissemination of varieties they develop.

The increasing number of patents, increasing patent breadth, and the issuance of patents on more basic discoveries has created a patent thicket in biotechnology: "an overlapping set of patent rights requiring that those seeking to commercialize new technology obtain licenses from multiple patentees."

The Patent Thicket and Its Consequences

This pattern—the increasing number of patents, increasing patent breadth, and the issuance of patents on more basic discoveries—has created what some call a patent thicket in biotechnology: "an overlapping set of patent rights requiring that those seeking to commercialize new technology obtain licenses from multiple patentees."[88] The patent thicket is a problem because useful innovation in biotechnology requires multiple inventive steps and technologies. Biotechnology is a field particularly dependent on the cumulative work of many researchers, and therefore vulnerable to the problem of an "anticommons" mentioned earlier.[89]

The access problems blend into one another and the resulting barriers to further research and innovation are similar, whether it is a single broad patent on a genetically modified plant or many contributing research tools, or whether it is a single owner's refusal to license or the transaction costs of negotiating with many owners. The logic here applies to and has been debated in a number of fields. Widely discussed with respect to pharmaceutical biotechnology, the same observations apply to agricultural biotechnology. Academic scientists report problems of access to important technologies that have hampered their agricultural research. Many of their concerns are articulated in *Intellectual Property Rights and Plant Biotechnology*, the proceedings of a 1996 forum at the National Academy of Sciences. The most direct barriers they cite are simple

refusals by owners to license, a problem that comes with the dominance of private ownership described earlier. Owners can refuse out of mistrust for licensees,[90] the wish to retain a field of research for themselves,[91] or any other reason. Even public agencies, responding to ownership incentives, do not always promote access.[92] These simple refusals shade into the more complex problems of the patent thicket when the barrier is not one owner but the accumulated transaction costs:

Sometimes the shutting out of researchers from a technology or line of inquiry is less direct but no less effective. Bennett described one such conundrum in California. As part of a project funded by the Strawberry Commission, researchers had been working to insert a gene into strawberries that would cause the berries to produce fungus-killing chemicals and so reduce the need for fungicides. Researchers were using an anti-fungal gene and a strawberry cultivar both patented by the University of California, so access to them was no problem. Unfortunately, however, as the project progressed, those involved realized that access to other necessary technologies—Agrobacterium *to insert the gene, promoters, and selectable markers*—*was not nearly so clear. Indeed, Bennett said, it appeared that even if the researcher succeeded in developing a strawberry line with anti-fungal properties, difficulties in getting commercial rights to the various technologies would make it impossible to market the line. The Strawberry Commission dropped its funding of the program.*[93]

Academic researchers may be especially vulnerable to access obstructions, but as Heller and Eisenberg argue, the logic of the "anticommons" applies to all.

In response to the patent thicket, the commercial biotechnology industry has developed a number of strategies. Because of the many patents outstanding on the tools of biotechnology, companies often cannot avoid infringing patents in pursuit of their product-development research. They thus need protection from litigation, which spawns the growing practice of "defensive patenting":

Firms now attempt to protect themselves against [infringement] suits by acquiring patent portfolios (frequently on very minor inventions) of their own, so that they can deter litigation through the threat of reciprocal suit. The portfolios have become so substantial that every firm is likely to infringe patents held by each of its competitors. This is the pattern for products in the semiconductor industry; it may become the pattern for operating methods in the online services industry and for research and production methods in the agricultural biotechnology industry. Building the portfolio requires enormous legal cost but contributes little to research incentives.[94]

More cooperative responses, such as patent pooling or cross licensing, have been pursued in some industries,[95] but these also have their costs. Elaborate cross-license structures act as a barrier to entry to the industry,[96] and they can raise antitrust issues.[97] One solution to the high transaction costs of negotiating multiple patents is for companies to merge. Some commentators believe the extensive merger and acquisition activity in the agricultural biotechnology and seed industries is driven in part by the need to consolidate patent portfolios and thus ensure freedom to operate.[98] Though many other factors are also at work, the concentration in the industry has been dramatic.[99]

If the patent thicket is affecting access to and use of the tools of biotechnology by industrial and academic researchers, it will probably affect public-sector researchers working on developing country agricultural problems in a similar way.[100] An example of the patent thicket exists in the recent effort of the public-sector inventors of a vitamin A-enriched rice known as Golden Rice to make the necessary technologies available for adaptation in developing coun-

tries. Some 70 patents and existing licenses had to be considered as possible barriers.[101] Commentators have written about the access problem for developing countries,[102] and it was cited by 31 of 33 (94%) respondents to our survey, who said that the "multiplicity of patents and patent owners affecting product development" is of "high" importance for access to the tools of biotechnology by researchers working on developing country problems. We will explore this impact further in the next chapter after a brief overview of the strongly propatent orientation of the U.S. patent system.

The Propatent Orientation of the U.S. Patent and Trademark Office

There is much academic debate over whether the patenting practices of the PTO result in too many patents. Whether current patenting practices and outcomes are optimal depends, of course, on one's point of view and the criteria one applies to assessing the operation of the system. As noted at the outset of this report and discussed further below, we see evidence that the system inhibits access to biotechnology and its potential application to developing country agricultural problems. Regardless of one's point of view or the interest one brings to analysis of the U.S. patent system, however, it is important to recognize the core values and orientation of the government agency charged with managing the system.

The PTO exists to issue patents. Although the agency is charged with making patent decisions based on statutory criteria that patent applicants must satisfy—and denying patents when the criteria are not satisfied—the PTO's orientation and pervasive culture are strongly propatent. This approach is seen in what the agency says about its mission and strategic goals and whom it considers its constituency. The PTO does not exist in a vacuum. Like most government agencies, its orientation reflects the demands and expectations of society as filtered through the Congress, the courts, and the stakeholders with whom the agency comes in contact daily—primarily patent applicants and patent attorneys. Thus, the propatent orientation of the PTO simply mirrors the propatent orientation of its immediate context and of the U.S. patent system as a whole. The assumption implicit in the PTO's own statements about its role is that society will benefit if the agency does a good job responding to the needs of inventors for prompt, strong intellectual property protection. There is little evidence from the agency's statements that it sees itself as responsible, in the way it does its daily work, for balancing the interests of inventors in having patent protection against the broader interests of society in having access to useful innovation.

This propatent culture is evident throughout PTO publications: "For more than 200 years, those who depend on the protection of intellectual property have known that they could rely on the USPTO as the advocate and guardian of the rights of inventors, creators and innovators."[103] The PTO considers its commitment to inventors essential to the needs of the modern economy: "The strength and vitality of America's high-technology economy depends directly on the availability of effective mechanisms to protect new ideas and investments in innovation."[104]

The PTO's plan for 2001–06 has as a strategic goal that the agency "[m]aintain and grow our domestic and international leadership roles in intellectual property rights policy." The corresponding performance goal is to "strengthen intellectual property protection in the United States and abroad, making it more accessible, affordable, and enforceable." This goal, says the

PTO, "relates to our Intellectual Property Leadership function, which provides executive direction to the USPTO and serves to champion intellectual property at home and abroad."[105]

The role of the PTO as a champion of intellectual property is also expressed in the first testimony given to Congress by the new director of the agency, James E. Rogan, in April 2002. In his prepared statement, Rogan focused on the pending backlog of patent applications and his five-year plan for reducing it:

The current projections—where patent pendency remains in excess of two years because of backlogs . . . should be deemed unacceptable. Our customers deserve—and the reality of our high-tech economy demands—that we provide the highest quality patent in the shortest feasible timeframe. Issuing a high quality patent is our primary goal. Issuing it in a timely manner is essential. Balancing these goals is our challenge.[106]

The PTO's focus on the patent applicant, rather than the public-at-large, as the agency's customer is pervasive. It cites its customer satisfaction surveys, customer-service training for employees, and customer feedback activities, all in line with its goal to "define service from our customers' perspective."[107] The PTO's Public Advisory Committees, which the agency says are "drawn from a cross-section of our private-sector customers,"[108] consist of representatives of "entrepreneurial businesses, inventors, universities, large U.S.-based corporations, and law firms."[109] The public at large, the presumed beneficiary of the innovation the patent system is intended to stimulate, is not represented.

The focus on the patent applicant as the customer is reinforced by the fact that the agency depends for its revenues on applicants' fees.[110] In addition to application fees, there are also maintenance fees, which the PTO receives only on issued patents. The fact that the applicant pays for the review and will pay in the future only if the patent is issued, though not the only explanation for the PTO's propatent orientation, creates a positive atmosphere for the issuance of patents that inevitably contributes to the volume of applications, and that volume, in turn, directly affects PTO revenues. Like any organization, the PTO has an institutional interest in maintaining its revenues.

The PTO's customer focus and dependence on patent applicants for revenue make the relationship between the agency and the applicant very different from the arm's-length relationship that typically exists between a regulatory agency and a regulated entity.

The PTO also manages its resources to ensure that applications are processed in an efficient and timely manner. Examiners have very little time for each application, about 20 to 30 hours.[111] Pendancy time—the time from application to issue—is carefully monitored, and the law provides patent-term extensions for applicants when the PTO fails to meet various deadlines, which is both an embarrassment and a transaction cost for the agency.[112] Improperly structured applications may be returned to the applicant for revision, but those will come back again.

One of the primary grounds for denying a patent is if the examiner finds that there is evidence that the invention is actually not new (that is, there is "prior art" covering the patent claims). If other requirements for patenting are met, a patent will be issued unless prior art is discovered under great time pressure. This can create a particularly strong propatent tendency in new and dynamic areas of research and innovation, such as biotechnology, where many researchers in diverse institutions are engaged in in-

ventive activity, new work is not published in the usual sources of prior art, and alternative databases and information systems may not be in place to make prior art readily available to the examiner. The examiner necessarily relies heavily on the prior-art search of the applicant, who is not unbiased. On top of this, the examiners' work performance evaluations and bonuses (up to 10% of salaries) depend on maintaining their production schedule in accordance with the limited time allotted for each application.[113] All these factors put significant pressure on patent examiners to err on the side of granting rather than denying patents.[114]

The PTO's customer focus and dependence on patent applicants for revenue make the relationship between the agency and the applicant very different from the arm's-length relationship that typically exists between a regulatory agency and a regulated entity. Rather than acting as neutral arbiters of whether a valuable public license should be issued, based on an assessment of whether criteria designed to advance a broad public interest have been satisfied, patent examiners are under pressure to act more as partners of the applicant, with the responsibility to manage an application to a prompt conclusion with the issuance of a defensible patent.

The tendency to favor the issuance of patents is reinforced by some of the traditional rules governing the examination process. Those who oppose a patent, or would have an interest in opposing it, are not represented in the process. Until the American Inventors Protection Act of 1999 instituted an 18-month publication rule (the first actual early publications took place in mid-2002), patent applications were not published before they were granted. Therefore, no one could oppose the granting of a patent until after it was issued, and although challenges were allowed, there was—and there remains—a strong presumption that an issued patent is valid. The patent statute explicitly presumes validity, placing the burden of proof on the challenger.[115] Furthermore, challengers must undertake the time and expense of litigation, with the patent generally remaining in force until the case is resolved. The only exception that allows fast-track challenges is patent reexamination, which is narrowly limited to challenges that claim prior art was overlooked by the examiner. Reexaminations give far less opportunity than courts do for third-party challengers to be heard or to rebut patent holders' arguments. Some of these procedural obstacles have been eased by changes passed in the American Inventors Protection Act, such as allowing challengers to participate in appeals to the Board of Patent Appeals and Interferences, though still not in appeals to the Court of Appeals for the Federal Circuit.[116] Since applications are now published after 18 months, they can be challenged before issuance, but still with restrictions on the challenger's legal standing, and the improvements have been modest:

The 1992 Report of the Advisory Commission on Patent Law Reform urged strengthening of the reexamination process, and a weak reform was included in the legislation enacted last fall. Even as reformed, the process deals only with newly discovered prior art; it offers no way to reconsider a patent on the grounds that the examiner misapplied the law.[117]

The new law also creates ambiguous incentives for challengers, even on prior-art grounds, as the PTO acknowledges:

Those third-party requesters who choose to use the optional procedure, however, will not be able to appeal adverse decisions beyond the Board of Patent Appeals and Interferences. Also, they will not be able to challenge, in any later civil action, any fact determined during the process of the optional reexamination procedure.[118]

A challenge may actually weaken a third party's position in future court cases by giving any prior art submitted by the third party the status of a fact already considered in the application.

Our description of the propatent orientation of the U.S. patent system and the pressures on examiners to proceed with dispatch toward the issuance of patents is not intended to suggest that the system behaves illicitly, or even necessarily to be critical. It is intended simply to describe the system as it is. There is ample room to debate whether current patent law and the PTO's approach to implementing it are in the public interest. Many academic commentators argue that they are not.[119] Many other defenders and proponents of the system argue that the PTO is doing just what Congress intended and that it is acting profoundly in the public interest.[120]

The conclusion we draw for purposes of this report is that, regardless of whether U.S. patenting practices are in the "public interest," however that is defined, they are not likely to be changed to address interests that lie outside the normal scope of political and economic factors affecting how the PTO issues patents. The culture of the PTO and its immediate constituencies is well entrenched and strongly supported politically, in Congress and elsewhere. Consequently, if U.S. patent policy is to be adjusted to address access to biotechnology for developing country purposes, it is more realistic to consider adjustments in policies that do not directly affect the issuing of U.S. patents, but rather policies that affect subsequent access to patented technologies and those that affect international harmonization of patents.

Policies to Ease Access

We will address here, and in the later discussion of possible policy change, five areas of patent policy that affect the conditions under which parties may access and use patented technologies. These all provide opportunities to address the technology transfer problem of concern here, namely access to the tools of biotechnology by public-sector researchers and others who want to use them for developing country purposes. The five policy areas are: (1) exemptions for research use of patented technology, (2) patent working requirements, (3) compulsory licensing of patented technology, (4) the government's eminent domain authority over patents, and (5) provisions for access to patented technology that is government-owned or developed with government funding.

Research Exemptions

The utility patent statute in the United States does not explicitly allow researchers to use patented inventions freely in their research. Traditionally, however, the U.S. courts have interpreted the law as implicitly exempting from infringement the use of patented inventions in noncommercial research. This was in keeping with the purpose of the patent law to make patented technologies known and available so they could be the basis for developing new knowledge, while protecting the monopoly marketing rights accorded to inventors by their patents. This judicially recognized research exemption was narrow, however, in the sense that it did not permit the use of patented technology in the research and development of new technologies for use in commercial research or nonresearch settings. In a recent decision, the U.S. Court of Appeals for the Federal Circuit narrowed the exemption even further, to the point, apparently, of eliminating it for practical purposes.[121] The Court held that the exemption did not protect from infringement claims the use of a patented technology "in keeping with the alleged infringer's legitimate

business, regardless of commercial implications." This means that the exemption does not protect even purely academic research conducted by a university, since academic research is the university's "business." Similarly, the exemption would not be available to public-sector researchers using patented tools of biotechnology to develop applications for developing countries, even if the research has no "commercial implications."

The lack of a meaningful research exemption under the U.S. utility patent statute differs from the approach taken in Japan and many European countries, which exempt from infringement suits research done for noncommercial, experimental purposes.[122] It also contrasts with the explicit exemption from protection provided in the Plant Variety Protection Act for the use of a protected plant variety to develop new commercial varieties.[123]

Compulsory License Provisions

U.S. statutes currently provide for the granting of mandatory, nonexclusive licenses for certain technologies that serve an important "public interest" purpose. The Clean Air Act, for example, has a compulsory licensing provision for pollution-prevention technology; and the Atomic Energy Act has a compulsory license provision for certain patented technologies "affected with the public interest."[124] U.S. law also provides for compulsory licenses to make a technology available for the government's use or, more commonly, to ameliorate anticompetitive practices by patent holders.[125] Compulsory licenses, like research exemptions, are tools for adjusting the balance between the private interests of the patent holder and a broader public interest by providing an exception from the exclusive rights normally provided by a patent.

Article 30 of the TRIPs Agreement provides member countries general flexibility to grant "limited exceptions" to normal patent rights when that would "not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."[126] Such exceptions could take the form of compulsory licenses. Article 31 of TRIPs authorizes compulsory licenses for "other uses"—ones that might conflict with normal exploitation or prejudice the interests of the patent holder—but subject to several conditions, such as remuneration to the patent holder, designed to minimize the patent holder's economic loss.[127] There are no similarly broad compulsory license provisions in U.S. law, and the United States has not addressed the need for compulsory licenses to address the specific problem of access to biotechnology for food security purposes.

U.S. patent law contains no requirement that patent holders "work" their patents, by either using the patented invention themselves or licensing it to others, as a prerequisite to keeping the patent in full force.

Working Requirements

U.S. patent law contains no requirement that patent holders "work" their patents, by either using the patented invention themselves or licensing it to others, as a prerequisite to keeping the patent in full force. Most countries do impose working requirements, either modeled on the working provision in the Paris Convention for the Protection of Intellectual Property, or incorporated into their compulsory license provisions.[128] Such requirements commonly provide that after a certain period of time, for example three years, if a patent holder has not worked the

patent, another party may obtain from a designated authority a nonexclusive license to use the invention for its own purposes, commercial or otherwise.

Since biotechnology has so far been used mainly for first-world farmers rather than to meet developing country needs, working requirements offer an obvious possibility to redress this within the norms of traditional patent policy and existing international agreements. The TRIPs Agreement requires compliance with the Paris Convention and accepts compulsory licensing, and so allows for the use by others of patented technologies that have not been worked by the patent holder for a particular purpose.

Eminent Domain Authority

Closely analogous to the compulsory license concept is the concept of eminent domain, which has existed in U.S. patent law since 1910.[129] Under the government's eminent domain authority, government authorization of the use of a patented technology insulates a user from any patent infringement claim by the patent holder. There are no subject matter, purpose, or other substantive restrictions on the uses of the technology for which eminent domain authority may be exercised, and there is no requirement for formal action by the government to invoke it:

The requirements for 'authorization or consent' by the government are quick and virtually automatic in practice. Any governmental purchase order will do—there is no need for a high-level blessing by a cabinet officer. There is no waiting period. There are no formalities, no notice to the patent holder, no hearing. In fact, the order need not even mention the patent or specify an authorization to operate within it; implicit authorization or consent for an infringement has been found, at least where government contracts require an infringement in order to secure fulfillment. See, e.g., Bereslavsky v. Esso Standard Oil Co., *175 F.2d 148 (4th Cir. 1949).*[130]

The existing eminent domain authority has been used primarily for military purposes, although its use was considered recently in a health context to make the anthrax drug CIPRO available more cheaply.[131] Eminent domain authority has not been exercised with respect to patents on the tools of agricultural biotechnology.

Access to Government-Funded Technology

The USDA and other government agencies fund research in their own laboratories and in academic facilities that sometimes leads to patented tools or applications of agricultural biotechnology. The Bayh-Dole Act encourages the patenting of government-funded research as a means of fostering its dissemination and use,[132] and USDA's current patent policy is based on the goal of making government-developed technology available for development and application.[133] This is consistent with the patent law, which declares:

It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development; . . . to ensure that the Government obtains sufficient rights to federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions . . . .[134]

This declaration of policy is backed up by restrictions on the granting of exclusive or partially exclusive licenses on government-owned inventions, including requiring that "the Federal

agency finds that the public will be served by the granting of the license . . . and that the proposed scope of exclusivity is not greater than reasonably necessary."[135]

On inventions owned by a private party but whose development was funded by the government under a cooperative research and development agreement (CRADA), the Bayh-Dole Act grants the government a license in the inventions to be exercised "as necessary for meeting the obligations of the United States under any treaty, international agreement, arrangement of cooperation, memorandum of understanding, or similar arrangement."[136] The Rome Declaration issued at the World Food Summit of 1996, which the United States signed, says, "We pledge our actions and support to implement the World Food Summit Plan of Action."[137] To date, the United States has not exercised its retained licenses on CRADA-funded technology to advance the food security purposes of the World Food Summit.

U.S. Foreign Policy on Patents

Patents are legally enforceable only in the issuing country, which is why patent law is often described as only territorial in its effect. On this basis, one might reasonably contend that U.S. patents and patent policy have little impact on the use of biotechnology to solve developing country agricultural problems, especially to the extent that the R&D work is done outside the United States. Researchers in developing countries are free legally to use U.S. patented technologies as they wish, assuming they could gain physical access to them.

As we shall discuss in the following chapter of this report, however, the ways in which the U.S. patent system affects developing countries are complex and multifaceted. They include the direct and indirect effects of the patent thicket that has grown up around biotechnology in the United States. They include also the impact of patent-related policies the U.S. government pursues in the international arena. The PTO has declared itself a "champion" of intellectual property "at home and abroad" and has expressly adopted the goal of "strengthen[ing] intellectual property protection in the United States and abroad, making it more accessible, affordable, and enforceable."[138] In furtherance of this goal, the United States pursues "foreign" policies in at least three patent-related areas: implementation of the TRIPs Agreement; support for international harmonization and strengthening of patent law beyond what is required by TRIPs, and the use of trade agreements and trade sanctions to protect U.S. intellectual property overseas and promote adoption of strong intellectual property regimes in other countries.

A central theme of these policies is the preference of the United States for an international patent regime in which all countries adopt patent protections similar or identical to the protection in the United States and in which it is procedurally simple for inventors to gain worldwide patent protection for their inventions. Under such a regime, U.S.-developed and owned intellectual property would more readily be protected from unlicensed use in other countries, and the territoriality of U.S.-issued patents would become largely moot.

It is important to distinguish conceptually between "domestic" and "foreign" patent policies. The former, which include the rules governing patenting in the United States and access to U.S.-patented technologies, arises from the U.S. Constitution's call for a patent system to foster technological progress in the United States. It involves trade-offs between the need to provide incentives for invention and the need to ensure that inventions and the knowledge behind them are shared for the public good. The trade-offs inherent in domestic patent law and policy occur

within the U.S. society and market. They can be and are adjusted over time, through administrative practice, court decisions, and legislation, to meet changing U.S. social and economic needs. In domestic patent policy, U.S. interests are balanced against U.S. interests, and the balance can be assessed in light of the traditional principles and objectives of patent law and policy, as outlined in Chapter 3.

U.S. "foreign" policy on patents, as we outline it below, arises outside the traditional confines of patent law and policy and is grounded in a different set of interests and values. It rests on the conviction that strong intellectual property protection is important to the economic success of U.S.-based technology companies, but it does not involve balancing competing interests (invention and dissemination, benefits and costs) within the United States to achieve that goal. Rather, it involves the one-dimensional task of pursuing the economic interest that the United States and U.S. technology companies have in a strong, global patent system. The countervailing interests and costs fall largely within and upon other countries: U.S. inventors gain the benefit of patent protection in other countries, and the costs of that protection, such as higher prices and restricted access, are borne by individuals and businesses in the other country.

U.S. "foreign" policy on patents involves the one-dimensional task of pursuing the economic interest that the United States and U.S. technology companies have in a strong, global patent system.

For these reasons, determining the right foreign policy on patents is not a matter of balancing competing invention and dissemination interests within the United States. Rather, it involves balancing U.S. economic interests associated with a harmonized global patent system against other international interests of the United States and the interests of other countries, including the innovation and development interests of developing countries. U.S. foreign policy on patents is thus better thought of not as a species of patent policy per se, but as a species of U.S. foreign policy in the broader sense of that term or, more specifically, U.S. trade and development policy.

U.S. foreign policy on patents manifests itself in three main contexts: implementation of the TRIPs Agreement, international harmonization through the World Intellectual Property Organization (WIPO), and use of bilateral trade relationships to strengthen patent protections.

Implementation of the TRIPs Agreement

The TRIPs Agreement (formally the Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1c of the Marrakesh Agreement Establishing the World Trade Organization) is, as its name implies, a trade agreement.[139] It was negotiated as part of the Uruguay Round of trade negotiations that concluded in 1994 and created the WTO. Its primary objective was to reduce impediments to trade, taking into account the need both to "promote effective and adequate" intellectual property rights and to ensure that such rights do not themselves become barriers to trade. With respect to patents, the core requirement of the TRIPs Agreement is that members provide for the patenting of all forms of technology in accordance with widely accepted principles of novelty, nonobviousness, and usefulness, and that "national treatment" be accorded all members. This means that member countries must permit nationals of other countries to obtain patents on terms no less favorable than those accorded to their own nationals.

The TRIPs Agreement explicitly recognizes in its preamble the need of developing countries for "maximum flexibility" in implementing their patent laws in a way that enables their creation of "a sound and viable technological base." Article 7 explicitly embraces the instrumental or utilitarian understanding of patent policy and the need for patent policy to balance potentially competing social interests:

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Article 8.1 specifically recognizes that countries may:

. . . adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided such measures are consistent with the provisions of this Agreement.[140]

These provisions speak directly to the need many developing countries have in the agriculture sector to provide basic food security and nutrition for their people. They also reflect the reality documented by expert commissions and commentators that the patent and other intellectual property needs of developing countries vary and can be sharply different from the needs of industrialized countries.[141]

To further address the reality of varying needs, the TRIPs Agreement contains several provisions that give countries the flexibility to grant exceptions to patent rights under certain circumstances. These include the broad authority in Article 30 to grant exceptions when the interests of the patent holder will not be adversely affected,[142] and the authority in Article 31 to provide for compulsory licenses, subject to some conditions, when the patent holder's interests are affected. Furthermore, Article 27.3(b) permits countries to exclude plants and animals from patentability altogether, provided an alternative *sui generis* system of protection is provided. This is important flexibility for countries that might judge it in their interest to adopt a system of plant variety protection that allows for the use of protected plants for breeding of new varieties and for farmers to save their seed for planting the next year.

The United States was a prime mover in the negotiations leading to the TRIPs Agreement and, working through the Office of the U.S. Trade Representative, remains a strong TRIPs supporter. At the June 2003 meeting of the TRIPs Council—the body comprised of all WTO members and responsible for monitoring implementation of the TRIPs Agreement—the United States lauded the flexibility TRIPs provides to developing countries to make patented drugs available to battle HIV/AIDS among those that cannot afford expensive medicines.[143] The U.S. statement said TRIPs "strikes the proper balance" between stimulating development and commercialization of new drugs and providing access to the poor, specifically citing the broad flexibility in Article 30 to provide exceptions to patent rights if the exception does not unreasonably conflict with normal exploitation of the patent or unreasonably prejudice the patent owner's legitimate interests.

