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AMERICAN PATENT POLICY, BIOTECHNOLOGY, AND AFRICAN AGRICULTURE: THE CASE FOR POLICY CHANGE

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TABLE OF CONTENTS

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I. INTRODUCTION

A. Overview

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

U.S. patent policy in the agricultural biotechnology field calls into question the Unites States' general commitment to worldwide food security. In international forums, senior officials of the current U.S. administration have emphasized the importance of improving the agricultural capacities of developing countries as a means of reducing poverty and achieving food security.[2] The United States embraces the United Nations' Millennium Development Goals, of which the first objective is eradication of extreme poverty and hunger.[3] President George W. Bush told a World Bank audience early in his term that a "world where some live in comfort and plenty, while half of the human race lives on less than $2 a day is neither just, nor sta-

1. Food security exists in a country when "all people at all times have the food they need for an active and healthy life." Food and Agriculture Organization of the United Nations, FAO: What It Is — What It Does, *at* http://www.fao.org/UNFAO/e/wmain-e.htm (last visited Apr. 16, 2004). Poverty and food insecurity are inextricably linked. Poverty is a prime cause of many people's food insecurity, and food insecurity, with its negative consequences for health as well as physical and intellectual development, is an obstacle to poverty reduction.

2. *See* Andrew S. Natsios, Administrator, U.S. Agency for International Development ("USAID"), Introductory Comments at the U.S.-Sub-Saharan Africa Trade Forum (Jan. 15, 2003), *available at* http://www.usaid.gov/press/speeches/2003/sp030115.html; Alan P. Larson, Undersecretary of State for Business, Economic and Agricultural Affairs, Address to the House Comm. on Int'l Relations (Apr. 1, 2003), *available at* http://www.useu.be/Categories/Sustainable%20Development/Apr0103LarsonFoodSecurity.html.

3. *See* The World Bank Group, Millennium Development Goals, *at* http://www.developmentgoals.org (last modified Sept. 23, 2003).

ble,"[4] and Undersecretary of State Alan Larson recently declared that "[f]ood security is a serious foreign policy concern that profoundly threatens human health, economic prosperity and political stability."[5] The policies the United States has in place, however, do not always align with its interests in global food security. The portion of U.S. development assistance devoted to improving agriculture in developing countries remains small.[6] Food aid, the largest single component of U.S. development assistance, tends to undermine support for agriculture in recipient countries.[7] The government's subsidy of agricultural overproduction in the United States, which was increased and extended in the 2002 Farm Bill,[8] distorts global commodity markets and contributes to the creation of an uneven playing field — one on which many developing-country farmers cannot afford to compete.[9] Given the substantial impacts of U.S. policies and programs on agriculture in Africa, it is important to consider whether they can be modified in ways that will help achieve the declared goals of reducing poverty and achieving food security.

The U.S. government's stances on biotechnology and patents invite such an inquiry. U.S.-based companies and researchers generate much of the world's innovation in plant biotechnology. The U.S. government is a strong advocate of developing biotechnology for the needs of not only U.S. farmers, but also farmers in developing countries.[10] The U.S. patent system has enthusiastically embraced plant biotechnology by issuing thousands of patents, and the United States generally champions strong patent protection worldwide, favoring international adherence to the stringent U.S. model. It is thus important to explore how U.S. patent policy might be changed to harmonize U.S. positions on patents, biotechnology, and the need for progress in developing-country agriculture, thereby enhancing both food security

4. George W. Bush, Remarks by President Bush to the World Bank (July 17, 2001), *available at* http://www.whitehouse.gov/news/releases/2001/07/20010717-1.html.

5. Larson, *supra* note 2.

6. For a recent and accessible overview of how agricultural, trade, and food aid policies of the United States and Europe adversely affect agriculture and food security in developing countries, see BREAD FOR THE WORLD INSTITUTE, AGRICULTURE IN THE GLOBAL ECONOMY: HUNGER 2003 (Sandra Bunch ed., Mar. 2003), *available at* http://www.bread.org/institute/hunger_report/2003-pdf.htm.

7. *See id*.

8. *See* Pub. L. No. 107-171, 116 Stat. 134 (2002) (codified as amended in scattered sections of 2, 7, 16, 21 U.S.C.).

9. *See* BREAD FOR THE WORLD INSTITUTE, *supra* note 6.

10. At a June 2003 biotechnology conference in Washington, D.C., for example, President George W. Bush said, "For the sake of a continent threatened by famine [Africa], I urge the European governments to end their opposition to biotechnology. We should encourage the spread of safe, effective biotechnology to win the fight against global hunger." BBC News, *US in New Global GM Push*, *at* http://news.bbc.co.uk/2/hi/science/nature/3013394.stm (last visited Feb. 12, 2004); *see also* Press Release, USAID, CABIO: Mobilizing Science and Technology to Reduce Poverty and Hunger (June 23, 2003), *available at* http://www.usaid.gov/press/factsheets/2003/fs030623_1.html.

of developing countries and broad U.S. foreign policy interests. It is particularly important and timely to address these questions as the "development round" of trade negotiations launched by the World Trade Organization ("WTO") at Doha unfolds with heavy emphasis on agriculture, and as the international debate heats up about the role of intellectual property in development.[11]

We begin the next section by describing the potential role of biotechnology in improving agriculture in Africa and, in turn, contributing to poverty reduction and sustainable food security. This discussion considers the factors that affect the success of agriculture and food security in Africa, the trend toward privatization of agricultural research and innovation, and the continuing need in Africa for a strong public research sector and for public-private collaborations to improve agriculture. Section III provides an overview of the theory underlying the U.S. patent system, which serves as a background for comparing the actual impact of the system with its innovation and technology dissemination goals. Section IV describes how the patent system's practices and policies have been applied to the patenting of plant biotechnology. This includes discussion of the so-called "patent thicket" surrounding plant biotechnology, policies affecting access to patented technologies, and U.S. foreign policy on patents, including the U.S. stance on implementation of the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS") and other efforts to harmonize patent policy internationally. Section V analyzes the impact of U.S. patenting practices and policies on access to biotechnology in developing countries, considering both the current impact of the patent thicket and the potential future impact of U.S. efforts to harmonize patent policy globally. This section also presents the case for change by the United States across a spectrum of domestic and foreign patent policies as a means of advancing the U.S. interest in improving agriculture and achieving food security in Africa. In Section VI, we outline a framework for analyzing proposed policy changes, taking into account both the innovation and dissemination objectives of the patent system and the goals of poverty reduction and food security in Africa. With this framework in mind, we identify and briefly analyze ideas for policy change.

11. Much of this debate is captured in a recent report commissioned by the United Kingdom to which we refer later in this Article. *See* COMM'N ON INTELLECTUAL PROP. RIGHTS, INTEGRATING INTELLECTUAL PROPERTY RIGHTS AND DEVELOPMENT POLICY (2002), *available at* http://www.iprcommission.org/graphic/documents/final_report.htm (last visited Apr. 16, 2004).

B. Information Sources

This Article draws extensively on existing literature to establish a base understanding of the U.S. patent system, how it is being implemented with respect to agricultural biotechnology, its effect on developing-country access to biotechnology, and the lively international debate on the role of patent policy in development. We supplemented this literature review by interacting with a broad cross-section of experts and stakeholders in the arenas of patent policy, biotechnology, developing-country agriculture, and food security. This included interviews with a core group of experts and stakeholders, along with an informal written survey of a broader group of experts and stakeholders. Based on this research, we produced a discussion paper that served as the basis for a workshop in October 2002, consisting of invited experts, convened by the authors and in collaboration with Professor Walter Falcon of the Center for Environmental Science and Policy at Stanford University.[12]

Our interactions with a diverse spectrum of experts and stakeholders have had a significant impact on our analysis and conclusions. Our initial focus was on U.S. patenting practices and features of U.S. law that directly affect access to patented technologies. We discovered how difficult it is to isolate U.S. patenting practices and legal rules from the many other factors affecting access to biotechnology in developing countries. U.S. patent policy in the international arena will be important to the future of technological innovation in developing countries, including their adoption of patent laws. We have thus expanded our focus to include the efforts of the U.S. government to influence international patent laws through the WTO and the United Nations World Intellectual Property Organization ("WIPO") programs, which harmonize patent law and policy across international borders.

C. Goal and Perspective of the Article

This Article will succeed if it stimulates thinking among policymakers and stakeholders about how U.S. policies involving patents and the international patent system affect the United States' interest in poverty reduction and food security in Africa, and how those policies might usefully be altered to advance that interest. The authors are neither pro-patent nor anti-patent. We assume that patents have played and will continue to play an important role in stimulating private in-

12. MICHAEL R. TAYLOR & JERRY CAYFORD, THE U.S. PATENT SYSTEM AND DEVELOPING-COUNTRY ACCESS TO BIOTECHNOLOGY: DOES THE BALANCE NEED ADJUSTING? (Resources for the Future, Discussion Paper No. 02-51, Oct. 2002), *available at* http://www.iprcommission.org/graphic/documents/final_report.htm.

vestment in plant biotechnology; any change in U.S. patent policy must take account of the patent system's goal of stimulating invention. We do not claim to have the final answer on the ideal mix of policies in this complex area.

We are convinced, however, of one thing: U.S. policies on matters such as patents, agricultural subsidies, trade, and food aid — all of which are grounded in their own set of policy goals and political interests — have spillover effects beyond their original intent. These policies have a deep impact on important, unanticipated U.S. interests, such as reducing poverty, increasing subsistence farmers' yields, and achieving food security in developing regions like Africa. In today's interconnected world, the United States cannot afford to develop and maintain these policies without considering their widespread impacts and attempting to reconcile them with the nation's broader interests. With regard to patent policy in light of the goals of food security and economic development in Africa, we believe there is a strong case for policy change.[13]

II. FOOD SECURITY, BIOTECHNOLOGY, AND AGRICULTURAL INNOVATION IN AFRICA

A. Food Security and Agricultural Productivity

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 the target of reducing by half the number of undernourished people by no later than the year 2015."[14] The Food and Agriculture Organization ("FAO") of the United Nations estimates that 800 million people in the world experience chronic hunger, indicating a lack of food security on an individual level.[15] Millions of people, many of them children, die annually from hunger-related causes.[16]

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

14. FAO, REPORT OF THE WORLD FOOD SUMMIT (Nov. 13–17, 1996), *at* http://www.fao.org/wfs/index_en.htm.

15. FAO, The Special Programme for Food Security: Objectives and Approach, *at* http://www.fao.org/spfs/objectives_en.stm (last visited Feb. 7, 2004) ("800 million people in developing countries — about 20 percent of their total population — are chronically undernourished.").

16. FAO, THE STATE OF FOOD AND AGRICULTURE 2001, *available at* http://www.fao.org/docrep/003/x9800e/x9800e07.htm#P15_2570 (last visited Feb. 12, 2004) ("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 insecurity is closely linked to poverty and concentrated in the developing countries of South Asia, Africa, and Latin America.[17] It is, however, an extraordinarily complex social, economic, and political problem whose causes and solutions vary from country to country.[18] 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.[19] These countries produce enough food to feed their populations, and in some cases, have become food exporters, but many people in these countries are hungry because they lack the economic means to purchase or produce the food they need for themselves and their families. Poverty and social instability are obstacles to food security in many African countries, but the basic problem of poor agricultural productivity has never been solved. The Green Revolution largely bypassed sub-Saharan Africa,[20] and areas in that region have soil, water, climate, and plant pest conditions that make productivity gains hard to achieve and sustain.

There is no single solution to the problem of hunger in Africa or other developing regions. A common reality in many developing and food-insecure countries, however, is that a large majority of the people depends on agriculture for their livelihood, directly or indirectly. In sub-Saharan Africa, 70% of the people are rural and largely agriculture-dependent, ranging from 39% in the Republic of the Congo to 93.7% in Rwanda.[21] 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

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17. According to the FAO, India has more hungry people than any other country, 225.3 million (23% of the population), reflecting India's large poor population. However, hunger is most widespread in sub-Saharan Africa, where 34% of the population, or 194 million people, are considered food insecure. *See* FAO, FAO's role on MDGs, ch. 5, *at* http://www.fao.org/es/ESS/mdg_kit/progress.asp (last visited Feb. 12, 2004).

18. 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 Walter P. Falcon, *Globalizing Germ Plasm: Barriers, Benefits, and Boundaries*, *in* TOMORROW'S AGRICULTURE: INCENTIVES, INSTITUTIONS, INFRASTRUCTURE AND INNOVATIONS (G.H. Peters & Prabhu Pingali eds., 2000); and JOSEPH DE VRIES & GARY TOENNIESSEN, SECURING THE HARVEST: BIOTECHNOLOGY, BREEDING AND SEED SYSTEMS FOR AFRICAN CROPS (2001).

19. *See* GORDON CONWAY, THE DOUBLY GREEN REVOLUTION: FOOD FOR ALL IN THE 21ST CENTURY (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 results included dramatic increases in productivity, but also fertilizer and pesticide runoff into surface waters, greater soil erosion, and other environmental costs.

20. *See* PER PINSTRUP-ANDERSEN ET AL., WORLD FOOD PROSPECTS: CRITICAL ISSUES FOR THE EARLY TWENTY-FIRST CENTURY (1999), *available at* http://www.ifpri.org/pubs/fpr/fpr29.pdf.

21. *See* AFRICAN DEVELOPMENT BANK GROUP, GENDER, POVERTY AND ENVIRONMENTAL INDICATORS ON AFRICAN COUNTRIES, Table 3.1 (2002–2003), *at* http://www.afdb.org/knowledge/statistics/statistics_indicators_gender/environment/indicators_environment.htm.

improve their agriculture and food systems to achieve economic growth and food security.[22] Moreover, according to the World Bank, global food production will have to double by 2025 to meet rising demand.[23] By improving agricultural productivity and local food processing and distribution systems, developing countries can increase locally available food stocks to feed their people and also generate income, allowing workers to purchase food in the marketplace, supplementing local production. Improving agricultural and food systems in developing countries is critical to meeting the world's long-term food needs. Especially in sub-Saharan Africa, any solution to food insecurity will require increased agricultural productivity, to which biotechnology can contribute.

B. Biotechnology and Food Security

Successful agricultural systems require a combination of natural resources, productive farming methods, and market outlets for surplus production. No element is sufficient by itself, but all are necessary. Natural resources — soil, water, and climate — are the least malleable, but successful agricultural systems have been created all over the world in diverse soil, water, and climatic conditions.[24]

In developing countries, the lack of effective and fair markets for surplus food production may be the greatest obstacle to agricultural development. Access to local, national, and international markets provides farmers with an incentive to risk their labor and capital on expanded production. Without workable markets, the best natural resources and farming techniques are not enough to produce successful food systems. Many developing countries lack a basic framework for establishing effective markets: sound political, economic, and social institutions and policies, as well as transportation systems and other physical infrastructure. The creation of effective markets in developing countries will require changing some of the agricultural and trade policies of the United States and other industrialized countries, which currently distort market prices for staple commodities and create obstacles to developing-country exports.

We recognize that improving the productivity of farmers is not by itself the solution to food insecurity. Improved productivity is, however, an important part of the picture, especially in sub-Saharan Africa. In the face of difficult growing conditions, better access to the

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22. *See* THE WORLD BANK GROUP, AN INTERNATIONAL ASSESSMENT ON THE ROLE OF AGRICULTURAL SCIENCE AND TECHNOLOGY IN REDUCING HUNGER AND IMPROVING RURAL LIVELIHOODS (2002), *available at* http://www.agassessment.org/pdfs/roleofag.pdf.

23. *See* THE WORLD BANK GROUP, ENVIRONMENTALLY AND SOCIALLY SUSTAINABLE DEVELOPMENT STUDIES AND MONOGRAPH SERIES 12, RURAL DEVELOPMENT: FROM VISION TO ACTION 2 (1997).

24. *See* PINSTRUP-ANDERSEN ET AL., *supra* note 20, at 26.

basic Green Revolution tools of fertilizer, pesticides, improved seeds, and irrigation can play an important role in improving African farmers' productivity. With the environmental lessons of the Green Revolution in mind, many agricultural experts also believe that the tools of modern biotechnology (including the use of recombinant DNA technology to produce genetically modified plants) can play a role in solving developing-country agronomic problems.[25] By building into the seed itself traits for drought and disease resistance, insect and other pest control, and improved yield under specific local growing conditions, biotechnology may enable farmers to increase their productivity without as much reliance on the external inputs that characterized the Green Revolution.

