The U.S. Patent System and Developing Country Access to Biotechnology: Does the Balance Need Adjusting?

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Abstract

Many agricultural and food security experts believe that biotechnology has potential to assist developing country farmers in meeting current and future food needs. Most of the tools of biotechnology have been developed, however, by companies, governments, and universities in industrialized nations; are the subject of U.S. patents; and have so far been applied commercially to address the needs of large-scale growers in the United States and other developed countries. For commercial and other reasons, applications of biotechnology that might benefit developing country farmers are unlikely in the foreseeable future to be developed and disseminated through commercial channels. At the same time, noncommercial, public sector researchers report that their access to tools of biotechnology for creating developing country applications is impeded by the array of existing patents. After reviewing the basis for these observations, this paper outlines the utilitarian theory and objectives of the U.S. patent system, how the system has been applied to agricultural biotechnology, the "patent thicket" that has resulted, and the general pro-patent orientation of the U.S. Patent and Trademark Office. The paper then describes how the U.S. patent system affects developing country access to biotechnology, based in part on an informal survey the authors conducted among experts and stakeholders in this field, and outlines a normative and analytical framework for evaluating possible changes in patent policy that might improve developing country access without undercutting the patent system's incentives for invention. The central argument is that developing country food security is a legitimate interest to consider when evaluating the operation of the U.S. patent system and possible alternatives to current patent policy. The paper then briefly describes six specific policy alternatives, all addressing access to patented technology rather than the rules governing patenting. This paper serves as the basis for a fall 2002 workshop to be held by Resources for the Future (RFF), at which the policy alternatives and the framework for evaluating them will be explored in more detail and refined by a small group of invited experts and stakeholders. The authors invite comment on the paper, which should be addressed to Dr. Jerry Cayford at cayford@rff.org.

Key Words: United States patents, agricultural biotechnology, developing countries, food security

JEL Classification Numbers: O34, Q16

Contents

The U.S. Patent System and Developing Country Access to Biotechnology: Does the Balance Need Adjusting?

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1. Introduction

This paper is part of a study the authors are conducting on the impact of the U.S. patent system on developing country access to the tools of agricultural biotechnology. The social issue that motivates the study is food insecurity in developing countries. Biotechnology seems to have the potential to improve food production in the developing world. Yet the companies that control agricultural biotechnology patents are not rapidly deploying them for that purpose, nor making them readily available to researchers who would do so. Our central question, then, is whether U.S. patent policy can and should be changed to make access to biotechnology easier for developing country food security purposes. To answer that question, we first put it in context by describing the U.S. patent system, its application to biotechnology, and the effects on developing country access. Then we present a framework for evaluating policy options and propose six possible policy changes.

The six patent policy alternatives are all legislative changes, and they address postpatent access to patented technologies rather than the rules of what gets patented in the first place. All are limited to the use of tools of biotechnology for developing country purposes, meaning that those tools would be available, without risk of patent infringement, for use by researchers in the United States or elsewhere to develop crops that would be planted in developing countries, but with minimal potential for export to the United States. By keeping the proposals narrowly focused on the problem at hand, we hope to improve their chances of serious consideration and possible adoption. Still, a great many questions need to be answered.

* Mr. Taylor is a Senior Fellow at Resources for the Future (RFF). Dr. Cayford is an RFF Research Associate. We thank the Rockefeller Foundation for its financial support of our research. We also thank the dozens of people who responded to our surveyand shared their knowledge and views in other ways. We alone, however, are responsible for the content of this paper, including any errors of fact or interpretation.

Food Security and Biotechnology

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."[1] The Food and Agriculture Organization (FAO) of the United Nations estimates that 800 million people in the world experience chronic hunger and thus lack food security at an individual level. Millions of people, many of them children, die annually from hunger-related causes.[2] Food insecurity is closely linked to poverty, and thus is concentrated in the developing countries of South Asia, Africa, and Latin America.[3]

Food security is a complex social, economic, and political problem whose causes and solutions vary from country to country.[4] 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.[5] These countries produce enough food to

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[1] Rome Declaration on World Food Security, in Food and Agriculture Organization of the United Nations, *Report of the World Food Summit 13-17 November 1996, Part One* (1997), http://www.fao.org/wfs/index_en.htm. Food security exists in a society when all people at all times have physical and economic access to the food they need to thrive. The Food and Agriculture Organization (FAO) defines food security as "the access of all people at all times to the food they need for an active and healthy life." Food and Agriculture Organization of the United Nations, *FAO: What It Is—What It Does* (2002), http://www.fao.org/UNFAO/e/wmain-e.htm.

[2] "800 million people in developing countries—about 20 percent of their total population—are chronically undernourished." Food and Agriculture Organization of the United Nations, *The Special Program for Food Security: Objective and Approach* (2002), http://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." Food and Agriculture Organization of the United Nations, *The State of Food and Agriculture 2001* (2001), http://www.fao.org/es/ESA/sofa.htm.

[3] According to the FAO, India has more hungry people than any other country (225.3 million, or 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. Food and Agriculture Organization of the United Nations, "The State of Food Insecurity in the World 2001," Table 1 (2001), Population, per capita dietary energy supply and prevalence of undernourishment in developing countries and countries in transition.

[4] 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 Falcon, W.P., "Globalizing germplasm: barriers, benefits, and boundaries," *Tomorrow's Agriculture: Incentives, Institutions, Infrastructure and Innovations,* Ashgate (2000); and DeVries, J., and G. Toenniessen, *Securing the Harvest: Biotechnology, Breeding and Seed Systems for African Crops*, CABI (2001).

[5] Conway, Gordon, *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.

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.[6]

There is no single solution to the problem of hunger in developing countries. A common reality in most developing and food-insecure countries, however, is that a large majority of the people live in rural areas, and they depend on agriculture, directly or indirectly, for their livelihood. In sub-Saharan Africa, 70% of the people are rural and largely agriculture-dependent, ranging from 43.3% in Mauritania to 93.9% in Rwanda.[7] 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.[8] Moreover, according to the World Bank, global food production will have to double by 2050 to meet rising demand.[9] By improving agricultural productivity and local food processing and distribution systems, developing countries can increase locally available food stocks to feed their people and generate income to purchase food in the marketplace, as needed to supplement local production. Improvement in developing country agricultural and food systems is also critical to meeting the world's long-term food needs.

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[6] Pinstrup-Andersen, Per, 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), http://www.ifpri.org/pubs/fpr/fpr29.pdf.

[7] World Bank, *World Bank Rural Development Strategy: Reaching the Poor (Annex 3, Regional Strategy Summaries: Africa)* (2002), http://wbln0018.worldbank.org/ESSD/rdv/vta.nsf/Gweb/Strategy; African Development Bank, *Gender, Poverty and Environmental Indicators on African Countries[seems a comma or other punctuation should be here] Cross-Country Tables: Environment, Table 3.1: Urbanization Profile* (2001–2002), http://www.afdb.org/knowledge/statistics/statistics_indicators_gender/environment/indicators_environment.htm.

[8] World Bank, *World Bank Rural Development Strategy: Reaching the Poor (Africa Section)* (2002), http://wbln0018.worldbank.org/ESSD/rdv/vta.nsf/Gweb/Strategy.

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

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.[10]

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 a successful agricultural food system. Effective markets require sound political, economic, and social institutions and policies, which are lacking in many developing countries. They 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, 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. As noted above, farmers there 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 African agriculture. With the environmental lessons of the Green Revolution in mind, however, many agricultural experts believe that the tools of modern biotechnology (including the use of recombinant DNA technology to produce genetically modified plants) can also play a role in solving developing country agronomic problems and increasing productivity.[11] 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.

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[10] Pinstrup-Andersen, Pandya-Lorch, and Rosegrant, *supra* note 6, at 26.

[11] Conway, *supra* note 5 and many IFPRI publications, such as Serageldin, Ismail, and G.J. Persley, *Promethean Science: Agricultural Biotechnology, the Environment, and the Poor,* CGIAR (2000), http://www.ifpri.org/themes/biotech/biotech.htm.

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.[12] 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.[13] Biotechnology companies also promote the potential of biotechnology to improve developing country agriculture and food security.[14]

We recognize there is debate about the ultimate value of biotechnology for developing country farmers, and that issues of food safety and environmental and social impacts should be addressed prior to adoption of the technology. This paper does not address these issues, which are discussed abundantly elsewhere.[15] It 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 paper focuses on the specific problem of access to biotechnology for developing country purposes, as affected by the U.S. patent system.

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[12] CGIAR, http://www.cgiar.org/publications/index.html, has links to international centers. Mitchell, Loraine, "Biotechnology and Food Security," USDA Agriculture Information Bulletin 765-11 (2001). http://www.ers.usda.gov/publications/aib76511/; Cohen, Joel I., 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), http://www.ifpri.org/2020/focus/focus02.htm.

[13] 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 Appendix A. 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.

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

[15] Food and Agriculture Organization, *Agricultural Biotechnology in the Developing World* (1995), http://www.fao.org/docrep/v4845e/v4845e00.htm; The Royal Society et al., "Transgenic Plants and World Agriculture" (2000), http://www.ictp.trieste.it/~twas/TransSummary.htm; Ervin, David E., et al., "Transgenic Crops: An Environmental Assessment," Henry A. Wallace Center for Agriculture & Environmental Policy at Winrock International (2000), http://www.winrock.org/what/wallace_center.asp; McLean et al. (ISNAR), "A Conceptual Framework for Implementing Biosafety: Linking Policy, Capacity and Regulation" (2002), ftp://ftp.cgiar.org/isnar/publicat/bp-47.pdf; Cohen, Joel I., ed., *Managing Agricultural Biotechnology. Addressing Research Program Needs and Policy Implications* (1999), http://www.isnar.cgiar.org/ibs/biobook.htm.

Definition of the Problem and Question to Be Addressed

The access problem addressed in this paper 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,[16] but, 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*,[17] have spawned substantial investment in biotechnology by large agricultural chemical companies and small biotech startup companies, primarily in the United States and Europe. This 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.[18]

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 the early 20th century, USDA's largest budget item was a program that provided the latest seed free to farmers. 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.

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

[17] 447 U.S. 303,(1980), http://people.bu.edu/ebortman/index/chakrabarty.html. See *infra* notes 50 to 52 and accompanying text.

[18] Graff, Gregory, "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 (2000); Barham, Bradford, Jeremy Foltz, and Kwamsoo Kim, "Trends in University Ag-Biotech Patent Production," Food Marketing Policy Center, Research Report 58 (2001), http://www.biotech.wisc.edu/seebiotech/raefinalbbkk.pdf .

In most developing countries, seed innovation remains largely a public good. Farmers produce, save, and share improved seed. National and international agricultural research laboratories pursue 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.[19] There are fledgling seed industries in developing countries that are marketing privately developed hybrids and serving as distribution channels for publicly developed seed innovation,[20] 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, the majority of the investment in research to produce improved seeds is now financed and conducted privately, much of it by biotechnology companies.[21] 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

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[19] Persley, G.J., and M.M. Lantin, eds., *Agricultural Biotechnology and the Poor: An International Conference on Biotechnology,* CGIAR and U.S. National Academy of Sciences (1999), http://www.cgiar.org/biotech/rep0100/contents.htm; Applied Biotechnology Center at the International Maize and Wheat Improvement Center, "Reaching inside the Genome, Reaching Farmers" (2002), http://www.cimmyt.org/ABC/map/about/BROCHURE97ABC/BROCHURE97ABC.htm.

[20] Personal communication with Mark Condon, Vice President, International Marketing, American Seed Trade Association, January 24, 2002.

[21] Amounts of research can be calculated many different ways, and USDA's Economic Research Service has several useful papers on this, especially Heisey, Paul W., C.S. Srinivasan, and Colin Thirtle, "Public Sector Plant Breeding in a Privatizing World," *Agriculture Information Bulletin* 772, USDA Economic Research Service (2001), http://www.ers.usda.gov/publications/aib772/; see also Shoemaker, Robbin, ed., "Economic Issues in Agricultural Biotechnology," *Agriculture Information Bulletin* 762, USDA Economic Research Service (2001), http://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 by 1994. (Heisey, Srinivasan, and Thirtle at 6–8; also Frey, K.J., "National Plant Breeding Study-I: Human and Financial Resources Devoted to Plant Breeding and Development in the United States in 1994," Iowa Agricultural and Home Economics Experiment Station, Iowa State University, Ames, Iowa (1996).)