The United States has not addressed how Article 30 or the compulsory license provisions in Article 31 would apply to allow access to the tools of biotechnology for developing country food security purposes. It has, however, questioned the flexibility developing countries have in

Article 27.3(b) to exclude plants from patentability, arguing the advantages of plant patents.[144] Article 27.3(b) is undergoing a review mandated by the original TRIPs Agreement. If this exclusion right were repealed, developing countries would lose an important source of flexibility to tailor their intellectual property systems to meet their particular needs in relation to biotechnology.

International Harmonization of Patent Law

A concerted effort is under way to achieve international harmonization of patent law beyond that provided for in the TRIPs Agreement. The effort, led by the United States and other Western industrialized nations, is being pursued through the World Intellectual Property Organization (WIPO). WIPO evolved out of two 19th century international conventions on intellectual property[145] and became a United Nations agency in 1974. WIPO administers two main treaties. One is the Patent Cooperation Treaty (PCT), which seeks to harmonize standards for obtaining patents. The other is the Patent Law Treaty, which aims to integrate the paperwork for obtaining patents and promote mutual recognition of patents among the treaty parties by ensuring that one international patent filing will have effect in all signatory countries. WIPO's strategic goals are similar to those of the PTO, including "maintenance and further development of the respect of intellectual property throughout the world" and ensuring that acquiring and enforcing patents "should be simpler, cheaper and more secure."[146] Having many patent offices review applications on essentially the same invention is a duplication of effort that is costly to patent offices and patent applicants.

In November 2000, WIPO launched its Patent Agenda, which is an effort to integrate and extend the two aforementioned treaties in the form of a new one, to be called the Substantive Patent Law Treaty (SPLT).[147] The objectives of the SPLT are to harmonize the basic legal principles that govern the issuance of patents, such as the definitions of "prior art" and utility, so that:

> *. . . applicants, in all contracting parties of the SPLT, are subject to the same substantive conditions for the grant of patents and for the invalidation of granted patents. Such harmonization would lead to lower costs for applicants and patent offices by contributing to a future reduction in the duplication of search and examination work.*[148]

This approach differs from the harmonization effort embodied in the TRIPs Agreement, which only established minimum standards for adoption of patent systems by WTO members and left considerable flexibility to tailor the system to local needs. WIPO, through the SPLT negotiations, appears to be pursuing a much more standardized "one size fits all" approach to patents that would support the move toward a single patent application being sufficient to establish patent rights to an invention worldwide. Though this standardizing would have labor-saving benefits, it has costs as well. Some commentators have expressed concern that this "universal concept of patentability" would require the patenting by developing countries of technologies that it might not be in their interest to patent and for which patents could be rejected under the terms of the current TRIPs Agreement,[149] and that it could "represent, in reality, a step backwards from the limited aspects of flexibility stipulated in the TRIPs Agreement."[150]

The United States strongly supports the WIPO effort to develop a "streamlined and simple system for obtaining patent rights."[151] In its 2000 Annual Report, the PTO took credit for putting forward a "comprehensive proposal for PCT reform" that would "allow applicants to prepare a relatively simplified patent application in a single format, which would be accepted by all patent offices throughout the world as a national patent application or an international PCT application."[152]

Use of Trade Measures to Expand Intellectual Property Protection

As the TRIPs and WIPO processes go forward toward formal harmonization, the United States uses its current leverage in trade negotiations, as well as trade sanctions and tariff benefits, to press observance of U.S. intellectual property rights in other countries and to seek adoption of patent regimes that go beyond what is required by TRIPs. The consequence of these efforts is to overcome, at least partially, the territorial limitations on U.S. intellectual property protections and to reduce the flexibility of other countries to adopt systems tailored to their local circumstances, including provisions that might grant weaker intellectual property protection than the U.S. system grants.

Many developing countries and regions, and ones with emerging economies, seek free trade agreements (FTAs) with the United States to speed their economic growth. In October 2002 the White House issued "A Roadmap for FTAs," which calls for prospective FTA partners first to join the WTO, if they have not already done so, thereby incurring the obligations of the TRIPs Agreement, and then to adopt intellectual property protections that are stronger than those required by TRIPs. The U.S. expectation is that FTAs will be based on the standards set in several existing FTAs, especially the recently completed U.S.–Singapore FTA and those with Jordan and Chile.[153] According to the Singapore Ministry of Trade and Industry, the U.S.–Singapore FTA will go "way above" the parties' WTO commitments.[154] It includes, for example, provisions that eliminate the flexibility accorded by Article 27.3(b) of the TRIPs Agreement for countries not to grant utility patents on plants. The UK Commission on Intellectual Property Rights documents other situations in which the United States has obtained "TRIPs-plus" intellectual property provisions in bilateral trade agreements.[155]

Beyond its leverage in trade negotiations, the United States uses trade sanctions and tariff benefits to push for protection of U.S. intellectual property in other countries, even when that country has no legal obligation to provide such protection. This can be the case either because the country is not a WTO member or because, as in the case of many of the least developed countries, their TRIPs obligations have not yet come into force. The Office of the U.S. Trade Representative (USTR) has explained how this works:

First, we intercede directly in countries where piracy is especially prevalent or governments are exceptionally tolerant of piracy. Among our most effective tools in this effort is the annual "Special 301" review mandated by Congress in the 1988 Trade Act. This tool has vastly improved intellectual property standards around the world. Publication of the Special 301 list warns a country of our concerns. And it warns potential investors in that country that their intellectual property rights are not likely to be satisfactorily protected. The listing process itself has often helped win improvements in enforcement. In many cases, these actions lead to permanent improvement in the situation. At times, however, we must use the sanction authority granted to us for worst case offenders. Another bilateral tool is preferential tariff benefit treatment, such as the Generalized System of

Preferences, the Caribbean Basin Initiative, and Andean Trade Preferences Act. These programs provide tariff-free treatment to certain products of beneficiary countries, subject to certain conditions, including adequate and effective protection of intellectual property rights. The threat of loss of these benefits has proven to be an effective point of leverage with some of our trading partners.[156]

This statement from USTR shows the U.S. government at work as a vigorous advocate for U.S. companies doing business abroad and for shaping the intellectual property practices of other countries to protect the intellectual property of those companies. U.S. companies have good reasons for seeking this assistance from the government, and the government has good reasons for providing it, grounded in the economic self-interest of the United States and constituency politics. But the U.S. role in the international patent arena has consequences. We turn in the next chapter to an analysis of how the U.S. patent system and patent policies—domestic and foreign—affect access to biotechnology for developing country food-security purposes, and we sketch the case for policy change.

■ ■ ■

CHAPTER FIVE

Impact of U.S. Patents and Patent Policy and the Case for Change

The preceding discussion shows how U.S.-issued patents have enveloped agricultural biotechnology and how U.S. patent policy addresses access to patented technologies domestically and attempts to shape patent practices internationally. In brief, U.S. patent policy has resulted in a patent thicket surrounding biotechnology, most of the policy tools that are potentially available to promote broad dissemination and use of patented biotechnologies have not been applied, and the United States is promoting policies internationally that would reduce the flexibility of developing countries to adopt patent systems tailored to their local innovation and development needs. The questions to address now are: what is the impact of U.S. patents and patent policy on developing country access to biotechnology for food-security purposes? and what is the case for altering U.S. patent policy and related technology transfer policies to improve that access?

In considering these questions, we have in mind the scenario to which we alluded in Chapter 2: researchers in public research institutions, located in the United States or elsewhere, seek access to patented tools of agricultural biotechnology—typically tools for genetically modifying plants, specific gene traits, or genetically modified germplasm—for research and development of applications of the technology that can address developing country agronomic problems and improve food security. If U.S. patents and patent policy are not inhibiting access to biotechnology for these purposes, there may still be a technology transfer problem, but we have no need to consider patent policy change. And even if patent policy is inhibiting access, it is fair to ask why U.S. patent policy should consider the access needs of these particular researchers in the first place. We address these questions in this section.

Impact of U.S. Patents and Patent Policy

There are many constraints, besides U.S. patents and patent policy, on the ability of developing countries to access and effectively use biotechnology for food security purposes. These have been studied and documented extensively by others[157] and well summarized recently by Walter Falcon.[158] One of the most fundamental is the shift of agricultural research resources from the public to the private sector. This has not only placed many of the tools of biotechnology in the hands of private companies that lack an economic incentive to apply them to the problems of subsistence and small-scale African farmers, it has also diminished the capacity of public-sector

researchers to take full advantage of the latest technology. As discussed in Chapter 2, if the potential of biotechnology to address developing country agronomic and food security problems is to be realized in the near term, the technology needs to be in the hands of public-sector researchers in the very institutions—national agricultural research organizations and the international research system[159]—that have experienced funding declines in recent years. Their ability to take advantage of biotechnology is thus constrained by a scarcity of research infrastructure, financial resources, and scientists trained to conduct biotechnology research.[160]

Other constraints not attributable to patents or patent policy per se include the ways in which patent holders use the power granted them by their patents, such as through strict material transfer agreements (MTAs),[161] and the regulatory controls and innovation policies of the developing countries themselves.

These factors interact in complex ways, and we find it impossible to isolate cleanly the impact of U.S. patents and patent policy from the other factors. We find several ways, however, in which U.S. patents and patent policy do contribute to the difficulties researchers face in applying biotechnology to the solution of developing country food security problems.

Direct Legal Impacts of U.S. Patents

The clearest cases are the ones in which U.S. patents directly block the researcher's access to a technology. This occurs when the researcher works in the United States, where the patent monopoly is a legal bar to unlicensed use of a patented technology, or the patent thicket creates obstacles that can be difficult to overcome, as discussed in Chapter 3. Many researchers in U.S. universities and other nonprofit institutions are working on, or may have an interest in working on, applications of biotechnology that could benefit developing country farmers and improve food security.[162] To do so with U.S.-patented technology, they must obtain the necessary licenses or else risk liability for patent infringement. As discussed in Chapter 4, the transaction costs involved in researching the patent status of multiple tools and gaining the necessary licenses for them can be substantial and act as a deterrent to research, even in today's universities and other institutions that are relatively sophisticated concerning intellectual property.

The direct legal impact of U.S. patents can also reach researchers working in developing countries if they are working on applications of biotechnology to crops that are intended to be exported to the United States, even on a limited basis. The importation into the United States of a crop produced with a U.S.-patented technology would constitute an infringement of the patent, unless the use is licensed. Because researchers and research institutions in developing countries frequently lack the skills and resources required to manage their way through the patent thicket,[163] the possibility that a crop will be exported to the United States—where applicable patents may exist—is a legal obstacle and a disincentive for developing country researchers to use U.S.-patented technologies.

Indirect Impacts of U.S. Patents

Most of the R&D work to apply biotechnology to developing country agronomic problems and improve food security is likely to be conducted in developing countries, CGIAR institutions, or national agricultural research organizations, and on subsistence or other crops that have little or no export potential. It is sometimes argued that researchers outside the United States who want

to use a U.S.-patented tool to develop an improved plant for such purposes are not affected by U.S. patents because U.S. patents are binding only in the United States. While the legal point is correct, this argument overlooks the indirect but very real impact that U.S. patents have on use of patented technology by these researchers.

First, these researchers and their institutions rely heavily on the U.S. government and international financial institutions for their funding. As discussed above, the U.S. government pushes hard for foreign countries and institutions to protect the intellectual property rights of U.S. companies. National agricultural research systems and CGIAR institutions could jeopardize their funding if they systematically violated U.S. patents to develop useful applications of biotechnology.[164]

Second, to the extent that developing country research institutions are currently involved in biotechnology, they often seek and rely upon cooperation from the Western biotechnology companies that hold many of the necessary patents.[165] These companies jealously guard their patent rights and are less likely to cooperate with institutions that do not respect their patents.

Third, the holding of patents by biotechnology companies provides them with incentive and leverage to tightly control use of technologies, whether or not they choose to share access. To gain physical access to patented gene traits or enabling technologies and necessary know-how, researchers typically must enter into material transfer agreements (MTAs) that place strict restrictions on the use of the technology, including prohibitions on commercialization.[166] The leverage to impose strict MTA conditions arises in part from the patent holder's ability to exercise close control over the use of the patented technology. MTA provisions can thus operate as a de facto extension of the patent to the country where the researcher works: to the extent the researcher was legally free to use the invention outside the United States, that freedom is usually lost in the MTA. Workshop participants and survey respondents alike considered this a particularly important barrier to the use of biotechnology in other countries. One survey comment asserted that "limitations imposed through MTAs by patent holders on the use of their inventions by researchers is often precluding applications in developing countries." Strictly speaking, this use of MTAs is a function of contract law and choices made by patent holders, not of patents or patent policy per se; but, as a practical matter, it can extend the impact of U.S. biotechnology patents beyond the United States.

Overall, these indirect impacts of U.S. patent law, combined with the large number of patents in the patent thicket surrounding biotechnology, are a deterrent to the development of biotechnology applications by researchers in developing country institutions.

The U.S. Vision of the Future in International Patent Policy

Finally, in assessing the impact of U.S. patent policy on developing country access to biotechnology, it is appropriate to consider the U.S. government's vision for the future. As discussed in Chapter 4, the United States is promoting harmonization of patent law and policy internationally, based on the U.S. model of strong patent protection. If this vision were fulfilled, U.S. and other technology developers would be able much more readily than today to gain patent protection for their inventions not only in the United States, Europe, and a few other industrialized countries, but in developing countries as well. It is not clear whether this would produce a biotechnology patent thicket in these countries, as has evolved in the United States. However, to the extent that more technologies come under patent in the developing countries and remain

in the hands of companies that lack the incentive to fully develop them for food security purposes, access for that purpose will be further impaired.

Moreover, if current U.S. policies concerning access to patented technologies—such as the U.S. approach to research exemptions and working requirements—become the international norm, public-sector researchers will face a regime that provides few vehicles and little flexibility to access patented technology, even for food security applications that pose little or no threat to the legitimate commercial monopoly granted by the patent. There are features of U.S. patent law—such as eminent domain authority and the retention of licenses on publicly funded inventions—that potentially provide such flexibility, but they have yet to be exercised in the United States on behalf of developing countries and thus do not appear at present to be part of the U.S. vision of the future for international patent policy.

If current U.S. patent policies concerning access to patented technologies become the international norm, public-sector researchers will face a regime that provides few vehicles and little flexibility to access patent technology, even for food security applications that pose little or no threat to the legitimate commercial monopoly granted by the patent.

Regardless of what specific features a harmonized international system may come to have, any such system will entail some lessening of flexibility for developing countries. Many developing countries do not yet have patent systems at all, and many that do have systems have weaker patent coverage than anything WIPO and the developed countries are considering. Since patents are territorial, those developing countries currently have no legal obligation to respect patents issued elsewhere. Though, as we argued in Chapter 4, there are reasons why the legal freedom to copy patented inventions has had only very limited practical value for developing countries, that legal power may have more potential importance than it has so far fulfilled, and so its loss could be significant. In any case, the U.S. vision of a harmonized international system would increase the practical difficulties of preserving the territoriality of patents.

Conclusion on the Impact of U.S. Patent Policy on Developing Country Access

When considered together, the direct legal effects of U.S. patents, the indirect impacts of current U.S. policies and practices of patent holders, and the U.S. vision for the future have clear potential to inhibit access to biotechnology for developing country food security purposes, now and even more so in the future. Others have written about the impact of the patent system on access to biotechnology for developing country purposes,[167] and our conclusion that U.S. patent policy adversely affects developing country access to biotechnology is further corroborated by our informal survey of experts and stakeholders.[168]

When asked whether the U.S. patent system and the existence of U.S. patents are adversely affecting the ability of researchers to access and use various technologies for developing country purposes, most answered in the affirmative for most categories of technology. Of those who responded to our informal survey on this point, 86% agreed that the system has an adverse impact on access to one or more categories of biotechnology: 80% said the U.S. patent system and the existence of U.S. patents affected access for developing country purposes to specific gene

traits; 64% said they affected access to transformation tools; and 76% said they affected access to genetically modified germplasm for specific useful plants.[169]

Our survey was in no sense a scientific investigation of views on the impact of patents on access to biotechnology, but it provides texture and corroboration for our analysis, based on the aforementioned responses and responses we received to other questions. There was considerable agreement, for example, that patents are being granted that are too broad,[170] but the multiplicity of patents (the patent thicket) was considered the single biggest problem overall flowing from U.S. patent practices.[171] Responses to open-ended questions tended to confirm that the effect of the patent system on access is intertwined with other factors. Some cited the general deterrent effect that extensive patent estates have on decisions about what research to pursue, out of fear that products resulting from unlicensed use of patented tools will be challenged, and thus unmarketable, and also out of concern about the transaction costs involved in negotiating licenses. Others mentioned the extraterritorial attitude of the U.S. government toward its patent system, as reflected in advocacy by the PTO for countries to adopt patent systems based on the U.S. model,[172] and inclusion by the U.S. Agency for International Development (USAID) of patent requirements with its assistance to foreign countries.[173]

Finally, the fact that developing country researchers are affected by the U.S. patent system is evidenced by the effort of some research institutions, biotechnology companies, and other organizations to create technology-sharing mechanisms that are intended, at least in part, to deal with the extensive patent estates that surround the tools and products of biotechnology. For example, the Rockefeller Foundation and the Meridian Institute are collaborating with some Western biotechnology companies and developing country parties to establish a mechanism for sharing patented technologies called the African Agricultural Technology Foundation (AATF).[174] This mechanism will address both transgenic and nontransgenic technologies and will facilitate the transfer for developing country purposes of technological know-how and critical research materials, as well as the legal right to make use of patented technologies. Though its purposes are broader than just removing patent obstacles, the need for the mechanism arises in large part from the proprietary (and frequently patented) nature of modern agricultural innovation and the need to assist developing country research institutions in negotiating the intellectual property thicket surrounding biotechnology.

With this understanding of how U.S. patents and patent policy can affect developing country access to biotechnology, we turn now to the question of whether and why the United States should consider change in patent policy to improve access.

The Case for Policy Change

It can be argued that the impacts on developing country access to biotechnology described above are irrelevant to the formation of U.S. patent policy and do not justify changing it. The argument might be based on the views, expressed by the PTO itself, that the U.S. patent system is successful to the extent it issues legally sound patents on a timely basis and that the interests of the United States are best served by international harmonization of patent policy and patenting procedures. This view reflects the strongly held belief among many patent practitioners that current U.S. patent policies are vital to innovation and U.S. economic interests and that the broader social consequences of the patent status quo are beyond the ken of patent policy. We accept that

patents play an important role in stimulating the inventive process in many fields, including agricultural biotechnology. We disagree, however, that the broader social consequences of patent policy should be off-limits for policymakers.

It would be ideal in making the case for patent policy change to evaluate empirically how the patent system is achieving its multiple social objectives, which are outlined in Chapter 3. If it could be demonstrated empirically that the system is impeding rather than fostering dissemination of useful technology, the prima facie case for policy change would be clear. Unfortunately, there are significant gaps in empirical data on both the overall impact of the patent system and its effects in specific fields like biotechnology, which makes it impossible to assess current policies and justify changes on an empirical basis.

The empirical data are so lacking that, according to Samuel Oddi, "There is no general agreement that any of the macro theories of the overall patent system can rigorously demonstrate that a patent system provides a net societal benefit."[175] According to George Priest, "The ratio of empirical demonstration to assumption in [patent economic] literature must be very close to zero."[176] Oddi says further that the question of the patent system's demonstrable net benefits to society has not been resolved since Fritz Machlup said in 1958:

If we did not have a patent system, it would be irresponsible, on the basis of our present knowledge of its economic consequences, to recommend instituting one. But since we have had a patent system for a long time, it would be irresponsible on the basis of our present knowledge, to recommend abolishing it.[177]

Biotechnology may be an area in which the patent system has particularly important benefits in terms of commercial investment in inventive activity, but we are not aware of any empirical evaluations of the benefits and costs of the patent system as applied to agricultural biotechnology.[178] We follow Machlup in concluding that it would be irresponsible to recommend abolishing the patent system. The lack of empirical data demonstrating the net benefits of the current system frees us, however, to consider policy change.

As discussed earlier, domestic patent policy and foreign patent policy are distinct in the interests and principles that underlie them and thus differ in the case that can be made for change. In the case of domestic patent policy, we think that policy change to address the food security needs of developing countries is justified by our qualitative analysis of its impact on this interest, our instrumental understanding of patent policy as a tool of social policy, the possibility of change that improves access without significantly undercutting invention incentives, and specific circumstances that bring the problem of food security within the scope of domestic patent policy. The case for change in U.S. foreign policy on patents draws on some of the same elements but rests in the end on judgments about the broader international interests and obligations of the United States.

The Case for Domestic Policy Change

The case for domestic patent policy change is best made by examining how the patent system is working currently to achieve the system's several objectives, as outlined in Chapter 3: increasing the amount of invention; disseminating knowledge about inventions; regulating the orderly investigation of new research areas; and facilitating the practical use, including the production, application, and commercialization, of inventions.

Our qualitative analysis suggests that, in the field of agricultural biotechnology, the system

is likely increasing the amount of invention, at least among commercially motivated inventors, and the disclosure requirements of patent law are presumably working to disseminate basic knowledge about patented technology, though the effectiveness of disclosures in U.S. patents is a matter of debate.[179] Our analyses of the patent thicket (Chapter 4) and of the impact of U.S. patents and patent policy on access to biotechnology for developing country food-security purposes (Chapter 5) demonstrate that the patent system is working less than optimally to ensure orderly investigation into and facilitate practical use of the technology.

This being so, the case for considering patent policy change is grounded in the very nature and purpose of the patent system, as discussed in Chapter 3. The patent system is an instrumental social construct intended to benefit society by fostering useful innovation. This understanding of the system requires us to evaluate its performance from a social outcome perspective.[180] From this perspective, the success of the patent system and possible changes in patent policy are fairly judged on the basis of whether and to what extent the societal benefits of the system, in terms of useful innovation, exceed the societal costs of the patent monopoly, in terms of higher prices to consumers or constraints on access to new inventions by those who are not patent holders.[181] If the patent system is not achieving this objective or could achieve it better, it is fair and appropriate to consider policy change.

Under this approach, if a policy change would reduce the societal costs of patents without sacrificing their benefits, such a policy change should be considered. This might occur in agricultural biotechnology if a policy change would improve dissemination of the tools of biotechnology without significantly undercutting incentives for the invention of such tools. In Chapter 6, we outline a number of possible changes in U.S. policy that appear to meet this test. If the current system is performing less than optimally and changes would preserve its benefits while reducing its costs, there is little basis for not considering those changes.

The case for patent policy change is grounded in the very nature and purpose of the patent system as an instrumental social construct intended to benefit society by fostering useful innovation.

Finally, even if we accept that patent policy is properly evaluated on the basis of its societal impacts, it is fair to ask why an international concern—food security in developing countries—is a societal interest against which U.S. patent policy is fairly judged. The answer is that the United States has chosen to bring international concerns in general, and food security in developing countries in particular, within the legitimate scope of domestic patent policymaking. As discussed in Sections 4 and 5, U.S. patents and patent policy have extraterritorial aspirations and impacts, including practical impacts on access to technology in other countries. Furthermore, it is the declared objective of the PTO to promote adoption of U.S.-like patent systems in other countries, including developing countries,[182] and the U.S. government frequently presses governments and other institutions in foreign countries to respect U.S. patents.[183] For these reasons alone, adverse effects of U.S. patents on technology access and transfer in other countries justify considering policy change.

Consideration of the global food-security impacts of U.S. patent policy is further justified by the fact that the United States has declared the achievement of global food security a national objective, as discussed earlier in this report and reiterated recently in the U.S. affirmation of the commitment it made to food security at the 1996 World Food Summit and in many

other settings.[184] If U.S. patent policy negatively affects the practical application of biotechnology for developing country food security purposes, this invokes a U.S. interest and social concern that justifies consideration of policy change.

Finally, fundamental principles of social justice and equity make global food security a legitimate concern of U.S. patent policy. As the world's leading technological and economic power, the United States and companies based here have a substantial impact on opportunities for economic progress throughout the world, including in developing countries. The United States cannot by itself solve the world's technological and economic problems. The United States has a moral duty, however, to contribute affirmatively to their solution, as well as a national security interest in reducing global poverty and hunger. At a minimum, the United States has a duty as the richest and most powerful country in the world to avoid actions and policies that have unnecessary adverse impacts on progress elsewhere. This includes patent policies that adversely affect food security in developing countries and that could be modified without undercutting legitimate U.S. interests.

The Case for Change in U.S. Foreign Policy on Patents

There is an irony in the case for considering change in the U.S. approach to international harmonization of patent policy and practice. In a global patent system grounded in the same instrumental principles as the U.S. patent system, the case for policy change to improve access to biotechnology for developing country food-security purposes would be the same as the case outlined above for domestic policy change, except stronger. Just as it would not be acceptable social policy in the United States if the patent system were helping keep important technologies from being applied to an important social problem, so too, in a truly global patent system, it will not be acceptable social policy if patents are one of the obstacles to solving the problem of food insecurity in developing countries.