Mindful of these potential benefits, researchers in national and international agricultural research organizations are experimenting with biotechnology and working to produce genetically modified plants that could be useful to farmers in developing countries.[26] The authors conducted an informal survey of experts in this field, and 79% of respondents (37 of 47) rated the importance of access to the tools of biotechnology by researchers working on developing-country agricultural problems as "very high" or "high" (60% and 19% of respondents, respectively).[27] Biotechnology companies also promote the potential of biotechnology to improve agriculture and food security in developing countries.[28]

There is debate about the ultimate value of biotechnology for developing-country farmers; issues including food safety, environmental impacts, and social consequences should be addressed. This Article does not address these issues, which are discussed abundantly elsewhere.[29] This Article takes as its starting point the interest in access to

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25. *See* CONWAY, *supra* note 19; ISMAIL SERAGELDIN & G.J. PERSLEY, PROMETHEAN SCIENCE: AGRICULTURAL BIOTECHNOLOGY, THE ENVIRONMENT, AND THE POOR (2000), *at* http://www.ifpri.org/themes/biotech/sergeldi.pdf.

26. *See* Mitchell Lorraine, *Biotechnology and Food Security*, AGRIC. INFO. BULL. 765-11 (USDA Econ. Research Serv., June 2001), *at* http://www.ers.usda.gov/publications/aib76511/; Joel I. Cohen et al., *Research Policy and Management Issues in Biotechnology for Developing-Country Agriculture: Problems and Opportunities*, 2020 VISION (Oct. 1999), *at* http://www.ifpri.org/2020/focus/focus02.htm.

27. Seventeen percent of respondents rated access to biotechnology to be of medium importance, and 2% said it was low. 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 agricultural problems in developing countries. We make no claims that the survey is statistically representative of expert opinion on the issues it addresses.

28. *See* Michael J. Phillips, Executive Director for Food and Agriculture, Biotechnology Industry Organization, *The Future of Agricultural Biotechnology* (Oct. 1, 2001), *available at* http://www.bio.org/foodag/weekly/lecture_100101.asp; *see also* Klaus M. Leisinger, The Socio-Political Impact of Biotechnology in Developing Countries (2001), *at* http://www.syngentafoundation.com/biotechnology_developing_countries.htm.

29. *See, e.g.*, FAO, AGRICULTURAL BIOTECHNOLOGY IN THE DEVELOPING WORLD (1995), *available at* http://www.fao.org/docrep/v4845e/v4845e00.htm; ROYAL SOCIETY ET

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 Article focuses on the specific problem of access to biotechnology for developing-country purposes, as affected by U.S. patents and patent policy.

C. The Privatization and Patenting of Agricultural Innovation

The access problem addressed in this Article arises from the recent shift of investment in agricultural innovation from the public to the private sector and biotechnology companies' use of the patent system to protect their investments. These developments are well described elsewhere.[30] Research breakthroughs in the use of recombinant DNA techniques to modify plants, coupled with the 1980 Supreme Court decision in *Diamond v. Chakrabarty*,[31] have spawned substantial investment in biotechnology by large agricultural chemical companies and small biotech startup companies, primarily in the United States and Europe. This shift has resulted in rapid development of the technological tools required to genetically transform plants; discovery of some specific, agronomically useful gene traits; and application of these traits in commercially significant food crops. Another result has been the extensive patenting of the tools of modern biotechnology and of the plants that result from their application.[32]

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

AL., TRANSGENIC PLANTS AND WORLD AGRICULTURE (2000), *available at* http://books.nap.edu/html/transgenic/; DAVID E. ERVIN ET AL., TRANSGENIC CROPS: AN ENVIRONMENTAL ASSESSMENT (Nov. 2000), *at* http://www.winrock.org/Transgenic.pdf; MORVEN A. MCLEAN ET AL., A CONCEPTUAL FRAMEWORK FOR IMPLEMENTING BIOSAFETY: LINKING POLICY, CAPACITY AND REGULATION (International Service for National Agricultural Research ("ISNAR"), 2002), *available at* ftp://ftp.cgiar.org/isnar/publicat/bp-47.pdf; MANAGING AGRICULTURAL BIOTECHNOLOGY: ADDRESSING RESEARCH PROGRAM NEEDS AND POLICY IMPLICATIONS (Joel I. Cohen ed. 1999).

30. *See* NAT'L RESEARCH COUNCIL, INTELLECTUAL PROPERTY RIGHTS AND PLANT BIOTECHNOLOGY (1997), *available at* http://www.nap.edu/html/intellectual/; John Barton, *The Impact of Contemporary Patent Law on Plant Biotechnology Research*, *in* INTELLECTUAL PROPERTY RIGHTS III, GLOBAL GENETIC RESOURCES: ACCESS AND PROPERTY RIGHTS (S.A. Eberhart et al. eds. 1998); Paul W. Heisey et al., *Public Sector Plant Breeding in a Privatizing World*, AGRIC. INFO. BULL. 722 (USDA Econ. Research Serv., Aug. 2001), *available at* http://www.ers.usda.gov/publications/aib772/; Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663 (1996).

31. 447 U.S. 303 (1980); *see infra* notes 74–76 and accompanying text.

32. *See* Gregory Graff, The Sources of Biological Technologies for Agriculture: Public and Private Innovation and Patenting (Apr. 10, 2000) (presented at the AAEA NC208 Conference on "R&D Policies and Impacts," Univ. of California-Berkeley, Mar. 30–31, 2001) (on file with the Harvard Journal of Law and Technology); Bradford L. Barham et al., *Trends in University Ag-Biotech Patent Production*, 24 REV. OF AGRIC. ECON. 294 (2002), *available at* http://www.biotech.wisc.edu/seebiotech/pdfs/raefinalbbkk.pdf.

For most of history, innovation in seed technology has been considered a public good.[33] Farmers freely shared the higher-yielding, better-performing varieties they developed with neighbors. From its founding in 1862, the U.S. Department of Agriculture ("USDA") has invested in research to develop improved seed.[34] Until 1925, USDA's largest budget item was a program that provided the latest seed free to farmers.[35] Not until the late 1920s did a large-scale private-sector seed industry, based on hybridization technology, develop in the United States and other industrialized countries.[36]

In most developing countries, farmers produce, save, and share improved seed, and national and international agricultural research laboratories produce innovations in seed technology that are commonly distributed through public channels. Internationally, the Consultative Group on International Agricultural Research ("CGIAR"), which is sponsored by the World Bank and funded largely by donor countries in the industrialized world, has played a leading role in seed innovation, and many of its laboratories are exploring the use of modern biotechnology to solve agronomic problems in developing countries.[37] There are fledgling seed industries in developing countries that are marketing privately developed hybrids and serving as distribution channels for publicly developed seed innovation, [38] but in many areas, such as sub-Saharan Africa, innovation remains largely a public enterprise and a public good.

With the advent of biotechnology and the availability of plant patents, the balance between the public and private sectors — in terms of research and control of technology — has shifted. In the United States, most of the investment in research to produce improved seeds is now financed and conducted privately, much of it by biotechnology companies.[39] Innovation in seed technology is commonly patented.

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33. *See* Nathan A. Busch, *Jack and the Beanstalk: Property Rights in Genetically Modified Plants*, 3 MINN. INTELL. PROP. REV. 1, 10 (2002).

34. *See id*. at 13.

35. *See id*. at 14.

36. *See id*. at 31.

37. *See* CGIAR, http://www.futureharvest.org/ (last visited Feb. 12, 2004) (providing background on the CGIAR system); *see also* AGRICULTURAL BIOTECHNOLOGY AND THE POOR: AN INTERNATIONAL CONFERENCE ON BIOTECHNOLOGY (G.J. Persley & M.M. Lantin eds., 1999), *available at* http://www.cgiar.org/biotech/rep0100/contents.htm; Int'l Maize & Wheat Improvement Ctr. Applied Biotech. Ctr., *Reaching inside the Genome, Reaching Farmers*, *at* http://www.cimmyt.org/ABC/map/about/BROCHURE97ABC/BROCHURE97ABC.htm (May 2003).

38. Personal communication with Mark Condon, Vice President of International Marketing, American Seed Trade Association (Jan. 24, 2002).

39. Amounts of research can be calculated many different ways. *See* Heisey et al., *supra* note 30; Robbin Shoemaker et al., *Economic Issues in Agricultural Biotechnology*, AGRIC. INFO. BULL. 762 (USDA Econ. Research Serv., 2001), *available at* http://www.ers.usda.gov/publications/aib762/. Generally, public-sector plant breeding expenditures for field crops have been relatively flat for decades, but they "appear to have started to decline in real terms from the mid-1990s. . . . In contrast, private-sector plant

This includes the tools used in the laboratory to transfer DNA and produce genetically modified plants — such as transformation vectors and systems, gene-expression promoters, and transformation marker systems — as well as specific gene traits that perform some useful agronomic function and the plants that contain these traits. Gregory Graff has compiled a database of 2,428 patents related to agricultural biotechnology that were issued from 1975 to 1998.[40] Of these, 76% are assigned to private individuals or corporations, with the remainder assigned to universities or public institutions. The four organizations holding the most patents are Pioneer Hi-Bred International, Mycogen, USDA, and Monsanto Company, which together hold 26% of the patents. Of the top thirty patent holders, twenty-two are U.S. or European corporations, which together hold 50% of the patents.[41]

The dominance of the private sector may be even greater than these numbers reveal. Since the Bayh-Dole Act of 1980, public and university research institutions have been allowed and encouraged to patent their results and to enter into public-private partnerships. These cooperative agreements often include an option for the private partner to receive an exclusive license to any resulting patents filed by the public institution or university. Consequently, not only are the majority of biotechnology patents in private hands, but some important patents remaining in public hands, or developed by university researchers with public money, are exclusively licensed to private corporations. Furthermore, the ability to patent has given public institutions and universities the incentive to treat their patents less as a public good than as a source of institutional revenue. In other words, this policy encourages public institutions to behave like the private sector.[42] The biotechnology industry cites the ability to patent the laboratory tools and marketable products of modern biotechnology as a crucial incen-

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breeding investment appears to have grown extremely rapidly" (perhaps by a factor of ten since 1960). *Id*. Depending on what one measures, private expenditures appear to have passed public expenditures around 1990. Measured in "scientist years," though, private-sector effort was more than double public effort by 1994. *See* Heisey et al., *supra* note 30, at 6–8.

40. *See* Graff, *supra* note 32. A more detailed picture of the distribution of biotechnology patents, summarized from Graff's data, is presented in Appendix A.

41. Seven of the top thirty 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. *See id.*

42. Much has been written in the popular and academic press on how changing approaches to intellectual property have affected the behavior of academic researchers and universities. *See* Eyal Press & Jennifer Washburn, *The Kept University*, 285 THE ATLANTIC MONTHLY 39 (2000); Rebecca Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177 (1987); Julia Porter Liebeskind & Amalya Oliver-Lumerman, *From Handshake to Contract: Intellectual Property, Trust, and the Social Structure of Academic Research*, *in* TRUST WITHIN AND BETWEEN ORGANIZATIONS: CONCEPTUAL ISSUES AND EMPIRICAL APPLICATIONS 118 (1998); Julia Porter Liebeskind, *Risky Business: Universities and Intellectual Property*, ACADEME, Sept.–Oct. 2001, at 49, *available at* http://www.aaup.org/publications/Academe/2001/01SO/so01lie.htm.

tive for their investment in the technology, and many observers see this incentive as the catalyst for important innovation in seed technology.[43] The role of the patent system in fostering innovation will be discussed later in this Article. One clear consequence of the widespread patenting of biotechnology, however, is that the technology is to a large extent in private hands or in the hands of universities or public institutions that have a new interest and ability to control access to the technology.

The privatization of research affects the kinds of research done and types of products developed.[44] Private development companies have invested heavily in the technology and in the seed companies required to bring new products to market. To capture a return on this investment, they have focused their commercial efforts, including product development, on applications that have mass appeal to farmers who can afford the technology. Thus, commercialization of agricultural biotechnology to date has consisted almost entirely of instilling two traits in cotton, corn, or soybeans for sale to farmers in the United States and a few other countries: insect control based on the *Bt* toxin and resistance to the herbicide glyphosate. This focus on commercially valuable traits and large-scale farming and markets is economically rational and, perhaps, the only thing that could reasonably be expected of companies working within our market system.

This economic reality creates a problem, however. The private-sector holders of biotechnology patents have little or no economic incentive to use the laboratory tools or gene traits they own to 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 small-scale and subsistence farmers. As a result, the finite capital resources of biotechnology companies will, for the foreseeable future, continue to be focused on meeting the needs of farmers in Western industrialized countries and will not be deployed in substantial measure to meet the needs of farmers in developing countries.

D. Channels for Agricultural Innovation in Africa

With the foregoing trends in mind, the ultimate concern of this Article is how innovative seed technology derived from patented tools of biotechnology can be developed and disseminated for the benefit of

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43. *See* Biotech. Indus. Org., Importance of Intellectual Property, *at* http://www.bio.org/ip/background.asp (last visited Feb. 19, 2004); Lila Feisee & Brian Stanton, *Are Biotechnology Patents Important?* PTO PULSE, Mar. 2000, *available at* http://www.uspto.gov/web/offices/ac/ahrpa/opa/pulse/200003.htm.

44. *See* Heisey et al., *supra* note 30.

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

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

We assume that for the foreseeable future — the next two decades at least — the development of biotechnology for the use of small-scale and subsistence farmers in Africa will proceed largely through the public and public-private cooperative channels. This assumption is based on two factors. One is the current reality that most agricultural research for Africa is conducted in public institutions.[45] The other is the situation articulated in the previous subsection: that large, private biotechnology companies lack adequate economic incentives to invest their R&D dollars in products to improve the local crops and germplasm that are important to small-scale and subsistence farmers.[46]

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45. *See* COMM'N ON INTELLECTUAL PROP. RIGHTS, *supra* note 11, at 60.

46. *See* Philip G. Pardey et al., *Are Intellectual Property Rights Stifling Agricultural Biotechnology in Developing Countries?*, *in* INTERNATIONAL FOOD POLICY RESEARCH INSTITUTE, IFPRI ANNUAL REPORT 2000–2001, *available at* http://www.ifpri.org/pubs/books/ar2000/ar2000_essay02.htm (last visited Feb. 19, 2004):

> Corporations concentrate their research efforts on crops such as hybrid corn, soybean, canola, cotton, and some specialty horticultural products, which are grown for markets with high commercial value . . . . Moreover, the development of a vast number of crops critical to food security throughout the developing world (such as cassava, yams, sweet potatoes, sorghum, millet), as well as crops that are globally grown (like rice, wheat, and maize), must continue to rely on public and nonprofit institutions as the principal source of genetic innovation.

This does not mean that there will be no commercial development of biotechnology in Africa and that larger-scale commercial agriculture will not grow and be important to the future of Africa.[47] Such growth is both desirable and likely to occur, especially if the recent new interest in agriculture among development-assistance donors grows and if progress is made through the WTO and bilateral trade agreements to reduce subsidies and generally level the playing field for African agricultural exports. The development of commercially viable private enterprises to distribute seed and other inputs is also desirable, and is not excluded by our assumption about the primacy of public and public-private channels of innovation.

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

III. THE THEORY AND SOCIAL OBJECTIVES OF THE U.S. PATENT SYSTEM

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

While our focus in this Article is on patents and patent policy, it is important to emphasize that patent law is part of a broader set of social arrangements and policies that might be grouped under the

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Id.; *see also* BRAZILIAN ACAD. OF SCIS. ET AL., TRANSGENIC PLANTS AND WORLD AGRICULTURE § 9.1, *at* http://www.biotech-info.net/GE_world_AG.pdf (last visited Feb. 19, 2004):

> Current industrial biotechnology is primarily orientated to the needs of large-scale commercial agriculture, rather than to those of the subsistence farmer . . . . [W]ithout changed incentives for sharing access to GM [genetic modification] technologies, the world is unlikely to direct much of its research for improved nutrition and employment-based access to staples for the poor.

Id.

47. Cotton genetically modified to resist insects is being grown today in South Africa. For information on African applications of biotechnology from a local organization, see AfricaBio, *at* http://www.africabio.com/index.html (last visited Feb. 19, 2004).

heading "innovation policy." Broadly speaking, innovation policy addresses the question of how a society obtains the technology required to meet its needs. It addresses not only how intellectual property is defined and protected legally, but also such matters as the allocation of innovation roles and responsibilities between the public and private sectors; the extent and focus of publicly funded R&D; public policy incentives for private-sector R&D and innovation, such as tax incentives, subsidies, and regulatory streamlining; and preferences for generating innovation internally versus transferring it from external sources. The innovation policy of any country should appropriately reflect its particular technological needs, as well as its current state of technological development and capacity for innovation. Because these circumstances vary so widely among countries, optimal innovation policies likewise will vary.[48]

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

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

A. 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."[49] 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 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

48. *See* COMM'N ON INTELLECTUAL PROP. RIGHTS, *supra* note 11.
49. U.S. CONST. art. I, § 8.