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.[22] Of these, 76% are assigned to private individuals or corporations, with the remainder assigned to universities or public institutions. The top four patenting organizations are Pioneer Hi-Bred International, Mycogen, USDA, and Monsanto Company, which together hold 26% of the patents. Of the top 30 patent holders, 22 are U.S. or European corporations, which together hold 50% of the patents.[23]

The dominance of the private sector may be even greater than these numbers reveal. Since the Bayh-Dole Act of 1980, public 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. Consequently, not only are the majority of biotechnology patents in private hands, but a substantial portion of the patents remaining in public hands are exclusively licensed to private corporations. Furthermore, the ability to patent has given public institutions the incentive to treat their patents—exclusively licensed or not—less as a public good than as a source of institutional revenue; that is, their incentive is to behave like the private sector.

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 it is credited by many observers as the catalyst for important innovation in seed technology.[24] The role of the patent system in fostering innovation will be discussed later in this paper. One clear consequence of the widespread patenting of biotechnology, however, is the fact 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.

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[22] Graff, *supra* note 18.

[23] 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.

[24] Biotechnology Industry Organization, "Importance of Intellectual Property," http://www.bio.org/ip/background.asp; Begemann et al., "The Importance of Intellectual Property to Product Development," *The Edge* (Monsanto's agribusiness and technology journal) 3(1) (2000), http://www.Farmsource.com/News_Trends/Edge/bus.htm; Feisee, Lila, and Brian Stanton, "Are Biotechnology Patents Important?" *PTO Pulse* (March 2000).

The privatization of research affects the kinds of research done and products developed.[25] 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 selling two traits to cotton, corn, and soybean farmers in the United States and a few other industrialized countries: insect control based on the *Bt* toxin, and resistance to the herbicide glyphosate. This focus is economically rational and 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 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, where agriculture is carried out largely by smallholder and subsistence farmers. Thus, 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.

Yet, as noted earlier, many experts consider access to biotechnology important for meeting developing country agricultural needs. Many also report that the U.S. patent system adversely affects the ability of researchers to access and use the tools of biotechnology for developing country purposes. Of those who responded to our informal survey on this point, 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.[26] Others have written about the impact of the patent system on access to biotechnology for developing

[25] Heisey, Srinivasan, and Thirtle, *supra* note 21.

[26] See tabulation of survey data in Appendix A.

country purposes, and the efforts that are often necessary to gain access within the existing system.[27]

In sum, the core problem we address is this: Tools for innovation in seed technology that have the potential to benefit developing country farmers and contribute to food security (1) exist in the hands of western biotechnology companies and public organizations; (2) are unlikely to be developed commercially for these purposes in the foreseeable future; and (3) are subject to patents that impede access by researchers working on those developing country problems.

The question, then, is this: Can the patent system be changed in ways that foster access for developing country purposes while preserving incentives for private sector investment in invention and development?

Study Methodology and the Role of this Paper

The authors are public policy researchers interested in the problem of food security. We thus approach this study not from a traditional patent law or technological perspective, but rather from the perspective of analysts asking questions about the objectives of a particular public policy enterprise (in this case the U.S. patent system), whether those objectives are being achieved, the interests affected, and whether the enterprise can be improved to better achieve its objectives and maximize social welfare. This starting point influences our study methodology, including our intention to synthesize the work of experts from various intersecting fields in reaching our conclusions.

Our study methodology includes four phases. The first is a data collection phase consisting of (1) an extensive literature review to establish a basic understanding of the U.S. patent system, how it is being implemented with respect to agricultural biotechnology, and its effect on developing country access to biotechnology; (2) interviews with a core group of experts and stakeholders; and (3) an informal written survey of a broader group of experts and stakeholders. This first phase is largely complete.

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[27] Falcon, *supra* note 4; Herdt, Robert W., "Enclosing the Global Plant Genetic Commons," Rockefeller Foundation (1999), http://www.rockfound.org/display.asp?context=3&SectionTypeID=17&DocID=220; ETC Group, "Monsanto's 'Submarine Patent' Torpedoes Ag Biotech: Monsanto & Syngenta Monopolize Key Gene Marker Technologies" (2002), http://www.rafi.org/documents/news_monsantosub.pdf; Salazar, Silvia, et al., "The Use of Proprietary Biotechnology Research Inputs at Selected Latin American NAROs," ISNAR Briefing Paper 44 (2000), http://www.cgiar.org/isnar/publications/catalog/briefing.htm.

The second phase consists of our analysis of the information we have collected and the preparation of this discussion paper. Based on our analysis of what we have learned so far, this paper (1) outlines the theory and social objectives of the U.S. patent system; (2) describes how those objectives are being pursued in practice in the implementation of the patent law generally and with respect to agricultural biotechnology particularly; (3) proposes 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 (4) briefly identifies several specific policy changes as candidates for evaluation within this framework. This paper will be circulated to a broad group of experts and stakeholders to stimulate comment, discussion, and further development of the policy change ideas.

The third phase of the study will be a small workshop of invited experts who will be asked to evaluate and further develop the policy ideas identified in this paper, as well as others they might suggest. They will be asked to consider whether the changes would meaningfully improve access to biotechnology for developing country purposes, and to what extent the changes would affect incentives for private investment in the technology. As discussed below, the literature contains very little empirical data that would be relevant to answering these questions. We thus will be asking well-informed experts for their personal analysis and judgment.

The final phase of the study will be an RFF report that builds on this discussion paper, presents the results of the analysis and discussion from the expert workshop, and proposes some policy ideas.

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

It is important to begin our analysis with an understanding of the objectives and theoretical underpinnings of the U.S. patent system because they provide essential context for our study and guide our analysis of policy alternatives. In this section, we describe the patent system and its objectives, and in the next section, we describe its role in the field of biotechnology.

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."[28] 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.[29]

Under the utilitarian or "instrumental"[30] conception of patents, the patent system is successful to the extent 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 the inventor has a natural right by virtue of his or her inventive efforts. This perspective and other nonutilitarian perspectives on patents continue to surface in scholarly writing[31] and in policy debates,[32] but they continue to be rebutted eloquently by the famous statement made in 1813 by noted American inventor and 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

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[28] U.S. Constitution, Article I, Section 8.

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

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

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

[32] 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 Biden, Joseph, "Theft of American Intellectual Property: Fighting Crime Abroad and at Home" (2002), http://www.senate.gov/~biden/IPREPORT.pdf.

> 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.[33]

Jefferson's understanding of patents as a benefit granted by society on terms designed to achieve social policy goals is central to this paper and our broader project. 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. They ensure that the inventor's contribution to society has value. Hence, there is a utility requirement,[34] so society will receive a useful invention. There is a novelty requirement,[35] so inventors cannot offer something that society already has. There is a nonobviousness requirement,[36] so inventors cannot offer what society would likely have in any case. And there is a disclosure or specification requirement,[37] 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 patent system is that society will benefit from new technology if inventors have the incentive and reward of a patent to induce their effort and their investment

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[33] Letter to Isaac McPherson, August 13, 1813, quoted in Merges, *supra* note 29, at 10. Also Menell: "Not surprisingly, the principal philosophical theory applied to the protection of utilitarian works—that is, technological inventions—has been utilitarianism." Menell, Peter S, "Intellectual Property: General Theories" (1999), in *Encyclopedia of Law and Economics, Volume I. The History and Methodology of Law and Economics,* Boudewijn Bouckaert and Gerrit De Geest, eds., Cheltenham, UK?: Edward Elgar (2000), http://encyclo.findlaw.com/1600book.pdf.

[34] 35 U.S.C. 101, Inventions patentable.

[35] 35 U.S.C. 101, Inventions patentable.

[36] 35 U.S.C. 103, Conditions for patentability; nonobvious subject matter.

[37] 35 U.S.C. 112, Specification.

in the creative act, but the patent is awarded to achieve the social objective, not to reward inventors for the sake of rewarding inventors.

Specific Objectives of the Patent System

To assess whether the patent system is working to achieve its social objectives or could be improved, we should be more specific about what those objectives are. Drawing on the work of Mazzoleni and Nelson,[38] 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.[39]

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.[40] 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 the inventor sought to protect commercial prospects by keeping the invention secret.

The third objective—regulating the orderly investigation of new research areas—is relevant mainly in complex fields like 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

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

[39] 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.

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

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 bring order to the research process and thereby help foster innovation.[41] 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.[42] 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. Among other things, the realization of practical social benefits from the application of new technology commonly requires more than the creative act of the lone inventor. It may, for example, require 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 is not 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 (i.e., 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,[43] which was enacted by the U.S. Congress in 1980 to authorize and encourage the patenting of inventions made by

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

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

[43] Eisenberg, *supra* note 16; Langinier, Corinne, and GianCarlo Moschini, "The Economics of Patents: An Overview," Center for Agriculture and Rural Development Working Paper 02-WP 293 (2002). Forthcoming in *Intellectual Property Rights and Patenting in Animal Breeding and Genetics*, Newman and Rothschild, eds., http://www.card.iastate.edu/publications/texts/02wp293.pdf.

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. [44]

Bayh-Dole was enacted for another 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.[45] The idea was that companies would not be willing to invest in commercial development unless they could do so under patent protection. Thus, 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 patent policy intended to facilitate not merely invention and information dissemination, but practical use through commercialization.[46]

Once we get past the simple picture of the lone inventor, patent policy must balance competing considerations. In the more complex situations, such as those surrounding development of biotechnology, the multiple objectives of the patent system—or even a single objective with respect to different parties—can be at cross purposes. Incentives for one step in a complex process of developing innovative technology, such as the initial invention, can become disincentives for further steps required to achieve useful application of the technology. For example, a patent on an invention that contributes early in a technology development process,

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[44] "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.

[45] *Ibid.*

[46] Eisenberg, *supra* note 16. The objective of facilitating innovation 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.

but far short of commercial application (such as an enabling technology for genetic transformation of plants), 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 blocks a later inventor's commercialization of products produced using the earlier invention. 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.

The objective of facilitating practical use of inventions is of particular interest here because it is at the heart of the problem we address in this study. Since the existence of patents can sometimes hinder the application of patented technologies for their full range of socially beneficial uses—such as applying biotechnology to developing world agricultural needs—it is legitimate to ask how the system might be changed to reduce obstacles to such uses.

With this background on the objectives of patents, we turn to a summary of how the U.S. patent system has been applied to plant biotechnology over the past two decades, since the U.S. Supreme Court first affirmed that genetically modified life forms are patentable and plant biotechnology has become a practical reality. We will then describe, in later sections, how the U.S. system affects access to the technology by researchers working on developing country problems, and will suggest a framework for assessing that impact and proposals for minimizing obstacles to access.

3. Overview of the U.S. Patent System and Its Application to Plant Biotechnology

Much has been written about the U.S. patent system and its application to agricultural (especially plant) biotechnology.[47] We will not summarize that literature, but we will sketch key elements of how the U.S. patent system has operated in this area. We do this, first, to provide context for our discussion in the next section of how the U.S. patent system affects access to biotechnology for developing country purposes and, second, to explain the need to consider policy change to improve access. In this section, we will look at the history of biotechnology patenting; summarize the number, types, distribution, and trends in that patenting; describe the practical results of the rapid expansion of patent coverage of the field; and discuss the orientation of the U.S. Patent and Trademark Office (PTO) that encourages that expansion.

[47] See bibliography.