Patent law remains, however, a national law system. The United States has adopted patent policies for itself that presumably reflect the values and innovation interests of the United States, taking into account the balancing of U.S. interests that is inherent in patent policy. Other countries have done and aspire to do the same thing. The question in considering change in the U.S. approach to patent policy in the international arena is why the United States should support other countries in adopting patent systems that are based on their own balancing of values and interests. This is not a question that is answerable in traditional patent policy terms, because it does not involve a balance of interests within a national market and patent system. It involves a balancing of potentially competing interests among nations, which falls into the realm of foreign policy and, more particularly in the context of this report, development policy. And, in this context, the case for U.S. policy change is strong. The case for changing U.S. foreign policy on patents is grounded in the distinctly different intellectual property needs of developed and developing countries, and the importance of developing countries, retaining flexibility to devise patent policies that reflect their level of technological development and their development strategies.[185] The United States

In a global patent system, it will not be acceptable social policy if patents are one of the obstacles to solving the problem of food insecurity in developing countries.

should support developing countries in preserving this flexibility for several reasons. The first is the importance of the U.S. national interest in solving food insecurity and promoting optimal, technology-driven development strategies in developing countries. Because food security and poverty reduction are vital to the economic and national security interests of the country, policies that would advance those interests, even incrementally, deserve consideration. Policies that promote the development of intellectual property systems tailored to local development needs are in this category. We are unaware of data that establish the importance to U.S. companies of being able to obtain patent protection in developing countries on all the same terms as in the United States. But, especially given the current nonprofitability of those markets for cutting-edge biotechnology, discussed in Chapter 3,[186] it seems clearly outweighed by the broader national interest in developing country food security and development.

Second, the United States has a vested interest in the success of the TRIPs Agreement, which already embraces the concept of flexibility. U.S. departure from the principles in TRIPs that address developing country needs risks loss of support for TRIPs among developing countries. If, for example, through the WIPO harmonization process or bilateral trade negotiations, the flexibility in the TRIPs Agreement is overridden, developing countries would justifiably question the basic fairness of the TRIPs obligations, which could undermine implementation of the agreement and developing country support for other elements of the WTO and U.S. trade agendas.

Finally, as in the case of domestic policy reform, there are important ways in which the flexibility in TRIPs can be used to improve access to biotechnology for developing country food-security purposes without significantly affecting the economic interests of U.S. biotechnology companies. We identify some of these in the next chapter.

■ ■ ■

CHAPTER SIX

Analyzing and Changing American Patent Policy

In this chapter, we briefly describe some specific changes in U.S. patent policy, both domestic and foreign, designed to improve access to the tools of biotechnology for developing country food security purposes. We offer these primarily to illustrate that policy change for this purpose is not necessarily at odds with, and indeed could advance, the basic goals of the patent system. The fact that there are possible policy changes that plausibly meet this test supports the case for considering change. It is important first, however, to set out more completely the approach we take to analyzing patent policy options and considering them for adoption.

Framework for Analyzing Alternative Policies

Ideally, no individual patent should be issued if its social benefits in terms of stimulating invention and useful innovation are outweighed by the social costs of the patent in terms of increased consumer costs and restricted access to the patented technology for useful purposes. As a practical matter, however, there is no basis for predicting at the time of granting how any individual patent will measure up to a societal cost-benefit test. It is thus not surprising that patent law and the PTO process do not contemplate any such analysis as part of case-by-case patent examination.

Rather than analyzing specific patents, it would be more realistic (and appropriate for purposes of considering policy change) to consider the aggregate benefits and costs of the patent system and patent policy as applied to a particular category of technology, such as agricultural biotechnology. Evaluating the benefits and costs of the patent system with respect to a particular category of technology makes sense because, as Mazzoleni and Nelson point out, the impact of the patent system is likely to vary widely from category to category, depending on the "context conditions" affecting technological progress in a given area.[187]

Even analyzing in hindsight the benefits and costs of patent policy for a category of technology is constrained, however, by the conceptual complexity of the analysis and the lack of empirical data. Evaluating fully the benefit of patents in the field of agricultural biotechnology would require considering and balancing the patent system's multiple potential benefits, including both fostering invention and facilitating dissemination of useful innovation, and answering such questions as:

- To what extent would biotechnology inventions have occurred without the issuance of patents?

- What are the tangible benefits of the inventions and any resulting innovation?
- What positive impacts have the patents had on dissemination of information, practical application by others, and research in new areas of biotechnology?

Evaluating the costs to society of granting patents in a particular category of technology similarly requires a multifactorial analysis that addresses such questions as:

- What are the direct costs of the patent monopoly in terms of higher consumer prices?
- What are the transaction costs (for example, license fees and related negotiating expenses) for gaining access to patented technology?
- What negative impact have the patents had on invention and practical application by others?
- What negative impact have they had on research in new areas?

Even if there were an accepted model for considering and balancing these factors, the facts required for the analysis are, at best, difficult to obtain, even looking retrospectively at the impact of current policy. The task here is even more difficult, because it requires looking ahead to consider the impact of possible policy change on the future benefits and costs associated with patents and the overall patent regime.

Alternative patent policies deserve serious consideration if they appear likely to improve access to the tools of biotechnology for developing country food-security purposes without significantly undercutting incentives for the invention of such tools.

We accept the practical limitations on the ability to apply a quantitative cost-benefit test in evaluating the patent system and patent policy change. Given the instrumental rationale for having a patent system, however, it remains fair to ask whether, in any particular area of invention, the benefits of patents in terms of stimulating invention and useful innovation exceed the social costs of the patent monopoly, even if the question must be answered qualitatively. The challenge is to frame the question in a way that it can be usefully answered.

Our specific goal is a manageable analytical approach to identifying and evaluating specific patent policy alternatives that could improve access to agricultural biotechnology for developing country purposes. The analysis should consider both sides of the cost-benefit equation, but do so in a simplified way that is realistic in light of the limited data available for quantitative analysis. We propose the following qualitative formulation: *alternative patent policies deserve serious consideration if they appear likely to improve access to the tools of biotechnology for developing country food-security purposes without significantly undercutting incentives for the invention of such tools.*

Under this simple framework for analyzing alternative patent policies, the goal of improving access to biotechnology for developing country food-security purposes is deemed achieved if a proposed policy change would make it generally easier for researchers and technology developers working on developing country problems to use patented technology in their research and development work, without risk of patent infringement. Access for developing country food-security purposes means that a tool is available for use by researchers and technology developers, located in the United States or elsewhere, to create improved crops that will be planted in developing countries with minimal potential for export to the United States or to otherwise compete with the exploitation of the patent in the United States.[188]

This concept of improved access and availability specifically for developing country food-security purposes is built into most of the policy alternatives. It makes them unlikely to undercut the invention incentives of U.S. patent law because it limits access to patented technology to cases in which that benefit is achieved without directly competing with the patent holder in the market for which the patent was granted.

As discussed in Chapter 4, we recognize that patents are not the only obstacles to developing country access to the tools of biotechnology and thus that patent policy change alone cannot ensure fully effective access. We also recognize that improved access by developing country researchers does not ensure that useful applications will necessarily be developed and made available to developing country farmers. Many factors will contribute to the outcome. The analysis we propose here addresses the more narrow question of whether patent policy change can help make the tools of biotechnology accessible for researchers who want to apply them to developing country food security problems, and it assumes, for reasons outlined in Chapter 5, that this improved access confers a societal benefit that is relevant to the formulation of U.S. patent policy.

This framework also assumes that patents provide an important incentive for investment in agricultural biotechnology and for the development of commercially attractive applications of the technology and that these incentives should be preserved. Though we cannot quantify the actual incentive effect of patents on invention and commercialization in agricultural biotechnology, we assume for the purposes of identifying and analyzing alternative patent policies that the incentive is real and that any significant reduction in the incentive would be undesirable.

These assumptions lead us to a final pragmatic choice: selecting policy alternatives within U.S. patent law that are tailored to directly affect access to patented technologies for developing country food security purposes. We choose not to address changes in practices and policies affecting how patents are issued, because such changes can readily be posited to have a negative effect on invention incentives, and it would be difficult to counter that possibility with available evidence. Moreover, policies that improve post-patent access address more directly the problem that motivated this study.

We do not doubt that changes in patenting practices and policies could improve how the patent system contributes to useful applications of biotechnology, including for developing-country food-security purposes. In fact, we assume that the U.S. patent system, taking into account its patenting practices and extraterritorial effects, strikes an imperfect balance between the benefits and costs of patents in the field of agricultural biotechnology and is not working optimally to foster useful innovation. As discussed earlier in this report, there has been much commentary on the tendency toward excessive patenting in the field of agricultural biotechnology.[189] This includes patents that have been issued inappropriately or are too broad because of, for example, inadequate prior art searches, the system's built-in presumption of patentability, or occasional lax application of the novelty, utility, and nonobviousness requirements. We also have seen that the multitude and breadth of patents have some blocking effect on access to biotechnology by people who could make good use of it. The assumption that the U.S. patent system and patent policy are not working optimally to foster useful innovation is another justification for considering policy alternatives that improve access to patented technologies.

Policy Alternatives

We outline below a set of possible changes in U.S. patent policy. They fall into three categories: changing U.S. law and policy to improve access to patented technologies; preserving the flexibility developing countries have in the current TRIPs Agreement to tailor their patent systems to their local needs; and more fully implementing Article 66.2 of TRIPs regarding support for technology transfer. Each policy change raises its own set of technical and implementation issues, some of which we addressed in a previous discussion paper,[190] and all of which require full consideration and critique by patent experts and policymakers. We limit ourselves here to a brief summary of each possible change, because our primary purpose is to make a simple point: if one accepts as a matter of principle that it is appropriate to consider access to biotechnology for developing country food-security purposes when formulating U.S. patent policy, there are a number of policy alternatives that, on their face, appear to meet the threshold test of improving access without significantly undercutting invention incentives.

Changes in U.S. Law and Policy That Improve Access to Patented Technologies

In this section, we outline five domestic patent policy alternatives, which build on the discussion in Chapter 4 of current domestic patent policies involving a research exemption, compulsory licensing, a working requirement, use of eminent domain authority, and placing USDA-funded technology in the public domain. All are grounded in familiar concepts, and some are already contained in different forms in national patent legislation in the United States or elsewhere or in international patent frameworks, such as the TRIPs Agreement. For reasons discussed earlier, all involve expanding access to patented technologies, rather than changing what gets patented, and all are designed to achieve a common goal: making U.S.-patented tools of biotechnology available for developing country purposes without undercutting incentives for private-sector investment in invention and commercialization of the technology.

Create a Strong Research and Development Exemption. Under this first policy alternative, Congress would enact a statutory limitation on the scope of the patent monopoly such that the use of a patented tool of biotechnology in the research and development of new applications for developing country food-security purposes would not constitute infringement of the patent. The research exemption—always very limited in U.S. patent law—is effectively nonexistent following the *Madey* decision. This proposal would improve access to patented biotechnology by freeing both U.S. and foreign-based researchers to work on applying patented technology to developing country food-security problems without concern about infringement claims. In the case of patented germplasm or transformation tools that are not themselves sold as part of a commercial research tools business,[191] this research and development exemption would not significantly undercut the invention incentives of the U.S. patent holder because the use of the resulting technology would be limited to noncompeting developing country applications.

The research and development exemption we are envisaging here is not limited to noncommercial users or uses of patented technology. Such a limitation is neither intrinsic to the notion of a research exemption nor feasible in the context of policy change to improve developing country food security. It is crucial to the food security purpose that researchers who develop new products using patented technology be able to give those products to farmers without

restrictions. The exemption is, however, only for research. If that research produces new products that contain the original patented invention or that cannot be exploited without infringing the original patent, a research exemption will not clear the way for free use of those products. The patent holder retains full control of the original invention (except for its use in research, and specifically for research in aid of developing country food security), and so the exploitation of such dependent products would still require permission from the patent holder.

Establish a Compulsory License Requirement for Agricultural Biotechnology. This policy alternative would add to U.S. patent law a procedure to grant nonexclusive licenses to any requesting party for the use of any patented tool of biotechnology for developing country food-security purposes. Royalties would be set at rates (including zero) that reflect the extent of the reasonably foreseeable value forgone by the patent holder, taking into account the likelihood of the patent holder's commercialization of the technology for the developing country purpose.

Such a compulsory license provision would improve access by ensuring that any patented tool of biotechnology could be used for developing country food-security purposes without risk of patent infringement. It would not significantly undercut invention incentives because the royalty provision would make the patent holder economically whole to the extent it would lose economic value from its own application of the technology for developing country food-security purposes. As with the other policy alternatives, the U.S. patent holder would also be protected because the use of the technology under the compulsory license would be limited to noncompeting developing country applications.

The compulsory license provision proposed here is not as general as those contained in many countries' patent laws or as allowed under TRIPs. Rather, it is a very limited one focused on a particular public policy goal—food security—comparable to other compulsory license provisions in U.S. law.[192] For example, the Clean Air Act Section 308 provision could be a possible model of such a limited provision. It provides for access to patented technologies to help "noncomplying parties" (cities or states that cannot meet their air quality obligations) when the technology in question is the only way they can meet the standard, and the technology is not otherwise available from the patent holder. Substituting "food-insecure countries" for "non-complying parties," a compulsory license provision like this might be appropriate if biotechnology offers solutions that cannot be had any other way.

Establish a "Working" Requirement for Agricultural Biotechnology Patents. A working requirement is a condition on the patent right to exclude others from using the invention: it limits the right to exclude those applications of the invention that the patent holder is actually working or exploiting. This policy alternative would add to U.S. patent law a working requirement for patented biotechnology, modeled on the working provision in the Paris Convention for the Protection of Intellectual Property.[193] If, within three years of the patent's being issued, the patent holder has not worked the patent for a specific developing country purpose or purposes, or has not made it readily available by license to those who seek to use it for such purpose(s), a party could apply to a designated authority for a nonexclusive license authorizing use for such purpose(s) and would obtain such a license absent immediate implementation by the patent holder of a plan to fully exploit the invention for the developing country purpose(s).

A working requirement along these lines would improve access by ensuring that, after a certain waiting period, patented tools of biotechnology would be available for developing country food-security purposes without risk of patent infringement. It would not significantly undercut invention incentives because it would limit access to cases in which the patent holder had chosen not to apply the invention to the specific developing country food-security need in question, and so the use of the technology would be limited to noncompeting developing country applications. Again, although working requirements are often general and limit all patent exclusivity to only those applications worked, this proposal is for a narrower working requirement only on applications of biotechnology for developing country food-security purposes. As such, it is targeted specifically on the problem this report addresses, lack of working of biotechnology on applications for which the patent holder has little incentive.

Exercise U.S. Eminent Domain Authority. Under this policy alternative, the U.S. government would exercise its existing statutory eminent domain authority under 28 USC 1498 to authorize the use of patented tools of biotechnology for developing country food-security purposes. A designated authority within the U.S. government could establish an administrative mechanism under which the technology developer who wanted to use the patented technology could make application and then be deemed to be using the technology for the United States. The U.S. government, rather than the technology developer, would then be liable for any compensation to which the patent holder could prove itself entitled in court.

This use of existing eminent domain authority would improve access by creating a mechanism for access to all U.S.-patented technology that could be used for developing country food-security purposes and with liability for any compensation to the patent holder falling on the U.S. government. It would not significantly undercut invention incentives because there is a mechanism for patent holders to be compensated if there is an economic loss to them, and the use of the technology under the compulsory license would be limited to noncompeting developing country applications.

Make Available U.S. Government-Funded or Owned Biotechnology. This alternative would establish as a matter of policy that all tools of agricultural biotechnology developed by USDA and other U.S. government agencies, whether patented or not, would be made available by the government, without the need for a license or other permission, when used for developing country food-security purposes. This would not entail any change to existing law. The patent law already establishes that licenses on patents owned by the government have only limited exclusivity, and that exclusivity does not extend to any applications that the licensee does not have an explicit business plan to develop. As for patents not owned by the government but developed with government money, this proposal would involve the government's exercising its retained licenses under the Bayh-Dole Act and allowing contractors to use government-patented technology for developing country food-security purposes. This proposal would provide ready access to technologies whose development was funded in whole or in part by the government, whether the patent is held by the government or by a private party. It would not significantly undercut invention incentives because the government presumably does not make research decisions in response to patent-driven economic incentives, and the private holders of patented inventions

developed under CRADAs are protected by the fact that the use of the technology would be limited to noncompeting developing country applications that are outside their business plans.

Preserving Flexibility for Developing Countries

The key issue in U.S. foreign policy on patents is the degree to which the United States will support the preservation and use of the flexibility now built into the TRIPs Agreement for developing countries to fashion patent regimes that serve their local technology and development needs. The United States has been ambivalent at best on this question, supporting TRIPs in general and touting its flexibility in dealing with access to drugs for HIV/AIDS while pursuing through WIPO and bilateral and regional trade negotiations a more stringent approach to harmonization. To help ensure access to biotechnology for developing country food-security purposes without undercutting invention incentives, the United States should support preservation and use of developing country flexibility in several ways.

Support Incorporating TRIPs Flexibility Provisions in Any New WIPO Agreement and in Any Bilateral or Regional Trade Agreements. As discussed in Chapter 4, the TRIPs Agreement provides significant flexibility for developing countries to devise patent regimes that serve their local technology and development needs, including explicit recognition of flexibility to adopt special nutrition-related measures (Article 8) and to grant exceptions to patent rights to address defined needs when the interests of the patent holder will not be adversely affected (Article 30). The United States could support the inclusion of these same general flexibility provisions in the draft Substantive Patent Law Treaty and oppose any efforts through the WIPO process to reduce the patent policy flexibility granted developing countries in the TRIPs Agreement.[194] Similarly, it could accept the inclusion of these flexibility provisions in trade agreements it negotiates with developing countries, reversing the trend against flexibility set in its recent Free Trade Agreements with Singapore and Chile. Perhaps more simply, the United States could refrain from incorporating any intellectual property provisions at all in new trade agreements with countries already bound by TRIPs.

To help ensure access to biotechnology for developing country food-security purposes, the United States should support preservation and use of developing country flexibility in patent law and policy.

Support Preserving the TRIPs Flexibility Provisions in TRIPs. The TRIPs Council is reviewing the TRIPs Agreement in the context of the Doha Round of WTO trade negotiations.[195] The United States could make clear in this review that it supports maintaining the current flexibility provisions in the TRIPs Agreement. There are many such provisions: the broad authority in Article 30 to grant benign exceptions to patents; the Article 27.3(b) explicit right to exclude plants and animals from patentable subject matter; the implicit right to set patentability standards (novelty, inventive step, utility, disclosure) so as to maximize disclosure, minimize patenting of discoveries, and narrow patent breadth; the right to grant compulsory licenses; and many others.[196] The United States could make clear that it considers these provisions broad enough to enable developing countries to adopt, if they choose, all the same provisions for access to patented technologies that we propose above for adoption by the United States. It could

also work within TRIPs and through WIPO to ensure that the flexibility provisions are used in a way that effectively serves the developing country food security interest without significantly undercutting invention incentives.

Endorse Application of Articles 8 and 30 to Food Security Needs. By their terms, Articles 8 and 30, as well as potentially other flexibility provisions in TRIPs, are available to allow developing countries to devise intellectual property approaches to agricultural biotechnology that best serve local food security needs. The United States could specifically endorse the use of these provisions for that purpose and support efforts to craft implementation schemes for these provisions that comply with TRIPs, meet the food security need, and preserve invention incentives.

Specifically Endorse Retention and Use of Article 27.3(b) in the TRIPs Agreement. Article 27.3(b) of TRIPs explicitly allows countries to exclude plants from patentability, provided they establish an effective *sui generis* alternative for protecting plant varieties. This is vital flexibility for countries that rely on publicly funded plant-breeding programs and on the saving and reuse of seed by farmers to develop and disseminate new seed varieties. This provision is under review by the TRIPs Council. The United States could endorse its retention and support its use in ways that meet developing country food-security needs without undercutting invention incentives.

Full Implementation of Article 66.2 of the TRIPs Agreement

Article 66.2 of the TRIPs Agreement says:

Developed countries shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least developed country members in order to enable them to create a sound and viable technological base.

This provision of TRIPs speaks directly to the disparity in innovation capacity and access to technology between developed and developing countries. It was part of the quid pro quo in the TRIPs negotiations, in which developing countries were to be provided assistance with technology transfer in exchange for establishing the patent systems that developed countries were seeking to protect their intellectual property. The perception among many in developing countries is that, while they are working to establish patent systems, the developed countries have not met their technology transfer obligations under Article 66.2.[197]

The United States' report to the WTO on its compliance with Article 66.2 recites several U.S. statutes and programs, most predating the TRIPs Agreement, that relate generally to technology transfer and trade development, and it identifies some capacity-building programs in areas of technology unrelated to agriculture and food security.[198] The United States has not taken steps targeted specifically at providing incentives to U.S. companies to transfer agricultural technologies to developing countries for food security purposes. Nor has it taken any steps to provide incentives to U.S. companies to transfer patented technology, such as the tools of biotechnology.[199]

The United States could work to fulfill its obligation under Article 66.2 with respect to agricultural biotechnology and food security in more than one way. One approach would be to provide incentives, perhaps in the form of tax credits or other economic subsidies, for companies to invest in the development and commercialization of applications of biotechnology that meet

developing country food security needs. As discussed in Chapter 2, though, the market incentives for such commercial investment do not exist on a viable scale in developing countries, and there is little commercial infrastructure for the delivery of seeds where they are needed for food security purposes. Government incentives on any reasonably foreseeable scale are thus not likely to make a significant or sustainable difference in the availability of improved seeds to improve food security. Moreover, subsidizing commercial applications of biotechnology is not likely to advance Article 66.2's objective of enabling developing countries "to create a sound and viable technological base" of their own.

A course more likely to achieve the objectives of Article 66.2 would be to provide incentives to U.S. companies to transfer the tools of biotechnology and other agricultural technologies to public and private-sector researchers based in developing countries, who can apply them to local food security problems and over time help build a local technological base for improving food security. Such an approach would help support both the public and public-private channels of innovation in African agriculture we posited in Chapter 2.

A model for the public-private channel is the newly founded, nonprofit African Agricultural Technology Foundation (AATF) that we mentioned in Chapter 5. With start-up funding from the Rockefeller Foundation and the U.S. Agency for International Development (USAID), the AATF describes itself as "a public-private partnership to serve smallholder farmers in sub-Saharan Africa."[200] It was established specifically "to identify and facilitate the royalty-free transfer of proprietary technologies that meet the needs of resource-poor African farmers in ways that address and resolve the concerns of technology providers," including concerns related to intellectual property, protection of commercially important markets, and liability.

To discharge its responsibility under Article 66.2, the United States could develop an agenda of concrete actions to encourage and support the transfer of technology from U.S.-based technology owners to those who can make good use of it for developing country food-security purposes, through AATF and similar organizations. The USAID support for the formation of AATF is one such action. In addition to covering some of the costs of the intermediary services provided by AATF, USAID provides an official imprimatur that may enhance the willingness of companies to participate.

Another action the United States could take would be to provide direct economic incentives for companies to make royalty-free transfers to the AATF. These could take the form of tax deductions or credits or could involve direct subsidies to companies to defray at least the out-of-pocket expense of collaborating on technology transfer projects.

Perhaps more important as an inducement to share technology through a mechanism like AATF than any direct economic incentive would be some protection from liability for harms associated, or alleged to be associated, with use of the product. Technology developers express concern that their technology, following transfer to an entity such as AATF, could be misused by a downstream user or used without the required regulatory approval, creating liability that potentially could fall on the developer of the technology. The U.S. government's ability to protect companies from such liability is limited, because it cannot preclude lawsuits or regulatory actions in other countries. It could, however, adopt measures that insulate the donor of a technology from liability in U.S. courts for any harms resulting from the use or misuse of the technology by another, assuming due diligence and a lack of negligence by the technology donor.[201] The United States could also offer companies indemnification for any costs incurred or judgments

imposed as a result of harms associated with the use of a donated technology in U.S. courts or elsewhere. Internationally, the United States could work directly with other countries and through the WTO to address the liability issue in a way that would encourage royalty-free transfer from commercial enterprises to institutions that could make good use of the technology to meet food security and development needs.

Implementation of Article 66.2 in these focused ways would contribute directly to solving the technology access problem. It would complement the creation of a policy framework that reduces obstacles to access, but it is not an adequate substitute for policy change. Developing countries need the flexibility to develop intellectual property systems that strike the right balance for them between inducing and rewarding invention and ensuring that inventions are put to practical uses that meet local needs. Full implementation of Article 66.2 can help, but, for purposes of gaining access to the tools they need to achieve basic food security, developing countries should not be dependent solely on decisions made in Washington or by biotechnology companies.

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CHAPTER SEVEN

Conclusion

The countries of sub-Saharan Africa face daunting social, economic, and health challenges. Achieving basic food security is the central one for many countries and individuals in that region. If basic nutritional needs are not being met, the consequences are seen, certainly, in individual suffering and failure to thrive, but also in the failure of societies to thrive socially and economically. Food security, economic development, and poverty reduction are thoroughly intertwined. So too are the interests of the United States and developing countries in Africa and elsewhere. In the post–September 11 environment, U.S. leaders increasingly recognize that the lack of food security outside the United States is related to our quest for physical security inside the United States.

There is also an increasing recognition in the U.S. media and policy circles that a wide range of U.S. policies affects the efforts of developing countries to address food security and other basic development problems. These include U.S. agricultural and trade policies, development assistance and food aid policies, and the approaches the United States takes in the international arena to address trade and other development-related policy issues. The importance of many of these topics for the development process is reflected in the fact that the current round of WTO trade negotiations launched at Doha in 2001 is labeled the "development round." Developing countries are demanding that, if trade liberalization is to proceed, policies and programs of industrialized countries that adversely affect development must be reformed, especially with respect to agriculture.

Patent policy is an important part of this picture. We document in this report the relationship between U.S. patents and patent policy and the opportunity of developing countries to access the latest technology to meet their food security needs. The relationship is enormously complex, due both to complexities inherent in how patents work and are used by their owners to control access and to the multitude of nonpatent factors that affect whether and how developing country farmers can make good use of any new technology. We conclude that the relationship, though murky in some respects, is real and important. And we conclude that there is a strong case for examining and changing U.S. patent policy with developing country food security in mind. Based on our analysis, there are changes the United States could make in both its domestic and foreign policies that would improve developing country access to the patented

tools of biotechnology without significantly undercutting the core invention incentives of the patent system. These changes deserve consideration as the United States grapples with its heightened national interest in global food security and works to build a harmonized global patent system that fairly embraces the needs of developed and developing countries alike.

Notes

All website references verified in August 2003.