> 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.[50]

Under the utilitarian or "instrumental" conception of patents, the patent system is successful to the extent it results in getting more useful things for society.[51]

The counter theory for patents is the "natural rights" view that patents are a form of property to which inventors have a natural right by virtue of their inventive efforts. This perspective and other nonutilitarian perspectives on patents continue to surface in scholarly writings[52] and in policy debates,[53] but they continue to be rebutted eloquently by the famous statement made in 1813 by a noted American inventor and the first patent administrator, Thomas Jefferson:

> It has been pretended by some . . . that inventors have a natural and exclusive right to their inventions . . . . If nature has made any one thing less susceptible than all others of exclusive property, it is the action of the thinking power called an idea . . . . Its peculiar character, too, is that no one possesses the less, because every other possesses the whole of it. He who receives an idea from me, receives instruction himself without lessening mine; as he who lights his taper at mine, receives light without darkening me. That ideas should freely spread from one to another over the globe, for the moral and mutual instruction of man, and improvement of his condition, seems to have been peculiarly and benevolently designed by nature . . . . Inventions then cannot, in nature, be a subject of property. Society may give an

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50. ROBERT P. MERGES, PATENT LAW AND POLICY: CASES AND MATERIALS 2 (2d ed. 1997).

51. *See* Paul B. Thompson, *Conceptions of Property and the Biotechnology Debate*, 45 BIOSCIENCE 275 (1995).

52. *See* A. Samuel Oddi, *Un-Unified Economic Theories of Patents — The Not-Quite-Holy Grail*, 71 NOTRE DAME L. REV. 267 (1996).

53. 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: "[A] significant part of our international efforts at the USPTO are devoted to strengthening IP enforcement abroad and combating IP piracy." James E. Rogan, Statement Before the House Appropriations Subcommittee on Commerce, Justice, State and the Judiciary (Apr. 23, 2002), *available at* http://www.uspto.gov/web/offices/speeches/houseapprop.htm; *see also* JOSEPH R. BIDEN, THEFT OF AMERICAN INTELLECTUAL PROPERTY: FIGHTING CRIME ABROAD AND AT HOME (Feb. 12, 2002), *at* http://biden.senate.gov/IPREPORT.pdf.

> 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.[54]

Jefferson's understanding of patents as a benefit granted by society on terms designed to achieve social policy goals is central to our case for considering policy change. It is also embedded in U.S. patent law, which sets out the basic terms of what amounts to a contract between the inventor and society. Through operation of 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. The utility requirement guarantees that society will receive a useful invention.[55] The novelty requirement prohibits inventors from offering something that society already has.[56] The nonobviousness requirement bars inventors from giving exclusive rights to something that society would likely soon have in any case.[57] The disclosure or specification requirement ensures society actually receives the invention, in the sense that it becomes part of the common knowledge, usable by others.[58]

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

B. Specific Objectives of the Patent System

To assess whether or not the patent system is working to achieve its social objectives, we should be more specific about what those objectives are. Drawing on the work of Mazzoleni and Nelson, we identify four: (1) increasing the amount of invention; (2) disseminat-

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54. Letter to Isaac McPherson (Aug. 13, 1813), *quoted in* MERGES, *supra* note 50, at 10. "Not surprisingly, the principal philosophical theory applied to the protection of utilitarian works — that is, technological inventions — has been utilitarianism." Peter S. Menell, *Intellectual Property: General Theories*, *in* 2 ENCYCLOPEDIA OF L. & ECONS. 129, 129 (Boudewijn Bouckaert & Gerrit De Geest eds., 2000).

55. *See* 35 U.S.C. § 101 (2003).

56. *See id*.

57. *See* 35 U.S.C. § 103 (2003).

58. *See* 35 U.S.C. § 112 (2003).

ing knowledge about inventions; (3) regulating the orderly investigation of new research areas; and (4) facilitating the practical use of inventions, including their production, application, and commercialization.[59]

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.[60] They reflect and are well satisfied by the simple paradigm of the lone inventor who is induced to invest effort in making the invention by the promise of a temporary monopoly on commercialization. With the inducement of the patent monopoly, it is reasonable to expect more rather than less inventive effort. With the disclosure requirement, there is at least some dissemination of knowledge, more certainly than if inventors sought to protect their commercial prospects by keeping their inventions secret.

The third objective — regulating the orderly investigation of new research areas — is relevant mainly in complex fields like agricultural biotechnology. Practical applications of biotechnology rarely occur through the efforts of the lone inventor, but rather through the creative efforts of many. They typically require the use of transformation tools, marker systems, and other enabling technologies, as well as specific gene traits. Biotechnology is analogous in this respect to computer-based information technology, which has advanced through the assembly of multiple technological building blocks from multiple sources. Patent scholars have theorized that the issuance of patents in such areas can, in principle, bring order to the research process and thereby help foster innovation.[61] By disclosing the invention, the patent enables others to learn from and build upon the invention and, at

59. *See* Richard D. Nelson & Roberto Mazzoleni, *Economic Theories about the Benefits and Costs of Patents*, 32 J. ECON. ISSUES 1031 (1998). 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, refinement, 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.

60. *See* Fritz Machlup & Edith Penrose, *The Patent Controversy in the Nineteenth Century*, 10 J. ECON. HIST. 1, 10 (1950); Robert P. Merges, *The Economic Impact of Intellectual Property Rights: An Overview and Guide*, 19 J. CULTURAL ECON. 103 (1995).

61. *See* Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 916 (1990); Suzanne Scotchmer, *Standing on the Shoulders of Giants: Cumulative Research and the Patent Law*, 5 J. ECON. PERSPECTIVES 29 (1991); Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265 (1977).

the same time, directs them away from research that might wastefully duplicate the now-proprietary work of the patent holder.

The fourth objective — facilitating practical use — flows directly from the broad utilitarian purpose of the patent system. More invention and information do not help society unless they result in more practical progress in the useful arts. For example, this may require more than one invention, and it certainly requires that the invention be in the hands of a party having the interest and practical savvy to make use of the invention for a worthwhile purpose. With control of a patented technology safely in hand, inventors can negotiate for financial backing and can offer investors protection from surprise competition.[62] With ownership clear, inventors can also license their inventions, so that development of practical, innovative applications proceeds cooperatively instead of in wasteful races.

The objective of fostering practical innovation, not just new invention, is more than just an academic construct — it has been reflected in patent policy and policy debates. In Europe, Japan, and most of the rest of the world, patent law requires that patent holders "work" their patents (that is, put them to practical use) or else lose the right to exclude others from working them. The U.S. patent law does not include such a requirement. However, recognition of facilitating practical development as an objective of the patent system is embedded in the rationale for the Bayh-Dole Act,[63] which was enacted by the U.S. Congress in 1980 to authorize and encourage the patenting of inventions made by universities and other institutions with federal funding.[64] 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; quite the opposite, they have every incentive to publish.[65]

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62. *See* Rebecca S. Eisenberg, Intellectual Property Rights and Research Tools in Molecular Biology (Summary of Workshop held at National Academy of Sciences, Feb. 15–16, 1996), ch. 2, *at* http://www.nap.edu/readingroom/books/property/2.html#chap2 (last visited Apr. 16, 2004).

63. 35 U.S.C. §§ 200–211 (1980).

64. *See* Eisenberg, *supra* note 30; Corinne Langinier & GianCarlo Moschini, *The Economics of Patents: An Overview* (Iowa State University Center for Agriculture and Rural Development Working Paper 02-WP 293, 2002), *at* http://www.econ.iastate.edu/research/webpapers/paper_2061.pdf.

65. *See* Langinier & Moschini, *supra* note 64, at 6:

> 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

Bayh-Dole was enacted for a different purpose: to increase the likelihood that publicly funded inventions would get into the hands of parties who would have the incentive to develop them commercially and thus turn inventions into useful products.[66] The idea was that companies would not be willing to invest in commercial development unless they could do so under patent protection. Consequently, publicly funded inventors were encouraged to patent their inventions so that they could transfer technology, through license or sale, with the benefit of patent protection. This is a clear instance of U.S. patent policy intending to facilitate not merely invention and information dissemination, but practical use through commercialization.[67]

C. Complications in Achieving the Patent System's Goals

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

Similarly, when patents are very broad in their scope or cover tools that are widely applicable to the work of researchers studying diverse problems, they can have a significant blocking effect on inno-

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> use for trade secrets, and because it is difficult to improve on the dissemination of information achieved by simply publishing a discovery.

Id.

66. *See id*.

67. *See* Eisenberg, *supra* note 30, at 1677–79. The objective of facilitating practical application is not new. Professor Eisenberg traces, from the 1940s through the 1970s, the debate 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. This debate surfaces in documents such as 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. These documents discuss how best to accomplish the objective of patent policy: to help bring inventions to actual commercial use. *See id*.

vation.[68] Researchers, including those 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 using a patented invention. Such "blocking patents" have come under critical scrutiny by patent scholars:

> [H]ighly basic patents that preempt a large area of research are unlikely to be beneficial. The application of the basic technology is unpredictable so that restriction of a relatively basic research tool to a small number of researchers is likely to cost more in improvement research and lost insight to other research teams than it contributes to incentive and funding potential for the favored research team. This is the clear implication of the Merges and Nelson study of patent scope in a variety of sectors; its examples show that overly broad patents can particularly slow innovation in a highly scientific sector such as biotechnology.[69]

The danger of too many or too broad or too early patents has been described by Heller and Eisenberg as an "anticommons,"[70] 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. According to one commentator writing about biotechnology patents in the pharmaceutical field, "[w]ith cumulative innovation and multiple blocking patents, stronger patent rights can have the perverse effect of stifling, not encouraging, innovation."[71] So, whether the initial patent facilitates or stifles practical innovation and orderly investigation depends on the circumstances. Sound patent policies need to consider these effects.

The objective of facilitating practical use of inventions — which might be called technology transfer — is at the heart of the problem we address in this Article. Since the existence of patents can sometimes hinder the application of patented technologies for their full range of socially beneficial uses, it is legitimate, as a matter of sound

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68. *See* Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698; John H. Barton, *Patent Scope in Biotechnology*, 26 INT'L REV. INDUS. PROP. & COPYRIGHT L. 605 (1995).

69. *See* Barton, *supra* note 68, at 614 (referring to Merges & Nelson, *supra* note 61); *see also* Jeroen Van Wijk, *Broad Biotechnology Patents Hamper Innovation*, BIOTECH. & DEV. MONITOR, Dec. 1995, at 15, *available at* http://www.biotech-monitor.nl/2506.htm.

70. Heller & Eisenberg, *supra* note 68.

71. Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting*, *in* 1 INNOVATION POL'Y & THE ECON. 119, 120 (Adam Jaffe et al. eds., 2001) (citing Joseph Stiglitz at a 1995 Federal Trade Commission hearing).

patent theory and policy, to ask how policies might be changed to reduce obstacles to such uses. First, however, we examine how the U.S. patent system has been implemented with respect to plant biotechnology and how this, coupled with U.S. patent policy in the international arena, affects access to the technology to meet agricultural needs in Africa and other developing regions.

IV. PATENT PROLIFERATION AND U.S. PATENT POLICY

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

In this discussion, we will address 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 U.S. patent policy. The PTO is part of a patent policymaking system that begins with the Constitution but is directed by Congress through statute.[72] The system is heavily influenced by the courts, including the U.S. Supreme Court and the Court of Appeals for the Federal Circuit.[73] The following discussion suggests, however, why the primary locus for policy change to address developing-country concerns will lie not with the courts but with Congress, the PTO, and the executive branch agencies responsible for managing trade and international affairs.

A. Background on Biotechnology Patenting

The history of agricultural biotechnology patenting is generally considered to have started in 1980 with the famous and controversial five-to-four Supreme Court decision in *Diamond v. Chakrabarty*.[74] Chakrabarty applied for a patent on a genetically engineered bacte-

72. The basic patent law is the Patent Act of 1952, 35 U.S.C. §§ 1–376 (1952), which has been amended repeatedly since its inception.

73. Many publications describe this structure in greater detail. *See, e.g.*, MERGES, *supra* note 50, at 37–39.

74. 447 U.S. 303 (1980).

rium 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*,[75] the PTO expanded the scope of what it considered patentable biotechnologies from microorganisms to genetically modified plants.[76]

These decisions only directly affect the subcategory of biotechnology that involves a living organism — the genetically modified plants themselves. Laboratory tools required to transform plants were not directly affected and would have been considered patentable — consistent with the statutory criteria of novelty, utility, and nonobviousness — without the *Chakrabarty* and *Hibberd* rulings. Moreover, plants themselves had long been subject to limited patent or patent-like protection under the Plant Patent Act of 1930[77] and the Plant Variety Protection Act of 1970.[78] The Plant Patent Act, administered by the PTO, covers asexually reproduced plants (those not produced from seed) and provides protection against the sale by others of novel varieties produced in this fashion.[79] The Plant Variety Protection Act, administered by the USDA, provides similar protection for novel plant varieties that are sexually reproduced. In contrast to the core patent statute, no showing of utility is required under these two plant-specific laws, but they confer considerably more limited rights on inventors than standard (or "utility") patents. In particular, they do not include the right to control what people do with derivatives of the plant in question, which means, among other things, that researchers are free to use plants patented under the Plant Patent Act when developing and commercializing new plants. The Plant Variety Protection Act explicitly contains both a research exemption and a farmer's exemption (allowing farmers to save and reuse seed from a protected variety).[80]

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75. 227 U.S.P.Q. 443 (Bd. of Patent App. and Interferences, 1985).

76. In 1987, the PTO announced its new policy that all nonhuman, nonnatural creatures are patentable. *See* PTO, *Patent and Trademark Office Notice: Animals-Patentability*, OG 24 OFFICIAL GAZETTE U.S. PAT. & TRADEMARK OFF.: PAT. 1077 (1987). The next year, the PTO issued a patent on the famous Harvard "onco-mouse," genetically altered to be more likely to get cancer. Recently, the Supreme Court confirmed this PTO policy as consistent with the law. *See* J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, 534 U.S. 124, 130 (2001).

77. 35 U.S.C. §§ 161–164 (2003).

78. 7 U.S.C. §§ 2321–2583 (2003).

79. *See* Keith Fuglie et al., *Agricultural Research and Development: Public and Private Investments under Alternative Markets and Institutions*, USDA AGRIC. ECON. REP. 735 (1996), *available at* http://www.ers.usda.gov/publications/aer735/. The term for plant patents was seventeen years until the 1994, when an amendment extended the term to twenty years.

80. 7 U.S.C. §§ 2543, 2544 (2003).

The practical impact of *Chakrabarty* and *Hibberd* was far-reaching.[81] The ability to patent genetically modified plants solved one of the major problems developers of biotechnology faced in devising an effective model for commercial exploitation of the advances they were making in the laboratory. In the absence of utility patents, farmers would be free to save the seed from their genetically modified crops and use them the next year and thereafter, which meant that most return on investment for technology developers would have to come from one-time sales. Given the size of the investment required to develop commercially viable varieties of genetically modified plants, developers prefer (and investors may require) the more sizable income that can be derived from annual sales over the life of the patent. With a utility patent on the plant, reuse of the seed would constitute patent infringement and, on that basis, could be prevented through strict license agreements with growers, as well as litigation to enforce licenses and patents.[82]

Utility patents thus changed fundamentally the incentives for investment and invention in the field of agricultural biotechnology.[83] 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 genetically modified corn, soybeans, and cotton, that have captured large shares of the U.S. market.[84] The ability to patent and control the use of such plants made them more

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81. 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. *See* J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 130 (2001).

82. It is common practice among companies selling genetically modified seeds to require that their customers agree, among other things, not to save seed for replanting the next year and to vigorously enforce those agreements. The power of companies to limit the use of their products to customers who enter such agreements came most famously to light when Monsanto sued Canadian canola farmer Percy Schmeiser for having its Roundup Ready canola in his fields. Since Monsanto won a judgment against Schmeiser, it has brought many more suits against farmers. *See* DAVID R. MOELLER, GMO LIABILITY THREATS FOR FARMERS: LEGAL ISSUES SURROUNDING THE PLANTING OF GENETICALLY MODIFIED CROPS 6 (Farmers' Legal Action Group, Inc., 2001) ("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."), *at* http://www.flaginc.com/pubs/arts/GMOthreats.pdf; *see also* E. Ann Clark, A FANCIFUL TALE . . . ON THE APPEAL OF THE PERCY SCHMEISER DECISION (2002) ("With over 2000 similar lawsuits already reportedly hanging on this decision, one of the key segments of [Monsanto's] overall global strategy would be at stake"), *at* http://www.plant.uoguelph.ca/research/homepages/eclark/judge.htm.

83. *See* Heisey et al., *supra* note 30, at 3, 5–6.

84. William W. Lin et al., *Biotechnology: U.S. Grain Handlers Look Ahead*, AGRIC. OUTLOOK 29–34 (USDA Economic Research Service, Oct. 2001) ("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"), *at* http://www.ers.usda.gov/publications/agoutlook/apr2000/ao270h.pdf.

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 basic utility patent law, these traits and tools are themselves patentable and have been patented in large numbers.