We will address in this discussion the activities of the PTO in its role both as the decisionmaker on whether to grant a patent and as an important contributor to the making of patent policy. The PTO is part of a patent policymaking system that begins with the Constitution but is directed by Congress through statute.[48] The system is heavily influenced by the courts, including the U.S. Supreme Court and the Court of Appeals for the Federal Circuit (CAFC), which was created in 1982 and replaced the Court of Customs and Patent Appeals as the court with immediate jurisdiction over judicial appeals of patent decisions.[49] Reviewing how the PTO plays its role will help explain why we have chosen for evaluation patent policy alternatives that would have to be acted upon by Congress.

Background on Biotechnology Patenting

The history of agricultural biotechnology patenting is generally considered to start in 1980 with the famous and controversial five-to-four Supreme Court decision in *Diamond v. Chakrabarty*.[50] 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,*[51] the PTO expanded the scope of what it considered patentable biotechnologies from microorganisms to genetically modified plants.[52]

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

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[48] 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.

[49] Many publications describe this structure in greater detail, such as Merges, *supra* note 29 (especially 37–39).

[50] S*upra* note 17.

[51] 227 U.S.P.Q. 443 (Board of Patent Appeals and Interferences, 1985).

[52] In 1987, the PTO announced its new policy that all nonhuman, nonnatural creatures are patentable ("Patent and Trademark Office Notice: Animals-Patentability," 1077 *Official Gazette U.S. Pat. & Trademark Office* 24, 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 57.

protection under the Plant Patent Act of 1930[53] and the Plant Variety Protection Act of 1970.[54] 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.[55] 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 are considerably more limited than standard (or so-called utility) patents in the rights they confer on inventors. 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 and a research exemption.[56]

The practical impact of *Chakrabarty* and *Hibberd* was far-reaching.[57] 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 any return on investment for technology developers would have to come in that first year of sales. Given the size of the investment required to develop commercially viable varieties of genetically modified plants, this would be difficult if not impossible. With a utility patent on the plant, reuse of the seed would constitute patent infringement and could on that basis be prevented through

[53] Plant Patent Act of 1930, 35 U.S.C. §§ 161–164

[54] Plant Variety Protection Act, 7 U.S.C. § 2321 et seq.

[55] Fuglie, Keith, 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), http://www.ers.usda.gov/publications/aer735/. The term for plant patents was 17 years until the 1994 amendments extended it to 20 years.

[56] Section 113. Right to Save Seed; Crop Exemption; and Section 114. Research Exemption.

[57] 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, http://www.supremecourtus.gov/opinions/01slipopinion.html).

strict license agreements with growers and litigation to enforce the licenses and patents, as needed.[58]

Utility patents thus changed fundamentally the incentives for investment and invention in the field of agricultural biotechnology.[59] 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.[60] 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, as discussed in the next section.

The Number and Pattern of Biotechnology Patents

Graff has compiled a unique dataset of agricultural plant biology patents,[61] 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: (1) a large number of biotechnology-related patents have been issued; (2) they are being issued at an

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[58] 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. This issue 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 Moeller, David R., "GMO Liability Threats for Farmers: Legal Issues Surrounding the Planting of Genetically Modified Crops," Farmers' Legal Action Group, Inc. (2001), http://www.gefoodalert.org/pages/home.cfm (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 Clark, E. Ann, "A fanciful tale … On the Appeal of the Percy Schmeiser Decision" (2002), http://www.plant.uoguelph.ca/faculty/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").

[59] See Heisey, Srinivasan, and Thirtle, *supra* note 21, at 3 and 5–6.

[60] Lin, William W., William Chambers, and Joy Harwood, "Biotechnology: U.S. Grain Handlers Look Ahead," *Agricultural Outlook*, October 2001, ERS/USDA, at 29–34 (2001), http://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."

[61] Graff, *supra* note 18.

increasing rate; (3) they cover traits, transformation tools, and modified plants, with many patents in each category; (4) the majority of the patents are in private hands; and (5) the subject matter and breadth of some biotechnology patents have broad impact on access to the technology.

The number of biotechnology patents

Graff's dataset of patents granted from 1975 through 1998 comprises 30 categories of "biology-based agricultural technology." He 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 included 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 covered 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.)

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, startup firm, or individual:	Assigned to corporation:
	Total patents in sample and proportions by organizational type	**2,428**	**645**	**893**	**955**
			0.27	**0.37**	**0.39**
1	Beneficial microorganisms linked to health and performance of plants: soil bacteria and fungi, nitrogen fixating bacteria	96	34	43	22
			0.35	0.45	0.23
2	Behavior of plant insect pests: sex attractants and integrated insect pest management	86	51	23	14
			0.59	0.27	0.16
3	Molecular biology, genetics, and genetic modification of plant insect pests	39	31	3	5
			0.79	0.08	0.13
4	Biological control of plant pathogens: viruses, microbes, nematodes, fungi	179	66	53	66
			0.37	0.30	0.37
5	Bt bioinsecticides and Bt-based biological control of plant insect pests (but not genetic modification of plants)	130	17	79	35
			0.13	0.61	0.27
6	Other (not Bt-based) bioinsecticides and biological control of plant insect pests	164	55	60	56
			0.34	0.37	0.34
7	Bioherbicides and biological control of weeds	62	39	16	10
			0.63	0.26	0.16
8	Plant genetic markers	66	18	32	20
			0.27	0.48	0.30
9	Plant genetic transformation vectors and systems: agrobacterium, electroporation, biolistics, viral vectors, etc.	151	45	67	50
			0.30	0.44	0.33
10	General plant gene expression: promoters, suppressors	81	25	29	27
			0.31	0.36	0.33
11	Controllable or inducible plant gene promoters	108	28	35	47
			0.26	0.32	0.44
12	Antisense suppressor technology	37	15	6	18
			0.41	0.16	0.49
13	Plant cell, tissue, and embryo culture techniques	73	15	31	28
			0.21	0.42	0.38
14	*In vitro* selection, somaclonal, and gametoclonal variation	57	16	26	17
			0.28	0.46	0.30
15	Genetic traits and modification for plant	64	23	17	24

	nutrition, metabolism, and growth		0.36	0.27	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 bio-molecules: 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

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.[62] 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: class 435 (Chemistry: Molecular Biology and Microbiology) and class 800 (Multicellular Living Organisms and Unmodified Parts Thereof and Related Processes). Not all of the patents granted in these classes involve agricultural 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 almost ninefold since 1981, from 518 patents in 1981 to 4,561 in 2001.[63] Over the same period, overall utility patents per year slightly more than doubled.[64]

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.[65] 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).

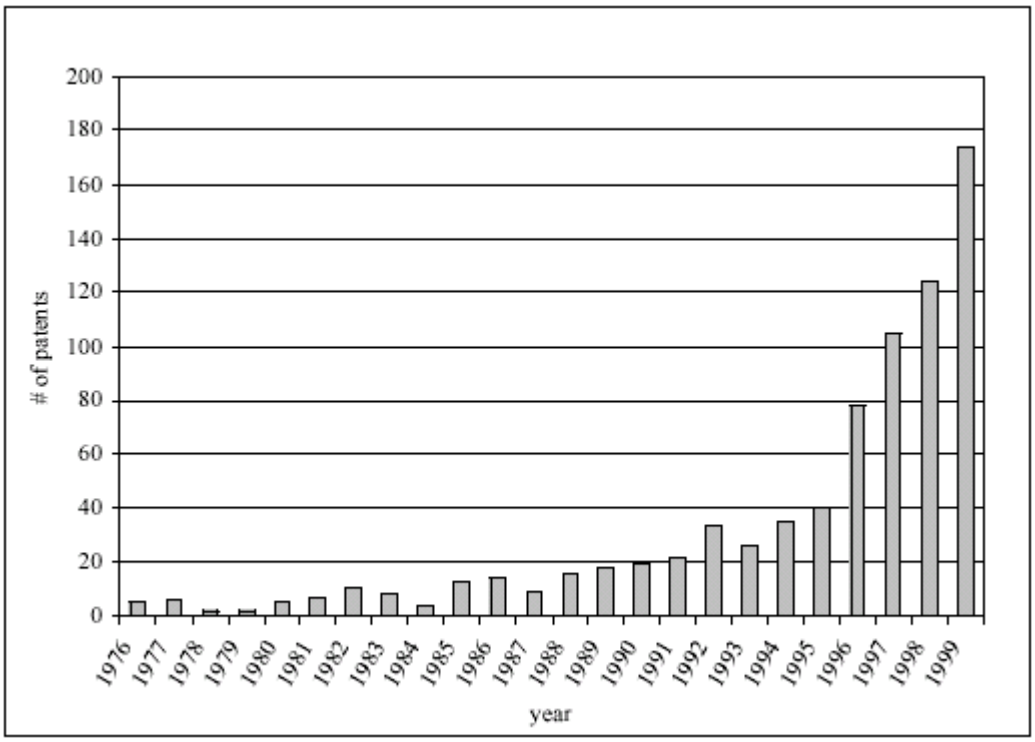
[62] Barham, Foltz, and Kim, *supra* note 18.

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

[64] USPTO, "Patent Counts by Country/State and Year, Utility Patents: January 1, 1963–December 31, 2001," http://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 biotechnolgy and the newness of utility patents being allowed on plants.

[65] 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.

Figure 1: University ag-biotech patent production by year



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

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 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).[66]

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, startup firm, or individual:	Assigned to corporation:
Transformation technologies	536	147	220	189
Traits	1151	325	396	470
Germplasm	560	53	196	311
Totals	2247	525	812	970

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

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 startup 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 to small firms or individuals, and 970 to corporations. 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 types 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

[66] 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.

tools that are so widely applicable to the work of researchers studying diverse problems that they can have a blocking effect on innovation.[67]

For example, in 1992, Agracetus (now a subsidiary of Monsanto Company) was granted a U.S. patent covering all genetically engineered cotton plants.[68] 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."[69] 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.[70]

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[71]; the widely applicable *Agrobacterium tumefaciens* vector system for transforming cotton plants, which Agracetus patented in the United States in 1991[72]; 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."[73] Such consequences

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[67] Heller, Michael A., and Rebecca S. Eisenberg, "Can Patents Deter Innovation? The Anticommons in Biomedical Research," *Science* 280: 5364 (1998), http://www.sciencemag.org/cgi/content/full/280/5364/698; Barton, *supra* note 16; Barton, John, "Patent Scope in Biotechnology," *International Review of Industrial Property and Copyright Law* 26: 605 (1995).

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

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

[70] *Ibid.*

[71] ETC Group, *supra* note 27.

[72] U.S. Patent No. 5,004,863.

[73] ETC Group, *supra* note 27.

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 or risk an infringement claim if they develop a useful new product.

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.[74]

The Patent Thicket and Its Consequences

This pattern—the increasing number and breadth of patents, 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

[74] Barton, *supra* note 67, at 614. The reference is to Merges and Nelson, *supra* note 41. See also Van Wijk, Jeroen, "Broad Biotechnology Patents Hamper Innovation," *Biotechnology and Development Monitor* 25 (1995), http://www.biotech-monitor.nl/2506.htm.

obtain licenses from multiple patentees."[75] The patent thicket is a problem because useful innovation in biotechnology requires multiple inventive steps and technologies. 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."[76] The danger of too many or too broad or too early patents has been described by Heller and Eisenberg as an "anticommons,"[77] 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.

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 grant licenses to use the technology, a problem that comes with the dominance of private ownership described earlier. Owners can refuse out of mistrust of

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[75] Shapiro, Carl, "Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting," forthcoming in *Innovation Policy and the Economy, Volume I*, Jaffe, Lerner and Stern, eds., MIT Press (2001), www.haas.berkeley.edu/~shapiro/thicket.pdf . See also Barton, John, "Patent Breadth and Antitrust: A Rethinking," (1995), http://www.ftc.gov/opp/global/barton.htm; Graff, Gregory and David Zilberman, "Towards an Intellectual Property Clearinghouse for Ag-Biotechnology," *IP Strategy Today* 3-2001 (2001), http://www.biodevelopments.org/ip/ipst3hr.pdf; Barton, John, "Reforming the Patent System," *Science* 287 (March 17, 2000), http://www.biotech-info.net/reforming.html; and Rai, Arti Kaur, and Rebecca S. Eisenberg, "The Public and the Private in Biopharmaceutical Research," Duke Law School Conference on the Public Domain (2001), http://www.law.duke.edu/pd/papers/raieisen.pdf.