1 Food security exists in a country when all people at all times have the food they need for an active and healthy life. Food and Agriculture Organization (FAO) of the United Nations, *FAO: What It Is—What It Does* (2002), www.fao.org/UNFAO/e/wmain-e.htm. Poverty and food insecurity are inextricably linked. Poverty is a prime cause of many people's food insecurity, and food insecurity, with its negative consequences for physical and intellectual development and for health, is an obstacle to poverty reduction.

2 See Andrew Natsios, Administrator, United States Agency for International Development (USAID), Opening comments at the U.S.–Sub-Saharan Africa Trade Forum, January 15, 2003, www.agoa.mu/speech/opjan15.doc; and Alan P. Larson, undersecretary of state for Business, Economic and Agricultural Affairs, Address to the House Committee on International Relations, April 1, 2003, www.useu.be/Categories/Sustainable%20Development/Apr0103LarsonFoodSecurity.html.

3 www.developmentgoals.org.

4 Remarks by President Bush to the World Bank, July 17, 2001, www.whitehouse.gov/news/releases/2001/07/20010717–1.html.

5 The United States Mission to the European Union, "Larson Calls Food Security 'Serious Foreign Policy Concern,'" April 1, 2003, www.useu.be/Categories/Sustainable%20Development/Apr0103LarsonFoodSecurity.html.

6 For a recent and accessible overview of how agricultural, trade, and food aid policies of the United States and Europe adversely affect developing country agriculture and food security, see Sandra Bunch, "Agriculture in the Global Economy: Hunger 2003" (Bread for the World Institute, March 2003), www.bread.org/institute/hunger_report/2003-pdf.htm.

7 At a June 2003 biotechnology conference in Washington, DC, for example, President Bush said, "For the sake of a continent threatened by famine [Africa], I urge the European governments to end their opposition to biotechnology. We should encourage the spread of safe, effective biotechnology to win the fight against global hunger." (Reported many places, including BBC News, "US in New Global GM Push," news.bbc.co.uk/2/hi/science/nature/3013394.stm.) See also many actions and statements by the U.S. Trade Representative or USAID, such as the agency's press release on their Collaborative Agricultural Biotechnology Initiative (CABIO), www.usaid.gov/press/factsheets/2003/fs030623_1.html.

8 Much of this debate is captured in a recent report commissioned by the United Kingdom to which we refer later in this report. Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy* (London, September 2002), www.iprcommission.org.

9 Michael R. Taylor and Jerry Cayford, "The U.S. Patent System and Developing Country Access to Biotechnology: Does the Balance Need Adjusting?" (RFF Discussion Paper 02–51, October 2002), www.rff.org/rff/Documents/RFF-DP-02–51.pdf.

10 We do not address in this report the politics of policy change, which we recognize to be difficult. The political difficulty of change should not deter policy analysis, which we provide in this report and which can help clarify how political forces might align around a specific policy change agenda.

11 Rome Declaration on World Food Security, FAO, *Report of the World Food Summit 13–17 November 1996, Part One* (1997), www.fao.org/wfs/index_en.htm.

12 "800 million people in developing countries—about 20 percent of their total population—are chronically undernourished." FAO, *The Special Program for Food Security: Objective and Approach* (2002), www.fao.org/spfs/objectives_en.stm. "A staggering 55 percent of the nearly 12 million deaths each year among children under five in the developing world are associated with malnutrition."FAO, *The State of Food and Agriculture 2001* (2001), www.fao.org/es/ESA/sofa.htm.

13 According to the FAO, India has more hungry people than any other country, 225.3 million (23% of the population), reflecting India's large poor population, but hunger is most widespread in Africa, where 34% of the population, or 194 million people, are considered food insecure. FAO, "FAO's role on MDGs—Basic information" (2001), Chapter 5, MDGs/targets monitored by FAO, Table 1, Population, per capita dietary energy supply and prevalence of undernourishment in developing countries and countries in transition, www.fao.org/es/ESS/mdg_kit/progress.asp.

14 This discussion draws on the work of many others who have discussed the problem of food security and the role of technology in addressing it, including W.P. Falcon, "Globalizing germplasm: barriers, benefits, and boundaries," in *Tomorrow's Agriculture: Incentives, Institutions, Infrastructure and Innovations* (Ashgate, 2000); and J. DeVries and G. Toenniessen, *Securing the Harvest: Biotechnology, Breeding and Seed Systems for African Crops (*CABI, 2001).

15 Gordon Conway, *The Doubly Green Revolution: Food for All in the 21st Century* (Cornell University Press, 1999). The Green Revolution promoted the use of irrigation, fertilizers, pesticides, high-yield varieties, and the greater efficiencies of monoculture and large farm size. The result was dramatic increases in productivity, but also fertilizer and pesticide runoff into surface waters, greater soil erosion, and other environmental costs.

16 Per Pinstrup-Andersen, Rajul Pandya-Lorch, and Mark W. Rosegrant, *World Food Prospects: Critical Issues for the Early Twenty-First Century* (Washington, DC: International Food Policy Research Institute, at 24 (1999), www.ifpri.org/pubs/fpr/fpr29.pdf.

17 African Development Bank, *Gender, Poverty and Environmental Indicators on African Countries* (2002–2003), Table 3.1: Urbanization Profile, www.afdb.org/knowledge/statistics/statistics_indicators_gender/environment/indicators_environment.htm.

18 World Bank, An International Assessment on the Role of Agricultural Science and Technology in Reducing Hunger and Improving Rural Livelihoods (2002), www.agassessment.org/pdfs/roleofag.pdf.

19 World Bank, *Rural Development: From Vision to Action* (1997), wbln0018.worldbank.org/essd/rdv/vta.nsf/Gweb/Concept.

20 Pinstrup-Andersen, Pandya-Lorch, and Rosegrant, *supra* note 16, at 26.

21 Conway, *supra* note 15 and many International Food Policy Research Institute (IFPRI) publications, such as Serageldin, Ismail, and G.J. Persley, *Promethean Science: Agricultural Biotechnology, the Environment, and the Poor* (Consultative Group on International Agricultural Research (CGIAR) 2000), www.ifpri.org/themes/biotech/biotech.htm.

22 CGIAR, www.cgiar.org/publications/index.html, has links to international centers. Loraine Mitchell, "Biotechnology and Food Security," *Agriculture Information Bulletin* 765–11, U.S. Department of Agriculture Economic Research Service (June, 2001). www.ers.usda.gov/publications/aib76511/; Joel I. Cohen, Cesar Falconi, and John Komen, "Research Policy and Management Issues in Biotechnology for developing country Agriculture: Problems and Opportunities," International Food Policy Research Institute 2020 Vision (1999), www.ifpri.org/2020/focus/focus02.htm.

23 17% rated access to biotechnology to be of medium importance, and 2% said it was low. A tabulation of the survey results, including the names and institutions of the respondents, is in Appendices B and C. The survey was conducted informally as a means to assist the authors in identifying issues and diverse expert perspectives on the subject of access to biotechnology for use by researchers working on developing country agricultural problems. We make no claims that the survey is statistically representative of expert opinion on the issues it addresses.

24 See Michael J. Phillips, "The Future of Agricultural Biotechnology" (Biotechnology Industry Organization, 2001), www.bio.org/foodag/weekly/lecture_100101.asp. Also Syngenta Foundation, "The Socio-Political Impact of Biotechnology in Developing Countries" (2001), www.syngentafoundation.com/biotechnology_developing_countries.htm.

25 Among many publications are: Food and Agriculture Organization, *Agricultural Biotechnology in the Developing World* (1995), www.fao.org/docrep/v4845e/v4845e00.htm; The Royal Society et al., "Transgenic Plants and World Agriculture" (2000), www.ictp.trieste.it/~twas/TransSummary.htm; Ervin et al., "Transgenic Crops: An Environmental Assessment" (Henry A. Wallace Center for

Agriculture & Environmental Policy at Winrock International, 2000), www.winrock.org/Transgenic.pdf; McLean et al., "A Conceptual Framework for Implementing Biosafety: Linking Policy, Capacity and Regulation" (ISNAR, 2002), ftp://ftp.cgiar.org/isnar/publicat/bp-47.pdf; Joel I. Cohen, ed., *Managing Agricultural Biotechnology. Addressing Research Program Needs and Policy Implications* (1999), www.isnar.cgiar.org/ibs/biobook.htm.

26 National Research Council, *Intellectual Property Rights and Plant Biotechnology* (Washington, DC: National Academy Press, 1997), www.nap.edu/html/intellectual/; John Barton, "The Impact of Contemporary Patent Law on Plant Biotechnology Research," *Intellectual Property Rights III Global Genetic Resources: Access and Property Rights* (1998); USDA, "Public Sector Plant Breeding in a Privatizing World" (2001), www.ers.usda.gov/publications/aib772/; Rebecca S. Eisenberg, "Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research," *Virginia Law Review* 82: 1663–1727 (1996).

27 447 U.S. 303, (1980), people.bu.edu/ebortman/index/chakrabarty.html. See *infra* notes 68 to 70 and accompanying text on pages 28–29.

28 Gregory Graff, "The Sources of Biological Technologies for Agriculture: Public and Private Innovation and Patenting" (paper presented at the AAEA NC208 Conference on "R&D Policies and Impacts," March 30–31, 2001 at University of California, Berkeley, (excerpted from Graff's dissertation)); Bradford Barham, Jeremy Foltz, and Kwansoo Kim, "Trends in University Ag-Biotech Patent Production" (Food Marketing Policy Center, Research Report 58, 2001), www.biotech.wisc.edu/seebiotech/pdfs/raefinalbbkk.pdf.

29 Nathan A. Busch, "Jack and the Beanstalk: Property Rights in Genetically Modified Plants," *Minnesota Intellectual Property Review* 3(2): 1–234 (2002), mipr.umn.edu/archive/v3n2/busch.pdf.

30 For background on the CGIAR system, see the Future Harvest website, www.futureharvest.org/. See also G.J. Persley and M.M. Lantin, eds., *Agricultural Biotechnology and the Poor: An International Conference on Biotechnology* (CGIAR and U.S. National Academy of Sciences, 1999), www.cgiar.org/biotech/repo100/contents.htm; Applied Biotechnology Center at the International Maize and Wheat Improvement Center, "Reaching inside the Genome, Reaching Farmers" (2002), www.cimmyt.org/ABC/map/about/BROCHURE97ABC/BROCHURE97ABC.htm.

31 Personal communication with Mark Condon, vice president, international marketing, American Seed Trade Association, January 24, 2002.

32 Amounts of research can be calculated many different ways, and USDA's Economic Research Service has several useful papers on this, especially Paul W. Heisey, C.S. Srinivasan, and Colin Thirtle, "Public Sector Plant Breeding in a Privatizing World," *Agriculture Information Bulletin* 772, USDA Economic Research Service (2001), www.ers.usda.gov/publications/aib772/; see also Robbin Shoemaker, ed., "Economic Issues in Agricultural Biotechnology," *Agriculture Information Bulletin* 762, USDA Economic Research Service (2001), www.ers.usda.gov/publications/aib762/, especially pages 38–39. Generally, public-sector plant breeding expenditures for field crops have been relatively flat for decades but "appear to have started to decline in real terms from the mid-1990s.... In contrast, private-sector plant breeding investment appears to have grown extremely rapidly" (perhaps by a factor of 10 since 1960). Depending on what one measures, private expenditures appear to have passed public expenditures around 1990. Measured in scientist years, though, private-sector effort was more than double public effort by 1994. (Heisey, Srinivasan, and Thirtle at 6–8; also K.J. Frey, "National Plant Breeding Study-I: Human and Financial Resources Devoted to Plant Breeding and Development in the United States in 1994" (Ames, Iowa: Iowa Agricultural and Home Economics Experiment Station, Iowa State University, 1996).

33 Graff, *supra* note 28. A more detailed picture of the distribution of biotechnology patents, summarized from Graff's data, is presented in Appendix A.

34 Seven of the top 30 patent holders are universities (holding about 9% of the total), with the University of California and Cornell University together holding 95 of the 213 university-held patents.

35 Much has been written in the popular and academic press on how changing approaches to intellectual property have affected the behavior of academic researchers and universities. See Eyal Press and Jennifer Washburn, "The Kept University," *The Atlantic Monthly* 285(3) (2000), www.theatlan

tic.com/issues/2000/03/press.htm.; Rebecca Eisenberg, "Proprietary Rights and the Norms of Science in Biotechnology Research," *Yale Law Journal* 97: 177–231 (1987); National Research Council (1997) *Intellectual Property Rights and Plant Biotechnology;* Julia Porter Liebeskind and Amalya Oliver-Lumerman, "From Handshake to Contract: Intellectual Property, Trust, and the Social Structure of Academic Research," in *Trust Within and Between Organizations: Conceptual Issues and Empirical Applications;* and several articles in *Academe* 87(5) (2001), www.aaup.org/publications/Academe/01SO/So01toc.htm, especially Julia Porter Liebeskind, "Risky Business: Universities and Intellectual Property," and Nancy P. Goldschmidt and James H. Finkelstein, "Academics on Board: University Presidents as Corporate Directors."

36 Biotechnology Industry Organization, "Importance of Intellectual Property," www.bio.org/ip/background.asp; Lila Feisee and Brian Stanton, "Are Biotechnology Patents Important?" *PTO Pulse* (March 2000).

37 Heisey, Srinivasan, and Thirtle, *supra* note 32.

38 See Commission on Intellectual Property Rights, *supra* note 8 at 60.

39 "Corporations concentrate their research efforts on crops such as hybrid corn, soybean, canola, cotton, and some specialty horticultural products, which are grown for markets with high commercial value. . . . Moreover, the development of a vast number of crops critical to food security throughout the developing world (such as cassava, yams, sweet potatoes, sorghum, millet), as well as crops that are globally grown (like rice, wheat, and maize), must continue to rely on public and nonprofit institutions as the principal source of genetic innovation." (Philip G. Pardey, Brian D. Wright, and Carol Nottenburg, "Are Intellectual Property Rights Stifling Agricultural Biotechnology In Developing Countries?" in IFPRI Annual Report 2000–2001, www.ifpri.org/pubs/books/ ar2000/ar2000_essay02.htm); "Current industrial biotechnology is primarily orientated to the needs of large-scale commercial agriculture, rather than to those of the subsistence farmer. . . . [W]ithout changed incentives for sharing access to GM technologies, the world is unlikely to direct much of its research for improved nutrition and employment-based access to staples for the poor." ("Transgenic Crops and World Agriculture" a report by a working group representing seven science academies (U.S. National Academy of Sciences, the Royal Society, and others), www.biotech-info.net/GE_world_AG.pdf.

40 Cotton genetically modified to resist insects is being grown today in South Africa. For information on African applications of biotechnology, from a local organization, see AfricaBio's website, www.africabio.com/index.shtml.

41 Commission on Intellectual Property Rights, *supra* note 8.

42 U.S. Constitution, Article I, Section 8.

43 Robert P. Merges, *Patent Law and Policy: Cases and Materials*, second edition (Charlottesville, VA: Michie, Law Publishers, 1997), at 2.

44 Paul B. Thompson, "Conceptions of Property and the Biotechnology Debate," *BioScience* 45 (April 1995).

45 See A. Samuel Oddi, "Un-Unified Economic Theories of Patents—The Not-Quite-Holy Grail," *Notre Dame Law Review* 71: 267–327 (1996).

46 Though rarely expressed in natural-rights terms, arguments by the United States that other countries should respect U.S. patents and copyrights are often couched in terms of unjust deprivation of property: "As part of our international efforts, the USPTO focuses significant attention on the enforcement of IP abroad and combating IP piracy." Rogan, statement before the House Subcommittee on Courts, the Internet and Intellectual Property. See also Joseph Biden, "Theft of American Intellectual Property: Fighting Crime Abroad and at Home" (2002), www.senate.gov/~biden/IPREPORT.pdf.

47 Letter to Isaac McPherson, August 13, 1813, quoted in Merges, *supra* note 43, at 10. Also Menell: "Not surprisingly, the principal philosophical theory applied to the protection of utilitarian works—that is, technological inventions—has been utilitarianism." Peter S. Menell, "Intellectual Property: General Theories" (1999), in *Encyclopedia of Law and Economics*, *Volume I. The History and Methodology of Law and Economics*, edited by Boudewijn Bouckaert and Gerrit De Geest (Cheltenham: Edward Elgar, 2000), encyclo.findlaw.com/1600book.pdf.

48 35 U.S.C. 101, Inventions patentable.

49 35 U.S.C. 101, Inventions patentable.

50 35 U.S.C. 103, Conditions for patentability; non-obvious subject matter.

51 35 U.S.C. 112, Specification.

52 Roberto Mazzoleni and Richard R. Nelson, "Economic Theories about the Benefits and Costs of Patents," *Journal of Economic Issues* 32(4) (1998), www.nap.edu/readingroom/books/property/3.html.

53 There is a bit of jargon in patent discussions that should be mentioned: many scholars distinguish between "invention" and "innovation." Roughly, "invention" is the creation of a new thing, and "innovation" is the adaptation or refinement or combination or application of things to a new or better use. This terminology can be somewhat awkward because it does not match ordinary usage. The idea, though, is that "innovation" implies the practical exploitation of the invention. This puts innovation ambiguously between the first and the fourth objectives. Since patents should benefit society, we emphasize this fourth objective to make clear that the patent system encompasses both the creation of the invention and its socially useful exploitation and dissemination.

54 Fritz Machlup and Edith Penrose, "The Patent Controversy in the Nineteenth Century," *Journal of Economic History* 10(1) (1950); Robert P. Merges, "The Economic Impact of Intellectual Property Rights: An Overview and Guide," *Journal of Cultural Economics* 19 (1995).

55 Robert Merges and Richard Nelson, "On the Complex Economics of Patent Scope," *Columbia Law Review* 90 (1990); Suzanne Scotchmer, "Standing on the Shoulders of Giants: Cumulative Research and the Patent Law," *Journal of Economic Perspectives* 5(1) (1991); Edmund W. Kitch, "The Nature and Function of the Patent System," *Journal of Law and Economics* 20 (1977).

56 Rebecca S. Eisenberg, "Patenting Research Tools and the Law," in *Intellectual Property Rights and Research Tools in Molecular Biology* (National Research Council, 1996).

57 Eisenberg, *supra* note 26; Corinne Langinier and GianCarlo Moschini, "The Economics of Patents," in *Intellectual Property Rights and Patenting in Animal Breeding and Genetics*, edited by Max F. Rothschild and Scott Newman (Center for Agriculture and Rural Development Working Paper 02-WP 293, 2002), www.econ.iastate.edu/research/webpapers/paper_2061.pdf.

58 "Based on the view that the main role of patents is to provide incentives for innovation that would not occur otherwise, it would be difficult to make an economic case for public institutions' patenting discoveries that already have been publicly funded and accomplished. Likewise the role of patents in transferring information would be irrelevant in this case, because public research institutions have little use for trade secrets, and because it is difficult to improve on the dissemination of information achieved by simply publishing a discovery." Langinier and Moschini, *ibid.*, at 6.

59 *Ibid.*

60 Eisenberg, *supra* note 26. The objective of facilitating practical application is not new. Professor Eisenberg traces the debate from the 1940s to the 1970s over whether a "title" policy or a "license" policy best promotes commercial use—that is, whether the government should take title to inventions it funded or take just a license and leave title with the contractor—including Kennedy's 1963 Presidential Memorandum, the Harbridge House study, Nixon's 1971 Memorandum, the Committee on Government Procurement, and Carter's Domestic Policy Review on Industrial Innovation. All these started from the objective of patent policy to help bring inventions to actual commercial use, and then discussed how best to accomplish it.

61 Michael A. Heller and Rebecca S. Eisenberg, "Can Patents Deter Innovation? The Anticommons in Biomedical Research," *Science* 280: 5364 (1998), www.sciencemag.org/cgi/content/full/280/5364/698; Barton, *supra* note 26; John Barton, "Patent Scope in Biotechnology," *International Review of Industrial Property and Copyright Law* 26: 605 (1995).

62 Barton, *ibid*, "Patent Scope in Biotechnology," at 614. The reference is to Merges and Nelson, *supra* note 55. See also Jeroen Van Wijk, "Broad Biotechnology Patents Hamper Innovation," *Biotechnology and Development Monitor* 25 (1995), www.biotech-monitor.nl/2506.htm.

63 Carl Shapiro, "Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting," in *Innovation Policy and the Economy*,

Volume I, edited by Adam Jaffe, Joshua Lerner, and Scott Stern (MIT Press, 2001), www.haas.berkeley.edu/~shapiro/thicket.pdf, at 2. Shapiro cites Joseph Stiglitz at a 1995 Federal Trade Commission hearing.

64 Heller and Eisenberg, *supra* note 61.

65 See bibliography.

66 The basic patent law is the Patent Act of 1952, codified in title 35 of the U.S. Code, sections 1–376, and amended repeatedly since then.

67 Many publications describe this structure in greater detail, such as Merges, *supra* note 43 (especially 37–39).

68 S*upra* note 27.

69 227 U.S.P.Q. 443 (Board of Patent Appeals and Interferences, 1985).

70 In 1987, the PTO announced its new policy that all nonhuman, nonnatural creatures are patentable ("Patent and Trademark Office Notice: Animals-Patentability," *Official Gazette U.S. Pat. & Trademark Office* 24: 1077 (April 21, 1987). The next year, the PTO issued a patent on the famous Harvard "onco-mouse," genetically altered to likely get cancer. Recently, the Supreme Court confirmed this PTO policy as consistent with the law (*J.E.M. Ag Supply v. Pioneer Hi-Bred*, 2001). See *infra* note 75.

71 Plant Patent Act of 1930, 35 U.S.C. §161–164

72 Plant Variety Protection Act, 7 U.S.C. §§2321 et seq.

73 Keith Fuglie, Nicole Ballenger, Kelly Day, Cassandra Klotz, Michael Ollinger, John Reilly, Utpal Vasavada, and Jet Yee, "Agricultural Research and Development: Public and Private Investments under Alternative Markets and Institutions," USDA *Agricultural Economics Report* 735 (1996), www.ers.usda.gov/publications/aer735/. The term for plant patents was 17 years until the 1994 amendments extended it to 20 years.

74 Section 113. Right to Save Seed; Crop Exemption; and Section 114. Research Exemption.

75 The Supreme Court recently upheld the issuance of utility patents for genetically modified plants, concluding that the existence of the Plant Patent Act and the Plant Variety Protection Act did not imply a congressional intent not to allow utility patents for new plant varieties, assuming the statutory requirements for such patents are met, including the utility requirement. *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International* (docket 99–1996, www.supremecourtus.gov/opinions/01slipopinion.html).

76 It is common practice among companies selling genetically modified seeds to require that their customers agree, among other things, not to save seed for replanting the next year and to vigorously enforce those agreements. The power of companies to limit the use of their products to customers who enter such agreements came most famously to light when Monsanto sued Canadian canola farmer Percy Schmeiser for having its Roundup Ready canola in his fields. Since Monsanto won a judgment against Schmeiser, it has reportedly brought many more suits against farmers. See David R. Moeller, "GMO Liability Threats for Farmers: Legal Issues Surrounding the Planting of Genetically Modified Crops" (Farmers' Legal Action Group, Inc., 2001), www.flaginc.com/pubs/arts/GMOthreats.pdf (at 6: "Monsanto has recently brought similar actions in the United States against farmers throughout the nation, including farmers in North Dakota, South Dakota, Indiana, and Louisiana"); and E. Ann Clark, "A fanciful tale… On the Appeal of the Percy Schmeiser Decision" (2002), www.plant.uoguelph.ca/research/homepages/eclark/judge.htm ("With over 2000 similar lawsuits already reportedly hanging on this decision, one of the key segments of their employer's [Monsanto's] overall global strategy would be at stake").

77 See Heisey, Srinivasan, and Thirtle, *supra* note 32, at 3 and 5–6.

78 William W. Lin, William Chambers, and Joy Harwood, "Biotechnology: U.S. Grain Handlers Look Ahead," *Agricultural Outlook* (October 2001, ERS/USDA), at 29–34, www.ers.usda.gov/publications/agoutlook/apr2000/ao270h.pdf: "By 1999, nearly 60 percent of soybean-harvested acres in the U.S. was planted to herbicide-tolerant soybeans, while nearly 40 percent of corn-harvested acreage…was planted to biotech varieties."

79 Graff, *supra* note 28.

80 See USPTO, "Patent Counts by Class by Year: January 1977–December 2001" (2002), www.uspto.gov/web/offices/ac/ido/oeip/taf/cbcby.pdf.

81 Barham, Foltz, and Kim, *supra* note 28.

82 U.S. Patent Number 5,159,135. J. Bijman, "Agracetus: Patenting All Transgenetic Cotton," *Biotechnology and Development Monitor* 21 (1994), www.biotech-monitor.nl/2105.htm, at 8–9.

83 Devlin Kuyek, *Intellectual Property Rights: Ultimate Control of Agricultural R&D in Asia* (Biothai, GRAIN, etc., 2001), www.grain.org/adhoc.htm, at 15.

84 *Ibid.*

85 ETC Group, "Monsanto's 'Submarine Patent' Torpedoes Ag Biotech: Monsanto & Syngenta Monopolize Key Gene Marker Technologies" (2002), www.etcgroup.org/documents/news_monsanto sub.pdf.

86 U.S. Patent No. 5,004,863.

87 ETC Group, *supra* note 85.

88 Shapiro, *supra* note 63, in abstract. See also John Barton, "Patent Breadth and Antitrust: A Rethinking," (1995), www.ftc.gov/opp/global/barton.htm; Gregory Graff and David Zilberman, "Towards an Intellectual Property Clearinghouse for Ag-Biotechnology," *IP Strategy Today* 3–2001 (2001), www.biodevelopments.org/ip/ipst3n.pdf; John Barton, "Reforming the Patent System," *Science* 287 (March 17, 2000), www.biotech-info.net/reforming.html; and Arti Kaur Rai and Rebecca S. Eisenberg, "The Public and the Private in Biopharmaceutical Research" (Duke Law School Conference on the Public Domain, 2001), www.law.duke.edu/pd/papers/raieisen.pdf.