1. The Number and Pattern of Biotechnology Patents

Gregory Graff has compiled a unique dataset of agricultural plant biology patents,[85] on which we rely extensively for our analysis of the number and pattern of biotechnology patents. The bulk of our analysis is in appendix A, and we only summarize it here. Graff's 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 increasing rate; and (3) the majority of the patents are in private hands.[86]

Many biotechnology patents have already been issued. Considering only biotechnology specifically applicable to agriculture, and focusing on specific genetic traits, plant germplasm, and tools to modify the genome of plants, we calculate that about 2,247 inventions were patented between 1975 and 1998. Beyond just the overall number of patents, the rate at which biotechnology patents are being issued is increasing. Data on this were not available specifically for agriculturally applied biotechnology, but in scientific areas closely related to plant biotechnology, PTO data show that the number of patents issued per year increased almost nine-fold between 1981 and 2001.[87] In the same time, overall utility patents per year slightly more than doubled. In agricultural biotechnology specifically, we can get an idea of the trend from a study of patents issued to universities. 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 twenty years (314).[88] We assume that the trend is similar for patents assigned to private individuals and corporations, though we have not found an analysis of that trend in the literature.

Graff's data also show how agricultural biotechnology patents are distributed among three groups of patent holders: universities and other public institutions, individuals and small or startup firms, and

85. Graff, *supra* note 32.

86. The appendix gives additional detail on both the numbers and kinds of technology being patented.

87. *See* PTO, *Patent Counts by Class by Year: January 1977–December 2001*, A TECH. ASSESSMENT & FORECAST REP. (2002), *at* http://www.uspto.gov/web/offices/ac/ido/oeip/taf/cbcby.pdf; *see also* Appendix, notes 254-55 and accompanying text.

88. *See* Barham et al., *supra* note 32, at 4, 28.

large corporations. Of the 2,247 inventions covered by agricultural biotechnology patents that were issued from 1975 to 1998, 525 were patented by universities or public institutions, 812 by small firms or individuals, and 970 by corporations.[89] These data confirm that most of the agricultural biotechnology patents (79%) are in private hands.

2. The Breadth of Biotechnology Patents

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

For example, in 1992, Agracetus (now a subsidiary of Monsanto Company) was granted a U.S. patent covering all genetically engineered cotton plants.[90] 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 eighty-one 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."[91] 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.[92]

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 transformed plants that employ antibiotic resistance markers," a widely used tech-

89. The sum of the patent holders exceeds 2,247 because a single patent can be granted to multiple assignees. *See id*.

90. *See* J. Bijman, *Agracetus: Patenting All Transgenetic Cotton*, 21 BIOTECH. & DEV. MONITOR 1, 8–9 (1994), *available at* http://www.biotech-monitor.nl/2105.htm.

91. DEVLIN KUYEK, INTELLECTUAL PROPERTY RIGHTS: ULTIMATE CONTROL OF AGRICULTURAL R&D IN ASIA, at 15 (Biothai 2001), *at* http://www.grain.org/docs/asiaipr.pdf.

92. *See id*.

nique.[93] Monsanto also has patents on the CaMV 35S promoter and the widely applicable *Agrobacterium tumefaciens* vector system for transforming cotton plants, which Agracetus patented in the United States in 1991.[94]

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

B. The Patent Thicket and Its Consequences

This pattern — the increasing number of patents, increasing patent breadth, and the issuance of patents on more basic discoveries — has created what some call a patent thicket in biotechnology: "an overlapping set of patent rights requiring that those seeking to commercialize new technology obtain licenses from multiple patentees."[96] The patent thicket is a problem because useful innovation in biotechnology requires multiple inventive steps and technologies. The field of biotechnology is particularly dependent on the cumulative work of

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93. Press Release, Rural Advancement Found. Int'l, Monsanto's "Submarine Patent" Torpedoes Ag Biotech: Monsanto & Syngenta Monopolize Key Gene Marker Technologies (Apr. 26, 2001), *at* http://www.etcgroup.org/documents/news_monsantosub.pdf.

94. U.S. Patent No. 5,004,863 (issued Apr. 2, 1991).

95. Rural Advancement Found. Int'l, *supra* note 93.

96. Shapiro, *supra* note 71, in abstract; *see also* John Barton, Patent Breadth and Antitrust: A Rethinking (1995), *at* http://www.ftc.gov/opp/global/barton.htm; Gregory Graff & David Zilberman, *Towards an Intellectual Property Clearinghouse for Ag-Biotechnology*, IP STRATEGY TODAY 3-2001 (2001), *at* http://www.biodevelopments.org/ip/ipst3n.pdf; John H. Barton, *Reforming the Patent System*, 287 SCI. 1933 (2000), *available at* http://www.biotech-info.net/reforming.html; ARTI K. RAI & REBECCA S. EISENBERG, THE PUBLIC AND THE PRIVATE IN BIOPHARMACEUTICAL RESEARCH (Duke Law School Conference on the Public Domain, 2001), *at* http://www.law.duke.edu/pd/papers/raieisen.pdf.

many researchers, and therefore is vulnerable to the "anticommons" problem mentioned earlier.[97]

The access problems blend into one another and the resulting barriers to further research and innovation are similar, whether the bar is singular, such as one broad patent on a genetically modified plant or one owner's refusal to license, or whether the problem is cumulative, such as patents on many contributing research tools 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.[98] The most direct barriers they cite are simple refusals by owners to license, a problem that comes with the dominance of private ownership described earlier. Owners can refuse because they mistrust licensees,[99] wish to retain a field of research for themselves,[100] or for any other reason. Even public agencies, responding to ownership incentives, do not always promote access.[101] These simple refusals shade into the more complex prob-

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97. *See* Heller & Eisenberg, *supra* note 68.

98. *See* NAT'L RESEARCH COUNCIL, *supra* note 30, at 8.

99. *See id.*:

> 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."

Id.

100. Agracetus, for example, uses its patent on all transgenic cotton to prevent anyone else from researching a certain aspect of cotton production:

> It is also possible that the patentee prohibits the exploitation of the technological area that is covered by the patent. Agracetus, for example, has licensed companies such as Monsanto and Calgene that use the technology to improve the insect resistance of cotton. But all efforts to alter the genome of cotton to improve its fiber characteristics have not been authorized by the company. This is the area which is monopolized by Agracetus.

Van Wijk, *supra* note 69, at 16.

101. *See* NAT'L RESEARCH COUNCIL, *supra* note 30, 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

lems of the patent thicket when the barrier is not one owner but the accumulated transaction costs:

> Sometimes the shutting out of researchers from a technology or line of inquiry is less direct but no less effective. Bennett [Associate Dean of Plant Sciences at the University of California, Davis] described one such conundrum in California. As part of a project funded by the Strawberry Commission, researchers had been working to insert a gene into strawberries that would cause the berries to produce fungus-killing chemicals and so reduce the need for fungicides. Researchers were using an anti-fungal gene and a strawberry cultivar both patented by the University of California, so access to them was no problem. Unfortunately, however, as the project progressed, those involved realized that access to other necessary technologies — *Agrobacterium* to insert the gene, promoters, and selectable markers — was not nearly so clear. Indeed, Bennett said, it appeared that even if the researcher succeeded in developing a strawberry line with anti-fungal properties, difficulties in getting commercial rights to the various technologies would make it impossible to market the line. The Strawberry Commission dropped its funding of the program.[102]

Academic researchers may be especially vulnerable to access obstructions, but as Heller and Eisenberg argue, the logic of the "anticommons" applies to all.[103]

In response to the patent thicket, the commercial biotechnology industry has developed a number of strategies. Because of the many patents outstanding on the tools of biotechnology, companies often

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> 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."

Id.

102. *Id*. at 9. The patent thicket deters investors as well:

> "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."

Id.

103. Heller & Eisenberg, *supra* note 68.

cannot avoid infringing patents when conducting 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.[104]

More cooperative responses, such as patent pooling or cross licensing, have been pursued in some industries,[105] but these also have their costs. Elaborate cross-license structures act as a barrier to entry to the industry,[106] and they can raise antitrust issues.[107] One solution to the high transaction costs of negotiating multiple patents is for companies to merge. Some commentators believe the extensive merger and acquisition activity in the agricultural biotechnology and seed industries is driven in part by the need to consolidate patent portfolios and thus ensure freedom to operate.[108] Though many other fac-

104. Barton, *Reforming the Patent System*, *supra* note 96; *see also* Shapiro, *supra* note 71, at 3.

105. *See* Graff & Zilberman, *supra* note 96, at 3–4; *see generally* Robert P. Merges, *Institutions for Intellectual Property Transactions: The Case of Patent Pools* (1999), *at* http://www.law.berkeley.edu/institutes/bclt/pubs/merges/ (last visited Feb. 25, 2004).

106. Barton, *Patent Breadth and Antitrust*, *supra* note 96.

107. *See* Shapiro, *supra* note 71, at 122.

108. *See, e.g.*, Barton, *supra* note 30; John L. King, *Concentration and Technology in Agricultural Input Industries*, AGRIC. INFO. BULL. 763 (USDA Economic Research Service 2001), *at* http://www.ers.usda.gov/publications/aib763.pdf; Murray Fulton & Konstantinos Giannakas, *Agricultural Biotechnology and Industry Structure*, 4 AGBIOFORUM 137 (2001), *at* http://www.agbioforum.org/v4n2a08-fulton.pdf; William H. Lesser, *Intellectual Property Rights and Concentration in Agricultural Biotechnology*, 1 AGBIOFORUM 56 (1998), *at* http://www.agbioforum.missouri.edu/v1n2/v1n2a03-lesser.pdf; Nicholas Kalaitzandonakes & Marvin Hayenga, *Structural Change in the Biotechnology and Seed Industrial Complex: Theory and Evidence*, *in* TRANSITIONS IN AGBIOTECH: ECONOMICS OF STRATEGY AND POLICY 217 (William H. Lesser ed., Food Mktg. Policy Ctr. 2000), *at* http://agecon.lib.umn.edu/cgi-bin/pdf_view.pl?paperid=1907&ftype=.pdf.

tors are also at work, the concentration in the industry has been dramatic.[109]

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.[110] One can see the difficulties of the patent thicket in the recent efforts by the public sector inventors of vitamin A-enriched "Golden Rice" to make the necessary technologies available for adaptation in developing countries. Some seventy patents and existing licenses had to be considered as possible barriers.[111] Commentators have written about the access problem for developing countries.[112] Thirty-one of thirty-three (94%) respondents to

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109. *See, e.g.*, Gregory D. Graff et al., Agricultural Biotechnology's Complementary Intellectual Assets 1, *at* http://ssrn.com/abstract=280107 (August 2001). The authors propose that:

> Concurrent with these technical changes in the R&D process, the agricultural inputs industry has over the past two decades witnessed a comprehensive restructuring. Several large chemical firms including Monsanto, Dow, and DuPont moved aggressively into plant biotechnology, making huge investments in the life sciences. As newly minted "agronomic systems" companies, these firms acquired all of the large, national seed firms in North America, including Pioneer, DeKalb, Asgrow, Garst, and many others. Meanwhile, the research-intensive agricultural biotechnology sector, from its appearance in the 1980s as a large set of small start-up firms, had by the end of the 1990s already reached a second stage, with most of the start-ups either folded or acquired by the new agronomic systems giants.

Id.

110. Several examples are mentioned in COMM'N ON INTELLECTUAL PROP. RIGHTS, WORKSHOP 10: RESEARCH TOOLS, PUBLIC PRIVATE PARTNERSHIPS AND GENE PATENTING (2002), *at* http://www.iprcommission.org/papers/pdfs/workshops/workshop10.pdf; *see also* Graff & Zilberman, *supra* note 96.

111. *See* R. DAVID KRYDER ET AL., THE INTELLECTUAL AND TECHNICAL PROPERTY COMPONENTS OF PRO-VITAMIN A RICE (GOLDEN RICE™): A PRELIMINARY FREEDOM-TO-OPERATE REVIEW (ISAAA Brief 20, 2000), *at* http://www.isaaa.org/Publications/briefs/briefs_20.htm.

112. 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. *See* ROBERT W. HERDT, ENCLOSING THE GLOBAL PLANT GENETIC COMMONS (Rockefeller Foundation, 1999), at 15, *at* http://www.rockfound.org/Documents/182/proprights.pdf; *see also* ERAN BINENBAUM ET AL., SOUTH-NORTH TRADE, INTELLECTUAL PROPERTY JURISDICTIONS, AND FREEDOM TO OPERATE IN AGRICULTURAL RESEARCH ON STAPLE CROPS (IFPRI EPTD Discussion Paper 70, 2000), *at* http://www.ifpri.org/divs/eptd/dp/papers/eptdp70.pdf; Joel I. Cohen, *Managing Intellectual Property — Challenges and Responses for Agricultural Research Institutes*, *in* Persley & Lantin eds., *supra* note 37, at 209; *and* SILVIA SALAZAR ET AL., THE USE OF PROPRIETARY BIOTECHNOLOGY RESEARCH INPUTS AT SELECTED LATIN AMERICAN NAROS (ISNAR Briefing Paper No. 44, 2000), *at* http://www.isnar.cgiar.org/publications/briefing/Bp44.htm. While acknowledging the access problem for developing countries, some of these commen-

our survey ranked "multiplicity of patents and patent owners affecting product development" as highly important for access to the tools of biotechnology by researchers working on problems in developing countries. We will explore the impact of the patent thicket further in the next section, after a brief overview of the strongly pro-patent orientation of the U.S. patent system.

C. 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 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 Article and discussed further below, we see evidence that the system inhibits access to biotechnology and its potential application to agricultural problems in developing countries. Regardless of one's point of view or interest, it is important to recognize the core values and orientation of the government agency charged with managing the U.S. patent system.

The PTO exists to issue patents. Although the agency is charged with making patent decisions based on statutory criteria that patent applicants must satisfy — and denying patents when the criteria are not satisfied — the PTO's orientation and pervasive culture are strongly pro-patent. One can see this approach in the agency's mission and strategic goals, as well as whom it considers its constituency.[113] The PTO does not exist in a vacuum. Like most government agencies, its orientation reflects the demands and expectations of society as filtered through Congress, the courts, and 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 for balancing the interests of inventors in having patent protection against the broader interests of society in having access to innovation.

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tators argue that it has been exaggerated, since patents have no legal jurisdiction in foreign countries. We address this point in the final subsection of this section.

113. *See* PTO, *A New Organization for a New Millennium: Performance and Accountability Report, Foreword* to 2000 PTO PERFORMANCE & ACCOUNTABILITY REPORT. 1, *at* http://www.uspto.gov/web/offices/com/annual/2000/ (last visited Apr. 16, 2004).

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 PTO as the advocate and guardian of the rights of inventors, creators, and innovators."[114] 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."[115]

One of the PTO's strategic goals for 2001–2006 is to "[m]aintain and grow our domestic and international leadership roles in intellectual property rights policy."[116] The corresponding performance goal is to "strengthen intellectual property protection in the United States and abroad, making it more accessible, affordable, and enforceable."[117] This goal, says the PTO, "relates to our Intellectual Property Leadership function, which provides executive direction to the PTO and serves to champion intellectual property at home and abroad."[118]

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

> The current projections — where patent pendency remains in excess of two years because of backlogs . . . should be deemed unacceptable. Our customers deserve — and the reality of our high-tech economy demands — that we provide the highest quality patent in the shortest feasible timeframe. Issuing a high quality patent is our primary goal. Issuing it in a timely manner is essential. Balancing these goals is our challenge.[119]

The PTO's focus on the patent applicant as the agency's customer, rather than the public at large, is pervasive. It cites its customer satisfaction surveys, customer-service training for employees, and customer feedback activities as all in line with its goal to "define ser-

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114. *Id*.
115. *Id*.
116. *Id*. at 17.
117. *Id*.
118. *Id*.
119. *Fiscal 2003 Budget: Patent and Trademark Office: Hearing Before the Subcomm. on Courts, the Internet, & Intellectual Prop., House Comm. on the Judiciary*, 107th Cong. (Apr. 11, 2002) (Statement of James E. Rogan, Director, PTO), *at* http://www.uspto.gov/web/offices/com/speeches/househrg2002/htm.

vice from our customers' perspective."[120] The PTO's Public Advisory Committees, which are "drawn from a cross-section of our private-sector customers,"[121] consist of representatives from "entrepreneurial businesses, inventors, universities, large U.S.-based corporations, and law firms."[122] The general public, the presumed beneficiary of the innovation the patent system is intended to stimulate, is not represented.

The focus on the patent applicant as customer is reinforced by the fact that the agency depends on applicants' fees for its revenues.[123] In addition to application fees, there are maintenance fees, which the PTO receives only on issued patents. The fact that the applicant pays for the initial review and pays in the future only if the patent is issued creates an incentive for the issuance of patents. Such a positive atmosphere inevitably contributes to the volume of applications, and that volume, in turn, directly affects PTO revenues. Like any organization, the PTO has an institutional interest in maintaining its revenues.