[76] Shapiro, *ibid.* at 2; Shapiro cites Joseph Stiglitz at a 1995 Federal Trade Commission hearing.

[77] Heller and Eisenberg, *supra* note 67.

licensees,[78] the wish to retain a field of research for themselves,[79] or any other reason. Even public agencies, responding to ownership incentives, do not always promote access.[80] These simple refusals shade into the more complex problems of the patent thicket when the barrier is not one owner but the cumulative costs of gaining access to the technologies:

> 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 antifungal 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 antifungal properties, difficulties in getting commercial rights to the various

[78] "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), http://www.nap.edu/html/intellectual/, at 8.

[79] 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 fibre characteristics have not been authorized by the company. This is the area which is monopolized by Agracetus." Van Wijk, *supra* note 74, at 16.

[80] National Research Council, *supra* note 78, 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.'"

> technologies would make it impossible to market the line. The Strawberry Commission dropped its funding of the program.[81]

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 existing patents 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.[82]

More cooperative responses, such as patent pooling or cross-licensing, have been pursued in some industries,[83] but these also have their costs. Elaborate cross-license structures act as a barrier to entry to the industry,[84] and they can raise antitrust issues.[85] 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

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[81] *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.'"

[82] Barton, "Reforming the Patent System," *supra* note 75; Shapiro, *supra* note 75, at 3.

[83] Graff and Zilberman, *supra* note 75; Merges, Robert P., "Institutions for Intellectual Property Transactions: The Case of Patent Pools" (1999), http://www.law.berkeley.edu/institutes/bclt/pubs/merges/pools.pdf.

[84] Barton, *supra* notes 67 and 75 ("Patent Breadth and Antitrust" and "Reforming the Patent System").

[85] Shapiro, *supra* note 75, at 4.

to operate.[86] Though many other factors are also at work, consolidation in the industry has been dramatic.[87]

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.[88] 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 countries. Some 70 patents and existing licenses had to be addressed.[89] Commentators have written about

[86] Barton, *supra* note 16; King, John L., "Concentration and Technology in Agricultural Input Industries," *Agriculture Information Bulletin* 763, USDA Economic Research Service (2001), http://www.ers.usda.gov/publications/aib763/; Fulton, Murray, and Konstantinos Giannakas, "Agricultural Biotechnology and Industry Structure," *AgBioForum* 4(2) (2001), http://www.agbioforum.org/Default/vol4no2ar8fulton.htm; Lesser, William H., "Intellectual Property Rights and Concentration in Agricultural Biotechnology," *AgBioForum* 1(2) (1998), http://www.agbioforum.org/vol1no2/lesser.htm; Kalaitzandonakes, N., and M. Hayenga, "Structural Change in the Biotechnology and Seed Industrial Complex: Theory and Evidence," in *Transitions in Agbiotech: Economics of Strategy and Policy*, W.H. Lesser, ed. (2000), http://agecon.lib.umn.edu/cgi-bin/pdf_view.pl?paperid=1907&ftype=.pdf.

[87] "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." Graff, Gregory, Gordon C. Rausser, and Arthur A. Small, "Agricultural Biotechnology's Complementary Intellectual Assets" (2000), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=280107, at 1.

[88] Several examples are mentioned in "Workshop 10: Research Tools, Public Private Partnerships and Gene Patenting," Commission on Intellectual Property Rights (2002), http://www.iprcommission.org/papers/pdfs/workshops/workshop10.pdf). See also Graff and Zilberman, *supra* note 75.

[89] Kryder, R. David, 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), http://www.isaaa.org/publications/briefs/Brief_20.htm.

the access problem for developing countries,[90] 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 section after a brief overview of the strong pro-patent orientation of the U.S. patent system.

The Pro-Patent 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 paper 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 Patent and Trademark Office exists to issue patents. Although the agency is charged with making patent decisions based on statutory criteria that applicants must satisfy—and denying patents when the criteria are not satisfied—the PTO's orientation and pervasive culture are strongly pro-patent. 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

[90] 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" (Herdt, *supra* note 27, at 15). See also Binenbaum, Eran, 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), http://www.ifpri.org/divs/eptd/dp/eptdp70.htm; Cohen, Joel I., "Managing Intellectual Property—Challenges and Responses for Agricultural Research Institutes," in *Agricultural Biotechnology and the Poor,* Persley and Lantin, eds. (2000), http://www.cgiar.org/biotech/rep0100/jcohen.pdf; Salazar, Silvia, Joel Cohen, Cesar Falconi, and John Komen, "The Use of Proprietary Biotechnology Research Inputs at Selected Latin American NAROs," ISNAR Briefing Paper 44 (2000), http://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 below in Section 4: Impact of the U.S. Patent System on Developing Country Access to Biotechnology.

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 pro-patent orientation of the PTO simply mirrors the pro-patent 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 protecting the broader interests of society in having access to useful innovation.

This pro-patent 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."[91] 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."[92]

The PTO's pro-patent orientation is not just rhetoric, though. The agency's plan for 2001–2006 has as a strategic goal to "[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."[93]

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—

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

[92] *Ibid.*

[93] USPTO, *supra* note 91, at 17 (Highlights).

> 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.[94]

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."[95] The PTO's Public Advisory Committees, which the agency says are "drawn from a cross-section of our private sector customers,"[96] consist of representatives of "entrepreneurial businesses, inventors, universities, large U.S.-based corporations, and law firms."[97] The public-at-large, the presumed beneficiaries of the innovation the patent system is intended to stimulate, are 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.[98] 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 pro-patent orientation, creates a positive atmosphere for the issuance of patents that inevitably contributes to the volume of applications; that volume, in turn, directly affects PTO revenues. Like any organization, the PTO has an institutional interest in maintaining its revenues.

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[94] Italics added. Statement of James E. Rogan, Under Secretary 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.

[95] USPTO, *supra* note 91, at 17 (Highlights).

[96] USPTO, *supra* note 91, at 46 (Financial Discussion and Analysis).

[97] USPTO, *supra* note 91, at 12 (Highlights).

[98] "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 [*sic*] customers in exchange for fees which are used to fully fund their operations." *About[?]* "An Introduction to the PTO," http://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." USPTO, "Fiscal Year 2001 Corporate Plan," http://www.osec.doc.gov/bmi/budget/PB2001/BROWSE/bjpto.PDF.

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.[99] Pendancy time—the time from application to issue—is carefully monitored, and the law provides term extensions for applicants when the PTO fails to meet various deadlines, which is both an embarrassment and a transaction cost for the agency.[100] Improperly structured applications may be returned to the applicant for revision, but those will come back again. Generally, to reject a patent, the examiner must find that there is "prior art" covering the patent claims. A patent will be issued unless prior art is discovered, and this decision is reached under great time pressure. This can create a particularly strong pro-patent tendency in new and dynamic areas of research and innovation, such as biotechnology, where many researchers in diverse institutions are engaged in inventive 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.[101] All these factors put significant pressure on patent examiners to err on the side of granting rather than denying patents.[102]

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

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[99] Lecture by Brian Stanton of the PTO. Barton (*supra* note 75, 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 testimony of H. Manbeck, former commissioner of the PTO, who says 15 to 17 hours per application.

[100] 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.

[101] "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)." *Radio Free PTO,* the Patent Office Professional Association's website, vol. 00 no. 1 (February, 2000), http://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 "Fifth Biennial Patent System Major Problems Conference: Future of the U.S.P.T.O." *IDEA: The Journal of Law and Technology* 36(2) (1996), http://www.idea.piercelaw.edu/articles/36/.

[102] 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," http://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.pdf.

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 bring 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 postpatent challenges were allowed, there was—and there remains—a strong presumption that an issued patent is valid. Statute explicitly presumes validity, placing the burden of proof on the challenger.[103] 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.[104] 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

[103] 35 U.S.C. Sec. 282, Presumption of validity; defenses.

[104] Gresens, John J., "Patent Reexamination: What You Need to Know," *Merchant & Gould Bulletin* (no date), http://www.merchant-gould.com/news/newsletters/bulletins/bulletin2a.html. See also Yarbrough, Robert J., "Patent Reexamination" (2000), http://www.yarbroughlaw.com/reexamination2.htm.

> newly discovered prior art; it offers no way to reconsider a patent on the grounds that the examiner misapplied the law.[105]

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.[106]

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 pro-patent 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 is in the public interest. Many academic commentators argue that it is not.[107] 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.[108] We have chosen, for reasons discussed below, not to tackle this question, but rather to address whether the public interest and the broad social objectives of the patent system could be better served by adjusting policies that govern access to technologies after they have been patented. We think it is

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[105] Barton, *supra* note 75.

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

[107] Eisenberg, *supra* note 42; Barton, John, "Patents and Antitrust: A Rethinking in Light of Patent Breadth and Sequential Innovation," *Antitrust Law Journal* 65: 449 (1997); Barton, *supra* note 16; McFetridge, Donald, "Intellectual Property, Technology Diffusion, and Growth in the Canadian Economy," in *Competition Policy and Intellectual Property Rights in the Knowledge-Based Economy,* Robert Anderson and Nancy Gallini, eds., University of Calgary Press, Alberta (1998).

[108] Mossinghoff, Gerald J., Statement to FTC and DOJ hearings on Competition & Intellectual Property Law and Policy in the Knowledge-Based Economy (2002), http://www.ftc.gov/os/comments/intelpropertycomments/mossinghoffgeraldj.pdf; Kieff, F. Scott, "Facilitating Scientific Research: Intellectual Property Rights and the Norms of Science—A Response to Rai and Eisenberg," *Northwestern University Law Review* 95(2) (2001); Dodds, J.H., 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), http://www.bioDevelopments.org/ip/index.htm.

important to proceed, however, with a clear understanding of the system as it exists and operates today.

We turn now in the next section to the impact the system has on access to biotechnology for developing country purposes. Once we understand the nature of that impact, we can proceed in the following sections to consider policy alternatives to improve access.

4. Impact of the U.S. Patent System on Developing Country Access to Biotechnology

There is good reason to believe that the U.S. patent system plays an important role and has a negative impact on access to biotechnology for developing country purposes. The starting point for this proposition is the large number of important technologies that are subject to U.S. patents, as documented in the previous section. Clearly, any U.S.-based researcher who wants to use one or more of these technologies to develop an application to address a specific developing country agronomic problem would be directly affected by the existence of U.S. patents. Such a researcher would be precluded from using the patented technology for such a purpose without the permission of the patent holder(s).

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 use in a developing country are not affected by the U.S. patent system because U.S. patents are binding only in the United States. It is true that the U.S. patent system, like others around the world, is legally binding only within the territory of the United States, but this does not solve the problem of developing country access. If a genetically modified crop produced outside the United States using a U.S.-patented technology were exported to the United States, the patent holder could enforce the patent through an infringement claim. Moreover, patent holders typically patent their inventions in many foreign countries, closing off unlicensed exports to those countries as well. By itself, this is a strong legal disincentive for developing country researchers to use U.S.-patented technologies without the permission of the patent holder, if there is any possibility that the resulting crops will be exported.