89 Heller and Eisenberg, *supra* note 61.

90 "Even when the ownership of a technology is not in doubt, academic researchers sometimes find they are shut out from using inventions whose rights are controlled by private companies. At Iowa State University, for example, plant breeders have been rebuffed a couple of times when they approached a company about licensing a technology. 'We were refused, even though the company is licensing to many other companies,' said Patricia Swan, vice provost for research and advanced studies at Iowa State University. 'The company indicated that [it] did not want to license to us because [it] did not believe that universities were capable of managing and looking after the intellectual property in the way that it should be looked after.'" National Research Council, *Intellectual Property Rights and Plant Biotechnology* (1997), at 8, www.nap.edu/html/intellectual/.

91 Agracetus, for example, uses its patent on all transgenic cotton to prevent anyone else from researching a certain aspect of cotton production: "It is also possible that the patentee prohibits the exploitation of the technological area that is covered by the patent. Agracetus, for example, has licensed companies such as Monsanto and Calgene that use the technology to improve the insect resistance of cotton. But all efforts to alter the genome of cotton to improve its fiber characteristics have not been authorized by the company. This is the area which is monopolized by Agracetus." Van Wijk, *supra* note 62, at 16.

92 National Research Council, *supra* note 90, at 8: "Researchers at government agencies face the same problem, said Robert Swank, director of research at the U.S. Environmental Protection Agency's (EPA) National Exposure Research Laboratory in Athens, Georgia: 'Not all companies and not all universities are very free in giving us their proprietary information, even in a research domain. In effect, we operate in a research-exemption mode. Everything we do is yours. But the converse of that is not true, and it does hamper our ability to conduct research.'"

93 *Ibid.* at 9. The passage continues: "'We now find that this is rippling throughout many commodity boards,' Bennett said. 'It is affecting their willingness to support research in the genetic engineering of minor crops because of the uncertainty as to how things can reach the commercial market. Until we find some path to access enabling technologies, participation in public research programs on this direct application of genetic engineering is effectively on hold.'"

94 Barton, "Reforming the Patent System," *supra* note 88; Shapiro, *supra* note 63, at 3.

95 Graff and Zilberman, *supra* note 88; Robert P. Merges, "Institutions for Intellectual Property Transactions: The Case of Patent Pools" (1999), www.law.berkeley.edu/institutes/bclt/pubs/merges/.

96 Barton, *supra* note 88 ("Patent Breadth and Antitrust" and "Reforming the Patent System").

97 Shapiro, *supra* note 63, at 4.

98 Barton, *supra* note 26; John L. King, "Concentration and Technology in Agricultural Input Industries," *Agriculture Information Bulletin* 763, USDA Economic Research Service (2001), www.ers.usda.gov/publications/aib763/; Murray Fulton and Konstantinos Giannakas, "Agricultural Biotechnology and Industry Structure," *AgBioForum* 4(2) (2001), www.agbioforum.org/v4n2a08-fulton.htm; William H. Lesser, "Intellectual Property Rights and Concentration in Agricultural Biotechnology," *AgBioForum* 1(2) (1998), www.agbioforum.org/v1n2/v1n2a03-lesser.htm; N. Kalaitzandonakes and M. Hayenga, "Structural Change in the Biotechnology and Seed Industrial Complex: Theory and Evidence," in *Transitions in Agbiotech: Economics of Strategy and Policy*, edited by W.H. Lesser (2000), agecon.lib.umn.edu/cgi-bin/pdf_view.pl?paperid=1907&ftype=.pdf.

99 "Over the past twenty years, the agricultural inputs industry has witnessed a significant restructuring. Large chemical firms such as Monsanto, Dow and DuPont have made huge investments in life sciences. These newly integrated 'life sciences' companies have made attempts to acquire all of the large, national seed firms in North America. Meanwhile, the research-intensive agricultural biotechnology industry has, from its appearance in the 1980s as a large set of small start-ups, already reached a second stage, with most of these start-ups either folded or acquired by the new agricultural systems giants." Gregory Graff, Gordon C. Rausser, and Arthur A. Small, "Agricultural Biotechnology's Complementary Intellectual Assets" (2000), papers.ssrn.com/sol3/papers.cfm?abstract_id=280107, at 1.

100 Several examples are mentioned in "Workshop 10: Research Tools, Public Private Partnerships and Gene Patenting," Commission on Intellectual Property Rights (2002), www.iprcommission.org/papers/pdfs/workshops/workshop10.pdf. Also Graff and Zilberman, *supra* note 88.

101 R. David Kryder, Stanley P. Kowalski, and Anatole F. Krattiger, "The Intellectual and Technical Property Components of Pro-Vitamin A Rice (GoldenRice™): A Preliminary Freedom-to-Operate Review" (ISAAA Brief 20, 2000), www.isaaa.org/publications/briefs/Brief_20.htm.

102 Again, access problems are a blend of individual barriers and cumulative burdens. "Examples of power plays by companies are making the rounds of the academic plant biology community, and they extend to the developing world. A developing country research institution working with a CGIAR research center using public support seeks agreement to use a proprietary gene in the development of technology to address a major problem confronting smallholder farmers in Africa. The company holding the IPR agrees to license the gene only if it and it alone can determine how commercialization will proceed in the event the research proves successful" (Robert W. Herdt, "Enclosing the Global Plant Genetic Commons" (Rockefeller Foundation, 1999), www.rockfound.org/display.asp?context=3&SectionTypeID=17&DocID=220, at 15). See also Eran Binenbaum, Carol Nottenburg, Philip G. Pardey, Brian D. Wright, and Patricia Zambrano, "South-North Trade, Intellectual Property Jurisdictions, and Freedom to Operate in Agricultural Research on Staple Crops" (IFPRI EPTD Discussion Paper 70, 2000), www.ifpri.org/divs/eptd/dp/eptdp70.htm; Joel I. Cohen, "Managing Intellectual Property—Challenges and Responses for Agricultural Research Institutes," in *Agricultural Biotechnology and the Poor*, edited by G.J. Persley and M.M. Lantin (2000), www.cgiar.org/biotech/repo100/jcohen.pdf; Silvia Salazar, Joel Cohen, Cesar Falconi, and John Komen, "The Use of Proprietary Biotechnology Research Inputs at Selected Latin American NAROs" (ISNAR Briefing Paper 44, 2000), www.cgiar.org/isnar/publications/catalog/briefing.htm. While acknowledging the access problem for developing countries, some of these commentators argue that it has been exaggerated, since patents have no legal jurisdiction in foreign countries. We address this point in the final section of this chapter, U.S. Foreign Policy on Patents.

103 PTO, "A New Organization for a New Millennium: Performance and Accountability Report, Fiscal Year 2000" (2000), www.uspto.gov/web/offices/com/annual/2000/, at 1 (Foreword).

104 *Ibid.*

105 PTO, *supra* note 103, at 17 (Intellectual Property Leadership).

106 Statement of James E. Rogan, Undersecretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, before the Subcommittee on Courts, the Internet and Intellectual Property, Committee on the Judiciary, U.S. House of Representatives, April 11,

2002, www.uspto.gov/web/offices/com/speeches/househrg2002.htm.

107 PTO, *supra* note 103, at 17 (Intellectual Property Leadership).

108 PTO, *supra* note 103, at 46 (Financial Discussion and Analysis).

109 PTO, *supra* note 103, at 12 (Highlights).

110 "Since 1991—under the Omnibus Budget Reconciliation Act (OBRA) of 1990—the PTO has operated in much the same way as a private business, providing valued products and services to our customers in exchange for fees which are used to fully fund their operations." Mary Bellis, "An Introduction to the PTO," on *About: Inventors*, inventors.about.com/library/bl/toc/blintropto.htm; "PTO is requesting $1,039 million or an increase of $158 million above the fiscal year 2000 enacted level. We project our collections from fiscal year 2001 user fees to be $1,152 million, and expect to carry forward $26 million from 1999 fee collections and $229 million from fiscal year 2000 fee collections." PTO, "Fiscal Year 2001 Corporate Plan," www.osec.doc.gov/bmi/budget/PB2001/BROWSE/bjpto.PDF.

111 Lecture by Brian Stanton of the PTO. Barton ("Reforming the Patent System," *supra* note 88, at 1934) says, "A PTO examiner can give each application an average of 25 to 30 hours, and may in fact give much less." He cites 1993 PTO statistics, a personal communication, and H. Manbeck, former commissioner of the PTO, who has testified that examiners spend 15 to 17 hours per application.

112 The American Inventors Protection Act of 1999 elaborates the various deadlines as a revision to 35 USC 154(b), in Subtitle D, the Patent Term Guarantee Act of 1999.

113 "The regulations allow the PTO to pay up to 10 percent of salary for fully successful performance and up to 20 percent for exceptional performance, to an annual limit of $10,000 (or, with OPM approval, up to $25,000)." Patent Office Professional Association, "Pay As You Go: Ways to improve compensation and cut attrition, *Radio Free PTO*, 00(1) (February 2000), www.popa.org/newsletters/feb00.shtml, urging the PTO to fully utilize these regulations. "One of the problems with the PTO right now is the disposal system, a type of performance bonus, where quantity rather than quality of the work seems to rule the roost." Steve Goldstein, in PTC Research Foundation of Franklin Pierce Law Center, "Fifth Biennial Patent System Major Problems Conference: III. Future of the U.S.P.T.O." *IDEA: The Journal of Law and Technology* 36(2) (1996), www.idea.pierce law.edu/articles/36/36_2/8.Conference.III.pdf.

114 According to PTO statistics, 60% of all patent applications result in the issuance of a patent. The patent may be different in scope or other details from what the applicant originally sought, but the majority of applications yield a patent. "U.S. Patent Statistics, Calendar Years 1963–2001," www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.pdf.

115 35 U.S.C. Sec. 282, Presumption of validity; defenses.

116 Robert J. Yarbrough, "Patent Reexamination" (2000), www.yarbroughlaw.com/reexamination2.htm.

117 Barton, *supra* note 88.

118 Talis Dzenitis, "American Inventors Protection Act of 1999 Is Law" (2000), www.uspto.gov/web/offices/dcom/olia/aipa/summary.htm.

119 Eisenberg, *supra* note 56; John Barton, "Patents and Antitrust: A Rethinking in Light of Patent Breadth and Sequential Innovation," *Antitrust Law Journal* 65: 449 (1997); Barton, *supra* note 26; Donald McFetridge, "Intellectual Property, Technology Diffusion, and Growth in the Canadian Economy," in *Competition Policy and Intellectual Property Rights in the Knowledge-Based Economy*, edited by Robert Anderson and Nancy Gallini (Alberta: University of Calgary Press, 1998).

120 Gerald J. Mossinghoff, Statement to FTC and DOJ hearings on Competition & Intellectual Property Law and Policy in the Knowledge-Based Economy (2002), www.ftc.gov/os/comments/intelpropertycomments/mossinghoffgeraldj.pdf; F. Scott Kieff, "Facilitating Scientific Research: Intellectual Property Rights and the Norms of Science—A Response to Rai and Eisenberg," *Northwestern University Law Review* 95(2) (2001); J.H. Dodds, R. Ortiz, J.H. Crouch, V. Mahalasksmi, and K.K. Sharma, "Biotechnology, the Gene Revolution, and Proprietary Technology in Agriculture: A Strategic Note for the World Bank," *IP Strategy Today* 2–2001 (2001), www.bioDevelopments.org/ip/index.htm.

121 See *Madey v. Duke University*, 307 F.3d 1351 (October 3, 2002). An excellent brief analysis of the *Madey* case and a summary of the current status of the research exemption is provided by Rebecca S. Eisenberg in "Patent Swords and Shields," *Science* 299: 1018–1019 (February 14, 2003).

122 *Ibid.*

123 "The use and reproduction of a protected variety for plant breeding or other bona fide research shall not constitute an infringement of the protection provided under this chapter" (7 U.S.C. §2544—Research exemption). See Janice M. Strachan, "Plant Variety Protection: An Alternative to Patents," USDA Plant Variety Protection Office (no date), www.nal.usda.gov/pgdic/Probe/v2n2/plant.html.

124 See James Love and Michael Palmedo, "Examples of Compulsory Licensing of Intellectual Property in the United States" (CPTech Background paper 1, Chapter IV: Misc Compulsory Licensing Programs, 2001), www.cptech.org/ip/health/cl/us-misc .html:

42 USC Sec 2183, for atomic energy.

(a) Declaration of public interest

The Commission may, after giving the patent owner an opportunity for a hearing, declare any patent to be affected with the public interest if (1) the invention or discovery covered by the patent is of primary importance in the production or utilization of special nuclear material or atomic energy; and (2) the licensing of such invention or discovery under this section is of primary importance to effectuate the policies and purposes of this chapter.

(b) Action by Commission

Whenever any patent has been declared affected with the public interest, pursuant to subsection (a) of this section (1) the Commission is licensed to use the invention or discovery covered by such patent in performing any of its powers under this chapter; and (2) any person may apply to the Commission for a nonexclusive patent license to use the invention or discovery covered by such patent, and the Commission shall grant such patent license to the extent that it finds that the use of the invention or discovery is of primary importance to the conduct of an activity by such person authorized under this chapter.

125 *Ibid.* Chapter III: Compulsory Licensing as Remedy to Anticompetitive Practices (www.cptech.org/ip/health/cl/us-cl.html), and Chapter II: Government Use Under 28 USC 1498 (www.cptech.org/ip/health/cl/us-1498.html).

126 Article 30 of the TRIPs Agreement (docsonline.wto.org/DDFDocuments/t/UR/FA/27-trips.doc).

127 Article 31 of the TRIPs Agreement (docsonline.wto.org/DDFDocuments/t/UR/FA/27trips.doc). For further discussion of compulsory licenses under the TRIPs Agreement, see Carlos M. Correa, *Intellectual Property Rights, the WTO and Developing Countries: The TRIPs Agreement and Policy Options* (London and New York: Zed Books Ltd., 2000), at 89–94.

128 See Section5(A)(4) of the Paris Convention, which was enacted in 1883. A variety of related measures can all be considered "working" requirements, if they justify compulsory licenses by a failure of the patent holder to supply a market. Thus—in addition to the direct working requirement articulated in the Paris Convention—"refusal to deal," inadequate supply, and "dependent patents" are all forms of a working requirement, if they are grounds for a compulsory license. Useful discussions by Carlos M. Correa are in Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries (South Centre working paper 5, 1999), www.southcentre.org/publications/complicence/toc.htm, especially Chapter IV: Grounds for Granting Compulsory Licenses; and in *Integrating Public Health Concerns into Patent Legislation in Developing Countries* (Geneva: South Centre, 2000), www.southcentre.org/publications/publichealth/toc.htm, Chapter X: Compulsory Licensing.

129 See 28 U.S.C. §1498, Act of June 25, 1910, c. 423, 36 Stat. 851.

130 Paul Janicke, "Current State of U.S. Patent Law Regarding Infringement of Drug Patents by the Government" (Intellectual Property and Information Law Program, University of Houston Law Center, 2001), www.law.uh.edu/healthlawperspectives.

131 The Consumer Project on Technology (see *supra* note 124) has a web page of information on the event, "Ciprofloxacin: the dispute over compulsory licenses," www.cptech.org/ip/health/cl/cipro.

132 A good summary of the options allowed government agencies under existing legislation, especially the Bayh-Dole Act, is in National Institutes of

Health, *Report of the National Institutes of Health (NIH) Working Group on Research Tools* (1998), www.nih.gov/news/researchtools/, especially Appendix D, "Analysis of NIH Options Under Current Law."

133 USDA, "Technology Transfer in ARS," 141.2-ARS (2000), www.afm.ars.usda.gov/ppweb/141–2.htm.

134 35 U.S.C. §200 (Policy and Objectives) (largely from the Bayh-Dole Act), www4.law.cornell.edu/uscode/35/200.html. Notice the implicit working requirement in "protect the public against nonuse."

135 See 35 U.S.C. §209(a)(2) (from the Technology Transfer Commercialization Act of 2000).

136 See 35 U.S.C. §202(c)(4) (from the Bayh-Dole Act).

137 The World Food Summit Plan of Action says, "1. ...concerted action at all levels is required. Each nation must adopt a strategy consistent with its resources and capacities"; "3. ...Governments are responsible for creating an enabling environment for private and group initiatives to devote their skills, efforts and resources, and in particular investment, towards the common goal of food for all"; and "8. ...The international community has a key role to play in supporting the adoption of appropriate national policies and, where necessary and appropriate, in providing technical and financial assistance to assist developing countries and countries with economies in transition in fostering food security." www.fao.org/docrep/003/w36 13e/w3613e00.htm.

138 PTO, *supra* note 103, at 17 (Intellectual Property Leadership).

139 For general background on the TRIPs Agreement, including its text, origins, and implementation, see the TRIPs page on the WTO website, www.wto.org/english/tratop_e/trips_e/trips_e.htm#NegHist.

140 World Trade Organization, "Agreement on Trade-Related Aspects of Intellectual Property Rights" (1994), docsonline.wto.org/DDFDocuments/t/UR/ FA/27-trips.doc.

141 For a broad overview of this topic, see Commission on Intellectual Property Rights, *supra* note 8. For an analysis specifically of issues concerning TRIPs and development, see Correa, *supra* note 128.

142 Article 30 says: "Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."

143 "U.S. Statement on Intellectual Property and Access to Medicines at the June 20 TRIPs Council Meeting" (2003), www.ustr.gov/sectors/speech01.PDF.

144 U.S. Trade Representative, "1999 Annual Report to the Council on Trade-Related Aspects of Intellectual Property Rights," www.ustr.gov/wto/99ustrrpt/ustr99_trips.pdf.

145 These are the Paris Convention for the Protection of Intellectual Property (1883) and the Berne Convention for the Protection of Literary and Artistic Works (1886).

146 Memorandum of the WIPO Director General on "Vision and Strategic Direction of WIPO," www.wipo.org/about-wipo/en/dgo/pub487.htm.

147 WIPO gives a brief introduction at www.wipo.int/patent/agenda/en.

148 WIPO, "Progress on Discussions to Harmonize Patent Law," *Update* 164/2002 (Geneva, 14 May 2002) www.wipo.int/pressroom/en/updates/2002/upd164.htm.

149 "One of the most significant issues on which some developing countries expressed their position at the SCP Sixth Session was whether an invention should show a 'technical character' in order to be patentable. The United States argued—supported by the Representatives of some of the users group NGOs—that 'requiring a technical character was unnecessarily limiting the innovations in new fields of endeavor, such as information technology and biotechnology, and that the term "in all fields of technology" which appeared in Article27.1 of the TRIPs Agreement was not mandating any requirement relating to technical character.'...In sum, dropping the requirement of 'technical character' of inventions would substantially expand the scope of the patent system, beyond its basic intent of promoting technical progress. Such a step will go well beyond the TRIPs Agreement (which only prescribes patenting in 'fields of technology') and the current PCT, according to which the invention must be of 'technical character.'" Carlos

Correa, "WIPO's Patent Agenda: For Whom?" *South Centre Bulletin* 48, www.southcentre.org/info/south bulletin/bulletin48/bulletin48-01.htm.

150 Statement of the Egyptian Delegation at the 37th series of the Meetings of the Assemblies of Member States of WIPO, "The WIPO Patent Agenda Must Promote Development," *South Centre Bulletin* 48, www.southcentre.org/info/southbulletin/bulletin48/bulletin48-01.htm.

151 WIPO, "General Report on the Thirty-Seventh Series of Meetings of the Assemblies of the Member States of WIPO, September 23 to October 1, 2002," paragraph 327, www.wipo.int/patent/agenda/en/.

152 PTO, "Annual Report 2000," www.uspto.gov/web/offices/com/annual/2000/00intellec.pdf.

153 Fact Sheet: Enterprise for ASEAN Initiative, www.whitehouse.gov/news/releases/2002/10/20021026-7.html.

154 "The USSFTA will be a world-class agreement. Both sides will go way above their WTO commitments. It will be NAFTA-plus in a number of areas including the protection of intellectual property…." (www.mti.gov.sg/public/FTA/frm_FTA_Default.asp?sid=36).

155 Commission on Intellectual Property Rights, *supra* note 8 at 163.

156 USTR Fact Sheet, "The Work of USTR—Intellectual Property," usinfo.state.gov/topical/econ/ipr/ipr-ustrwork.htm.

157 UNEP Intergovernmental Panel on Climate Change, *Methodological and Technological Issues in Technology Transfer* (2000), www.grida.no/climate/ipcc/tectran/index.htm; Allen Blackman, "Obstacles to a Doubly Green Revolution," Resources for the Future (2000), www.rff.org/CFDOCS/disc_papers/PDF_files/0048.pdf.

158 Falcon, *supra* note 14.

159 Principally the CGIAR system, now known as Future Harvest: www.futureharvest.org/.

160 Joel I. Cohen, et al., "Proprietary Biotechnology Inputs and International Agricultural Research" (ISNAR Briefing Paper 39, 1998), www.cgiar.org/isnar/publications/briefing/BP39.htm; Binenbaum et al., *supra* note 102; David Kryl, "Environmental and Industrial Biotechnology in Developing Countries" (U.N. Industrial Development Organisation, 2001), www.ejb.org/content/vol4/issue3/issues/03/; Gerd Junne, "Biotechnology: The Impact on Food and Nutrition in Developing Countries," *Food, Nutrition and Agriculture* 1 (1991), www.fao.org/docrep/u3550t/u3550toh.htm.

161 Inventors of valuable new biological materials generally have physical control of the material. If others want to use it, they have to get it from the inventor. (Other ways to get it may be illegal, are almost certainly far more cumbersome, and will not include support and know-how from the inventor.) The inventors generally require recipients to sign material transfer agreements (MTAs), which are contracts setting out the conditions attached to the transfer. Those conditions can be whatever the two parties agree to, and they may include conditions on the publishing or the patenting of subsequent results. Since MTAs are contracts, they are not limited or directly affected by patent laws or policies. But the power to set terms does depend on control of materials, which patents do affect.

162 A group of universities and other public institutions recently announced the formation of the Public-Sector Intellectual Property Resource for Agriculture (PIPRA) "to help public-sector agricultural research institutions achieve their public missions by ensuring access to intellectual property to develop and distribute improved staple crops and improved specialty crops" (www.pipra.org/purpose.php). The consortium identifies the problem they seek to address: "limited or conditional access to a wide range of patented technologies has been identified as a significant barrier to the applications of biotechnology in the development of new crops. This is particularly true for subsistence and specialty crops," (Atkinson et al., "Public Sector Collaboration for Agricultural IP Management," *Science* 301: 174 (July 11, 2003).

163 One developing country participant at our workshop pointed out that, for agricultural research centers in the developing world, every dollar spent on legal counsel or other patent activities is a dollar taken away from scientific research. This creates a strong institutional bias against patented technologies and a wariness of even entering the legalistic world of non-public-domain research tools. It also inclines them, when they do enter that realm, to devote the barest minimum of resources to legal patent work, making them vulnerable to mistakes and disadvantageous contracts.

This situation has led many people to emphasize the value of model licenses or other methods to reduce the costs of navigating the world of patents. One survey respondent urged examination of "potential collective bargaining agreements for access to products and tools." The African Agricultural Technology Foundation mentioned later in this chapter is an effort along these lines. It seeks to license and distribute royalty-free technology donated by biotechnology companies. An effort to alleviate the lack of legal resources is the Public Interest Intellectual Property Advisors (PIIPA), which seeks to organize intellectual property lawyers to donate their time and expertise to help developing countries and public interest organizations. Michael A. Gollin, "Answering the Call: Public Interest Intellectual Property Advisors" (discussion paper, Biodiversity and Biotechnology and the Protection of Traditional Knowledge Conference, April 4–6, 2003, St. Louis, Missouri: Washington University School of Law).

164 Personal communications with Walter Falcon (on June 29, 2001), director of the Center for Environmental Science and Policy at Stanford University, and Timothy Reeves (on August 6, 2001), former director general of the International Maize and Wheat Improvement Center (CIMMYT).

165 John Komen, "International Collaboration in Agricultural Biotechnology" in *Managing Agricultural Biotechnology: Addressing Research Program Needs and Policy Implications*, and other chapters in the book (1999), www.isnar.cgiar.org/ibs/biobook.htm.

166 Steven C. Price, "Public and Private Plant Breeding," *Nature Biotechnology* 17(10) (1999), www.biotech.iastate.edu/IFAFS/Steven_Price_Article.html and www.biotech-info.net/public_private.html; Charles Benbrook, "Who Controls and Who Will Benefit from Plant Genomics?" AAAS Annual Meeting (2000), www.biotech-info.net/AAASgen.pdf.

167 Falcon, *supra* note 14; Herdt, *supra* note 102; ETC Group, *supra* note 85; Silvia Salazar et al., "The Use of Proprietary Biotechnology Research Inputs at Selected Latin American NAROs" (ISNAR Briefing Paper 44, 2000), www.cgiar.org/isnar/publications/catalog/briefing.htm.

168 The survey we conducted of experts and stakeholders is described in Chapter 1, under the heading "Information Sources."

169 See tabulation of survey data in Appendix B.

170 See responses to questions 5–8 in Appendix B.

171 See responses to question 6.

172 See James E. Rogan, Statement to the House Subcommittee on Courts, the Internet and Intellectual Property: "Just as the Framers of the Constitution created standard intellectual property rules for the nation, we are working to develop consistent rules for the rest of the world."

173 USAID foreign assistance "is governed by USAID Regulation 26 (22 CFR 226), OMB Circulars, and the ADS [Automated Directives System]" ("Creating Opportunities for U.S. Small Business: USAID Acquisition And Assistance Instruments," www.usaid.gov/procurement_bus_opp/osdbu/book-instruments.htm). The ADS chapter on patent rights says, "The objective is to promote the use of inventions arising from U.S. Government (USG)-supported research or development, to ensure that the inventor's and USG's rights regarding inventions that are conceived or first actually reduced to practice under a funding agreement (contract, grant, or cooperative agreement) with USAID are protected, and that taxpayers' rights to the technology are protected," www.usaid.gov/policy/ads/, chapter 318 under series 300. To secure these rights, the ADS instructs USAID grantors to ensure "that the patents provision [Regulation 26] is included in grants and cooperative agreements with non-U.S. organizations when applicable." That is, USAID regulations require all funding agreements to include language requiring foreign grantees to secure IP rights. Elsewhere, U.S. AID also details its "capacity building" activities: "Capacity building in IPR is one of the areas in which the ABSP [the agency's Agricultural Biotechnology Support Project] has achieved unique success, and can serve as an effective model for other programs in agricultural biotechnology and development," www.iia.msu.edu/absp/ipr.html

174 Further discussion of the AATF is at *infra* note 200 and accompanying text on page 64. Two other similar mechanisms, PIPRA and PIIPA, were mentioned above, *supra* notes 162 and 163.