The PTO 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 twenty to thirty hours.[124] Pendency — the time from application to issue — is carefully monitored, and the law provides patent-term extensions for applicants when the PTO fails to meet various deadlines, which is both an embarrassment and a transaction cost for the agency.[125] Improperly structured applications may be returned to the applicant for revision, but applicants will likely resubmit them.

One of the primary grounds for denying a patent is if the examiner finds that there is evidence that the invention is actually not new (that is, there is "prior art" covering the patent claims). If other re-

120. PTO, *supra* note 113, at 17.

121. *Id*. at 46.

122. *Id.* at 12.

123. "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." Mary Bellis, An Introduction to the PTO, *at* http://inventors.about.com/library/bl/toc/blintropto.htm (2004); *see also* PTO, Fiscal Year 2001 Corporate Plan, *at* http://www.osec.doc.gov/bmi/budget/PB2001/BROWSE/bjpto.PDF (2001) (projecting collections for the fiscal year 2001 of $1.15 billion and outstanding collections from previous fiscal years of $255 million).

124. "A PTO examiner can give each application an average of twenty-five to thirty hours, and may in fact give much less." Barton, *Reforming the Patent System*, *supra* note 96, at 1934 (citing 1993 PTO statistics, a personal communication, and H. Manbeck, former commissioner of the PTO, who has testified that examiners spend fifteen to seventeen hours per application).

125. *See* 35 U.S.C.A. § 154(b) (1999) (amended by The American Inventors Protection Act of 1999, Pub. L. 106-113, 113 Stat. 1501 (1999) (codified as amended in scattered sections of 35 U.S.C.), to elaborate the various deadlines).

quirements for patenting are met, a patent will be issued unless prior art is discovered under great time pressure. This can create a particularly strong pro-patent tendency in new and dynamic areas of research and innovation, 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 obviously not unbiased. In addition, the examiners' performance evaluations and bonuses (up to ten percent of salaries) depend on maintaining production schedules with limited time allotted for each application.[126] All these factors put significant pressure on patent examiners to err on the side of granting rather than denying patents.[127]

The PTO's customer focus and dependence on patent applicants for revenue make the relationship between the agency and the applicant very different from the arm's-length relationship that typically exists between a regulatory agency and a regulated entity. Rather than acting in the public interest as neutral arbiters of whether a valuable public license should be issued, patent examiners are under pressure to act more as partners of the applicant, responsible for managing an application to prompt conclusion by issuing 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 eighteen-month publication rule[128] (the first early publications took place in mid-2002), patent applications were not published before they were granted. Therefore, no one could oppose the granting of a patent until after it was issued, and although challenges were allowed, there was — and there remains —

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126. "The regulations allow the PTO to pay up to [ten] percent of salary for fully successful performance and up to [twenty] percent for exceptional performance, to an annual limit of $10,000 (or, with OPM approval, up to $25,000)." *Pay As You Go: Ways to Improve Compensation and Cut Attrition*, POPA NEWSL. (Patent Office Prof'l Ass'n), Feb. 2000, *at* 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, Future of the USPTO, Remarks at the Fifth Biennial Patent System Major Problems Conference, *in* 36 IDEA 383, 389 (1996), *available at* http://www.idea.piercelaw.edu/articles/36/36_2/8.Conference.III.pdf.

127. According to PTO statistics, sixty percent 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, *at* http://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.pdf (last visited Feb. 25, 2004).

128. *See* Changes to Implement Eighteen-Month Publication of Patent Applications; Correction, 65 Fed. Reg. 66,502 (Nov. 6, 2000) (codified in 37 C.F.R. § 1).

a strong presumption that an issued patent is valid. The patent statute explicitly presumes validity, placing the burden of proof on the challenger.[129] 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 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 challengers cannot appeal to the Court of Appeals for the Federal Circuit.[130] Since the adoption of the eighteen-month rule, applications can be challenged before issuance, but there are still restrictions on the challenger's legal standing, and the improvements have been modest:

> The 1992 Report of the Advisory Commission on Patent Law Reform urged strengthening of the reexamination process, and a weak reform was included in the legislation enacted last fall. Even as reformed, the process deals only with newly discovered prior art; it offers no way to reconsider a patent on the grounds that the examiner misapplied the law.[131]

The new law also creates conflicting 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.[132]

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129. *See* 35 U.S.C. § 282 (2003).

130. *See* Robert J. Yarbrough, Patent Reexamination (2000), *at* http://www.yarbroughlaw.com/reexamination2.htm.

131. Barton, *Reforming the Patent System*, *supra* note 96.

132. TALIS DZENITIS, PTO, AMERICAN INVENTORS PROTECTION ACT OF 1999 IS LAW (2003), *available at* http://www.uspto.gov/web/offices/dcom/olia/aipa/summary.htm.

A challenge may actually weaken a third party's position in future court cases by giving any evidence of 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 performs illicitly. It is intended simply to describe the system in its current form. There is ample room to debate whether current patent law and the PTO's approach to implementing it are in the public interest; many academic commentators argue that they are not.[133] Many others defend it, arguing that the PTO is doing just what Congress intended and that it is acting profoundly in the public interest.[134]

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

D. Policies to Ease Access

We will address here, and in the later discussion of possible policy change, five areas of patent policy that affect the conditions under which parties may access and use patented technologies. These all provide opportunities to address the technology transfer problem of concern here, namely access to the tools of biotechnology by public-sector researchers and others who want to use them for developing

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133. *See* Eisenberg, *supra* note 62; John H. Barton, *Patents and Antitrust: A Rethinking in Light of Patent Breadth and Sequential Innovation*, 65 ANTITRUST L.J. 449 (1997); Barton, *supra* note 30; Donald G. McFetridge, *Intellectual Property, Technology Diffusion, and Growth in the Canadian Economy*, *in* COMPETITION POLICY AND INTELLECTUAL PROPERTY RIGHTS IN THE KNOWLEDGE-BASED ECONOMY (Robert D. Anderson & Nancy T. Gallini, eds., 1998).

134. *See Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy, Hearing Before the Fed. Trade Comm'n and Dep't of Justice Antitrust Div.* (Feb. 6, 2002) (Statement of Gerald J. Mossinghoff), *at* http://www.ftc.gov/os/comments/intelpropertycomments/mossinghoffgeraldj.pdf; F. Scott Kieff, *Facilitating Scientific Research: Intellectual Property Rights and the Norms of Science — A Response to Rai and Eisenberg*, 95 NW. U. L. REV. 691, 700 (2001); J.H. Dodds et al., *Biotechnology, the Gene Revolution, and Proprietary Technology in Agriculture: A Strategic Note for the World Bank*, 2 IP STRATEGY TODAY (2001), *at* http://www.biodevelopments.org/ip/ipst2n.pdf.

countries. The five policy areas are: (1) exemptions for research use of patented technology, (2) patent working requirements, (3) compulsory licensing of patented technology, (4) the government's eminent domain authority over patents, and (5) provisions for access to patented technology that is government-owned or developed with government funding.

1. Research Exemptions

The utility patent statute in the United States does not explicitly allow researchers to use patented inventions freely in their research. Traditionally, however, the U.S. courts interpreted the law as implicitly exempting the use of patented inventions in noncommercial research from infringement. This was in keeping with the purpose of the patent law to make patented technologies known and available so they could be the basis for developing new knowledge, while protecting the monopoly marketing rights accorded to inventors by their patents. This judicially recognized research exemption was narrow, however, in the sense that it did not permit the use of patented technology in the research and development of new technologies for use in commercial research or nonresearch settings. In a recent decision, the U.S. Court of Appeals for the Federal Circuit narrowed the exemption to the point of eliminating it for practical purposes.[135] The Court held that the exemption did not protect the use of a patented technology from infringement claims when such use is "in keeping with the alleged infringer's legitimate business, regardless of commercial implications."[136] This means that the exemption does not protect even purely academic research conducted by a university, since academic research is the university's "business." Similarly, the exemption would not be available to public-sector researchers using patented tools of biotechnology to research new applications that benefit developing countries, even if the research has no "commercial implications."

The lack of a meaningful research exemption under the U.S. utility patent statute differs from those of Japan and many European countries, which exempt research done for noncommercial, experimental purposes from infringement suits.[137] It also contrasts with the explicit exemption from protection provided in the Plant Variety Protection Act for the use of a protected plant variety to develop new commercial varieties.[138]

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135. *See* Madey v. Duke Univ., 307 F.3d 1351 (Fed. Cir. 2002); *see also* Rebecca S. Eisenberg, *Patent Swords and Shields*, 299 SCI. 1018–19 (2003) (analyzing *Madey* and summarizing the current status of the research exemption).

136. *Madey*, 307 F.3d at 1362.

137. *See* Eisenberg, *supra* note 135, at 1018.

138. "The use and reproduction of a protected variety for plant breeding or other bona fide research shall not constitute an infringement of the protection provided under this chap-

2. Compulsory License Provisions

U.S. statutes currently provide for granting mandatory, nonexclusive licenses for certain technologies that serve an important public interest. The Clean Air Act, for example, has a compulsory licensing provision for pollution-prevention technology; and the Atomic Energy Act[139] has a compulsory license provision for certain patented technologies "affected with the public interest."[140] Under U.S. law, compulsory licenses make technology available for government use and ameliorate anti-competitive practices among patent holders.[141] Compulsory licenses, like research exemptions, are tools for adjusting the balance between public interests and the private interests of patent holders by providing an exception to the exclusive rights normally provided by a patent.

Article 30 of the TRIPS Agreement provides member countries general flexibility to grant "limited exceptions" to normal patent rights when that would "not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."[142] Such exceptions could take the form of compulsory licenses. Article 31 of TRIPS authorizes compulsory licenses for "other uses" — ones that might conflict with normal exploitation or prejudice the interests of the patent holder — but subject to several conditions, such as remuneration to the patent holder, designed to minimize the patent holder's economic loss.[143] There are no similarly broad compulsory license provisions in U.S. law, and the United States has not addressed the need for compulsory licenses to handle the specific problem of access to biotechnology for food security purposes.

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ter." 7 U.S.C. § 2544 (2000); *see* JANICE M. STRACHAN, PLANT VARIETY PROTECTION: AN ALTERNATIVE TO PATENTS, *available at* http://www.nal.usda.gov/pgdic/Probe/v2n2/plant.html (last visited Feb. 25, 2004).

139. *See, e.g.*, 42 U.S.C. § 2183 (1992) (outlining a compulsory licensing scheme for atomic energy).

140. JAMES LOVE & MICHAEL PALMEDO, EXAMPLES OF COMPULSORY LICENSING OF INTELLECTUAL PROPERTY IN THE UNITED STATES, at ch. IV (CPTech Background Paper, 2001), *available at* http://www.cptech.org/ip/health/cl/us-cl.html.

141. *See id*. chs. III–IV.

142. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, LEGAL INSTRUMENTS — RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 81, 95 (1994) [hereinafter TRIPS], *available at* http://docsonline.wto.org/DDFDocuments/t/UR/FA/27-TRIPS.doc.

143. TRIPS, *id*. art. 31; *see generally* CARLOS M. CORREA, INTELLECTUAL PROPERTY RIGHTS, THE WTO AND DEVELOPING COUNTRIES: THE TRIPS AGREEMENT AND POLICY OPTIONS 89–94 (2000) (discussing compulsory licenses under the TRIPS Agreement).

3. Working Requirements

U.S. patent law contains no requirement that patent holders "work" their patents, by either using the patented invention themselves or licensing it to others, as a prerequisite to keeping the patent in full force. Most countries do impose working requirements, either modeled on the working provision in the Paris Convention for the Protection of Intellectual Property, or incorporated into their compulsory license provisions.[144] Such requirements commonly provide that after a period of time, such as three years, if a patent holder has not worked the patent, another party may obtain, from a designated authority, a nonexclusive license to use the invention for their own purposes, commercial or otherwise.

Since biotechnology has been used mainly in commercialized agriculture rather than to meet the needs of developing countries, working requirements offer an obvious means to redress this within the norms of traditional patent policy and existing international agreements. The TRIPS Agreement requires compliance with the Paris Convention and accepts compulsory licensing, therefore allowing the use of patented technologies that the patent holder has not worked for food security purposes.

4. Eminent Domain Authority

Closely analogous to compulsory licensing is the concept of eminent domain, which has existed in U.S. patent law since 1910.[145] Under the government's eminent domain authority, government authorization of the use of patented technology insulates a user from any patent infringement claim by the patent holder. There are no subject-matter, purpose, or other substantive restrictions on the uses of the technology for which eminent domain authority may be exercised, and there is no requirement for formal action by the government to invoke it:

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144. *See* Paris Convention for the Protection of Industrial Property, July 14, 1967, 21 U.S.T. 1583, art. 5(A)(4) [hereinafter Paris Convention] (originally enacted in 1883, ratified with the exception of Articles 1–12, May 4, 1970). A variety of related measures can all be considered "working" requirements, if they justify compulsory licenses by a failure of the patent holder to supply a market. In addition to the direct working requirement articulated in the Paris Convention, refusal to deal, dependent patents, and inadequate supply are all forms of a working requirement, if they are grounds for a compulsory license. *See generally* CARLOS M. CORREA, INTELLECTUAL PROPERTY RIGHTS AND THE USE OF COMPULSORY LICENSES: OPTIONS FOR DEVELOPING COUNTRIES, ch. 4 (South Centre, Working Paper No. 5, 1999), *at* http://www.southcentre.org/publications/complicence/toc.htm; CARLOS M. CORREA, INTEGRATING PUBLIC HEALTH CONCERNS INTO PATENT LEGISLATION IN DEVELOPING COUNTRIES, ch. 10 (South Centre, 2000), *at* http://www.southcentre.org/publications/publichealth/toc.htm.

145. *See* Act of June 25, 1910, ch. 423, 36 Stat. 851 (1910) (codified as amended 28 U.S.C. § 1498 (1948)).

> 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.[146]

The existing eminent domain authority has been used primarily for military purposes, although its use was considered recently in a health context to make the anthrax drug CIPRO available more cheaply.[147] Eminent domain authority has not been exercised with respect to patents on the tools of agricultural biotechnology.

5. Access to Government-Funded Technology

The USDA and other government agencies fund research in their own laboratories and in academic facilities that sometimes leads to patented tools or applications of agricultural biotechnology. The Bayh-Dole Act encourages the patenting of government-funded research as a means of fostering its dissemination and use,[148] and USDA's current patent policy is based on the goal of making government-supported technology available for continued development and application.[149] This is consistent with the patent law, which declares:

> It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development, . . . to ensure that the Government ob-

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146. Paul Janicke, *Current State of U.S. Patent Law Regarding Infringement of Drug Patents by the Government*, Health L. Persp., ¶ 5 (Dec. 7, 2001) (discussing *Bereslavsky v. Esso Standard Oil Co.*, 175 F.2d 148 (4th Cir. 1949)), *at* http://www.law.uh.edu/healthlaw perspectives/Food/011207Current.html.

147. *See* Consumer Project on Technology ("CPTech"), *Ciprofloxacin: the Dispute Over Compulsory Licenses*, *at* http://www.cptech.org/ip/health/cl/cipro/ (last visited Feb. 13, 2004).

148. *See generally* NAT'L INSTS. OF HEALTH, REPORT OF THE NATIONAL INSTITUTES OF HEALTH (NIH) WORKING GROUP ON RESEARCH TOOLS, app. D (1998) (summarizing the options allowed government agencies under existing legislation), *at* http://www.nih.gov/news/researchtools/.

149. *See generally* USDA, TECHNOLOGY TRANSFER IN ARS, 141.2-ARS (Sept. 11, 2000), *at* http://www.afm.ars.usda.gov/ppweb/141-2.htm.

> tains sufficient rights to federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions . . . .[150]

This declaration of policy is backed by restrictions on granting exclusive or partially exclusive licenses for government-owned inventions, including requiring that "the Federal agency finds that the public will be served by the granting of the license . . . and that the proposed scope of exclusivity is not greater than reasonably necessary . . . ."[151]

On inventions owned by a private party but whose development was funded by the government under a cooperative research and development agreement ("CRADA"), the Bayh-Dole Act grants the government a license in the inventions to be exercised "as necessary for meeting the obligations of the United States under any treaty, international agreement, arrangement of cooperation, memorandum of understanding, or similar arrangement."[152] The Rome Declaration issued at the World Food Summit of 1996, signed by the United States, says, "We pledge our actions and support to implement the World Food Summit Plan of Action."[153] To date, the United States has not exercised its retained licenses on CRADA-funded technology to advance the food security purposes of the World Food Summit.

E. U.S. Foreign Policy on Patents

Patents are legally enforceable only in the issuing country, which is why patent law is often described as territorial in effect. On this basis, one might reasonably contend that U.S. patents and patent policy have little impact on the use of biotechnology in solving agricultural problems in developing countries, especially to the extent the R&D work is done outside the United States. Based on U.S. patent

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150. 35 U.S.C. § 200 (2003). Notice the working requirement implicit in "protect the public against nonuse." *Id*.