There are other compelling, nonlegal reasons why access to biotechnology by researchers in developing countries is affected by the existence of U.S. patents. First, these researchers and

their institutions rely heavily on the U.S. government and international financial institutions for their funding. The U.S. government pushes hard for foreign countries and institutions to protect the intellectual property rights of U.S. companies.[109] National agricultural research systems and CGIAR institutions could jeopardize their funding if they systematically violated U.S. patents to develop useful applications of biotechnology.[110]

Second, to the extent 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.[111] 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 tight

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[109] For example, the United States Trade Representative annually reviews the intellectual property compliance of foreign countries to decide whether to impose trade sanctions under section 301 of the Trade Act of 1974:

> United States Trade Representative Robert B. Zoellick today announced the results of the 2001 'Special 301' annual review, which examined in detail the adequacy and effectiveness of intellectual property protection in approximately 72 countries. USTR notes with disappointment the continued designation of Ukraine as a Priority Foreign Country due to its persistent failure to take effective action against significant levels of optical media piracy and to implement intellectual property laws that provide adequate and effective protection. As a result, the $75 million worth of sanctions imposed on Ukrainian products on January 23, 2002, remain in place. This continued failure to adequately protect intellectual property rights could also jeopardize Ukraine's efforts to join the World Trade Organization (WTO) and seriously undermine its efforts to attract trade and investment. The U.S. Government continues to remain actively engaged with Ukraine in encouraging the nation to combat piracy and to enact the necessary intellectual property rights legislation and regulations. The Special 301 report addresses significant concerns in such trading partners as Brazil, Colombia, India, Hungary, Taiwan, the Dominican Republic, Kuwait, the Philippines, Russia, Egypt, Turkey, Saudi Arabia, Uruguay, and members of the Andean Community. (USTR, "2002 Special 301 Report: Executive Summary" (2002), http://www.ustr.gov/reports/2002/special301-execsumm.PDF).

See also Sell, Susan K., *Power and Ideas: North-South Politics of Intellectual Property and Antitrust,* SUNY Press (1998).

[110] 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).

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

restrictions on the use of the technology, including prohibitions on commercialization.[112] 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 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. The practical impact of U.S. patents on access to biotechnology thus clearly extends beyond the United States.

That developing country researchers are affected by the U.S. patent system is also 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.[113] 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.

Finally, the impact of the U.S. patent system on access to biotechnology for developing country purposes was confirmed in our informal survey of experts and stakeholders. When asked whether the U.S. patent system and the existence of U.S. patents is 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.

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

[113] Personal communication with Jack Clough, Meridian Institute (on April 23, 2002).

Our survey was in no sense a scientific investigation of views of patents on biotechnology. Nevertheless, it produced responses that suggest how stakeholders are thinking about these issues. Here are some of them, based on either the numerical summaries of answers to specific questions or the comments of respondents, both of which are in Appendix A.

- There is very wide agreement that biotechnology has important benefits to offer.
- For the specific gene traits, 80% said the U.S. system adversely affects access. For the categories of transformation tools, transformation marker systems, and genetically modified germplasm for specific useful plants, adverse impact on access was affirmed by 64%, 69%, and 76% of respondents, respectively. For expressed sequence tags and genome sequence data on important plant species, the results were different, with 46% and 39%, respectively, saying that the U.S. patent system and U.S. patents adversely affect access.[114] This may reflect the shift away from patenting expressed sequence tags and other sequence data and the recent sharing of genome sequence data by some companies.[115]
- Patent experts differed significantly from all other groups in several answers. Our respondents selected their own areas of expertise. Those who considered themselves knowledgeable about the U.S. patent system were much more inclined than others to see the system as working well without special provisions to help developing countries gain access to patented technologies. A notable exception is that patent experts supported a stronger research exemption—the most widely supported patent system change—in about the same proportions as other respondents.
- There was considerable agreement that patents are being granted that are too broad. This was generally considered the most obstructive feature of the patent system (questions 6 and 7),

[114] The number of respondents for each of these categories ranged from 32 (for ESTs) to 36 for transformation tools and marker systems.

[115] For the history of changing standards of EST patenting, mostly the changing utility standard, see Kight, Andrew T., "Pregnant with Ambiguity: Credibility and the PTO Utility Guidelines in Light of *Brenner*," *Indiana Law Journal* 73: 997 (1998), http://www.law.indiana.edu/ilj/v73/no3/kight.html; Eisenberg, Rebecca S., and Robert P. Merges, "Opinion Letter as to the Patentability of Certain Inventions Associated with the Identification of Partial cDNA Sequences," *American Intellectual Property Law Association Quarterly Journal* 23(1): 21 (1995). Monsanto and Syngenta have both offered to widely share rice genome data—though with conditions attached (see Butler, Declan, "Geneticists Get Steamed Up over Public Access to Rice Genome," *Nature* 416 (March 14, 2002))—and other fungal and plant genomes are being made available to researchers (Oklahoma State University's Bioinformatics Laboratory lists available genomes: http://bioinfo.okstate.edu/pipeonline/).

the PTO's most significant deviation from law (question 8), and one of the most important problems for "fair and timely access" (question 5).

- Respondents were less concerned that there might be too many patents. At the same time, some said that things were being patented that should not be, such as discoveries (i.e., parts of nature), and that the "obviousness" criterion was too easy to meet. The multiplicity of patents (the patent thicket) was considered the single biggest problem with the patent system overall (question 6). Reading between the lines, then, the respondents may agree with the "too many patents" sentiment, but perceive "too many" as the wrong concept, too ad hoc, when what they want is a principled criterion.
- Material transfer agreements (MTAs) are a serious problem for developing country researchers, effectively creating patent restrictions in countries where the patents would not otherwise apply. Actually getting high-tech materials is difficult.
- "Developing countries" is too broad a category. Many respondents noted that the situations in nonindustrialized countries vary significantly and said that resolving the access problem will require looking more specifically at each country.
- Various respondents noted what we might call an authority vacuum in the patent system: Congress and the Supreme Court know little about patents and their consequences, and the PTO, whose role is to issue patents, should not, and is not competent to, make larger policy about social and economic progress. The result is that real power rests with the Court of Appeals for the Federal Circuit, which is unchecked by Congress, the Supreme Court (most of the time), and the PTO.

Those are some of the ideas that emerged from our survey. It revealed diverse views about the impact of the patent system and considerable complexity in the thinking of respondents about the interaction between U.S. patents and access to biotechnology for developing country purposes. The great majority (86%) agreed that the system has an adverse impact on access to one or more categories of biotechnology. Their explanations 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, due to fear that products resulting from unlicensed use of patented tools will be challenged, and thus unmarketable, and 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 and the U.S. Agency for International Development for countries to adopt patent systems based on the U.S. model.[116]

Certainly there are other factors, besides the U.S. patent system, that affect access to and development of biotechnology to solve developing country agronomic problems. These obstacles have been studied and documented extensively by others,[117] and they have been well summarized recently by Walter Falcon.[118] One is the lack of economic incentives for commercial development of the technology, as discussed earlier. The shift of agricultural research resources from the public to the private sector has placed many of the tools of biotechnology in the hands of private companies that lack an economic incentive to invest in the improvement of subsistence crops for African farmers, or even in potential commercial crops in markets that cannot deliver competitive returns on investment. Another obstacle to the use of biotechnology for food security is developing countries' lack of public sector capacity. 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 agricultural researchers who focus on developing country food security needs rather than on economic return to the technology developer. These researchers work primarily in public or quasi-public institutions, such as developing country national agricultural research systems and the international research system (principally CGIAR[119]), which have experienced funding declines in recent years. Apart from any impacts of the patent system, their access to and beneficial use of biotechnology is

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[116] See Rogan, James E., 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." U.S. AID 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."

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

[118] Falcon, *supra* note 4.

[119] http://www.cgiar.org/. Now known as Future Harvest: http://www.futureharvest.org/.

constrained by the scarcity of research infrastructure, financial resources, and scientists trained to conduct biotechnology research.[120]

For the purposes of this paper, we recognize that the interaction between the U.S. patent system and developing country access to biotechnology is complex, variable, and dynamic, and is only part of the story. But we believe the patent system has an adverse impact on access—in the sense that the system operates to constrain access by researchers who believe they could put biotechnology to good use to address developing country agronomic and food security problems. It is this impact that justifies considering policy change to improve access. It is necessary, then, to establish a framework for evaluating this impact of the patent system and of possible policy changes. In the next section, we suggest such a framework, and then in the following section we present six alternative ways the U.S. patent system could be changed to ease access to biotechnology and improve food security in the developing world.

5. Framework for Evaluating the Impact of the Patent System and Policy Alternatives

It is relatively easy to posit in general terms that the U.S. patent system has an adverse impact on access to biotechnology for developing country purposes. This does not suffice, however, as a basis for proposing change in patent policy to improve such access. As discussed in the introduction, the patent system has multiple objectives whose achievement should be considered and balanced, and, as discussed below, there are significant gaps in empirical data on the impact of the patent system that must be taken into account in any objective approach to

[120] Cohen, Joel I., et al., "Proprietary Biotechnology Inputs and International Agricultural Research," ISNAR Briefing Paper 39 (1998), http://www.cgiar.org/isnar/publications/briefing/BP39.htm; Binenbaum et al., *supra* note 90; Kryl, David, "Environmental and Industrial Biotechnology in Developing Countries," U.N. Industrial Development Organisation (2001), http://www.ejb.org/content/vol4/issue3/issues/03/; Junne, Gerd, "Biotechnology: The Impact on Food and Nutrition in Developing Countries," *Food, Nutrition and Agriculture* 1 (1991), http://www.fao.org/docrep/u3550t/u3550t0h.htm.

analyzing possible policy change.[121] To facilitate analysis of policy alternatives, we need a clearly articulated conceptual framework that includes both normative and analytical elements. The normative elements should spell out what values and perspectives guide the analysis of policy alternatives. The analytical elements of the framework include the questions that need to be asked about each policy alternative and an approach to answering them that both takes account of the relevant social values and compensates for the general lack of empirical data on many relevant points.

Normative Framework

The normative framework we adopt for this study draws on a large body of literature, research conducted for this paper, and experience, from which we distill the following values and perspectives to guide our analysis of patent system policy alternatives:

Normative Element 1: The patent system is an instrumental social construct intended to benefit society by fostering useful innovation. The success of the patent system and possible changes in the system 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.[122]

This normative perspective is critical to our study because it provides the justification for evaluating the performance of the system from a social outcome perspective and for considering

[121] The lack of confidence in empirical studies of the patent system is well summarized by 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" (Oddi, *supra* note 31, 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" (Grady, Mark F., and Jay I. Alexander, "Patent Law and Rent Dissipation," *Virginia Law Review* 28 (1992), at 309–310, quoted n. 18); and Priest saying, "The ratio of empirical demonstration to assumption in [patent economic] literature must be very close to zero" (Priest, George L., "What Economists Can Tell Lawyers about Intellectual Property," *Research in Law and Economics* 8(19) (1986), quoted n. 20); and he suggests that the issue has not been resolved since 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" (Machlup, Fritz, *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).

[122] See Thurow, Lester C., "Needed: A New System of Intellectual Property Rights," *Harvard Business Review* vol?9–10/97 (1997), http://vision.rc.ukans.edu/SPED997/unit3/thurow.htm; Eisenberg, Rebecca S., "Patents: Help or Hindrance to Technology Transfer," in *Biotechnology: Science, Engineering, and Ethical Challenges for the Twenty-First Century,* Rudolph and McIntire, eds., 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).

policy change. Under a natural rights theory of patents, social outcomes would matter less, if at all, and the question would be whether the system adequately protects the natural property rights of the inventor. From that perspective, there would be little basis for evaluating the social impact of the system or for considering policy change to improve social outcomes. From the instrumental perspective, however, the social outcome—the benefit to society from useful innovation—is the primary justification for granting patents and the basis upon which the success of the system should be judged.[123] If the patent system is not achieving this objective or could achieve it better, it is fair and appropriate to consider policy change.

Put positively, if a policy change would improve the relationship between the benefits and costs of patents, such a policy change should be considered. Though simple in concept, this normative perspective introduces considerable analytical complexity, as we discuss below.

Normative Element 2: It is fair to evaluate the success of the U.S. patent system and policy alternatives from a global food security perspective.

This element of our normative framework is also critical, since the purpose of our study is to evaluate possible alternatives to current U.S. patent policy that might benefit food security in developing countries by improving access to biotechnology. It is also more novel than the first element in the sense of being less well grounded in the existing patent literature. It flows, however, from the utilitarian or instrumental view of why we have a patent system. The question is how we justify including global food security among the societal interests against which the U.S. patent system is fairly judged. We propose three answers.