175 Oddi, *supra* note 45, at 270. Oddi goes on to cite and quote Grady and Alexander claiming it is appropriate "to be agnostic about whether patent rewards are a good idea" (Mark F. Grady and Jay I.

Alexander, "Patent Law and Rent Dissipation," *Virginia Law Review* 28 (1992), at 309–310, quoted n. 18).

176 George L. Priest, "What Economists Can Tell Lawyers about Intellectual Property," *Research in Law and Economics* 8(19) (1986), quoted n. 20. It is still extraordinarily difficult, if not impossible, to conduct such evaluations on a rigorous, empirical basis. Empirical studies are few, and their methodological problems and the costliness of obtaining necessary data have been widely recognized. R.C. Levin, A.K. Klevorick, R.R. Nelson, and S.G. Winter, "Appropriating the Returns from Industrial Research and Development" (Brookings Papers on Economic Activity, 1987); Wesley M. Cohen, Richard R. Nelson, and John P. Walsh, "Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)" (NBER Working Paper w7552, 2000), papers.nber.org/papers/W7552.

177 Fritz Machlup, *An Economic Review of the Patent System* (Study 15 for the Staff of the Senate Subcommittee on Patents, Trademarks and Copyrights, 1958), at 80, quoted n. 18.

178 Heisey, Srinivasan, and Thirtle, *supra* note 32, at 5, do some evaluation but likewise find little prior data: "To the best of our knowledge, no studies have analyzed the influence of utility patenting on plant breeding." Similarly, Blakeney et al. say, "In evaluating options for IPR protection, we must recognize that virtually no empirical analyses, either sociological or economic, have been done on the impact of IPR on food and agriculture, especially in developing countries" (Michael Blakeney, Joel I. Cohen, and Stephen Crespi, "Intellectual Property Rights and Agricultural Biotechnology," chapter 18 in *Managing Agricultural Biotechnology—Addressing Research Program Needs and Policy Implications*, edited by J.I. Cohen (1999), www.cabi-publishing.org/bookshop/ReadingRoom/0851994008/V_18.pdf).

179 See, for example, Barton, "Patent Breadth and Antitrust: A Rethinking," *supra* note 88. For histories of recent case law from the Court of Appeals for the Federal Circuit, see Margaret Sampson, "The Evolution of the Enablement and Written Description Requirements Under 35 U.S.C. §112 in the Area of Biotechnology" (Berkeley Technology Law Journal, 15(3), 2000); and Janice M. Mueller, "The Evolving Application of the Written Description Requirement to Biotechnological Inventions" (Berkeley Technology Law Journal, 13(2): 615, 1998).

180 We do not address in this study the issues some have raised about the morality of patenting life forms or the ethics of sanctioning, through patents and other legal devices, private ownership and control of the means of production of something as fundamental to human welfare as food. Implicit in our instrumental view of patents, however, is a willingness to accept the patenting of biotechnology, subject to the test of whether it, on balance, advances social welfare.

181 See Lester C. Thurow, "Needed: A New System of Intellectual Property Rights," *Harvard Business Review* 9–10/97 (1997), vision.rc.ukans.edu/SPED997/unit3/thurow.htm; Rebecca S. Eisenberg, "Patents: Help or Hindrance to Technology Transfer," in *Biotechnology: Science, Engineering, and Ethical Challenges for the Twenty-First Century*, edited by Frederick B. Rudolph and Larry V. McIntire (Washington, DC: Joseph Henry Press, 1996); and Eisenberg, Rebecca S., "Analyze This: A Law and Economics Agenda for the Patent System," *Vanderbilt Law Review* 53(6): 2081–2098 (2000).

182 James E. Rogan, "Remarks for Hearings on Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy," www.uspto.gov/web/menu/testspeech.html: "Further, the United States has made it a key part of its trade policy to create international frameworks for recognizing intellectual property rights." PTO, *supra* note 103 at 15 (Highlights): "Many developing countries were also provided technical assistance by the PTO to help them implement their obligations under the Trade Related Aspects of Intellectual Property Agreement (TRIPs)." PTO, *supra* note 103 at 19 (Intellectual Property Leadership): "As the largest intellectual property office in the world, the PTO is at the forefront of developing and strengthening intellectual property protection, both at home and abroad. The Undersecretary and Director is the organization's standard-bearer of intellectual property (IP) rights protection in the global arena, advocating more efficient and cost-effective means of protecting the IP rights of U.S. nationals throughout the world"; at 20: "To protect, promote, and expand intellectual property rights domestically and abroad, the PTO engaged in the following international activities…."

183 See *supra* note 46.

184 United States of America, "The World Food Summit: Five Years Later, Position Paper" (2002), usin fo.state.gov/topical/global/develop/wfsposition00.htm; "President Outlines U.S. Plan to Help World's Poor," Remarks by President Bush at United Nations Financing for Development Conference, Monterrey, Mexico (2002), www.whitehouse.gov/news/releases/2002/03/print/20020322-1.html.

185 The intellectual property needs of developing countries, including their need for flexibility, were discussed in the report of the UK Commission on Intellectual Property Rights, *supra* note 8.

186 See *supra* note 37 and accompanying text on pages 32–33.

187 Mazzoleni and Nelson, *supra* note 52, list five context conditions: (1) Would or could there be incentives to innovate in the absence of patents? (2) Are inventors working on unique, independent things, or are they competing to be the first to discover something they are all working toward? (3) What effect do patents have on unauthorized use and on transactions costs of licensing? (4) Are inventors the right people to bring their inventions to market, or should different organizations perform different parts of the process? (5) Are inventions part of a larger system of technological advance—that is, are there multiple uses for inventions, only some of which the inventor will have an incentive to develop?

188 This concept raises its own issues concerning which developing countries "qualify" for the improved access contemplated by each policy, whether both commercial and subsistence crops should be included, and what constitutes "minimal potential" for export to the United States. These issues, which were discussed but not resolved in Taylor and Cayford, *supra* note 9, will be important to the design of effective and politically viable policies.

189 *Supra* notes 82 to 102 and accompanying text on pages 32–35.

190 Taylor and Cayford, *supra* note 9.

191 A research exemption will likely affect the incentives to invent tools whose primary value is from commercial sale to researchers. At the same time, many of the reasons for a research exemption do not apply to patented inventions if they are readily available for purchase in an anonymous market. See Commission on Intellectual Property Rights, *supra* note 8; National Institutes of Health, *Report of the National Institutes of Health (NIH) Working Group on Research Tools* (1998), www.nih.gov/news/researchtools/; Rebecca S. Eisenberg, "Technology Transfer and the Genome Project: Problems with Patenting Research Tools," *Risk: Health, Safety, and Environment* 5: 163–74 (1994), www.fplc.edu/risk/vol5/spring/Eisenber.htm; Eisenberg, *supra* note 56; Eisenberg, *supra* note 26; Janice M. Mueller, "No 'Dilettante Affair': Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools," *Washington Law Review* 76(1) (2001).

192 U.S. law already has similar provisions in place under the Clean Air Act, to make air pollution prevention inventions available, and under the Atomic Energy Act. See James Love and Michael Palmedo, "Examples of Compulsory Licensing of Intellectual Property in the United States," CPTech Background paper 1 (2001), Chapter IV: Miscellaneous Compulsory Licensing Programs, www.cptech.org/ip/health/cl/us-misc.html.

193 See Section5(A)(4) of the Paris Convention. The TRIPs Agreement requires compliance with the Paris Convention, which was first enacted in 1883 and which permits but does not demand a working requirement. The United States is a signatory of the Paris Convention, but, unlike most other countries, has not adopted a working requirement.

194 This includes ensuring that the technical advice that WIPO provides to developing countries as they implement their TRIPs obligations takes full account of the flexibility provisions of TRIPs so they can be applied appropriately to meet the developing country's particular needs. See Commission on Intellectual Property Rights, *supra* note 8, at 160–161.

195 Ministerial Declaration (WT/MIN (01) DEC/1), Doha WTO Ministerial 2001, 20 November 2001, paragraph 19, www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm.

196 The Commission on Intellectual Property Rights, *supra* note 8, has a thorough discussion of these flexibility options in chapter 6. See "The Design of Patent Systems in Developing Countries," 114–122 (box summary on 122).

197 See "Special and Differential Treatment Provisions: Joint Communication from the African Group in the WTO" (2002), TN/CTD/W/3/Rev.1, docsonline.wto.org.

198 World Trade Organization, Council for Trade-Related Aspects of Intellectual Property Rights, Implementation of Article 66.2 of the TRIPs Agreement: Information from Developed Country Members, Addendum: United States (2003), docs online.wto.org/DDFDocuments/t/IP/C/W388A7.doc.

199 Although Article 66.2 does not explicitly state that the technology that developed countries must encourage their private sectors to transfer should be patented technology, this is implicit in its being an article within TRIPs, which is an agreement about intellectual property. This implication is strongly reinforced in the Doha Declaration on the TRIPs Agreement and Public Health, which created the obligation for developed countries to file reports on their compliance with Article 66.2, and which explicitly reminds countries that "each provision of the TRIPs Agreement shall be read in the light of the object and purpose of the Agreement" (paragraph 5(a), docsonline.wto.org/DDFDocuments/t/WT/min01/DEC2.doc).

200 www.aftechfound.org/index.php.

201 Since there has not yet been a liability suit over biotechnology, it is early to judge the significance of this concern. But there is a plausible analogy with medical biomaterials suppliers, whose liability concerns both have a history and provide an example of legislative relief. See Gary Marchant's presentation in a panel discussion, "Regulatory and Liability Considerations," *Journal of Science & Technology Law*, volume 6, 2000, www.bu.edu/law/scitech/volume6/Panel3.htm. Marchant shows that the long history of common law unambiguously protects materials suppliers from liability for what people do with those materials, as long as the materials meet their own specifications. Companies ("deep pockets") are routinely sued, but rarely if ever lose. Nevertheless, this imposes a considerable burden in legal fees, and Congress gave the industry a variety of relief measures in the Biomaterials Access Assurance Act of 1998.

■ ■ ■

APPENDIX A

The Number and Pattern of Biotechnology Patents

Graff has compiled a unique dataset of agricultural plant biology patents,[a] on which we rely extensively for our analysis of the number and pattern of biotechnology patents. These data, coupled with data reported by the PTO and others, document the following points: a large number of biotechnology-related patents have been issued; they are being issued at an increasing rate; they cover traits, transformation tools, and modified plants, with many patents in each category; and the majority of the patents are in private hands.

The number of biotechnology patents

Graff's dataset of patents granted from 1975 through 1998 comprises 30 categories of "biology-based agricultural technology." Graff used both the U.S. Patent Classification system and the International Patent Classification system to identify candidate patents. He then read each patent to identify ones relating to biology-based agricultural technology. Of Graff's 30 categories (see Table 1, reproduced from the Graff paper), we focus on 23, including specific genetic traits potentially useful in plants; tools used to modify the genome of plants through recombinant DNA techniques and other techniques of modern molecular biology, such as marker-assisted selection (MAS) of desirable gene traits; and the germplasm of plants. The Graff dataset includes patents on other technologies that do not involve genetic modification of plants, such as the use of biological control agents for plant pests and diseases. We exclude these (numbers 1 to 7 in Table 1) from our discussion. (Some of the patents in the Graff dataset cover more than one category of technology. As a result, the 2,428 patents he compiled cover 3,003 inventions across the 30 categories. Of these 3,003 inventions, 2,247 fall in the 23 categories we summarize.)

The increasing rate at which biotechnology patents are being issued

The Graff dataset does not show how the issuance of agricultural biotechnology patents is distributed over time, but the fact that biotechnology patents are being issued at an increasing rate is reflected in PTO reports and in a database of agricultural biotechnology patents granted to universities constructed by Barham et al.[b] A rough picture of the trend in biotechnology-related patents is provided by PTO data on patents issued annually from 1977 through 2000 in the U.S. Patent Classification system classes from which Barham et al. select their data: 435 (Chemistry: Molecular Biology and Microbiology) and 800 (Multicellular Living Organisms and Unmodified Parts Thereof and Related Processes). Not all of the patents granted in these classes involve agri-

TABLE 1.

Patents for Biology-based Agricultural Technologies Granted from 1975 Through 1998, by the Organizational Types of the Patent Assignees

Note: Proportions can sum to more than 1 because single patents can be granted to multiple assignees.

Technology Area	Total Patents	Assigned to University or Public Institution	Assigned to Small Firm, Start-up Firm, or Individual	Assigned to Corporation
Total patents in sample and proportions by organizational type	**2,428**	**645** **0.27**	**893** **0.37**	**955** **0.39**
1 Beneficial microorganisms linked to health and performance of plants: soil bacteria and fungi, nitrogen fixating bacteria	96	34 0.35	43 0.45	22 0.23
2 Behavior of plant insect pests: sex attractants and integrated insect pest management	86	51 0.59	23 0.27	14 0.16
3 Molecular biology, genetics, and genetic modification of plant insect pests	39	31 0.79	3 0.08	5 0.13
4 Biological control of plant pathogens: viruses, microbes, nematodes, fungi	179	66 0.37	53 0.30	66 0.37
5 Bt bioinsecticides and Bt-based biological control of plant insect pests (but not genetic modification of plants)	130	17 0.13	79 0.61	35 0.27
6 Other (not Bt-based) bioinsecticides and biological control of plant insect pests	164	55 0.34	60 0.37	56 0.34
7 Bioherbicides and biological control of weeds	62	39 0.63	16 0.26	10 0.16
8 Plant genetic markers	66	18 0.27	32 0.48	20 0.30
9 Plant genetic transformation vectors and systems: agrobacterium, electroporation, biolistics, viral vectors, etc.	151	45 0.30	67 0.44	50 0.33
10 General plant gene expression: promoters, suppressors	81	25 0.31	29 0.36	27 0.33
11 Controllable or inducible plant gene promoters	108	28 0.26	35 0.32	47 0.44
12 Antisense suppressor technology	37	15 0.41	6 0.16	18 0.49
13 Plant cell, tissue, and embryo culture techniques	73	15 0.21	31 0.42	28 0.38
14 In vitro selection, somaclonal, and gametoclonal variation	57	16 0.28	26 0.46	17 0.30
15 Genetic traits and modification for plant nutrition, metabolism, and growth	64	23 0.36	17 0.27	24 0.38
16 Genetic traits and modification for plant pathogen resistance: virus, microbe, nematode, fungus	166	62 0.37	27 0.16	86 0.52
17 Bt genetic traits and modification for plant insect resistance: Bt only	138	7 0.05	102 0.74	29 0.21
18 Other (not Bt) genetic traits and modification for plant insect resistance	67	20 0.30	27 0.40	28 0.42
19 Genetic traits and modification for plant herbicide tolerance: for all herbicides	122	34 0.28	16 0.13	72 0.59
20 Genetic traits and modification for stress tolerance: drought, salinity, temperature, toxins, soil pH	55	24 0.44	18 0.33	13 0.24

21 Genetic traits and modification for control of plant reproduction: male sterility, female sterility, apomixis, self-incompatibility	97	23 0.24	35 0.36	42 0.43
22 Genetic traits and modification controlling plant amino acid or protein profile	39	12 0.31	14 0.36	15 0.38
23 Genetic traits and modification controlling plant fatty acid or oil profile	92	28 0.30	25 0.27	39 0.42
24 Genetic traits and modification controlling plant carbohydrate (sugar or starch) profile	55	9 0.16	27 0.49	20 0.36
25 Genetic traits and modification controlling plant fruit ripening process, shelf life	44	15 0.34	10 0.23	19 0.43
26 Genetic traits and modification for other quality enhancements: appearance, flavor, fiber structure, solids content, pH level, etc.	61	24 0.39	26 0.43	18 0.30
27 Genetic traits and modification for plant production of biomolecules: enzymes, pharmaceuticals, vaccines, industrial or agricultural biochemicals, nutritionals, flavorings, sweeteners	114	29 0.25	46 0.40	47 0.41
28 Maize germplasm: breeding and hybridization methods, hybrid parental lines, inbred lines, hybrid varieties	298	2 0.01	42 0.14	254 0.85
29 Soybean germplasm: breeding, hybridization, and improvement methods, varieties	117	15 0.13	84 0.72	18 0.15
30 All other germplasm: breeding, hybridization, and improvement methods, plant varieties	145	36 0.25	70 0.48	39 0.27

Source: Gregory Graff, "The Sources of Biological Technologies for Agriculture: Public and Private Innovation and Patenting" (paper presented at the AAEA NC208 Conference on "R&D Policies and Impacts," March 30–31, 2001 at University of California, Berkeley.

cultural or plant biotechnology, but the data show that the number of patents issued per year in these two scientific areas closely related to plant biotechnology has increased since 1981 almost ninefold, from 518 patents in 1981 to 4,561 patents in 2001.[c] In the same time, overall utility patents per year slightly more than doubled.[d]

This trend is corroborated for agriculture specifically by the Barham et al. data, which describe agricultural biotechnology patents issued to universities during a comparable period.[e] The number of agricultural biotechnology patents issued to U.S. universities was about 10 per year in the early 1980s, rising to about 25 per year in the early 1990s. In 1996, the number rose sharply to 78 and grew to 174 in 1999 (see Figure 1).

University Ag-biotech Patent Production by Year

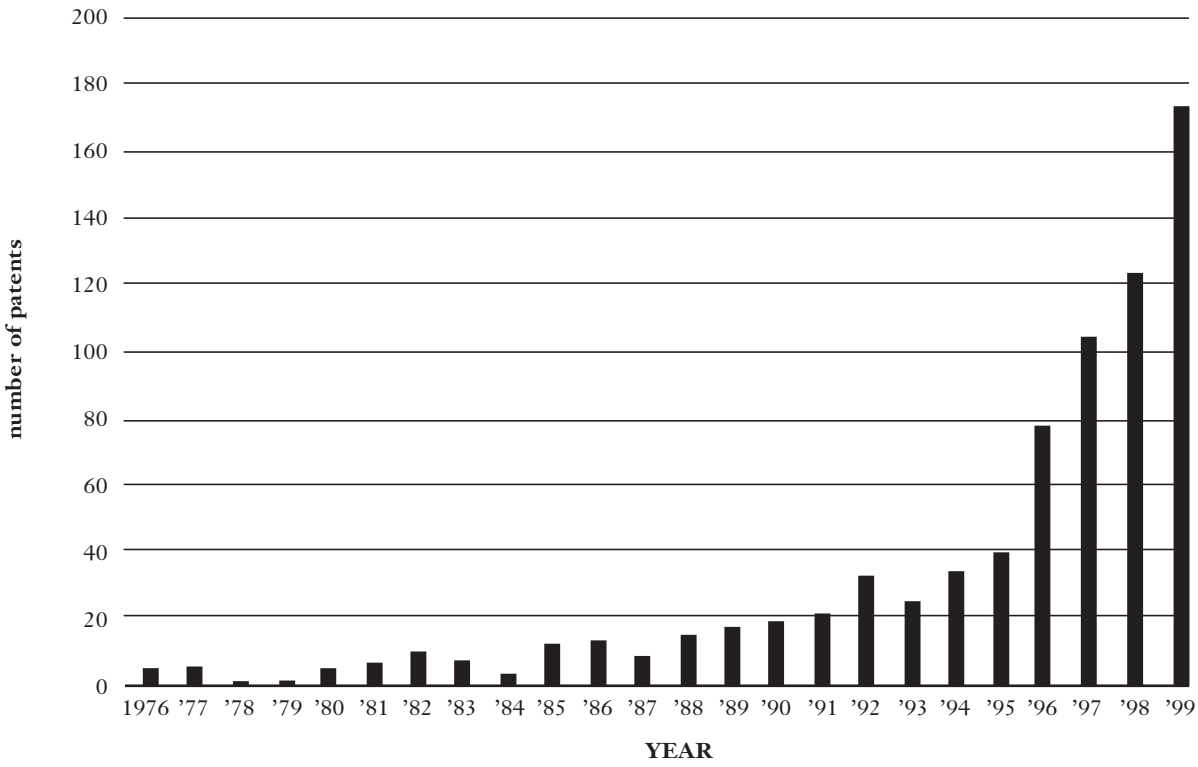
As Barham et al. point out, the number of agricultural biotechnology patents issued to universities in the four years from 1996 through 1999 (481) greatly exceeded the cumulative total of such patents issued in the previous 20 years (314). We assume that the trend is similar for patents assigned to private individuals and corporations, though we have not found an analysis of that trend in the literature.

The distribution of patents among types of technology

The Graff data show the distribution of agricultural biotechnology patents among 30 types of technology. In Table 2, we aggregate the data from the 23 types that fall under three major

FIGURE 1.

University Agricultural Biotechnology Patent Production by Year



Source: Bradford Barham, Jeremy Foltz, and Kwansoo Kim. 2001. Trends in University Ag-Biotech Patent Production. Food Marketing Policy Center, Research Report 58, Figure 1. www.biotech.wisc.edu/seebiotech/raefinalbbkk.pdf

TABLE 2.

Summary of Graff's Data (Table 1) Aggregated to Three Categories

Technology Area	Total Patents	Assigned to University or Public Institution	Assigned to Small Firm, Start-up Firm, or Individual	Assigned to Corporation
Transformation technologies	536	147	220	189
Traits	1,151	325	396	470
Germplasm	560	53	196	311
Totals	**2,247**	**525**	**812**	**970**

Note: Rows can sum to more than total, because single patents can be granted to multiple assignees.

categories of such technologies: genetic traits, transformation tools, and germplasm. Of the 2,247 patents from the Graff dataset issued from 1975 through 1998 and relating to these three categories, 1,151 patents covered a wide variety of genetic traits; 536 patents covered tools used in the transformation and selection of genetically modified plants; and 560 patents covered germplasm for maize (298), soybeans (117), and other plants (145).[f]

The distribution of patents among groups of patent holders

Graff's data show how agricultural biotechnology patents are distributed among three groups of patent holders: universities or other public institutions; individuals and small or start-up firms; and large corporations. Of the 2,247 agricultural biotechnology patents that were issued from 1975 to 1998, 525 were issued or assigned to universities or public institutions; 812 were issued or assigned to small firms or individuals; and 970 were issued or assigned to corporations. These data confirm that most of the agricultural biotechnology patents (79%) are in private hands.

a Graff, *supra* note 28.

b Bradford Barham, Jeremy Foltz and Kwamsoo Kim, "Trends in University Ag-Biotech Patent Production" (Food Marketing Policy Center, Research Report 58, 2001), www.biotech.wisc.edu/seebiotech/raefinalbbkk.pdf.

c See PTO, "Patent Counts by Class by Year: January 1977–December 2001" (2002), www. uspto .gov/web/offices/ac/ido/oeip/taf/cbcby.pdf.

d PTO, "Patent Counts by Country/State and Year, Utility Patents: January 1, 1963–December 31, 2001," www.uspto.gov/web/offices/ac/ido/oeip/taf/cst_utl.pdf. Some of this rapid growth is no doubt due to the newness of biotechnology and the newness of utility patents being allowed on plants.

e Barham, Foltz, and Kim generated data by a method similar to Graff's in that they started with patents issued to universities in the relevant patent classes and then read each patent to identify the agricultural ones.

f The germplasm patents do not all involve genetic modification through rDNA techniques or other techniques of modern molecular biology, but germplasm for food crops is an important part of the technology tool kit for those seeking to develop improved varieties.

APPENDIX B

Expert and Stakeholder Survey

To find out what experts from various institutions thought about the effects of the U.S. patent system on access to biotechnology, we sent the survey below to a diverse group. About 50 people or institutions responded (in September 2001).

To give an idea of the overall results, we aggregate the responses to each question and show them on the survey form. To give an idea of how the answers differed by background, we also aggregate the responses from people in four areas of expertise: agricultural research, U.S. patent system, developing country agriculture, and food security in developing countries. Respondents selected their own areas of experience and could choose more than one, so the total of responses in all four areas is far more than 50.

The Impact of the U.S. Patent System on Developing Country Access to Biotechnology: Expert and Stakeholder Survey

Background and Purpose of the Survey

Resources for the Future (RFF) is conducting a study of (1) how the U.S. patent system affects access to the tools of biotechnology by researchers working on agricultural problems that affect food security in developing countries; and (2) how the patent system could be changed in ways that would continue to encourage innovation while fostering more rapid dissemination of biotechnology to meet developing country agricultural and food security needs.

The study focuses primarily on the legal framework for patents and the activities of the U.S. Patent and Trademark Office (hereafter "PTO") as they affect the issuance and maintenance of patents. Other features of the patent system, such as the way private companies manage their patent estates, may be addressed tangentially, but are not the focus of the study. The work is being directed by RFF Senior Fellow Mike Taylor and funded by the Rockefeller Foundation.

The study is premised on the fact that private investment is yielding important innovation in agricultural biotechnology, which has significant potential to improve developing country agriculture. Companies that develop and own these proprietary technologies have relatively little near-term incentive, however, to apply them commercially to agronomic problems in less developed countries. At the same time, we hypothesize, complex patent estates surrounding genomic information, specific gene traits, and enabling technologies can present obstacles to access by researchers working on developing country problems, such as those in the CGIAR labs and national agricultural research systems, even though as a legal matter patents are enforceable only in the country in which issued. If this is so, researchers working on developing country problems could be substantially delayed by the patent system in obtaining the potential benefits of biotechnology.