151. Technology Transfer Commercialization Act of 2000, 35 U.S.C. § 209(a)(2) (2000).

152. 35 U.S.C. § 202(c)(4) (2000).

153. World Food Summit Plan of Action, Nov. 13–17, 1996, U.N. Doc. WFS 96/3 (1996), *available at* http://www.fao.org/docrep/003/w3613e/w3613e00.htm, stating:

> [C]oncerted action at all levels is required. Each nation must adopt a strategy consistent with its resources and capacities . . . . Govemments are responsible for creatin g 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 . . . . 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.

Id.

law alone, researchers in developing countries can legally use U.S. patented technologies as they wish, assuming they can physically gain access to them.

As we shall discuss in the following section of this Article, however, the ways in which the U.S. patent system affects developing countries are complex and multifaceted. They include the direct and indirect effects of the patent thicket that has grown up around biotechnology in the United States. They include also the impact of patent-related policies the U.S. government pursues in the international arena. The PTO has declared itself a "champion" of intellectual property "at home and abroad" and has expressly adopted the goal of "strengthen[ing] intellectual property protection in the United States and abroad, making it more accessible, affordable, and enforceable."[154] In furtherance of this goal, the United States pursues "foreign" policies in at least three patent-related areas: implementation of the TRIPS Agreement, support for international harmonization and strengthening of patent law beyond what is required by TRIPS, and the use of trade agreements and trade sanctions to both protect U.S. intellectual property overseas and promote adoption of strong intellectual property regimes in other countries.

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

It is important to distinguish conceptually between "domestic" and "foreign" patent policies. The former, which includes the rules that govern patenting in the United States and access to U.S.-patented technologies, arises from the U.S. Constitution's call for a patent system to foster technological progress in the United States. It involves trade-offs between the need to provide incentives for invention and the need to ensure that inventions and the knowledge behind them are shared for the public good. These trade-offs occur within U.S. society and its markets. They can be and are adjusted over time, through administrative practice, court decisions, and legislation, to meet changing U.S. social and economic needs. In domestic patent policy, U.S. interests are balanced internally, and the balance can be assessed in light of the traditional principles and objectives of patent law and policy outlined in Section III.

U.S. "foreign" policy on patents, as we outline it below, arises outside the traditional confines of patent law and policy and is

154. PTO, *supra* note 113, at 17.

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

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

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

1. Implementation of the TRIPS Agreement

The TRIPS Agreement (formally the Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization) is, as its name implies, a trade agreement.[155] It was negotiated as part of the Uruguay Round of trade negotiations that concluded after creating the WTO in 1994. The primary objective of TRIPS was to reduce impediments to trade, taking into account the need both to promote adequate and effective intellectual property rights and to ensure that such rights do not become barriers to trade. With respect to patents, the core requirement of the TRIPS Agreement is that members provide for the patenting of all forms of technology in accordance with widely accepted principles of novelty, nonobviousness, and usefulness, and that national treatment be accorded all members. This means that

155. For general background on the TRIPS Agreement, including its text, origins, and implementation, see WTO, TRIPS, *at* http://www.wto.org/english/tratop_e/trips_e/trips_e.htm#NegHist (last visited Feb. 25, 2004).

member countries must permit nationals of other countries to obtain patents on terms no less favorable than those accorded to their own nationals.

The TRIPS Agreement explicitly recognizes in its preamble that developing countries need "maximum flexibility" to implement their patent laws in a way that enables those countries to create "a sound and viable technological base."[156] Article 7 explicitly embraces the instrumental or utilitarian understanding of patent policy and the need for patent policy to balance potentially competing social interests:

> The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.[157]

Article 8.1 specifically recognizes that countries may:

> adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.[158]

These provisions speak directly to the need of many developing countries to provide basic food security and nutrition for their people. They also reflect the reality documented by expert commissions and commentators that the patent and other intellectual property needs of developing countries vary and can be sharply different from the needs of industrialized countries.[159]

To further address the reality of varying needs, the TRIPS Agreement contains several provisions that give countries the flexibility to grant exceptions to patent rights under certain circumstances. These include the broad authority in Article 30 to grant exceptions when the interests of the patent holder will not be adversely af-

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156. TRIPS, 33 I.L.M. 95 (1994), *available at* http://docsonline.wto.org/DDFDocuments/t/UR/FA/27-TRIPS.doc.

157. WTO, *Agreement on Trade-Related Aspects of Intellectual Property Rights* (1994), *at* http://docsonline.wto.org/DDFDocuments/t/UR/FA/27-TRIPS.doc.

158. *Id*.

159. For a broad overview of this topic, see COMM'N ON INTELLECTUAL PROP. RIGHTS, *supra* note 11. For an analysis specifically of issues concerning TRIPS and development, see CORREA, *supra* note 143.

fected,[160] and the authority in Article 31 to provide for compulsory licenses, subject to some conditions, when the patent holder's interests are affected. Furthermore, Article 27.3(b) permits countries to exclude plants and animals from patentability altogether, provided an alternative *sui generis* system of protection is provided. This allows countries to adopt a flexible system of plant variety protection that both permits the use of protected plants for breeding new varieties and authorizes farmers to save seed for future planting.

The United States was a prime mover in the negotiations leading to the TRIPS Agreement, and, working through the Office of the U.S. Trade Representative, remains a strong TRIPS supporter. On June 20, 2003, the United States lauded the flexibility TRIPS provides to developing countries in making patented drugs available to battle HIV/AIDS among those who cannot afford expensive medicines.[161] The United States stated that TRIPS "strikes the proper balance" between stimulating development and commercialization of new drugs and providing access for the poor, specifically citing the broad flexibility in Article 30 to provide exceptions to patent rights if the exception does not unreasonably conflict with the normal exploitation of the patent or unreasonably prejudice the patent owner's legitimate interests.

The United States has not addressed how Article 30 or the compulsory license provisions in Article 31 would apply to allow access to the tools of biotechnology for developing-country food security purposes. It has, however, questioned the flexibility developing countries are allowed under Article 27.3(b) to exclude plants from patentability, and has argued the advantages of plant patents.[162] Article 27.3(b) is undergoing a review mandated by the original TRIPS Agreement. If this exclusion right is repealed, developing countries will lose an important source of flexibility that allows them to tailor their intellectual property systems to meet their particular needs in relation to biotechnology.

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160. Article 30 says: "Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties." TRIPS, *supra* note 156.

161. *See* U.S. Trade Representative, U.S. Statement on Intellectual Property and Access to Medicines at the June 20 TRIPS Council Meeting (2003), *at* http://www.ustr.gov/sectors/speech01.PDF.

162. *See* 1999 USTR ANN. REP., COUNCIL ON TRIPS, *at* http://www.ustr.gov/wto/99ustrrpt/ustr99_TRIPSpdf.

2. International Harmonization of Patent Law

A concerted effort is underway to implement an international harmonization of patent law beyond that provided for in the TRIPS Agreement. The effort, led by the United States and other Western industrialized nations, is being pursued through WIPO. WIPO evolved out of two nineteenth-century international conventions on intellectual property[163] and became a United Nations agency in 1974. WIPO administers two main treaties. One is the Patent Cooperation Treaty, which seeks to harmonize standards for obtaining patents. The other is the Patent Law Treaty, which aims to integrate the paperwork for obtaining patents and promote mutual recognition of patents among the treaty parties by ensuring that one international patent filing will have the same effect in all signatory countries. WIPO's strategic goals are similar to those of the PTO, including "maintenance and further development of the respect for intellectual property throughout the world," and ensuring that acquiring and enforcing patents should be "simpler, cheaper and more secure."[164] Having many patent offices review applications on essentially the same invention is a duplication of effort that is costly to patent offices and patent applicants.

In November 2000, WIPO launched its Patent Agenda, which is an effort to integrate and extend the two aforementioned treaties in the form of a new one, to be called the Substantive Patent Law Treaty ("SPLT").[165] The objectives of the SPLT are to harmonize the basic legal principles that govern the issuance of patents, such as the definitions of "prior art" and utility, so that:

> applicants, in all contracting parties of the SPLT, are subject to the same substantive conditions for the grant of patents and for the invalidation of granted patents. Such harmonization would lead to lower costs for applicants and patent offices by contributing to a future reduction in the duplication of search and examination work.[166]

163. *See* Paris Convention for the Protection of Intellectual Property (1883), *supra* note 144; Berne Convention for the Protection of Literary and Artistic Works, Sept. 9, 1886, *available at* 1886 WL 13983.

164. Memorandum of the WIPO Director General, Vision and Strategic Direction of WIPO, *at* http://www.wipo.org/about-wipo/en/dgo/pub487.htm (last visited Apr. 16, 2004).

165. *See* WIPO, Introduction, *at* http://www.wipo.int/patent/agenda/en/ (last visited Apr. 16, 2004).

166. Press Release, WIPO, Progress on Discussions to Harmonize Patent Law, Update 164/2002 (May 14, 2002), *at* http://www.wipo.int/pressroom/en/updates/2002/upd164.htm.

This approach differs from the harmonization effort embodied in the TRIPS Agreement, which only established minimum standards for adoption of patent systems by WTO members, and left considerable flexibility to tailor the systems to local needs. WIPO, through the SPLT negotiations, appears to be pursuing a much more standardized "one size fits all" approach to patents that would support the move toward a single patent application sufficient to establish patent rights to an invention worldwide. Though this standardizing would have labor-saving benefits, it would have costs as well. Some commentators have expressed concern that this "universal concept of patentability" would require the patenting by developing countries of technologies that it might not be in their interest to patent and for which patents could be rejected under the terms of the current TRIPS Agreement.[167] This could "represent, in reality, a step backwards from the limited aspects of flexibility stipulated in the TRIPS agreement."[168]

The United States strongly supports the WIPO effort to develop a "streamlined and simple system for obtaining patent rights."[169] In its 2000 Annual Report, the PTO took credit for putting forward a "comprehensive proposal for PCT reform" that would "allow applicants to prepare a relatively simplified patent application in a single format, which would be accepted by all patent offices throughout the world as a national patent application or an international PCT application."[170]

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167. Carlos Correa, *WIPO's Patent Agenda: For Whom?*, S. BULL. 48, *at* http://www.southcentre.org/info/southbulletin/bulletin48/bulletin48-01.htm (last visited Feb. 25, 2004), which states:

> One of the most significant issues on which some developing countries expressed their position at the SCP Sixth Session was whether an invention should show a "technical character" in order to be patentable. The United States argued — supported by the Representatives of some of the users group NGOs — that "requiring a technical character was unnecessarily limiting the innovations in new fields of endeavor, such as information technology and biotechnology, and that the term 'in all fields of technology' which appeared in Article 27.1 of the TRIPS Agreement was not mandating any requirement relating to technical character . . . ." In sum, dropping the requirement of "technical character" of inventions would substantially expand the scope of the patent system, beyond its basic intent of promoting technical progress. Such a step will go well beyond the TRIPS Agreement (which only prescribes patenting in "fields of technology") and the current PCT, according to which the invention must be of "technical character."

Id.

168. *The WIPO Patent Agenda Must Promote Development*, S. BULL. 48, *at* http://www.southcentre.org/info/southbulletin/bulletin48/bulletin48-02.htm (last visited Feb. 25, 2004) (adapted from the statement of the Egyptian delegation at the 37th series of Meetings of the Assemblies of Member States of WIPO).

169. WIPO, GENERAL REPORT ON THE THIRTY-SEVENTH SERIES OF MEETINGS OF THE ASSEMBLIES OF THE MEMBER STATES OF WIPO, SEPTEMBER 23 TO OCTOBER 1, 2002, ¶ 327, *at* http://www.wipo.int/patent/agenda/en/ (last visited Feb. 14, 2004).

170. PTO, *supra* note 113, at 20.

3. Use of Trade Measures to Expand Intellectual Property Protection

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

Many developing countries and regions, and ones with emerging economies, seek free trade agreements ("FTAs") with the United States to speed their economic growth. In October 2002, the White House issued "A Roadmap for FTAs," which calls for prospective FTA partners first to join the WTO, if they have not already done so, thereby incurring the obligations of the TRIPS Agreement, and then to adopt intellectual property protections that are stronger than those required by TRIPS.[171] The U.S. expectation is that FTAs will be based on the standards set in several existing FTAs, especially the recently completed U.S.-Singapore FTA and those with Jordan and Chile. According to the Singapore Ministry of Trade and Industry, the U.S.-Singapore FTA will go "way above" the parties' WTO commitments.[172] It includes, for example, provisions that eliminate the flexibility accorded by Article 27.3(b) of the TRIPS Agreement for countries not to grant utility patents on plants. The UK Commission on Intellectual Property Rights documents other situations in which the United States has obtained "TRIPS-plus" intellectual property provisions in bilateral trade agreements.[173]

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

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171. *See* Fact Sheet: Enterprise for ASEAN Initiative, *at* http://www.whitehouse.gov/news/releases/2002/10/20021026-7.html (Oct. 26, 2002).

172. "The USSFTA will be a world-class agreement. Both sides will go way above their WTO commitments. It will be NAFTA-plus in a number of areas including the protection of intellectual property . . . ." Singapore Ministry of Trade and Industry, *at* http://www.mti.gov.sg/public/FTA/frm_FTA_Default.asp?sid=36 (last visited Apr. 16, 2004).

173. *See* COMM'N ON INTELLECTUAL PROP. RIGHTS, *supra* note 11, at 163.

> First, we intercede directly in countries where piracy is especially prevalent or governments are exceptionally tolerant of piracy. Among our most effective tools in this effort is the annual "Special 301" review mandated by Congress in the 1988 Trade Act.
>
> This tool has vastly improved intellectual property standards around the world. Publication of the Special 301 list warns a country of our concerns. And it warns potential investors in that country that their intellectual property rights are not likely to be satisfactorily protected. The listing process itself has often helped win improvements in enforcement. In many cases, these actions lead to permanent improvement in the situation. At times, however, we must use the sanction authority granted to us for worst case offenders. Another bilateral tool is preferential tariff benefit treatment, such as the Generalized System of Preferences, the Caribbean Basin Initiative and Andean Trade Preferences Act. These programs provide tariff-free treatment to certain products of beneficiary countries, subject to certain conditions, including adequate and effective protection of intellectual property rights. The threat of loss of these benefits has proven to be an effective point of leverage with some of our trading partners.[174]

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

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174. USTR, Fact Sheet: The Work of USTR — Intellectual Property, *at* http://usinfo.state.gov/topical/econ/ipr/ipr-ustrwork.htm (last visited Apr. 16, 2004).

V. IMPACT OF U.S. PATENTS AND PATENT POLICY AND THE CASE FOR CHANGE

The preceding discussion shows how U.S.-issued patents have enveloped agricultural biotechnology and how U.S. patent policy addresses access to patented technologies domestically and attempts to shape patent practices internationally. U.S. patent policy has resulted in a patent thicket surrounding biotechnology. Most of the policy tools that are potentially available to promote broad dissemination and use of patented biotechnologies have not been applied. Further, the United States is promoting policies internationally that would reduce the flexibility of developing countries to adopt patent systems tailored to their local innovation and development needs. The questions raised by this framework include: (1) what is the impact of U.S. patents and patent policy on developing-country access to biotechnology for food security purposes? and (2) what is the case for altering U.S. patent policy and related technology transfer policies to improve that access?

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

A. Impacts of U.S. Patents and Patent Policy

There are many constraints, besides U.S. patents and patent policy, on the ability of developing countries to access and effectively use biotechnology for food security purposes. These have been studied and documented extensively.[175] One of the most fundamental constraints is the shift of agricultural research resources from the public to the private sector. This has not only placed many of the tools of biotechnology in the hands of private companies that lack an eco-

175. *See* UNITED NATIONS ENVTL. PROGRAM INTERGOV'TAL PANEL ON CLIMATE CHANGE, METHODOLOGICAL AND TECHNOLOGICAL ISSUES IN TECHNOLOGY TRANSFER (2000), *available at* http://www.grida.no/climate/ipcc/tectran/index.htm; Allen Blackman, *Obstacles to a Doubly Green Revolution*, 6 ENV'T & DEV. ECON. 510 (2001); Falcon, *supra* note 18.

nomic incentive to apply them to the problems of subsistence and small-scale African farmers, but it has also diminished the capacity of public-sector researchers to take full advantage of the latest technology. As discussed in Section II, if the potential of biotechnology to address food security problems is to be realized in the near term, the technology needs to be in the hands of public-sector researchers in the same institutions — national agricultural research organizations and the international research system[176] — that have experienced funding declines in recent years. Their ability to take advantage of biotechnology is thus constrained by a scarcity of research infrastructure, financial resources, and scientists trained to conduct biotechnology research.[177]

Other constraints not attributable to patents or patent policy per se include the ways in which patent holders use the power granted them by their patents, such as through strict material transfer agreements ("MTAs"),[178] and the regulatory controls and innovation policies of the developing countries themselves.