First, the U.S. patent system has extraterritorial aspirations and impact. It is the declared objective of the PTO to promote adoption of U.S.-like patent systems in other countries,

[123] 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. The ethics of the patent system with respect to its impact on food security are addressed in Normative Element 2, below, and in our consideration of options to improve developing country access, as discussed below.

including developing countries.[124] Moreover, the U.S. government frequently presses other governments and other institutions in foreign countries to respect U.S. patents,[125] and, as discussed earlier, the U.S. patent system has practical impact on access to technology in other countries. In light of the U.S. system's extraterritorial aspirations and impact, it is fair to examine its extraterritorial consequences and consider how they can be ameliorated through change in U.S. policy.

Second, the United States has declared the achievement of international food security a national objective. In 1996, the United States joined most other nations at the World Food Summit in adopting the goal of cutting global hunger in half by 2015.[126] U.S. representatives declared at the summit that achieving global food security was vital to the national security and economic interests of the United States, and President Bush recently reiterated the U.S. commitment to this goal.[127] This makes food security a legitimate societal interest for purposes of assessing the impact of U.S. patent policy, or any other important element of U.S. policy.[128]

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

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[124] Rogan, James E., "Remarks for Hearings on Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy" (http://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." USPTO Annual Report 2000, 2000 Highlights: "Many developing countries were also provided technical assistance by the USPTO to help them implement their obligations under the Trade Related Aspects of Intellectual Property Agreement (TRIPs)." USPTO Annual Report 2000, Intellectual Property Leadership: "As the largest intellectual property office in the world, the USPTO is at the forefront of developing and strengthening intellectual property protection, both at home and abroad. The Under Secretary 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"; "To protect, promote, and expand intellectual property rights domestically and abroad, the USPTO engaged in the following international activities …."

[125] See *supra* note 32.

[126] "Rome Declaration," *supra* note 1.

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

[128] This conclusion applies to a host of U.S. policies and programs potentially affecting food security in developing countries, such as those in the areas of food aid programs and development assistance, agricultural subsidies and export promotion, international trade agreements, environmental protection, and food safety.

States cannot by itself solve the world's technological and economic problems. Many argue, however, that the United States has a moral duty to contribute affirmatively to their solution, as well as a national security interest that calls for action to reduce 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.

With this normative framework in mind, we turn now to the analytical framework we propose for evaluating patent policy alternatives.

Analytical Framework

Finding a way to evaluate patent policy is a daunting task. There is, for practical purposes, 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 appropriate in any event to consider the benefits and costs of the system as a whole for purposes of considering policy change. But to evaluate fully the benefit of patents would require considering and balancing the patent system's multiple objectives, by answering such questions as: Would the 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? Evaluating the costs to society of granting patents 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 (e.g., license fees and related negotiating expenses) for access to patented technology? What negative impacts have the patents had on invention and practical application by others? What negative impacts 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.

Perhaps the best way to approach the problem is to ask how the system affects a category of technological research and development (such as agricultural biotechnology). Evaluating the benefits and costs of the patent system in 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.[129] 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.[130] 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.[131]

We accept those practical limitations on the ability to apply a societal cost-benefit test in judging the success of the patent system. However, given the instrumental rationale for having a patent system, it is not acceptable to defend the current system solely on the basis of an assumption that current patent law and policy work effectively to benefit society. Whether, in any particular area of invention, the benefits of patents in terms of useful innovation exceed the costs remains a fair question. Likewise, it is fair to ask, as we do in this study, whether changes in patent law and policy would improve the relationship between patent benefits and patent costs. The challenge is to frame the question in a way that it can be usefully answered. We attempt to do that with the following analytical framework.

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[129] Mazzoleni and Nelson, *supra* note 38, 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?

[130] Levin, R.C., A.K. Klevorick, R.R. Nelson, and S.G. Winter, "Appropriating the Returns from Industrial Research and Development," Brookings Papers on Economic Activity (1987); Cohen, Wesley M., 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), http://papers.nber.org/papers/W7552.

[131] Heisey, Srinivasan, and Thirtle, *supra* note 21, 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" (Blakeney, Michael, 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,* J.I. Cohen, ed. (1999), http://www.cabi-publishing.org/bookshop/ReadingRoom/0851994008/V_18.pdf).

Simplifying Assumptions and Choices

Our goal is a manageable approach to identifying and evaluating specific patent policy options that could improve access to agricultural biotechnology for developing country purposes. In light of the analytical complexities and data limitations outlined above, we need to make some simplifying assumptions and choices. These include the following:

- *We will assume that the objective of food security is advanced if access to biotechnology is improved.* This is a critical simplifying assumption. As explained in the introduction, technology is just one of many factors that affect food security, and it would be impossible to prove in advance whether or to what extent any degree of improved access to biotechnology would improve food security. We make this simplifying assumption in reliance on the opinions of experts that biotechnology has promise for improving food security, and that access for this purpose is adversely affected by the patent system.
- *The goal of improved access will be 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*. With this definition of improved access, we recognize that patents are not the only obstacle to developing country access to the tools of biotechnology and thus that patent policy change alone cannot ensure 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. This study addresses the more narrow issue 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.
- *We assume 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 this study that it is real and that any significant reduction in the incentive would be undesirable.
- *We assume that the U.S. patent system, taking into account its 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 maximize useful innovation*. As discussed earlier in this paper, there has been much commentary on the tendency toward excessive

patenting in the field of agricultural biotechnology.[132] 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 system is not working optimally to foster useful innovation justifies the consideration of policy alternatives to improve the system.

- *We will focus on postpatent policy changes 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 for reasons of analytical and political feasibility. This pragmatic choice will simplify the analytical task by permitting us to focus on how the proposed policy changes specifically affect the food security interest that motivates this study, without having to analyze broader impacts. We do not doubt the possibility that changes in patenting practices and policies could improve how the patent system contributes to useful applications, including for developing country food security purposes. But changes in patenting practices and policies are inherently difficult to justify analytically, given the previously mentioned lack of empirical data, and we will limit our focus to postpatent changes.
- *We will take a qualitative rather than quantitative approach to evaluating the policy options.* This is necessitated by the lack of empirical data on the benefits and costs of the current system and the lack of quantitative models for predicting the impact of patent policy change in this area.

Analytical Questions and Decision Tree

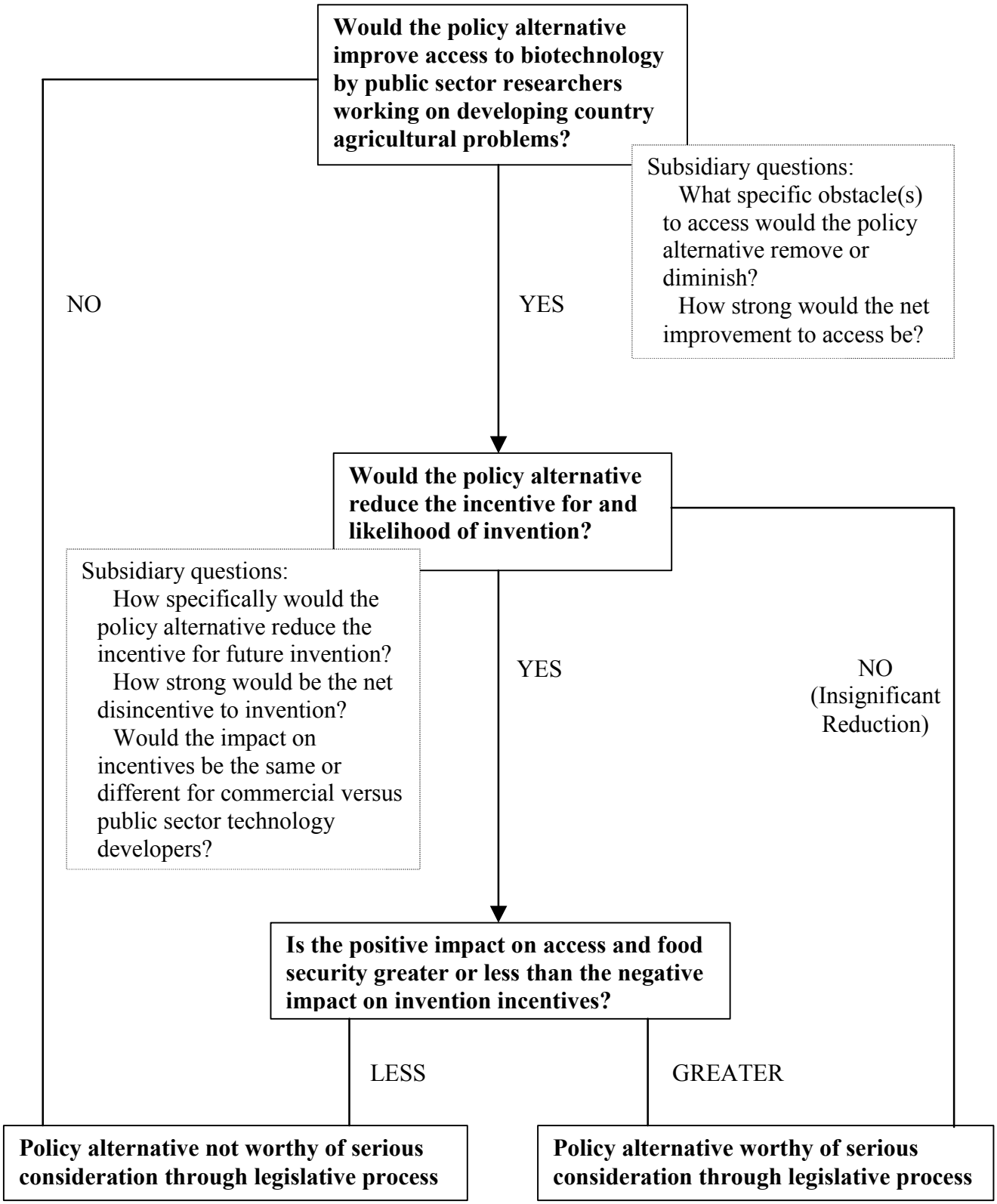
Based on those assumptions and choices, we have identified for evaluation six policy options that could improve access to biotechnology to address developing country agronomic and food security problems. For each policy alternative, we propose a thought experiment, consisting of two broad questions and some subsidiary questions that can be posed in a simple decision tree format. (See Figure 2.) The objective of the thought experiment is to identify which of the six policy alternatives, or others that might be proposed, are worthy of serious legislative consideration.

[132] *Supra* notes 67 to 90 and accompanying text.

The first broad question is whether the policy alternative would improve access to biotechnology by public sector researchers working on developing country agricultural problems. Subsidiary questions would include: What specific obstacle(s) to access would the policy alternative remove or diminish? How strong would the net improvement to access be? If the answer to the first broad question is no, the analysis ends and the policy alternative is rejected.

If the answer is yes, we will ask the second broad question, whether the policy alternative would reduce the incentive for future invention and useful innovation by technology developers and patent holders. Subsidiary questions here include: How, specifically, would the policy alternative reduce the incentive for future invention? How strong would the net disincentive to invention be? Would the impact on incentives be the same or different for commercial versus public sector technology developers? If the answer to the second broad question is that the policy alternative would have little or no adverse impact on incentives for invention, we would deem the policy alternative worthy of serious consideration through the legislative process.

Figure 1: Decision Tree for Policy Alternatives



If this analysis reveals that a policy option would improve access but may also have a significant impact on the incentive for invention and useful innovation by commercial technology developers and patent holders, we will compare qualitatively the adverse impact on invention incentives and the positive impact on developing country access, using the information generated by the subsidiary questions. If this comparison shows that the positive impact on access and food security outweighs the negative impact on invention incentives, we would consider the change worthy of legislative consideration.

We will make this comparative analysis separately for each of the three broad subcategories of biotechnology: (1) specific functional gene traits; (2) transformation tools and marker systems; and (3) genetically modified germplasm for specific useful plants. This is necessary because the analysis and comparison of impacts on invention incentives and developing country access could differ significantly from category to category. For example, some tools of biotechnology, such as transformation tools, may be more likely than others to be developed for research or commercial reasons regardless of patent protection, and thus postpatent access for developing country purposes would be expected to have less impact on incentives for invention than in other categories.