This survey instrument is designed to gather input for our study from a diverse group of experts and stakeholders on (1) the extent to which the workings of the U.S. patent system in issuing and maintaining patents affect fair and timely access to the tools of biotechnology by researchers working on developing country problems, and in what manner; and (2) possible changes in patent law and in the policies and procedures of the PTO that would improve access. The survey seeks perspectives on these questions that go beyond what is readily available in the literature, including specific examples of the patent system's impact on access, which features of the system have the most significant impact, and priorities for possible change. To lay the foundation for analyzing the impact of the patent system on developing country-related access, this questionnaire also solicits views on what the specific access needs are and the criteria by which one could judge whether access is being obtained on a "fair and timely" basis.

How to Complete and Return This Survey

The recipients of this survey all have substantial expertise and demonstrated interest in various aspects of the patent system, biotechnology, agricultural research, the problems of developing country agriculture, and the challenge of building sustainable food security in developing countries. We recognize, however, that individual recipients will feel more expert about some of the questions than others. Since we would rather hear your perspectives and opinions than not, we provide boxes for you to indicate when you feel less confident answering. We encourage you to answer each question anyway, if at all possible, based on whatever knowledge, experience, and personal perspective you can bring to bear. We will take the diverse backgrounds of the survey recipients into account in our analysis of the responses we receive.

Your answers on this survey are confidential. We plan to use the information to inform and guide our research. We may publish aggregated results from the survey or individual comments, but you will not be identified as the author of a comment without your express permission.

You will need to save the survey on your computer (that is, work on a saved copy, not the copy attached to our email message). You may then type directly on the electronic version of the survey. The spaces provided for lengthier answers should expand to accommodate however much text you insert. Once you have completed the survey, please attach it to an email and send it to cayford@rff.org. Alternatively, you may print the survey, write on it (feel free to use the back, or supplementary pages), and mail it to Jerry Cayford, Resources for the Future, 1616 P Street NW, Washington, DC 20036.

We would appreciate your response to the survey as soon as convenient. Thank you very much for your help.

PERSONAL INFORMATION (CONFIDENTIAL):

Date: _____

Name: _____

Position: _____

Area(s) of expertise: _____

27 Agricultural research

20 Plant breeder technology

21 Molecular biology/biotechnology

19 Biotechnology patenting
11 U.S. patent system
20 International patent issues
27 Developing country agriculture
22 Developing country technology needs
17 Economic and agricultural development
19 Food security in developing countries

[The areas of expertise are aggregated below into four areas: agricultural research (AgRes), U.S. patent system (USPat), developing country agriculture (DevAg), and food security in developing countries (FdSec).]

Developing Country Biotechnology Access Needs

1. What degree of importance do you place on access to the tools of biotechnology by researchers working on developing country agricultural problems? Mark one:

Total	AgRes	USPat	DevAg	FdSec	
28	16	5	17	11	Very high
9	5	4	4	2	High
8	4	2	4	4	Medium
2	2		2	2	Low
					Not important
4.34	4.30	4.27	4.33	4.16	Average (very high = 5)

Other comments (optional):
Less confident answering this question: 4

2. For which categories of biotechnology tools is access for developing country purposes most important? Please rate the importance of access to the tools listed below and others you consider important, using high, medium, or low (H, M, L).

☐ Less confident answering this question.

a = average, where low is 1, and high is 3; cnt = count; nc = not confident.

Total nc=8	AgRes nc=3	USPat nc=2	DevAg nc=4	FdSec nc=5	
L=10	L=6	L=2	L=9	L=6	Expressed sequence tags (ESTs)
M=15	M=11	M=4	M=9	M=6	
H=13	H=7	H=2	H=8	H=4	
a=2.08	a=2.04	a=2.00	a=1.96	a=1.875	
cnt=38	cnt=24	cnt=8	cnt=26	cnt=16	
L=14	L=12	L=1	L=10	L=6	Complete genome sequence data on key plant species
M=13	M=7	M=4	M=10	M=7	
H=12	H=5	H=3	H=6	H=3	
a=1.95	a=1.71	a=2.25	a=1.85	a=1.81	
cnt=39	cnt=24	cnt=8	cnt=26	cnt=16	

L=1 M=6 H=33 a=2.80 cnt=40	L=1 M=4 H=20 a=2.76 cnt=25	L=0 M=1 H=7 a=2.88 cnt=8	L=1 M=5 H=20 a=2.73 cnt=26	L=1 M=4 H=12 a=2.65 cnt=17	Specific gene traits
L=1 M=10 H=28 a=2.69 cnt=39	L=1 M=6 H=17 a=2.67 cnt=24	L=0 M=2 H=6 a=2.75 cnt=8	L=1 M=7 H=18 a=2.65 cnt=26	L=1 M=6 H=9 a=2.50 cnt=16	Transformation tools
L=2 M=13 H=24 a=2.56 cnt=39	L=2 M=7 H=15 a=2.54 cnt=24	L=0 M=3 H=5 a=2.63 cnt=8	L=2 M=7 H=17 a=2.58 cnt=26	L=2 M=5 H=9 a=2.44 cnt=16	Transformation marker systems
L=2 M=9 H=26 a=2.65 cnt=37	L=1 M=4 H=17 a=2.73 cnt=22	L=0 M=3 H=5 a=2.63 cnt=8	L=1 M=5 H=18 a=2.71 cnt=24	L=0 M=4 H=11 a=2.73 cnt=15	Genetically modified germplasm for specific useful plants
Other (brief description below)					

3. Although U.S. patents are legally enforceable only in the United States, some believe that the U.S. patent system affects access to the tools of biotechnology by researchers working on developing country agricultural problems not only in the United States, but also in other countries. For each example provided in question 2, please indicate (yes or no) whether you believe the U.S. patent system and the existence of U.S. patents is adversely affecting the ability of researchers to access and use the technologies for developing country purposes.

□ Less confident answering this question.

nc = not confident.

Total nc=12	**AgRes nc=6**	**USPat nc=2**	**DevAg nc=6**	**FdSec nc=6**	
No=17 Yes=15	No=12 Yes=8	No=4 Yes=3	No=11 Yes=9	No=4 Yes=7	Expressed sequence tags (ESTs)
No=20 Yes=13	No=12 Yes=8	No=5 Yes=2	No=12 Yes=9	No=5 Yes=7	Genome sequence data on key plant species
No=7 Yes=28	No=6 Yes=14	No=3 Yes=4	No=5 Yes=18	No=4 Yes=9	Specific gene traits
No=13 Yes=23	No=11 Yes=10	No=3 Yes=4	No=10 Yes=13	No=6 Yes=8	Transformation tools
No=11 Yes=25	No=9 Yes=12	No=2 Yes=5	No=9 Yes=14	No=5 Yes=9	Transformation marker systems
No=8 Yes=26	No=7 Yes=12	No=2 Yes=5	No=7 Yes=15	No=4 Yes=9	Genetically modified germplasm for specific useful plants
No=2 Yes=8					Other (brief description below)

4. For any "yes" answers in question 3, please explain briefly how you believe the U.S. patent system is adversely affecting access to and use of the technology for developing country purposes. If possible, please provide specific information on the technology and the features of the patent system affecting access.

Less confident answering this question: 8

Principles and Criteria for Fair and Timely Access

5. The broad goal of the U.S. patent system is to foster technological progress ("To promote the progress of . . . useful arts"). In light of this goal and the potential role of technology in improving food security in developing countries, what principles and criteria do you believe are relevant and appropriate in defining "fair and timely" access to the tools of biotechnology by researchers working on developing country problems?

Please indicate—in the space to the left—your agreement or disagreement with the statements below on a scale of 1 to 5 (from "strongly agree" to "strongly disagree").

□ Less confident answering this question.

1 = strongly agree, 2 = agree, 3 = neutral, 4 = disagree, 5 = strongly disagree; nc = not confident.

Total nc=1	**AgRes nc=0**	**USPat nc=0**	**DevAg nc=0**	**FdSec nc=0**	
3.40 (64% 4 or 5) cnt=45	3.31 (65% 4 or 5) cnt=26	2.20 (60% 1 or 2) cnt=10	3.58 (73% 4 or 5) cnt=26	3.72 (72% 4 or 5) cnt=18	Access is fair and timely if researchers working on developing country problems have access to biotechnology through the same licensing and commercial channels as any other researcher, with no special provisions in the patent system to foster access.
2.18 (73% 1or2) cnt=44	2.04 (76% 1or2) cnt=25	3.20 (40% 4or5) cnt=10	1.84 (84% 1or2) cnt=25	2.06 (76% 1or2) cnt=17	Researchers working on developing country problems should gain access to tools of biotechnology as the tools are developed, at roughly the same time as commercial researchers, even if this means making some special provisions in the patent system to foster such access.
2.25 (66% 1or2) cnt=44	2.04 (73% 1or2) cnt=26	3.10 (30% 4or5) cnt=10	2.19 (69% 1or2) cnt=26	2.18 (71% 1or2) cnt=17	The potential benefits of biotechnology in meeting food security needs in developing countries are relevant to judging whether access is "fair and timely" and justify some special provisions to ensure such access.
2.38 (64% 1or2) cnt=45	2.12 (72% 1or2) cnt=25	3.10 (30% 4or5) cnt=10	2.42 (65% 1or2) cnt=26	2.56 (61% 1or2) cnt=18	Any special provisions in the U.S. patent system to foster "fair and timely" access by researchers working on developing country problems should be conditioned on use of the technology to meet defined developing country needs, such as improvement of subsistence crops, specified agronomic issues, or other specific needs related to food security.

2.82 (51% 1or2) cnt=45	2.65 (58% 1or2) cnt=26	2.80 (50% 1or2) cnt=10	2.63 (59% 1or2) cnt=27	3.11 (42% 1or2) cnt=19	Any special provisions in the U.S. patent system to foster access to the tools of biotechnology by researchers working on developing country problems should be tied to conditions that protect the investment and commercial interests of inventors and technology owners, such as restrictions on the crops or countries in which the technology could be applied.
2.89 (42% 1or2) cnt=46	3.04 (38% 4or5) cnt=26	3.33 (58% 4or5) cnt=12	2.96 (37% 1or2) cnt=27	2.58 (53% 1or2) cnt=19	"Fair and timely" access to the tools of biotechnology for developing country purposes requires changes in the standards for patentability so that fewer tools are patented.
2.38 (67% 1or2) cnt=46	2.35 (65% 1or2) cnt=26	3.36 (45% 4or5) cnt=11	2.22 (70% 1or2) cnt=27	2.26 (68% 1or2) cnt=19	"Fair and timely" access to the tools of biotechnology for developing country purposes requires changes in the standards for patentability so that patents are less broad.
2.35 (69% 1or2) cnt=45	2.46 (65% 1or2) cnt=26	3.50 (60% 4or5) cnt=10	2.27 (73% 1or2) cnt=26	2.28 (78% 1or2) cnt=18	"Fair and timely" access requires that researchers working on developing country problems be able to use patented tools without the time and expense of negotiating individual licenses.
2.40 (58% 1or2) cnt=45	2.42 (58% 1or2) cnt=26	2.91 (45% 1or2) cnt=11	2.35 (58% 1or2) cnt=26	1.95 (79% 1or2) cnt=19	"Fair and timely" access requires that researchers working on developing country problems be able to use patented tools without the expense of paying royalties.
1.71 (76% 1or2) cnt=42	1.56 (84% 1or2) cnt=25	2.10 (50% 1or2) cnt=10	1.52 (84% 1or2) cnt=25	1.50 (89% 1or2) cnt=18	"Fair and timely" access means that researchers working on developing country problems are not precluded by patents or the patent system from full use of germplasm that is indigenous to or was developed noncommercially in the country or region in which they work.

Other principles or criteria you think are relevant for defining and judging "fair and timely" access (please specify):

Features of the Patent System Affecting Access

6. As a general matter, which features of the U.S. patent system do you believe are having or could potentially have the greatest impact on access to biotechnology by researchers working on developing country problems? Please rate the importance of the features below, using high, medium, or low (H, M, L).

☐ Less confident answering this question.

a = average, where low is 1, and high is 3; cnt = count; nc = not confident.

Total nc=17	**AgRes nc=11**	**USPat nc=1**	**DevAg nc=12**	**FdSec nc=9**	
L=4 M=3 H=30 a=2.70 cnt=37	L=3 M=1 H=17 a=2.67 cnt=21	L=1 M=2 H=7 a=2.60 cnt=10	L=2 M=0 H=19 a=2.81 cnt=21	L=2 M=0 H=13 a=2.73 cnt=15	Scope of patentability
L=18 M=11 H=8 a=1.83 cnt=35	L=10 M=6 H=5 a=1.76 cnt=21	L=9 M=1 H=0 a=1.10 cnt=10	L=8 M=8 H=5 a=1.86 cnt=21	L=6 M=5 H=3 a=1.79 cnt=14	Priority of inventorship rules
L=12 M=12 H=11 a=1.97 cnt=35	L=7 M=6 H=8 a=2.05 cnt=21	L=5 M=2 H=3 a=1.80 cnt=10	L=6 M=7 H=7 a=2.05 cnt=20	L=3 M=5 H=6 a=2.21 cnt=14	Adequacy of written description and enabling disclosure in patents
L=8 M=18 H=9 a=2.03 cnt=35	L=6 M=9 H=6 a=2.00 cnt=21	L=5 M=4 H=1 a=1.60 cnt=10	L=5 M=10 H=5 a=2.00 cnt=20	L=5 M=7 H=2 a=1.79 cnt=14	Difficulty of patent reexamination process at the U.S. PTO
L=7 M=8 H=22 a=2.41 cnt=37	L=6 M=5 H=10 a=2.19 cnt=21	L=2 M=3 H=5 a=2.30 cnt=10	L=5 M=4 H=12 a=2.33 cnt=21	L=4 M=8 H=3 a=2.27 cnt=15	Expense and difficulty of challenging patents in infringement cases

L=6 M=5 H=26 a=2.54 cnt=37	L=6 M=2 H=13 a=2.33 cnt=21	L=3 M=1 H=6 a=2.30 cnt=10	L=4 M=3 H=14 a=2.48 cnt=21	L=5 M=2 H=8 a=2.20 cnt=15	Risk and expense of defending use of a technology in an infringement case
L=0 M=2 H=31 a=2.94 cnt=33	L=0 M=6 H=15 a=2.71 cnt=21	L=0 M=2 H=8 a=2.80 cnt=10	L=0 M=5 H=16 a=2.76 cnt=21	L=0 M=3 H=12 a=2.80 cnt=15	Multiplicity of patents and patent owners affecting product development
L=3 M=12 H=20 a=2.49 cnt=35	L=2 M=6 H=13 a=2.52 cnt=21	L=1 M=3 H=5 a=2.44 cnt=9	L=2 M=8 H=11 a=2.43 cnt=21	L=1 M=6 H=7 a=2.43 cnt=14	Licensing practices of patent holders
L=1 M=8 H=25 a=2.71 cnt=34	L=1 M=7 H=12 a=2.55 cnt=20	L=0 M=4 H=6 a=2.60 cnt=10	L=1 M=5 H=15 a=2.67 cnt=21	L=0 M=5 H=9 a=2.64 cnt=14	Impact of broad blocking patents
L=8 M=11 H=17 a=2.25 cnt=36	L=6 M=6 H=9 a=2.14 cnt=21	L=1 M=2 H=7 a=2.60 cnt=10	L=4 M=7 H=10 a=2.29 cnt=21	L=2 M=5 H=7 a=2.36 cnt=14	Scope of the research exemption
Other (please specify below)					

7. With regard to the scope of patentability, which elements of patent law and policy have the greatest impact on access to the tools of biotechnology by researchers working on developing country problems? Please rate the importance of the elements below, using high, medium, or low (H, M, L).

☐ Less confident answering this question.

a = average, where low is 1, and high is 3; cnt = count; nc = not confident.

Total nc=15	**AgRes nc=10**	**USPat nc=1**	**DevAg nc=11**	**FdSec nc=9**	
L=9	L=5	L=5	L=4	L=2	Patentability of plants
M=8	M=2	M=3	M=4	M=4	
H=21	H=13	H=3	H=13	H=9	
a=2.32	a=2.40	a=1.82	a=2.43	a=2.47	
cnt=38	cnt=20	cnt=11	cnt=21	cnt=15	
L=11	L=6	L=7	L=3	L=3	Application of the novelty requirement
M=13	M=8	M=3	M=9	M=6	
H=12	H=6	H=1	H=9	H=4	
a=2.03	a=2.00	a=1.45	a=2.29	a=2.08	
cnt=36	cnt=20	cnt=11	cnt=21	cnt=13	
L=10	L=6	L=5	L=5	L=4	Application of the utility requirement
M=14	M=10	M=2	M=11	M=7	
H=12	H=4	H=4	H=5	H=2	
a=2.06	a=1.90	a=1.91	a=2.00	a=1.87	
cnt=36	cnt=20	cnt=11	cnt=21	cnt=13	
L=12	L=8	L=5	L=6	L=4	Application of the nonobviousness requirement
M=15	M=10	M=3	M=12	M=7	
H=8	H=2	H=3	H=3	H=2	
a=1.89	a=1.70	a=1.82	a=1.86	a=1.87	
cnt=35	cnt=20	cnt=11	cnt=21	cnt=13	
L=3	L=3	L=1	L=2	L=2	Breadth of claims allowed
M=7	M=4	M=3	M=3	M=1	
H=26	H=13	H=7	H=16	H=11	
a=2.64	a=2.50	a=2.55	a=2.67	a=2.64	
cnt=36	cnt=20	cnt=11	cnt=21	cnt=14	

Other (please specify below)

8. We would like to learn your views of the role that the U.S. PTO plays in implementing the patent laws of the United States. Please indicate—in the space to the left—your agreement or disagreement with each of the following statements about the PTO. Use a scale of 1 to 5 ("strongly agree" to "strongly disagree").

□ Less confident answering this question.

1 = strongly agree, 2 = agree, 3 = neutral, 4 = disagree, 5 = strongly disagree; cnt = count; nc = not confident

Total nc=16	**AgRes nc=8**	**USPat nc=1**	**DevAg nc=11**	**FdSec nc=10**	
3.05 (38% 4or5) cnt=42	2.83 (38% 1or2) cnt=24	2.18 (64% 1or2) cnt=11	3.21 (46% 4or5) cnt=24	3.31 (56% 4or5) cnt=16	The PTO has implemented the patent law with respect to agricultural biotechnology generally as the law intends.
3.07 (39% 4or5) cnt=41	3.04 (38% 4or5) cnt=24	3.91 (73% 4or5) cnt=11	3.00 (%) cnt=24	2.81 (50% 1or2) cnt=16	The PTO has gone beyond what the law intends and has issued too many patents relating to agricultural biotechnology.
2.31 (68% 1or2) cnt=43	2.33 (71% 1or2) cnt=24	2.58 (58% 1or2) cnt=12	2.20 (72% 1or2) cnt=25	2.24 (76% 1or2) cnt=17	The PTO has gone beyond what the law intends and has issued patents relating to agricultural biotechnology that are too broad.
3.18 (44% 4or5) cnt=42	3.25 (50% 4or5) cnt=24	2.83 (50% 1or2) cnt=12	3.28 (48% 4or5) cnt=25	3.59 (59% 4or5) cnt=17	The PTO has the expertise it needs to understand and rigorously evaluate biotechnology-related patent applications.
3.38 (52% 4or5) cnt=42	3.42 (54% 4or5) cnt=24	3.33 (58% 4or5) cnt=12	3.28 (48% 4or5) cnt=25	3.29 (53% 4or5) cnt=17	The PTO has the quantity of staff resources it needs to rigorously evaluate biotechnology-related patent applications.
2.75 (48% 1or2) cnt=40	2.64 (50% 1or2) cnt=22	2.45 (55% 1or2) cnt=11	2.54 (54% 1or2) cnt=24	2.82 (47% 1or2) cnt=17	For patent applicants, the patent process is predictable and transparent, in terms of having access to information about the operation of the system and appropriate opportunity to provide input on decisions.

3.61 (61% 4or5) cnt=38	3.32 (55% 4or5) cnt=22	4.00 (67% 4or5) cnt=9	3.42 (54% 4or5) cnt=24	3.82 (76% 4or5) cnt=17	For nonapplicants, the patent process is predictable and transparent, in terms of having access to information about the operation of the system and appropriate opportunity to provide input on decisions.
2.36 (57% 1or2) cnt=42	2.63 (42% 1or2) cnt=24	2.17 (67% 1or2) cnt=12	2.40 (52% 1or2) cnt=25	2.12 (71% 1or2) cnt=17	The PTO considers its customers to be patent applicants.
3.35 (46% 4or5) cnt=41	2.83 (38% 1or2) cnt=24	3.09 (45% 4or5) cnt=11	3.20 (40% 4or5) cnt=25	3.41 (53% 4or5) cnt=17	The PTO considers its customers to be those who can potentially benefit from new technology.
2.37 (63% 1or2) cnt=41	2.46 (54% 1or2) cnt=24	2.73 (55% 1or2) cnt=11	2.20 (64% 1or2) cnt=25	2.18 (71% 1or2) cnt=17	The PTO sees its role as protecting the economic interests of inventors.
3.27 (44% 4or5) cnt=41	2.88 (33% 1or2) cnt=24	3.09 (45% 4or5) cnt=11	3.16 (40% 4or5) cnt=25	3.29 (53% 4or5) cnt=17	In making policy decisions regarding implementation of the patent laws, the PTO takes into account the overall impact of the patent system on fostering technological progress.

Other impressions of the PTO that you consider relevant to the issue of access to biotechnology by researchers working on developing country problems (briefly describe):

9. We would like to learn your views of relations between the U.S. PTO, the courts, and the Congress. Please indicate—in the space to the left—your agreement or disagreement with each of the following statements. Use a scale of 1 to 5 ("strongly agree" to "strongly disagree").

☐ Less confident answering this question.

1 = strongly agree, 2 = agree, 3 = neutral, 4 = disagree, 5 = strongly disagree; cnt = count; nc = not confident

Total nc=20	**AgRes nc=12**	**USPat nc=1**	**DevAg nc=15**	**FdSec nc=11**	
2.75 (44% 1or2) cnt=32	2.68 (47% 1or2) cnt=19	2.10 (70% 1or2) cnt=10	2.82 (41% 1or2) cnt=17	3.15 (38% 4or5) cnt=13	The PTO straightforwardly and accurately implements the law as written by Congress and interpreted by the courts.
2.97 (31% 1or2) cnt=32	3.22 (44% 4or5) cnt=18	3.27 (45% 4or5) cnt=11	3.06 (31% 4or5) cnt=16	2.83 (42% 1or2) cnt=12	The PTO, whether because of budget and time constraints or differing interpretations or any other reason, does not implement the law as intended.
3.07 (17% 4or5) cnt=29	2.89 (22% 1or2) cnt=18	3.11 (22% 4or5) cnt=9	2.94 (19% 1or2) cnt=16	2.91 (27% 1or2) cnt=11	The courts' interpretations of patent law with respect to biotechnology correctly reflect what Congress intended.
2.67 (47% 1or2) cnt=30	3.00 (%) cnt=18	3.22 (44% 4or5) cnt=9	2.81 (44% 1or2) cnt=16	2.67 (50% 1or2) cnt=12	The courts have generally broadened the scope of patentability in biotechnology beyond what Congress intended.
3.69 (62% 4or5) cnt=39	3.53 (53% 4or5) cnt=17	3.89 (67% 4or5) cnt=9	3.60 (60% 4or5) cnt=15	4.00 (75% 4or5) cnt=12	The courts have generally narrowed the scope of patentability in biotechnology from what Congress intended.
2.98 (37% 1or2) cnt=31	2.67 (50% 1or2) cnt=18	2.30 (70% 1or2) cnt=10	3.00 (56% 4or5) cnt=16	3.33 (67% 4or5) cnt=12	The patent system as a whole is working and producing the results Congress intended.
2.84 (50% 1or2) cnt=32	2.78 (56% 1or2) cnt=18	3.73 (73% 4or5) cnt=11	2.56 (63% 1or2) cnt=16	2.42 (75% 1or2) cnt=12	Practical realities or changes in science have caused patent law not to function as intended.

Please comment on any of these ideas or any other impressions you have of the interrelations among the parts of the patent system.

Options for Change to Improve Developing Country Access

10. If the goal is to improve developing country access to the tools of biotechnology by changing how the patent system works in practice, where should the effort be focused? Please indicate importance in the space provided, using high, medium, or low (H, M, L).

☐ Less confident answering this question.

a = average, where low is 1, and high is 3; cnt = count; nc = not confident.

Total nc=9	**AgRes nc=4**	**USPat nc=1**	**DevAg nc=7**	**FdSec nc=4**	
L=15 M=6 H=19 a=2.10 cnt=40	L=10 M=3 H=8 a=1.90 cnt=21	L=7 M=1 H=3 a=1.64 cnt=11	L=7 M=5 H=10 a=2.14 cnt=22	L=7 M=2 H=7 a=2.00 cnt=16	Revising the patent laws to change the standards for patentability
L=17 M=12 H=12 a=1.88 cnt=41	L=9 M=8 H=5 a=1.82 cnt=22	L=10 M=0 H=1 a=1.18 cnt=11	L=6 M=11 H=6 a=2.00 cnt=23	L=4 M=7 H=5 a=2.06 cnt=16	Revising the patent laws to change procedural aspects of the patenting process
L=6 M=10 H=24 a=2.45 cnt=40	L=4 M=7 H=11 a=2.32 cnt=22	L=3 M=1 H=7 a=2.36 cnt=11	L=4 M=6 H=13 a=2.39 cnt=23	L=3 M=5 H=7 a=2.27 cnt=15	Revising the patent laws to change postpatent rules affecting the scope of the research exemption
L=11 M=9 H=19 a=2.21 cnt=39	L=5 M=7 H=9 a=2.19 cnt=21	L=6 M=2 H=3 a=1.73 cnt=11	L=5 M=6 H=12 a=2.30 cnt=23	L=4 M=3 H=8 a=2.27 cnt=15	Revising the patent laws to change postpatent rules affecting the standards and procedures for patent reexaminations and challenges
L=8 M=10 H=20 a=2.32 cnt=38	L=5 M=5 H=10 a=2.25 cnt=20	L=6 M=1 H=3 a=1.70 cnt=10	L=3 M=7 H=12 a=2.41 cnt=22	L=3 M=3 H=10 a=2.44 cnt=16	Changing PTO policies and practices that affect what gets patented

L=15	L=10	L=7	L=8	L=6	Changing PTO policies and procedures concerning the patenting process
M=11	M=4	M=1	M=8	M=5	
H=12	H=6	H=2	H=6	H=5	
a=1.92	a=1.80	a=1.50	a=1.91	a=1.94	
cnt=38	cnt=20	cnt=10	cnt=22	cnt=16	
L=12	L=7	L=7	L=5	L=4	Changing PTO policies and procedures on postpatent issues
M=10	M=6	M=1	M=8	M=5	
H=16	H=8	H=3	H=9	H=6	
a=2.11	a=2.05	a=1.64	a=2.18	a=2.13	
cnt=38	cnt=21	cnt=11	cnt=22	cnt=15	
L=8	L=7	L=2	L=7	L=4	Changing the licensing and other postpatent practices of patent holders
M=6	M=3	M=0	M=4	M=3	
H=23	H=11	H=7	H=11	H=9	
a=2.41	a=2.19	a=2.56	a=2.18	a=2.31	
cnt=37	cnt=21	cnt=9	cnt=22	cnt=16	
Other areas of focus (please specify below)					

11. What specific changes in the patent system do you believe should be adopted? Please list below in approximate order of priority.