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

1. Direct Legal Impacts of U.S. Patents

The clearest cases are the ones in which U.S. patents directly block the researcher's access to a technology. This occurs when the researcher works in the United States, where the patent monopoly is a legal bar to unlicensed use of a patented technology, or the patent

176. *See* Future Harvest, *at* http://www.futureharvest.org/ (last visited Feb. 25, 2004).

177. *See* JOEL I. COHEN ET AL., PROPRIETARY BIOTECHNOLOGY INPUTS AND INTERNATIONAL AGRICULTURAL RESEARCH (ISNAR Briefing Paper 39, 1998), *at* http://www.cgiar.org/isnar/publications/briefing/BP39.htm; BINENBAUM ET AL., *supra* note 112; David Kryl, *Environmental and Industrial Biotechnology in Developing Countries*, 4 ELECTRONIC J. OF BIOTECH. 3 (Dec. 15, 2001), *at* http://www.ejbiotechnology.info/content/vol4/issue3/issues/03/; Gerd Junne, *Biotechnology: The Impact on Food and Nutrition in Developing Countries*, 1 FOOD, NUTRITION & AGRIC. (1991), *at* http://www.fao.org/docrep/u3550t/u3550t0h.htm.

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

thicket creates obstacles that can be difficult to overcome, as discussed in Section III. Many researchers in U.S. universities and other nonprofit institutions are working on, or may have an interest in working on, applications of biotechnology that could benefit farmers in developing countries and improve food security for the poor in those countries.[179] To do so with U.S.-patented technology, they must obtain the necessary licenses or else risk liability for patent infringement. As discussed in Section IV, the transaction costs involved in researching the patent status of multiple tools and gaining the necessary licenses for them can be substantial and thus act as a deterrent to research, even in those universities and other institutions that are relatively sophisticated concerning intellectual property.

The direct legal impact of U.S. patents can also reach researchers working in developing countries if they are working on applications of biotechnology to crops that are intended to be exported to the United States, even on a limited basis. Importing a crop to the United States produced with U.S.-patented technology constitutes an infringement of the patent, unless the use is licensed. Because researchers and research institutions in developing countries frequently lack the skills and resources required to find their way through the patent thicket,[180] the possibility that a crop will be exported to the United States — where applicable patents may exist — is a legal obstacle and

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179. A group of universities and other public institutions recently announced the formation of the Public-Sector Intellectual Property Resource for Agriculture ("PIPRA") "to help public-sector agricultural research institutions achieve their public missions by ensuring access to intellectual property to develop and distribute improved staple crops and improved specialty crops." PIPRA, PURPOSE, *at* http://www.pipra.org/purpose.php (last visited Feb. 14, 2004). The consortium identifies the problem they seek to address: "Limited or conditional access to a wide range of patented technologies has been identified as a significant barrier to the applications of biotechnology in the development of new crops. This is particularly true for subsistence and specialty crops." Richard C. Atkinson et al., *Public Sector Collaboration for Agricultural IP Management*, 301 SCI. 174, 174 (2003).

180. One developing-country participant at our workshop pointed out that, for agricultural research centers in the developing world, every dollar spent on legal counsel or other patent activities is a dollar taken away from scientific research. This creates a strong institutional bias against patented technologies and a wariness of even entering the legalistic world of non-public-domain research tools. It also inclines them, when they do enter that realm, to devote the barest minimum of resources to legal patent work, making them vulnerable to mistakes and disadvantageous contracts. This situation has led many people to emphasize the value of model licenses or other methods to reduce the costs of navigating the world of patents. One survey respondent urged examination of "potential collective bargaining agreements for access to products and tools." The African Agricultural Technology Foundation mentioned later in this section is an effort along these lines. It seeks to license and distribute royalty-free technology donated by biotechnology companies. An effort to alleviate the lack of legal resources is the Public Interest Intellectual Property Advisors ("PIIPA"), which seeks to organize intellectual property lawyers to donate their time and expertise to help developing countries and public interest organizations. MICHAEL A. GOLLIN, ANSWERING THE CALL: PUBLIC INTEREST INTELLECTUAL PROPERTY ADVISORS (discussion paper, Biodiversity and Biotechnology and the Protection of Traditional Knowledge Conference (Washington University School of Law, April 4–6, 2003)), *at* http://law.wustl.edu/centeris/Confpapers/Gollin.html.

a disincentive for developing-country researchers to use U.S.-patented technologies.

2. Indirect Impacts of U.S. Patents

Most of the R&D work to apply biotechnology to food security problems is likely to be conducted in developing countries, CGIAR institutions, or national agricultural research organizations, and on subsistence or other crops that have little or no export potential. It is sometimes argued that researchers outside the United States who want to use a U.S.-patented tool to develop an improved plant for such purposes are not affected by U.S. patents because U.S. patents are binding only in the United States. While the legal point is correct, this argument overlooks the indirect but very real impact that U.S. patents have on use of patented technology by these researchers.

First, these researchers and their institutions rely heavily on the U.S. government and international financial institutions for their funding. As discussed above, the U.S. government pushes hard for foreign countries and institutions to protect the intellectual property rights of U.S. companies. National agricultural research systems and CGIAR institutions could jeopardize their funding if they systematically violated U.S. patents to develop useful applications of biotechnology.[181]

Second, to the extent that research institutions in developing countries are currently involved in biotechnology, they often seek and rely upon cooperation from the Western biotechnology companies that hold many of the necessary patents.[182] 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 the use of technologies, whether or not they choose to share access. To gain physical access to patented gene traits or enabling technologies and knowledge to exploit them, researchers typically must enter into MTAs that place strict restrictions on the use of the technology, including prohibitions on commercialization.[183] MTA provisions can thus operate as a de facto extension of the patent to the country where

181. *See* Interview with Walter Falcon, Director, Center for Environmental Science and Policy, Stanford University (June 29, 2001); Interview with Timothy Reeves, former Director General, International Maize and Wheat Improvement Center (Aug. 6, 2001).

182. *See* John Komen, *International Collaboration in Agricultural Biotechnology*, *in* MANAGING AGRICULTURAL BIOTECHNOLOGY: ADDRESSING RESEARCH PROGRAM NEEDS AND POLICY IMPLICATIONS (Joel I. Cohen ed., 1999), *available at* http://www.isnar.cgiar.org/ibs/biobook.htm.

183. *See* Steven C. Price, *Public and Private Plant Breeding*, 17 NATURE BIOTECH. 938 (1999), *available at* http://www.biotech-info.net/public_private.html; Charles Benbrook, Who Controls and Who Will Benefit from Plant Genomics? (Feb. 19, 2000), *at* http://www.biotech-info.net/AAASgen.pdf.

the researcher works; to the extent the researcher was legally free to use the invention outside the United States, that freedom is usually lost under the MTA. Workshop participants and survey respondents considered this a particularly important barrier to the use of biotechnology in other countries. One survey comment asserted that "limitations imposed through MTAs by patent holders on the use of their inventions by researchers precludes applications in developing countries." Strictly speaking, this use of MTAs is a function of contract law and choices made by patent holders, not of patents or patent policy per se. As a practical matter, it can extend the impact of U.S. biotechnology patents beyond the United States.

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

3. The U.S. Vision for the Future in International Patent Policy

Finally, in assessing the impact of U.S. patent policy on developing-country access to biotechnology, it is appropriate to consider the U.S. government's vision for the future. As discussed in Section IV, the United States is promoting harmonization of patent law and policy internationally, based on the U.S. model of strong patent protection. If this vision is fulfilled, U.S. and other technology developers will be able to gain patent protection for their inventions more easily, not only in the United States, Europe, and a few other industrialized countries, but in developing countries as well. It is not clear whether this would produce a biotechnology patent thicket in these countries, as in the United States. However, to the extent more technologies come under patent in developing countries and remain in the hands of companies that lack the incentive to fully develop them for food security purposes, access for that purpose will be further impaired.

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

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

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

When considered together, the direct legal effects of U.S. patents, the indirect impacts of current U.S. policies and practices of patent holders, and the U.S. vision for the future have the clear potential to inhibit access to biotechnology for developing-country food security purposes, now and even more so in the future. Others have written about the impact of the patent system on access to biotechnology for developing-country purposes,[184] and our conclusion that U.S. patent policy adversely affects developing-country access to biotechnology is further corroborated by our informal survey of experts and stakeholders.[185]

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 of our survey respondents answered in the affirmative for most categories of technology. Of those who responded to our informal survey on this point, 86% agreed that the system has an adverse impact on access to one or more categories of biotechnology, 80% said the U.S. patent system and the existence of U.S. patents affected access for developing-country purposes to specific gene traits, 64% said they affected access to transformation tools, and 76% said they affected access to genetically modified germplasm for specific useful plants.

Our survey was in no sense a scientific investigation of views on the impact of patents on access to biotechnology, but it provides tex-

184. *See, e.g.*, Falcon, *supra* note 18; HERDT, *supra* note 112; Rural Advancement Found. Int'l, *supra* note 93; SALAZAR ET AL., *supra* note 112.

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

ture and corroboration for our analysis, based on the aforementioned responses and responses we received to other questions. There was considerable agreement, for example, that overly broad patents are being granted; the patent thicket was considered the single biggest problem flowing from U.S. patent practices. Responses to open-ended questions tended to confirm that the effect of the patent system on access is intertwined with other factors. Some cited the general deterrent effect that extensive patent estates have on decisions about what research to pursue, out of fear that challenges to products resulting from unlicensed use of patented tools will render them unmarketable, and also out of concern about the transaction costs involved in negotiating licenses. Others mentioned the extraterritorial attitude of the U.S. government toward its patent system, as reflected in advocacy by the PTO for countries to adopt patent systems based on the U.S. model, [186] and the inclusion by the U.S. Agency for International Development of patent requirements with its assistance to foreign countries.[187]

Finally, the fact that developing-country researchers are affected by the U.S. patent system is evidenced by the effort of some research institutions, biotechnology companies, and other organizations to create technology-sharing mechanisms. These mechanisms 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

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186. *See, e.g.*, *Fiscal 2003 Budget: Patent and Trademark Office: Hearing Before the Subcomm. on Courts, the Internet, & Intellectual Prop.*, *House Comm. on the Judiciary*, 107th Cong. (Apr. 11, 2002) (Statement of James E. Rogan, Director, PTO), *at* http://www.uspto.gov/web/offices/com/speeches/househrg2002/htm. ("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.").

187. USAID foreign assistance "is governed by USAID Regulation 26 (22 CFR 226), OMB Circulars, and the ADS [Automated Directives System]." USAID, CREATING OPPORTUNITIES FOR U.S. SMALL BUSINESS: USAID ACQUISITION AND ASSISTANCE INSTRUMENTS (July 2003), *at* http://www.usaid.gov/business/small_business/CreatingOpportunities.pdf. The ADS chapter on patent rights says:

> The objective is to promote the use of inventions arising from U.S. Government (USG)-supported research or development, to ensure that the inventor's and USG's rights regarding inventions that are conceived or first actually reduced to practice under a funding agreement (contract, grant, or cooperative agreement) with USAID are protected, and that taxpayers' rights to the technology are protected.

USAID, AUTOMATED DIRECTIVES SYSTEM CHAPTER 318, *at* http://www.usaid.gov/policy/ads/300/318.pdf (last visited Feb. 25, 2004). To secure these rights, the ADS instructs USAID grantors to ensure "that the patents provision [Regulation 26] is included in grants and cooperative agreements with non-U.S. organizations when applicable." *Id*. That is, USAID regulations require all funding agreements to include language requiring foreign grantees to secure IP rights. Elsewhere, USAID also details its "capacity building" activities: "Capacity building in IPR is one of the areas in which [the Agricultural Biotechnology Support Project] has achieved unique success, and can serve as an effective model for other programs in agricultural biotechnology and development." Agric. Biotech. Support Project, Intellectual Property Rights, *at* http://www.iia.msu.edu/absp/ipr.html (last visited Feb. 25, 2004).

Foundation and the Meridian Institute are collaborating with some Western biotechnology companies and developing-country parties to establish a mechanism for sharing patented technologies called the African Agricultural Technology Foundation ("AATF").[188] This mechanism will address both transgenic and nontransgenic technologies and will facilitate the transfer of technological expertise and critical research materials, as well as the legal right to make use of patented technologies, to developing countries. Though its purposes are broader than just removing patent obstacles, the need for the mechanism arises in large part from the proprietary (and frequently patented) nature of modern agricultural innovation, and the need to assist developing-country research institutions in negotiating the intellectual property thicket surrounding biotechnology.

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

B. The Case for Policy Change

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

In making the case for patent policy change, it would be ideal to evaluate empirically how the patent system is achieving its multiple social objectives, which are outlined above.[189] Solid evidence that the system is impeding rather than fostering dissemination of useful technology would establish a clear prima facie case for policy change. Unfortunately, there are significant gaps in empirical data on both the overall impact of the patent system and its effects in specific fields

188. For further discussion of the AATF, see *infra* note 242 and accompanying text; for discussion of two similar mechanisms, PIPRA and PIIPA, see *supra* notes 179 and 180.

189. *See supra* Section III.

like biotechnology. Thus, it is impossible to assess current policies and justify changes on a strictly empirical basis.

The empirical data are so lacking that, according to Samuel Oddi, "There is no general agreement that any of the macro theories of the overall patent system can rigorously demonstrate that a patent system provides a net societal benefit."[190] According to George Priest, "The ratio of empirical demonstration to assumption in [patent economic] literature must be very close to zero."[191] These views echo Fritz Machlup's 1958 observation that:

> 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.[192]

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 specific benefits and costs for the agricultural subfield.[193] We follow Machlup in concluding that it would be irresponsible to recommend abolishing the patent system. However, the lack of empirical data demonstrating the net benefits of the current system frees us to consider policy change.

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190. Oddi, *supra* note 52, at 270. Oddi echoes scholars who defend the decision "to be agnostic about whether patent rewards are a good idea." *Id.* at 277 (quoting Mark F. Grady & Jay I. Alexander, *Patent Law and Rent Dissipation*, 78 VA. L. REV. 305, 309–10 (1992)).

191. George L. Priest, *What Economists Can Tell Lawyers about Intellectual Property*, 8 RES. IN L. & ECON. 19 (1986). 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. *See* Richard C. Levin et al., *Appropriating the Returns from Industrial Research and Development*, 3 BROOKINGS PAPERS ON ECONOMIC ACTIVITY 783 (1987); WESLEY M. COHEN ET AL., PROTECTING THEIR INTELLECTUAL ASSETS: APPROPRIABILITY CONDITIONS AND WHY U.S. MANUFACTURING FIRMS PATENT (OR NOT) (Nat'l Bureau of Econ. Research, Working Paper No. w7552, 2000), *available at* http://papers.nber.org/papers/W7552.v5.pdf.

192. STAFF OF SENATE SUBCOMM. ON PATENTS, TRADEMARKS, & COPYRIGHTS, 85TH CONG., AN ECONOMIC REVIEW OF THE PATENT SYSTEM 80 (Comm. Print 1958) (prepared by Fritz Machlup).

193. *See* Heisey et al., *supra* note 30, at 5 ("To the best of our knowledge, no studies have analyzed the influence of utility patenting on plant breeding."); Michael Blakeney et al., *Intellectual Property Rights and Agricultural Biotechnology*, *in* MANAGING AGRICULTURAL BIOTECHNOLOGY, *supra* note 182, at 209, 225, *available at* ftp://ftp.cgiar.org/isnar/ibs/V_18.pdf ("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.").

As discussed earlier,[194] American domestic patent policy and foreign patent policy reflect distinct sets of interests and principles, and arguments for change must be tailored to meet those demands. In the domestic case, we think that a policy shift to address the food security needs of developing countries is justified by our qualitative analysis of the current policy approach's impact on this interest, our instrumental understanding of patent policy as a tool of social policy, the possibility of change that improves access without significantly undercutting invention incentives, and specific circumstances that bring the problem of food security within the scope of domestic patent policy. The case for change in the global patent sphere draws on some of the same elements, but rests in the end on judgments about the broader international interests and obligations of the United States.

1. The Case for Domestic Policy Change

The case for domestic patent policy change is best made by examining how well the patent system is currently working to achieve the underlying objectives outlined above: increasing the amount of invention; disseminating knowledge about inventions; regulating the orderly investigation of new research areas; and facilitating the practical use, including the production, application, and commercialization, of inventions.[195]

Our qualitative analysis suggests that the system is likely increasing the amount of invention in the field of agricultural biotechnology, at least among commercially motivated inventors, and the disclosure requirements of patent law are presumably working to disseminate basic knowledge about the advances. However, the effectiveness of disclosures in U.S. patents is a matter of debate.[196] Our analyses of the patent thicket[197] and the impact of U.S. patents and patent policy on access to biotechnology for developing-country food security purposes[198] demonstrate that the patent system is working less than optimally to ensure orderly investigation into and facilitate practical use of the technology.