6. Policy Alternatives

In this section, we outline six patent policy alternatives. For reasons discussed earlier, they all involve expanding access to patented technologies, rather than changing what gets patented, and they are all designed to achieve a common goal: making U.S.-patented tools of biotechnology available for developing country purposes while preserving incentives for private sector investment in invention and commercialization. These are the six alternatives:

1. Codification and expansion of the research exemption to permit use of patented biotechnology tools to develop new products for specified developing country purposes.
2. A requirement that patents for technologies that could help address developing country problems be worked (put to practical use) for those purposes or be lost for those purposes.
3. Compulsory licensing of patented biotechnology tools for specified developing country purposes.

4. Use by the U.S. government of its eminent domain authority to take inventions, with appropriate compensation, and make them available for research and development for specified developing country purposes.
5. Change in USDA's patenting and licensing policies to place in the public domain, for specified developing country purposes, all patented biotechnology developed with USDA funding.
6. A blanket statutory exemption from infringement claims when patented biotechnology is used for defined developing country purposes.

It is important to reiterate here a point made earlier. The alternative policies address only the impacts of the U.S. patent system itself on access to biotechnology for developing country purposes. The issues of access to materials and know-how, and the availability of resources and expertise to exploit the tools of biotechnology for developing country purposes are not addressed. The assumption underlying each alternative, however, is that by reducing patent system constraints on access, the incentives and prospects for putting the other pieces in place will increase. This assumption deserves challenge and discussion.

Because the purpose of these policy alternatives is "to make the tools of biotechnology available for developing country purposes," we need to define that expression. We propose it to mean that a tool is available for use, without risk of patent infringement, by researchers and technology developers, located in the United States or anywhere else, to create genetically modified food crops that will be planted in developing countries with minimal potential for export to the United States. Under this definition,

- The uses that could proceed without risk of patent infringement would include research and development, subsistence (noncommercial) planting and consumption, and commercial planting and sale of resulting food crops, subject to the minimal export limitation.
- The researchers and technology developers could be in any organization, public or private, commercial or noncommercial, in the United States or elsewhere.
- The genetic modification could be for any agronomic, processing, or nutritional purpose.
- Given the food security goal, "developing countries" is a term that needs to be defined in a way that makes intuitive sense. We would tentatively include the 83 low-income, food-deficit

countries identified by the Food and Agriculture Organization of the United Nations, though other definitions should be evaluated in future work.[133]

- Food crops with minimal potential for export to the United States would have no history of significant export to the United States (greater than 10% of the developing country's production), and future exports would likely not exceed the 10% level.[134]

That understanding of developing country purposes will be assumed for each of the six policy alternatives.

The policy alternatives we have selected for analysis are generally grounded in familiar concepts, some of which are already contained in some form in national patent legislation or international patent frameworks, such as the Trade-Related Aspects of Intellectual Property (TRIPs) Agreement under the World Trade Organization. They represent a spectrum of

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[133] FAO, "Low-Income Food-Deficit Countries," http://apps.fao.org/notes/876-e.htm. The low-income food deficit designation is imperfect. It includes, for example, China, which may not be appropriate to include as a developing country for this purpose, and does not include Uganda, which probably should be included. Nevertheless, since the defining of criteria for special treatment is an issue on which many people are already working in many fora, we should probably be followers here, not leaders. Another possibility, besides the FAO's food deficit definition, would take more of a rule-setting perspective than an immediate food security perspective; what we are proposing here is virtually a form of "special and differential" (S&D) treatment for developing countries with respect to patent rules. The WTO is currently refining the definitions of S&D for various purposes, which has gained increased importance since the Fourth WTO Ministerial Conference last November in Doha, Qatar. Perhaps a definition can be adapted from there for purposes of special access to patented tools of biotechnology. Several countries have already submitted proposals defining S&D. If the goal is promoting access, an adapted definition presumably should be from the more permissive end of the range of proposals. And since sub-Saharan Africa is a particular target for agricultural improvement, perhaps the discussion of definitions should start from the Africa Group's proposal to the WTO on criteria for technical and financial assistance (TN/CTD/W/3/Rev.1, still restricted at time of writing; proposals from various countries and the *Report to the General Council* are available at http://docsonline.wto.org/ by searching on document symbol TN/CTD). The Africa Group has advocated "a full review of the implementation of the provisions of Article 66.2 by developed countries" (http://www.sis.gov.eg/public/africanmag/issue02/html/enafr20.htm). Article 66(2) of the TRIPs Agreement says, "Developed country Members 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."

[134] The 10% export limitation is somewhat arbitrary, but is intended to allow for some export without the risk of infringement while ensuring that the primary use of the technology is to meet developing country food production and food security needs. The threat of competition from developing countries may be less than it might seem at first glance, and easier to handle on a case-by-case basis. Binenbaum et al., *supra* note 90, discuss the trade patterns in the major food crops of developing countries: "Developing-country exports to the developed world are not only concentrated in a few commodities …. but the preponderance of exports originates from comparatively few countries. Just 9 LDC countries shipped 76 percent of the 15-crop total exports to the developed world …." (page 38).

approaches that vary primarily with respect to the degree of access afforded and the transaction costs involved in gaining access. For each policy alternative, we will briefly summarize the alternative, comment on the degree of access and patent-related transaction costs involved,[135] and pose some questions that deserve discussion. All the proposed policy alternatives would directly reduce patent protection for certain developing country applications of biotechnology, and thus all are likely to improve access to some degree. The degree of the impact would presumably be affected by the specific provisions of the policy alternative, such as the scope of the applications of biotechnology that are removed from patent protection and other possible variations.

The policy alternatives sketched out here require further discussion, analysis, and refinement. None have been fully fleshed out, and some may have implications that are beyond the scope of this paper. For example, owners of proprietary technologies may have concerns about their potential liability for biosafety problems and achieving regulatory compliance when their technologies are used by or are in the control of others. These and other possible implications deserve consideration in the public policy process. The primary purpose of presenting the alternatives in this simple format is to stimulate discussion and analysis and to invite input on how the alternatives could be further developed. The authors invite comments at any time on (1) the details of the policy alternatives as presented and how they could be refined or further developed; (2) additional policy alternatives to improve access to biotechnology for developing country purposes; (3) how these and other policy alternatives would improve access; and (4) what effect the policy alternatives would have on incentives for invention and practical innovation by commercial technology developers and other potential patent holders.

Alternative 1: Codification of a Strong Research Exemption

Proposal: Strengthen and codify the limited and judicially created research exemption in U.S. patent law such that the use of U.S.-patented inventions in research and development related to food crops intended for developing country purposes does not infringe the U.S. patent.

Improvement to access: Provides clear access to researchers and technology developers from the time the invention is patented, but does not directly address the use and possible commercialization of resulting crops in circumstances that might result in export of commodities or food products to the United States.

[135] Patent-related transaction costs include the expertise, effort, and financial resources required to know the patent status of technologies, negotiate licenses and royalties, and pay royalties.

Transaction costs: A statutory research exemption would be essentially free of transaction costs, since the researcher or technology developer would not be required to know the patent status of the technology in question, and no license or other form of permission would be required to use the technology for the covered purpose.

Questions and points to consider:

- This alternative is intended to strengthen and clarify the research exemption, which exists in U.S. patent law only as an interpretation by the courts of what constitutes infringement.
- It would decrease an invention's value to the patent owner to the extent that its value depends on commercial sales as a research tool (or at least sales to a segment of researchers). Does that value need to be protected sometimes, and, if so, in what circumstances?[136]
- It would also decrease an invention's value to the extent that its value derives from its use to limit research (or a certain portion of research). To what extent is that the value of patents in biotechnology? Do we want the patent system to allow or discourage that use of patents?
- Should the exemption cover only laboratory research, or should it extend to the transformation and field testing of plants for specific agronomic purposes?
- What scope is necessary to provide meaningful access for developing country purposes?
- Can or should a legislatively codified research exemption be applied retroactively to patents in existence at the time of the exemption's enactment?

[136] There is already a considerable discussion of the question of patenting research tools. 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 88; National Institutes of Health, *Report of the National Institutes of Health (NIH) Working Group on Research Tools* (1998), http://www.nih.gov/news/researchtools/; Eisenberg, Rebecca S., "Technology Transfer and the Genome Project: Problems with Patenting Research Tools," *Risk: Health, Safety, and Environment* 5: 163–74 (1994), http://www.fplc.edu/risk/vol5/spring/Eisenber.htm; Eisenberg, *supra* note 42; Eisenberg, *supra* note 16; Mueller, Janice M., "No 'Dilettante Affair': Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools," *Washington Law Review* 76(1) (2001).

Alternative 2: "Working" Requirement for Agricultural Biotechnology Patents

Proposal: Add to U.S. patent law a requirement that patented biotechnology be worked by the patent holder for developing country purposes, modeled on the working provision in the Paris Convention for the Protection of Intellectual Property as adopted in the TRIPs Agreement.[137] 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).

Improvement to access: Provides access for all research and development, subsistence, and commercial purposes, but only after a three-year waiting period.

Transaction costs: Requires the researcher or technology developer to be aware of the patent status, including the timing and scope of patents on targeted technologies, and to apply for a license.

Questions and points to consider:

- Most countries have a blanket working requirement—that is, one not limited to working for developing country purposes.
- How should "working the patent" for developing country purposes be defined?
- This proposal may be counter to the TRIPs Agreement, article 31(f), which requires that "any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use." This article is currently under review because it hampers developing country access to medicines; should food security considerations be included in that review?
- What purpose does a waiting period serve in the context of a statutory working requirement that is limited to agricultural biotechnology? Is three years the right amount of time? Does this waiting period give patent holders time to choose the uses

[137] See section 5(A)(4) of the Paris Convention. The TRIPs Agreement requires compliance with the Paris Convention, which was enacted in 1883. The United States is a signatory of the Paris Convention, but, unlike almost all other countries, has not adopted a working requirement.

of the invention they will exploit, so that unworked uses can be presumed to have no impact on their innovation incentives?

- Should the license be royalty-free, on the rationale that the patent holder has lost nothing? If not, on what basis should the royalty be determined?
- In the United States, should an existing agency serve as the designated authority for purposes of implementing the compulsory license provision? If so, which one? If not, in what department of government should this authority be housed?

Alternative 3: Compulsory License Requirement for Agricultural Biotechnology

Proposal: Add to U.S. law a procedure to grant nonexclusive licenses to any requesting party for the use of any patented tool of biotechnology for developing country purposes; royalties would be set at rates (including zero) that reflect the extent of the reasonably foreseeable value that the patent holder would forgo, taking into account the likelihood of the patent holder's commercialization of the technology for the developing country purpose.

Improvement to access: Would provide full access for developing country purposes from the time of patent issuance.

Transaction costs: Requires the researcher or technology developer to be aware of the patent status, including the timing and scope of patents, on targeted technologies; to request a license; and to negotiate and, as appropriate, pay a royalty.

Questions and points to consider:

- U.S. law already has similar provisions in place under the Clean Air Act to make air pollution prevention inventions available, and also under the Atomic Energy Act.[138]
- Under the TRIPs Agreement, compulsory license provisions are allowed for any purpose as long as they meet the constraints of article 31. The agreement mentions five broadly defined public purposes: (1) to ameliorate a refusal to deal (essentially a failure to work the patent); (2) to address a health or other emergency of extreme urgency; (3) to resolve anticompetitive practices; (4) for noncommercial use; and (5)

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

for dependent patents.[139] Under U.S. law, compulsory licenses are provided for in cases of anticompetitive practices, for the government's use, and most generally for the "public interest."[140]

- Is the proposed basis for determining royalties appropriate? Is it practicable? Will these royalties fully restore any innovation incentives that would otherwise be lessened by the loss of licensing control?
- What entity should resolve disputes about royalties? Through what process?