[All the suggested changes, ranked according to the respondent's priorities, are listed below, with asterisks indicating each new respondent.]

* 1. Stricter 103 requirement. Bring back Justice Douglas.

* 1. For patents involving germplasm, the research exemption should be revised.

* 1. Reduce the breadth of the claims of patents.

2. Recognize publications in other countries and traditional knowledge when considering the "novelty" requirement and priority of inventorship.

3. Make the disclosure of the origin and mode of access of biological material used in discoveries compulsory.

4. Include specific measures to facilitate access for developing country purposes.

* 1. Ease the cost of filing on LDC applicants from the public sector.

2. Improve the reexamination process to make it more equitable.

* 1. Fund more examiners in order to help the PTO maintain a qualified cadre of experts.

2. Provide the PTO with an up-to-date, functional, prior-art database and searching system.

* 1. Scope of protection.

2. Strict respect of utility criteria. (As indicated in the new guidelines).

* 1. Adoption of the African Group position in the WTO TRIPs negotiations.

2. No patents on life, including plants, plant varieties, animals, microorganisms, any living material, biological processes, etc., regardless of whether an innovative step has been taken altering its biological material or processes.

3. Strict disincentives to bio-piracy.

4. Flexible standards for prior art; full respect for the a priori rights of farmers, indigenous peoples, and local communities, including the right to prior informed consent.

* 1. Much higher demands regarding what is an innovative step.

2. Obligation to reveal origin of genetic material/information including prior informed consent (i.e., under CBD article 15, etc.).

3. Reduce scope of protection.

4. Differentiate time for protection depending on importance for public domain, morality and *ordre public*.

Patent on Enola bean pollen is an obvious almost insane protection.

5. Introduce compulsory requirements on prior art examination in patent law, especially when it comes to use of traditional/indigenous knowledge (under CBD article 8j).

* 1. Avoid issuing of broad scope patents. Claims should be described in structural, rather than functional, terms.

2. Apply a higher 'non-obviousness' standard for genetically engineered plants.

3. Patenting of genes (or sequences) at cell levels should not be allowed.

* 1. Scope is too broad.

2. European system is superior as it discloses information upon patent filing.

3. Reexamination process is very complex, if not impossible to revoke an unfair patent.

* 1. More stringent examination before issuing very broad patent claims.

1. Narrow the scope on claims that can be made when patenting. (My impression is that this may already be happening.)

2. Require the developer to demonstrate utility of the technology, as opposed to the current apparent situation of granting patents for ESTs, for example, for which no utility has been demonstrated.

3. Place greater emphasis on the non-obviousness criterion for patenting. Granting a patent on a gene just because it has been sequenced does not seem to fulfill any of the standards of novelty, usefulness, or non-obviousness, but especially neglects the criterion of non-obviousness.

4. Expedite the post-patent review process to respond to and sort out challenges.

* 1. I believe that patent holders have a collective responsibility to the developing world to share the wealth created by science to improve the lot of those people who are less fortunate than we are. At a meeting organized by CS Prakash at the World Food Prize Conference in Iowa last year, a number of company representatives who were present agreed with this principle and said they were interested in finding ways to implement it. Perhaps tax credits could be used as an incentive.

2. Filing patents has become very expensive and for many in the public sector it is something they can no longer afford. Simplification of those application procedures that require the expertise of specialist attorneys is needed.

3. The system should provide some help and arbitration in the use of patented IP, which would help in reaching agreements that do not disadvantage developing countries.

* 1. Elimination of patents for ESTs.

2. Making sure of the use/effects of patented portions of genes/genome.

3. Avoiding overly large/broad coverage of a patent, e.g., yellow bean case.

* 1. Do not give patents to unraveled natural DNA sequences, genes, and genomes.

2. Do not give patents to unraveled natural symbiotic systems, such as involving endosymbiotic microorganisms associated with plants.

* 1. Reduce the scope of patents.

2. Increase the breadth of the research exemption.

3. Overturn *Diamond v. Chakrabarty*.

* 1. Broader research exemption; make statutory (currently a judicial doctrine).

2. Utility standard—clarify; require functional data.

3. Written description standard—clarify; do not permit a laundry list.

* 1. Compulsory licenses.

2. Research exemption.

3. Refine utility standard.

4. Regulate licensing practices.

* 1. Revise patent laws to change post-patent rules affecting scope of research exemption.

* 1. Open genome access.

2. Reexamine the rate of technological change and obsolescence as relates to patent life.

* 1. Narrower interpretation of biotech claims.

2. Require a certificate (or equivalent) of source for plant patents.

3. Strict application of utility requirement. (Provide a 'non-obviousness' sort of requirement for utility. Even if the invention as a whole is not obvious, would it be obvious to use the invention as described.)

* 1. As already noted, patent holders should be willing to provide free access to developing countries in which there is little likelihood of a commercial market, and do so as a matter of course, rather than on an occasional ad hoc basis.

* 1. Focus the patenting consequences on commercial application and create the opportunity for free humanitarian application.

* 1. Narrow the scope of patentable subject matter.

2. Raise the standard of non-obviousness.

3. Provide an effective opposition process.

4. Strengthen the utility standard; broaden the research exemption.

* 1. There should be an automatic provision to use protected technology for research purposes only.

2. There should be a provision to permit fair and timely access of researchers working on developing country problems, with an obligation on patent holders to fair licensing of the proprietary technology.

3. Fair licensing should be adopted as a general principle in patent law and be explicit with respect to what this principle intends to promote and what it does not intend to cover.

4. Broadness of patents should be discouraged by providing easier reexamination conditions or changing infringement rules.

* 1. Operationalization of articles 7 and 8 of TRIPs.

2. A genuine implementation of technology transfer obligations under international treaties such as TRIPs and the likely text of the FAO International Undertaking.

3. A comprehensive, and internationally inclusive, review of PTO interpretations of its role and the legislation and regulations under which it operates. A precedent for this might be the recent creation of an IPR Commission by the UK government.

4. A review of the application of patents and plant breeders' rights, and perhaps even other forms of IPR, in agriculture in general to assess whether they are achieving their intended goals, and if not to develop proposals for change. This should be looked at broadly including socio-economic considerations and environmental/technical questions such as impacts on agrobiodiversity.

5. A recognition that the U.S. Trade Representative and the State Department should leave patent issues to the PTO, and a general delinking of U.S. policy on IPRs from other issues not concerned with the encouragement of innovation, such as access to the U.S. textiles market.

* 1. Limit scope of patentability to a more reasoned one.

2. Limit what is patentable.

* 1. Scope of research exemption.

2. Early publication.

* 1. Allow third parties to oppose patents in the process of the application.

2. Not leaving all the conflicts to be solved by a judicial system extremely expensive and inaccessible for people from the third world.

* 1. The presumption of patentability should be reversed.

2. Taking into account non-patent applicant, third-party concerns.

3. A research exemption.

4. The introduction and use of cross-licensing.

5. Scope of protection. Protectable subject matter.

* 1. Revisions that change the licensing and other post-patent practices of patent holders.

2. Examine implications for less developed countries (and particularly the poor subsistence farmers therein) before granting patents with broad application.

Additional Questions and Comments

12. Are there questions we should be asking experts and stakeholders that are not included in this questionnaire? If so, what are they?

[The comments are below, with bullets indicating each new respondent.]

- Is the high-tech road the most sensible path for promoting agricultural productivity in the developing world? What about more traditional plant breeding research, soil conservation, and other traditional approaches?
- A. ____ On a scale of 1- 5 how would you rate your political leanings? (1 = capitalist; 3 = neutral; 5 = socialist)

  B. Do you believe that there is a constitutional basis for the U.S. Supreme Court's determining Congress' intentions?

  C. In what way are an inventor's rights under patent law unlike a person's rights under property law?

  D. What is being talked about when one hears about "developing countries"? What is a "developing country"?

  E. Do you believe that all "developing countries" are homogeneous? Why? Or why not?
- The difference between modified and original germplasm is a gray area, which needs to be better defined.
- More on the international context: TRIPs, regional trade agreements, FAO International Undertaking, CBD.
- What is the long-term impact of introducing proprietary regimes in new areas (i.e., biology in the broad sense) using instruments originally developed to protect industrial hardware inventions like the phonograph, fuel engine, cars, airplanes, radios, etc.?

  In pharmaceuticals almost only patents are involved. In agriculture 5–6 different kinds of IP are involved (patents, PVP, farmer's privilege, farmer's rights including landraces under CBD 8j, nom d'origin, breeder's exemption). When you plant a pill you get nothing! When you plant a seed (whether proprietary or not) you get multiplied seed where the future use becomes conditioned. . . . Compare ISAAA on the IP-pedigrees of Golden Rice. Conclusions?

  IP in pharmaceuticals is very different from IP in agriculture/agrobiotechnology.
- Our organization has had a reexamination process on-going for months on a patent given to an existing crop variety developed and documented in a developing country. I am not sure we will win this highly unfair patent, where so much prior art existed. We are seeking potent legal firm free assistance to help us with a second case where existing variability was

patented. But based on the first example we are reluctant to enter into this time-consuming endeavor.

- Role of nonprofits: What stance should they take in countries where patents do not apply, if they are working also in countries where patents do apply?
- Standing back from the detail of patents, are we missing any major points affecting developing country agricultural and food security needs and the role the patent and IPR system more generally plays in that?
- The questionnaire should focus more on post-patenting issues including licensing practices and potential collective bargaining agreements for access to products and tools.
- Which one of the two licensing policies favorable to researchers working on developing country problems is the most fair and practical: To be based on free licensing to resource-poor farmers in developing countries or on farmers' anticipated incomes resulting from the use of the proprietary technology?
- Although we tend to disagree that the U.S. patent system itself discourages the use of ag biotech for developing country purposes, it may be the fact that perceptions about the reach of the U.S. patent system and the willingness of patent holders to share patented material and information may be in fact adversely affecting access to and use of technology for developing country purposes. Perhaps you should be asking if the experts and stakeholders believe that the system is well-understood by scientists seeking to apply technology patented for developing countries.

  Perhaps you should also be asking an open-ended question about what other issues, beyond the U.S. patent system, affect access to the tools of biotechnology by researchers working on agriculture in developing countries. A further question would be what level of importance or impact each of these issues has on access, relative to the U.S. patent system and each other.
- In terms of the background of contributors, it might be useful for you to know more about their first hand contacts with different sectors such as small farmers, agroindustry, IP authorities, political fora, international negotiations, etc. These contacts generally provide a useful context for reactions; we all have biases and it is helpful to have information on what those are likely to be.
- Questions regarding other patent systems besides the U.S. system. It would be great if developing countries had a "champion" patent office and court systems that could balance the U.S. system. The patent offices of the EU occasionally take on this role.
- You did not really ask IF it is the role of the PTO to be concerned about access to proprietary technologies for developed countries. I am not sure that it is the role of the PTO to do this.
- Usefulness of alternate dispute resolution, mediation, and arbitration.
- 1) Use of gene banks, tissue banks, depositories, seed banks, gene data bases for the purposes of determining novelty etc.

  2) Relationship between patents and plant variety rights (both in its UPOV and non-UPOV guises).

  3) Issues relating to the first to invent and first to file differences.

  4) Use of tie-in clauses, material transfer agreements, bilateral agreements, etc.

  5) Role of licensing.

  6) Role of the research exemption.
- What estimates do the private sector give for the potential short-term economic value of biotech products in less developed countries?

13. Do you have any other comments or suggestions concerning this subject or our study?

[The comments are below, with bullets indicating each new respondent.]

- Although you mention in the background that "Other features of the patent system, such as the way private companies manage their patent estates, may be addressed tangentially but are not the focus of the study," I believe that these are maybe the most important obstacles to access to technology for developing country purposes. Indeed, many technologies are not patented in large numbers of developing countries and could therefore be used there without infringement, but the limitations imposed through MTAs by patent holders on the use of their inventions by researchers is often precluding applications in developing countries.
- If I could say so, the questions seem to be designed to elicit a particular set of answers; that is that the system is broken and needs to be fixed. This questionnaire is truly prejudiced. In fairness, I will say that you have offered no disclaimer saying that your study is reproducible or scientifically sound.
- The International Undertaking on Genetic Resources, now being negotiated, under FAO auspices, needs to be strongly supported by the U.S. Failure of the IU to be implemented will likely have long-term negative repercussions on access to germplasm and related technology. Processes and work mode at PTO have tremendous implications and spin-offs for international negotiations in CBD, FAO/IU, TRIPs, etc. (Compare questionable U.S. patents on Neem products, Basmati, Enola, turmeric, etc., etc. The study should make the links between PTO and, for example, TRIPs much clearer. Today most biologists/biotechnologists do not have a clue on what is up geopolitically, and especially the difference regarding impact of IP in pharmaceuticals as compared to agriculture.

- I understand the reasons for this survey. However, the survey does seem pointed in terms of soliciting answers that may not be very accurate, since many of the answers would differ depending on the specific technology or patent in question.

  I feel very strongly that gaining access to technologies for developing countries is not an issue of patentability in any one country or economic group. Access depends on the willingness of the owner of the information to share. While it is laudable to call for free access of technologies to developing countries or to specific research institutes dedicated to developing technologies targeted for release in developing countries, one must keep in mind that no company or individual in business can afford to give away technologies indefinitely. Obviously, the money for research and development has to come from somewhere. If the demands for free access of technology from the private sector is too great, then the result will include (1) keeping research results as trade secrets and/or (2) eliminating such research programs altogether because the company is either losing or not making [money] on the research efforts. In the end, the developing nations will suffer from the lack of interest and lack of research and development from the private sector.

- Is it feasible to provide privileges to researchers of the developing countries, which represent the major part of the human population of the earth? What about possible abuse of such privileges?

- It would seem that the practices of the patent holders are more critical than the actions or interpretations of PTO.

- Allow developing countries the same access as CGIAR centers and accommodate use of the technology in developing countries commercially under licensing arrangements commensurate with what they can reasonably pay. We accept that it can't be free; however, assuming that developed countries' use is paid for by them, then why can't developing countries gain access and use as soon as possible at reduced cost? One of course assumes that use in the developing countries must in no way compete with or undermine products for sale in the developed world.

- The problem is not the patenting system. If the attitude to use the power of IPRs and TPRs (and especially of very restrictive MTAs) would be changed to a liberal attitude which distinguishes between cases of potential commercial competitiveness and cases of non-competitive humanitarian uses, and gives free licenses for that humanitarian use, then I do not see the necessity to change the system at all.

  With the practical case of "Golden Rice" we have an example that I consider worth considering.

- From a reading of the questions I wonder if the study is going to be put into a broad enough context. The patent system and issues to do with IPRs are far too important for the future of economic and social development to be left to the insiders who practice within it—the lawyers, patent agents, etc., and requires a much broader public participation in framing the rules. Also the issue of the effect on the sharing of knowledge, perhaps the major key to feeding curiosity and sparking scientific and technological developments, is neglected. The effects on the scientific enterprise, the relations between scientists swapping stories, ideas, and experience are relevant in this area. So too is the drive to apply biotechnology solutions to problems in developing countries, only some of which may be best dealt with that way, especially if we are looking at the interests of the poor. This stems perhaps from a private sector-led approach to development in this area, which requires patent protection to secure gains.

- An IP survey of the CGIAR centers is under way by Dr. Phil Pardey at the International Food Policy Research Institute (IFPRI), Brian Wright, and Eran Binenbaum (UC–Berkeley). The objectives of this survey are quite different, but you may gain from a confrontation of the outcome of your survey with the ones of this CGIAR study.

- And finally, a counter-observation: European and developing country patent systems, with THEIR absolute novelty requirement, are greater impediments to prompt availability of patentable technology than the U.S. patent system. Absolute novelty patent systems, which are in place everywhere except the U.S., require inventors to file patent applications BEFORE they publish, while the U.S. patent system with its grace period allows inventors to publish first and then patent within one year. Stated simply, the substantive direction of this survey is off by 180°.

- I don't know who the various people consulted are, although I have come across a couple so far, but hope that they represent the full cross-section as it's not even always clear that those working in agricultural development are fully in tune with those they intend to assist, while the small farmers we are most worried about generally have a clear idea of the problems they face but don't necessarily understand all the factors influencing those problems. A key point here may be the question of relevant biotechnologies; are these actually targeting the problems farmers are most concerned with, or are they being driven from the supply side? Because IPRs have become so entwined with market strategies and have been distanced from innovation incentives, they seem to play a major role in supplier dominance of technology adoption strategies. Even where a technology may prove useful if it has been pushed by the supplier, rather than sought by the user, it may not always be the most effective, whether in terms of cost or technical standards.

  While not necessarily disputing the assumptions mentioned in the introduction to this study, I think they are risky and need to be supported for the information provided to be relevant.

- For question 3, we have data indicating the degree to which proprietary technologies are being used in developing country ag research, and it is quite high, indicating that IP is not key to restricting use. The key issues for getting products, at this point in time, are clearing regulatory, not IP, hurdles.

  Questions should be related to the current scenario as per trade and national patent law, and as to how things will or won't change as regards TRIPs and other international negotiations. Thus, some in-

creased worries regarding IP may develop in future, that don't exist now.

Rate exchange of U.S. currency with the currency of developing countries can be prohibitive with respect to patenting and challenging patent claims.

- We had some problems with answering many of these questions for the following reasons:

I) The term "researcher working on developing country agricultural problems" is not defined.

This person could be one of the following and the answers to particular questions will vary according to the form that researcher takes. The forms are:

a) a researcher who is working in a developing country on the needs of that country who is a national of that country;

b) a researcher who is working in a developing country on the needs of that country who is a not a national of that country, but is a national of another developing country (which might have alternative needs/IPR practices);

c) a researcher who is working in a developing country on the needs of other developing countries who is a national of the country within which s/he is working;

d) a researcher who is working in a developing country on the needs of other developing countries who is not a national of the country in which s/he is working (e.g., working for IRRI);

e) a researcher who is working in a developing country on the needs of that country who is a national of a developed country.

We actually could come up with a few more—but thought this might provide a flavor!

In respect of those working in developing countries, there is an issue of access to material held within developed countries. And an issue about what they are attempting to produce:

i) products/processes developed in a developing country to assist that country;

ii) products/processes developed in a developed country to assist developing countries;

iii) products/processes developed in a developed country based on material from developing countries for sale within developed countries; and

iv) products/processes developed in developed countries intended to supplant products from developing countries.

II) There was some confusion as to the legal environment we are supposed to be responding to. The manner in which the questions are posed implies that the researcher you are referring to is affected by U.S. patent law. As you correctly state in question 3, U.S. patent law only applies in the U.S. and concepts such as limitations on research use would imply that this is a researcher working on the problems within developing countries within a developed country. This would indicate that the researcher is based in the U.S.

III) Definition of Biotechnological Tools. We were unclear as to whether this term was being used in its correct broad sense as encompassing all forms of biological breeding activity, or only in the more restricted modern sense. Again this makes a difference to the answers given. For example in question 1 you ask about the degree of importance placed on the tools of biotechnology, but do not specify what is meant by a tool of biotechnology. Biotechnology is a term that can be used to cover all forms of plant breeding research. On the basis of this definition, we would answer "very high" to the first question if the tool in question is related to traditional breeding, and "medium" if it is related to modern breeding.

Thank you!! If you have any questions at all about this survey or our work, please feel free to call or write Mike Taylor (202–328–5066; taylor@rff.org) or Jerry Cayford (202–328–5157; cayford@rff.org) at Resources for the Future. We appreciate your taking the time to answer our questions, and we welcome your comments or your curiosity.

■ ■ ■

APPENDIX C

Workshop Participants and Survey Respondents

Workshop Participants

Prof. John Barton, Stanford University Law School

Dr. Jerry Cayford, Resources for the Future

Dr. Jack Clough, Meridian Institute

Ms. Carolyn Deere, The Rockefeller Foundation

Prof. Walter Falcon, Stanford University, Center for Environmental Science and Policy

Mr. Michael Gollin, Venable, Baetjer, Howard, and Civiletti

Mr. Stephen Hansen, American Association for the Advancement of Science

Dr. Robert Horsch, Monsanto Company

Mr. Richard Johnson, Arnold & Porter

Prof. Donald Kennedy, Stanford University, Center for Environmental Science and Policy

Mr. Robert Lettington, International Centre of Insect Physiology and Ecology (ICIPE)

Dr. Rosamond Naylor, Stanford University, Center for Environmental Science and Policy

Dr. Carol Nottenburg, Center for the Application of Molecular Biology to International Agriculture (CAMBIA)

Mr. Peter Odell, Sheffield Institute of Biotechnological Law and Ethics (SIBLE)

Mrs. Silvia Salazar, International Service for National Agricultural Research (ISNAR)

Ms. Susan Sechler, The Rockefeller Foundation

Dr. Stephen Smith, Pioneer Hi-Bred

Mr. Shawn Sullivan, International Maize and Wheat Improvement Center (CIMMYT)

Mr. Michael Taylor, Resources for the Future

Mr. Robert Weissman, Essential Action

Survey Respondents

Prof. Dr. Werner Arber, International Council for Science (ICSU)

Dr. Shawki Barghouti, World Bank

Prof. John Barton, Stanford University

Dr. Charles Benbrook, Northwest Science and Environmental Policy Center (NSEPC)

Dr. Bénédicte Callan, OECD-Biotechnology Unit of the Science, Technology and Industry Directorate

Dr. Ronald P. Cantrell, International Rice Research Institute (IRRI)

Dr. H. Arlington D. Chesney, Inter-American Institute for Cooperation on Agriculture (IICA)

Mr. Joel I. Cohen, International Service for National Agricultural Research (ISNAR)

Dr. Marc J. Cohen, International Food Policy Research Institute (IFPRI)

Dr. Wanda Collins, International Potato Center (CIP)

Dr. R. James Cook, Washington State University

Dr. Jonathan H. Crouch, International Crops Research Institute for the Semi-Arid Tropics (ICRISAT)

Ms. Kristin Dawkins, Institute for Agriculture and Trade Policy (IATP)

Dr. Peter Day, Rutgers University

Dr. John Hamilton Dodds, International Center for Agricultural Research in the Dry Areas (ICARDA)

Dr. R.N. Sam Dryden, Emergent Genetics

Dr. Walter Falcon, Stanford University

Dr. Christian Fatokun, International Institute of Tropical Agriculture (IITA)

Dr. Hank Fitzhugh, International Livestock Research Institute (ILRI)

Dr. Emile Frison, International Network for the Improvement of Banana and Plantain (INIBAP)

Dr. Marc Ghislain, International Potato Center (CIP)

Dr. Iain Gillespie, OECD-Biotechnology Unit of the Science, Technology and Industry Directorate

Dr. Neil E. Harl, Iowa State University

Dr. Victoria Henson-Apollonio, International Service for National Agricultural Research (ISNAR)

Dr. Anne-Marie Izac, ICRAF International Center for Research in Agroforestry

Mr. R. David Kryder, Cornell University, Strategic World Initiative for Technology Transfer (SWIFTT)

Dr. Bernard Le Buanec, International Seed Federation (FIS/ASSINSEL)

Mr. Robert Lettington, International Centre of Insect Physiology and Ecology (ICIPE)

Dr. Chien-An Liu, Asian Vegetable Research and Development Center (AVRDC)

Dr. Margaret Llewelyn, Sheffield Institute of Biotechnological Law and Ethics (SIBLE)

Ms. Michelle S. Marks, Shaw Pittman

Prof. Michael Meurer, Boston University

Monsanto Company

Ms. Rose Ndegwa, International Livestock Research Institute (ILRI)

Dr. Marie-Noelle Ndjiondjop, West Africa Rice Development Association (WARDA)

Dr. Compton Paul, Caribbean Agricultural Science and Technology Networking System (PROCICARIBE)

Dr. Eija Pehu, World Bank

Dr. Ingo Potrykus, Institute of Plant Sciences

Dr. Ken Riley, International Plant Genetic Resources Institute (IPGRI)

Dr. Cyril Roberts, Caribbean Agricultural Research & Development Institute (CARDI)

Mrs. Silvia Salazar, International Service for National Agricultural Research (ISNAR)

Dr. Stephen Smith, Pioneer Hi-Bred

Mr. Geoff Tansey, Quaker House

Prof. Jay Thomas, Georgetown University Law Center

Mr. Carl-Gustaf Thornstrom, Swedish International Development Agency / Department for Research Co-operation (Sida/SAREC)

Dr. Aart van Schoonhoven, International Center for Tropical Agriculture (CIAT)

Prof. Jeroen Van Wijk, International Service for National Agricultural Research (ISNAR)

Dr. Thanda Wai, International Rice Research Institute (IRRI)

Dr. Usha Barwale Zehr, Maharashtra Hybrid Seed Company (Mahyco)

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