Alternative 4: Exercise of U.S. Eminent Domain Authority

Proposal: Allow the U.S. government to exercise its existing statutory eminent domain authority under 28 USC 1498 to authorize any public or private sector technology developer to use patented tools of biotechnology for developing country purposes. A designated authority would establish an administrative mechanism under which the technology developer would be deemed to be using the technology for the United States, thus making the U.S. government rather than the technology developer liable for any compensation to which the patent holder could prove itself entitled in court.

Improvement to access: Would provide full access for developing country purposes following completion of the administrative process required for exercise of the eminent domain authority.

Transaction costs: Requires the researcher or technology developer to be aware of the patent status of the targeted technology and to submit whatever notice or request is required by the

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[139] These five are listed in Correa, Carlos M., *Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options.* London and New York: Zed Books Ltd. (2000), at 89–91. "Dependent patents" are patents on inventions that make some essential use of another patented invention, and which therefore cannot be exercised without infringing that other patent. Typically, they are either improvements on or new uses for the original invention. This enables the original patent to be used for "blocking," and most countries other than the United States do not allow that practice.

[140] Where the U.S emphasis on antitrust as the primary grounds for compulsory licenses seems to conflict with the rest of the world's emphasis on refusal to deal (failure to work) or dependent patents, Barton argues that there is some fungibility between these two positions. In a section titled "Refusal to license as an antitrust issue," he says, "The obvious and very controversial further question is whether the unwillingness of the holder of a broad or basic patent to license at reasonable terms should be read as a violation of § 2 of the Sherman Act. A monopoly on one product line is a reasonable incentive, within the traditional scope of the patent system. But to allow this monopoly to reach a variety of product lines is likely to harm innovation and competition far more than help such innovation and competition. In short, and again in contrast to traditional U.S. law, a § 2 interpretation that makes it illegal to refuse to grant a license may provide an antitrust analogue to a dependency license." Barton, *supra* note 75 (1995; see 1997).

government's administrative process. Requires the government to establish an administrative process sufficient to satisfy 28 USC 1498, and exposes the government to the possibility of having to negotiate, litigate, and pay compensation claims should they be pursued by patent holders.

Questions and points to consider:

- Eminent domain authority under 28 USC 1498 has existed in U.S. patent law since 1910.[141] There are no subject matter, purpose, or other substantive restrictions on its use, and 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)."[142]
- The existing 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.
- This alternative would insulate from infringement claims anyone seeking to use patented biotechnology for the defined developing country purposes and thus remove the existence of the patent(s) as an obstacle to their use.
- This alternative would presumably remove any prospect of patent rewards to investment in applications of biotechnology for developing country purposes. How significant a contribution, if any, does the prospect of such rewards make to the incentives to innovate in biotechnology?
- Would the proposed alternative fit within the existing eminent domain authority?

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[141] Act of June 25, 1910, c. 423, 36 Stat. 851.

[142] Janicke, Paul, "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), http://www.law.uh.edu/healthlawperspectives/.

Alternative 5: All U.S. Government-Funded Biotechnology in the Public Domain

Proposal: 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, are deemed to be in the public domain and are made available by the government, without the need for a license or other permission, when used for developing country purposes.

Improvement to access: Access to technologies developed by the government is immediate but limited in scope.

Transaction costs: The researcher or technology developer is required to know what technologies were developed by the U.S. government, but this alternative is otherwise relatively free of transaction costs since no license or royalty is required.

Questions and points to consider:

- USDA's current patent policy is based on the goal of making government-developed technology available for development and application.[143]
- Implementation of the current policy frequently results in technologies being patented and licensed to a commercial technology developer, often on an exclusive basis, on the grounds that only a commercial entity with the incentive of patent protection will invest the resources to develop the technology and make it available through the market. The practical consequence is to take many technologies developed with public funds out of the public domain and make them less accessible for developing country purposes.
- As proposed, this alternative would make any licenses granted to specific developers subject to a blanket license authorizing the use of any government-patented biotechnology for developing country purposes. Would this exception to the exclusivity of their licenses undermine the incentives for such developers to enter public-private partnerships or to otherwise invest in commercializing government-funded inventions?
- Should this alternative be expanded to include government-funded technologies developed by nongovernmental institutions? This could be accomplished by requiring

[143] USDA, "Technology Transfer in ARS," 141.2-ARS (2000), http://www.afm.ars.usda.gov/ppweb/141-2.htm.

that the nongovernmental inventor grant royalty-free, nonexclusive licenses to those who want to use the technology for developing country purposes when the government funding exceeds some threshold, such as 10%, 25%, or 50%. Would expansion of the alternative in this fashion significantly increase transaction costs?

- The Bayh-Dole Act included a government license in all funded 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" (section 202(c)(4)). The Rome Declaration, which the United States signed, says, "We pledge our actions and support to implement the World Food Summit Plan of Action."[144] Would this alternative, then, be a proper exercise of 202(c)(4)?

Alternative 6: Blanket Statutory Exemption for Developing Country Purposes

Proposal: Add to U.S. patent law a provision that the use for developing country purposes of any patented tool of biotechnology will be deemed not to infringe the U.S. patent.

Improvement to access: Access is complete and immediate.

Transaction costs: There are no patent-related transaction costs.

Questions and points to consider:

- This is the broadest alternative because it exempts from infringement claims any use of a patented biotechnology for developing country purposes, as defined above.
- It is tantamount to a statutory, nonexclusive, royalty-free compulsory license for all developing country purposes, but without the transaction costs normally associated with compulsory licenses.
- As with alternative 4, this alternative would presumably remove any prospect of patent rewards to investment in applications of biotechnology for developing country

[144] 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." http://www.fao.org/docrep/003/w3613e/w3613e00.htm.

purposes. How significant a contribution, if any, does the prospect of such rewards make to the incentives to innovate in biotechnology?

We invite comments on any aspect of the six policy alternatives. In addition, we are interested in comments on the background discussion provided in this paper, and on the framework we have proposed for analyzing patent policy alternatives. We seek written input from a broad cross-section of experts and stakeholders, whether based on experience, expert opinion, or empirical data. Based on this input, combined with the results of a small workshop of invited experts to be convened this fall, we will issue a final report on our research.

7. Conclusion

No social system is perfect. In the case of the patent system, society has created a one-size-fits-all tool that the U.S. Patent and Trademark Office must apply to a broad and highly diverse spectrum of technologies. The system is bound to work better in some areas than in others, but it is unlikely to achieve a perfect balance among its multiple objectives in any area. This paper proceeds from the simple premise that if companies patent technologies that they are unlikely to exploit for the important social purpose of meeting developing country food security needs, the existence of the patents should not be allowed to bar access to the technologies by those who will use them for that purpose. If changes in public policy can foster access without significantly undercutting the incentives for creation of the technology in the first place, such changes in public policy should be considered. Based on our research, we think the balance in the U.S. patent system may need adjusting to foster developing country access to biotechnology. Further analysis of the policy alternatives outlined in this paper will help us and others test this hypothesis and, if it holds up, develop specific proposals for policy change.

Appendix A: 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 aggregated 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 aggregated 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, but by **September 10** if possible. 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):

4	Less confident answering this question.

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

[8] Less confident answering this question.

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% 4or5) cnt=45	3.31 (65% 4or5) cnt=26	2.20 (60% 1or2) cnt=10	3.58 (73% 4or5) cnt=26	3.72 (72% 4or5) 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.

Total nc=1	AgRes nc=0	USPat nc=0	DevAg nc=0	FdSec nc=0	
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 re-examination 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 M=8 H=21 a=2.32 cnt=38	L=5 M=2 H=13 a=2.40 cnt=20	L=5 M=3 H=3 a=1.82 cnt=11	L=4 M=4 H=13 a=2.43 cnt=21	L=2 M=4 H=9 a=2.47 cnt=15	Patentability of plants
L=11 M=13 H=12 a=2.03 cnt=36	L=6 M=8 H=6 a=2.00 cnt=20	L=7 M=3 H=1 a=1.45 cnt=11	L=3 M=9 H=9 a=2.29 cnt=21	L=3 M=6 H=4 a=2.08 cnt=13	Application of the novelty requirement

Total nc=15	AgRes nc=10	USPat nc=1	DevAg nc=11	FdSec nc=9	
L=10 M=14 H=12 a=2.06 cnt=36	L=6 M=10 H=4 a=1.90 cnt=20	L=5 M=2 H=4 a=1.91 cnt=11	L=5 M=11 H=5 a=2.00 cnt=21	L=4 M=7 H=2 a=1.87 cnt=13	Application of the utility requirement
L=12 M=15 H=8 a=1.89 cnt=35	L=8 M=10 H=2 a=1.70 cnt=20	L=5 M=3 H=3 a=1.82 cnt=11	L=6 M=12 H=3 a=1.86 cnt=21	L=4 M=7 H=2 a=1.87 cnt=13	Application of the nonobviousness requirement
L=3 M=7 H=26 a=2.64 cnt=36	L=3 M=4 H=13 a=2.50 cnt=20	L=1 M=3 H=7 a=2.55 cnt=11	L=2 M=3 H=16 a=2.67 cnt=21	L=2 M=1 H=11 a=2.64 cnt=14	Breadth of claims allowed
					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.

Total nc=16	AgRes nc=8	USPat nc=1	DevAg nc=11	FdSec nc=10	
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 Congress.
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 M=11 H=12 a=1.92 cnt=38	L=10 M=4 H=6 a=1.80 cnt=20	L=7 M=1 H=2 a=1.50 cnt=10	L=8 M=8 H=6 a=1.91 cnt=22	L=6 M=5 H=5 a=1.94 cnt=16	Changing PTO policies and procedures concerning the patenting process

Total nc=9	AgRes nc=4	USPat nc=1	DevAg nc=7	FdSec nc=4	
L=12 M=10 H=16 a=2.11 cnt=38	L=7 M=6 H=8 a=2.05 cnt=21	L=7 M=1 H=3 a=1.64 cnt=11	L=5 M=8 H=9 a=2.18 cnt=22	L=4 M=5 H=6 a=2.13 cnt=15	Changing PTO policies and procedures on postpatent issues
L=8 M=6 H=23 a=2.41 cnt=37	L=7 M=3 H=11 a=2.19 cnt=21	L=2 M=0 H=7 a=2.56 cnt=9	L=7 M=4 H=11 a=2.18 cnt=22	L=4 M=3 H=9 a=2.31 cnt=16	Changing the licensing and other postpatent practices of patent holders
					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. Recognise 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 re-examination process to make it more equitable.
* 1. Fund more examiners in order to help the USPTO maintain a qualified cadre of experts.
2. Provide the USPTO 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, micro-organisms, any living material, biological processes, etc., regardless of whether an innovative step has been taken altering their 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 unravelled natural DNA sequences, genes and genomes.
2. Do not give patents to unravelled 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 subect 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 re-examination conditions or changing infringement rules.

* 1. Operationalisation 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 USPTO 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 USTR and the State Department should leave patent issues to the USPTO, 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 US Supreme Court's determining Congress' intentions?

C. In what way is 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 homogenous? Why? Or why not?

- The difference between modified and original germplasm is a grey 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, aeroplanes, radios, etc?

In pharmaceuticals almost only patents are involved. In agriculture 5-6 different kinds of IP are involved (patents, PVP, farmers' privilege, farmers' 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 are 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 non-profits: 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 USPTO 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 holder 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 USPTO 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, tumeric, etc., etc. The study should make the links between USPTO 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 all together because the company is either losing or not making 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 USPTO.
- 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 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 competitivness and cases of non-competitive humanitarian uses, and gives free licences 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 which 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 underway 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 increased 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 flavour!

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 they are a researcher working on the problems within developing countries within a developed country. This would indicate that they are 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 which 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 B: 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. Wally Falcon	Stanford University, Institute for International Studies
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. Margaret Llewelyn	Sheffield Institute of Biotechnological Law and Ethics (SIBLE)
Dr. Chien-An Liu	Asian Vegetable Research and Development Center (AVRDC)
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)
Dr. Thanda Wai	International Rice Research Institute (IRRI)
Prof. Jeroen van Wijk	International Service for National Agricultural Research (ISNAR)
Dr. Usha Barwale Zehr	Maharashtra Hybrid Seed Company (Mahyco)

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