Thus, the case for considering patent policy change is grounded in the very nature and purpose of the patent system discussed in Section

194. *See supra* text accompanying notes 154–55.

195. *See supra* Section III.

196. *See, e.g.*, Barton, *Reforming the Patent System*, *supra* note 96. For histories of recent case law from the Court of Appeals for the Federal Circuit, see Margaret Sampson, Comment, *The Evolution of the Enablement and Written Description Requirements Under 35 U.S.C. § 112 in the Area of Biotechnology*, 15 BERKELEY TECH. L.J. 1233 (2000) and Janice M. Mueller, *The Evolving Application of the Written Description Requirement to Biotechnological Inventions*, 13 BERKELEY TECH. L.J. 615 (1998).

197. *See supra* Section IV.

198. *See supra* Section V.

III. Since it is an instrumental social construct intended to benefit society by fostering useful innovation, one must evaluate the system's performance from a social outcome perspective.[199] Accordingly, the success of the current approach and the wisdom of possible changes in patent policy are fairly judged on the basis of whether and to what extent the societal benefits of useful innovations that the system promotes exceed the societal costs of the associated monopoly, including higher prices and constraints on access to new inventions.[200] If the patent system is not affording an optimal balance, it is fair and appropriate to consider policy change.

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

Granted, it is reasonable to ask why one should consider an international concern — food security in developing countries — when assessing internal U.S. patent policy. The answer is that the United States has chosen to bring international concerns in general, and food security in developing countries in particular, within the legitimate scope of domestic patent policymaking. U.S. patents and patent policy have extraterritorial aspirations and impacts, including practical impacts on access to technology in other countries.[201] Furthermore, the PTO has made clear its efforts to promote adoption of U.S.-like patent systems in other countries, including developing ones,[202] and the

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199. We do not address in this study the issues some have raised about the morality of patenting life forms or the ethics of sanctioning 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 in the end it advances social welfare.

200. *See* Lester C. Thurow, *Needed: A New System of Intellectual Property Rights*, HARV. BUS. REV. Sept.–Oct. 1997, at 95, *available at* http://vision.rc.ukans.edu/SPED997/unit3/thurow.htm; Rebecca Eisenberg, *Patents: Help or Hindrance to Technology Transfer*, *in* BIOTECHNOLOGY: SCIENCE, ENGINEERING, AND ETHICAL CHALLENGES FOR THE TWENTY-FIRST CENTURY 161, 163 (Frederick B. Rudolph & Larry V. McIntire eds., 1996); Rebecca S. Eisenberg, *Analyze This: A Law and Economics Agenda for the Patent System*, 53 VAND. L. REV. 2081, 2082 (2000).

201. *See supra* Sections IV–V.

202. *See Federal Trade Comm'n: Hearings on Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy* (Feb. 6, 2002) (remarks of James E. Rogan) ("Further, the United States has made it a key part of its trade policy to create international frameworks for recognizing intellectual property rights."), *available at* http://www.uspto.gov/web/menu/testspeech.html; PTO, *supra* note 113, at 15 ("Many de-

United States frequently presses governments and other institutions in foreign nations to respect U.S. patents.[203] For these reasons alone, adverse effects of the U.S. system on technology access and transfer elsewhere in the world justify considering policy change.

The international impact of U.S. patent policy is also relevant in that the United States has recently affirmed its pledge that global food security is a national objective.[204] If the current approach interferes with the use of biotechnology to achieve these ends, there is accordingly a national interest in favor of possible policy change.

Finally, fundamental principles of social justice and equity make global food security a legitimate concern of U.S. patent policy. As the world's leading technological and economic power, the United States and companies based here have a substantial impact on opportunities for economic progress throughout the world, including in developing countries. While the United States alone cannot solve the world's technological and economic problems, the nation has a moral duty to support international efforts to solve them. There is also a compelling national security interest in reducing global poverty and hunger. At a minimum, the United States has an obligation as the richest and most powerful country in the world to avoid actions and policies that have unnecessary adverse impacts on progress elsewhere. This means spurning patent policies that adversely affect food security in developing countries when other approaches are available to protect the legitimate U.S. interests at issue.

2. The Case for Foreign Policy Change

In this context, the case for changing U.S. foreign policy on patents is strong. It is grounded in the distinctly different intellectual property needs of developed and developing countries and in the importance of developing countries retaining flexibility to devise patent policies that reflect their level of technological development and their

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veloping 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)."). This report states:

> 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.

Id. at 19.

203. *See* Rogan, *supra* note 53.

204. *See* THE WORLD FOOD SUMMIT: FIVE YEARS LATER (USAID Position Paper 2002), *at* http://www.fas.usda.gov/icd/summit/wfsposition.pdf; *see also supra* note 14 and accompanying text.

development strategies.[205] The United States should support developing countries in preserving this flexibility for several reasons. The first is the importance of the U.S. national interest in solving food insecurity and promoting optimal, technology-driven development strategies in developing countries. Because food security and poverty reduction are vital to the economic and national security interests of the United States, policies that would advance those interests, even incrementally, deserve consideration. Proposals that promote the development of intellectual property systems tailored to local development needs fall in this category. We are unaware of data that would conclusively establish the need for U.S. companies to obtain patent protection in developing countries comparable to that in the United States. Given the current unprofitability of those markets for cutting-edge biotechnology,[206] the broader national interest in developing-country food security outweighs the need for such protection.

Second, the United States has a vested interest in the success of the TRIPS Agreement, which already embraces the concept of flexibility.[207] Failing to respect the provisions that address the needs of developing countries could undermine support for the pact in many quarters. If, for example the WIPO harmonization process or bilateral trade negotiations resulted in less flexibility than the TRIPS Agreement itself envisioned, developing countries would justifiably question the basic fairness of their TRIPS obligations. This could complicate implementation of the agreement and reduce developing-country support for other elements of the WTO and U.S. trade agendas.

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

VI. ANALYZING AND CHANGING AMERICAN PATENT POLICY

In this section, we briefly describe some specific changes in U.S. domestic and foreign patent policy designed to improve access to the tools of biotechnology for promoting food security in developing countries. We offer these primarily to illustrate that policy change for this purpose is not necessarily at odds with (and, indeed, could ad-

205. *See* COMM'N ON INTELLECTUAL PROP. RIGHTS, *supra* note 11, at 1, 15, 24 (discussing the intellectual property needs of developing countries, including the importance of flexibility).

206. *See supra* note 44 and accompanying text.

207. *See supra* notes 155–58 and accompanying text.

vance) the basic goals of the patent system. The fact that there are possible policy changes that plausibly meet this test supports the case for considering change. However, it is important first to set out more completely the approach we take in analyzing patent policy options and considering them for adoption.

A. Framework for Analyzing Alternative Policies

Ideally, no individual patent should be issued if its social benefits in terms of stimulating invention and useful innovation are outweighed by the social harms of increased consumer costs and restricted access to the patented technology for useful purposes. At the time of its granting, there is no basis for predicting 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.

In contemplating policy change, it would be more appropriate to consider the aggregate benefits and costs of the patent system and patent policy as applied to a particular category of technology, such as agricultural biotechnology. Evaluating the benefits and costs of the patent system with respect to a particular category of technology makes sense because, as Nelson and Mazzoleni 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.[208]

Even with this simplification, analyzing in hindsight the benefits and costs of patent policy is a conceptually complex challenge that is complicated further by the lack of empirical data. Fully evaluating the benefit of patents in the field of agricultural biotechnology would require considering and balancing the patent system's multiple potential benefits, including fostering invention, facilitating dissemination of useful innovation, and answering such questions as:

- To what extent would biotechnology inventions have occurred without patenting?

208. Nelson & Mazzoleni, *supra* note 59. The conditions Mazzoleni and Nelson discuss suggest at least five relevant inquiries: (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 transaction 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? *See id*.

- What are the tangible benefits of the inventions and any resulting innovation?

- What positive impacts have the patents had on dissemination of information, practical application by others, and research in new areas of biotechnology?

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

- What are the direct costs of the patent monopoly in terms of higher consumer prices?

- What are the transaction costs (for example, license fees and related negotiating expenses) for gaining access to patented technology?

- What negative impact have the patents had on invention and practical application by others?

- What negative impact have they had on research in new areas?

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

We recognize the practical difficulties of applying a quantitative cost-benefit test in evaluating the patent system and patent policy change. Given the instrumental rationale for having a patent system, however, it remains fair in the case of particular fields of innovation to ask whether the benefits of patents exceed their social costs, even if the question must be answered qualitatively. The challenge is to frame the query so as to produce a useful answer. Our specific goal is a manageable analytical approach to identifying and evaluating specific patent policy alternatives that could improve access to agricultural biotechnology for developing-country purposes. The analysis should consider both sides of the cost-benefit equation, but do so in a simplified way that is realistic in light of the limited data available. We pro-

pose the following qualitative formulation: *alternative patent policies deserve serious consideration if they appear likely to improve access to the tools of biotechnology for developing-country food security purposes without significantly undercutting incentives for the invention of such tools.*

Under this simple framework, a proposal is assumed to achieve the goal of improving access to agronomic biotechnology in developing countries if the contemplated policy change would generally make it easier for researchers working on developing-country problems to use patented technology without risk of liability for infringement. Allowing access specifically for food security purposes means that a tool is available for use by researchers and technology developers, located in the United States or elsewhere, to create improved crops that will be planted in developing countries, with minimal potential for exportation or competition with the patent holder's rights in the United States.[209]

Most of the policy alternatives incorporate this concept of improved access and availability specifically for food security purposes in developing countries. The proposals are thus unlikely to undercut the invention incentives of U.S. patent law, for they don't provide access when it would mean directly competing with the patent holder in the market for which the patent was granted.

As discussed in Section IV, we recognize that patents are not the only obstacles between developing countries and access to the tools of biotechnology. Patent policy change alone is not a panacea. By the same token, improved access does not ensure that researchers will develop useful applications that will become available to farmers in developing countries. Many factors will contribute to the outcome. The analysis we propose here addresses the more narrow question of whether patent policy change can help make the tools of biotechnology accessible for researchers developing food security solutions, and it assumes, for reasons outlined in Section V, that this improved access confers a societal benefit that is relevant when considering U.S. patent policy.

This framework also assumes that patents provide worthwhile incentives for investment in agricultural biotechnology and the development of commercially attractive applications of the technology. Though we cannot quantify the actual incentive effect of patents on invention and commercialization in agricultural biotechnology, we assume for the purposes of identifying and analyzing alternative pat-

209. This concept raises its own issues concerning which "developing countries" qualify for the improved access contemplated by each policy, whether both commercial and subsistence crops should be included, and what constitutes "minimal potential" for export to the United States. These issues, which were discussed but not resolved in TAYLOR & CAYFORD, *supra* note 12, will be important to the design of effective and politically viable policies.

ent policies that the incentive is real and that any significant reduction in the incentive would be undesirable.

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

We do not doubt that changes in how patents are issued could improve how the patent system contributes to useful applications of biotechnology, including those that advance food security in developing countries. In fact, we assume that the U.S. patent system, taking into account its patenting practices and extraterritorial effects, strikes an imperfect balance between the benefits and costs of patents in the field of agricultural biotechnology and is not working optimally to foster useful innovation. There has been much commentary on the tendency toward excessive patenting in the field of agricultural biotechnology.[210] This includes patents that have been issued inappropriately or are too broad because of, for example, inadequate prior art searches, the system's built-in presumption of patentability, or occasional lax application of the novelty, utility, and nonobviousness requirements. We also have seen that the multitude and breadth of patents have some blocking effect on access to biotechnology by people who could make good use of it. The assumption that the U.S. patent system is not working optimally to foster useful innovation is another justification for considering policy alternatives that improve access to patented technologies.

B. Policy Alternatives

We outline below a set of possible changes in U.S. patent policy. They fall into three categories: (1) changing U.S. law and policy to improve access to patented technologies, (2) preserving the flexibility that developing countries enjoy under the current TRIPS Agreement to tailor their patent systems to their local needs, and (3) more fully implementing Article 66.2 of TRIPS, regarding support for technology transfer. Each policy change raises its own set of technical and implementation issues, some of which we addressed in a previous discussion paper,[211] and all of which require full consideration and

210. *See supra* notes 94–112 and accompanying text.
211. *See* TAYLOR & CAYFORD, *supra* note 12.

critique by patent experts and policymakers. We limit ourselves here to a brief summary of each possible change because our primary purpose is to make the simple point that, if one accepts as a matter of principle that it is appropriate when formulating U.S. patent policy to consider access to biotechnology for reducing hunger in developing countries, there are a number of policy alternatives that appear to meet the threshold test of improving access without significantly undercutting invention incentives.

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

In this section, we outline five domestic patent policy alternatives that build on current domestic patent policies: a research exemption, compulsory licensing, a working requirement, use of eminent domain authority, and placing USDA-funded technology in the public domain.[212] All are grounded in familiar concepts, and some are already contained in different forms in national patent legislation in the United States or international patent frameworks, such as the TRIPS Agreement. For reasons discussed earlier, they all involve expanding access to patented technologies rather than restricting what gets patented. Likewise, they are all designed to make U.S.-patented tools of biotechnology available for developing-country purposes, while preserving incentives for private-sector investment in invention and commercialization of the technology.

Create a Strong Research and Development Exemption — Under this first policy alternative, Congress would enact a statutory limitation on the scope of the patent monopoly, so that using a patented tool of biotechnology to conduct research that may establish food security in developing countries would not constitute patent infringement. The research exemption — always very limited in U.S. patent law — is now effectively nonexistent as a result of the *Madey* decision.[213] This proposal would reverse the trend and improve access to patented biotechnology by freeing both U.S.- and foreign-based researchers to work on applying patented technology to the food security problems of developing countries without concern about infringement claims. In the case of patented germplasm or transformation tools that are not themselves sold as part of a commercial research tools business,[214]

212. *See supra* Section IV.

213. Madey v. Duke Univ., 307 F.3d 1351 (Fed. Cir. 2002); *see supra* note 135 and accompanying text.

214. A research exemption will likely affect the in centives 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* COMM'N ON INTELLECTUAL PROP. RIGHTS, *supra* note 11, at 111, 122, 127, *available at* http://www.iprcommission.org/papers/pdfs/

this research and development exemption would not significantly undercut the invention incentives of the U.S. patent holder because the use of the resulting technology would be limited to applications in developing countries and hence not pose a competitive threat.

The research and development exemption we propose here is not limited to noncommercial users or uses of patented technology. Such a limitation is neither intrinsic to the notion of a research exemption nor feasible in the context of policy change to improve developing-country food security. It is crucial to the food security purpose that researchers who develop new products using patented technology are able to give those products to farmers without restrictions. However, the exemption is only for the developmental stage. If the research results in new products that contain the original patented invention or otherwise cannot be distributed without infringing the protected technology, the statutory provision will not clear the way for free use of those products. The patent holder retains full control of the original invention except for its use in research concerning food security in developing countries; exploitation of dependent products would still require the patent holder's permission.

Establish a Compulsory License Requirement for Agricultural Biotechnology — This policy alternative would add a procedure to U.S. patent law granting nonexclusive licenses to any party seeking to use patented biotechnology tools in research to improve food security in developing countries. Royalties would be set at rates that reflect the reasonably foreseeable value forgone by the patent holder, taking into account the likelihood of commercializing the planned application of the technology. This value may be negligible, given the current unprofitability of those markets.[215]

Such a compulsory license provision would improve access by ensuring that any patented tool of biotechnology could be used in efforts to promote food security without risk of patent infringement. It would not significantly undercut invention incentives because the royalty provision would compensate patent holders for the lost value of the relevant commercial application. As with the other policy alternatives, compulsory licenses would moreover not open the door for domestic competition. The compulsory license provision proposed here is not as general as those contained in many countries' patent

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final_report/ch6final.pdf (last visited Feb. 14, 2004); NAT'L INSTS. OF HEALTH, *supra* note 148; Rebecca S. Eisenberg, *Technology Transfer and the Genome Project: Problems with Patenting Research Tools*, 5 RISK: HEALTH, SAFETY, AND ENVIRONMENT 163, 168 (1994), *available at* http://www.fplc.edu/risk/vol5/spring/Eisenber.htm; Eisenberg, *supra* note 62; NAT'L RESEARCH COUNCIL, *supra* note 30; Janice M. Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1, 41–42 (2001).

215. *See supra* note 44 and accompanying text.

laws or as allowed under the TRIPS agreement.[216] Rather, it focuses on a particular public policy goal, much like other compulsory license provisions in U.S. law.[217] For example, Section 308 of the Clean Air Act provides for access to patented technologies when "necessary to enable" parties to comply with air-quality standards.[218] An analogous compulsory license provision might entitle food-insecure countries to exploit biotechnology that offers solutions to otherwise intractable problems.

Establish a "Working" Requirement for Agricultural Biotechnology Patents — Another possible approach would add to U.S. patent law a working requirement[219] for patented biotechnology modeled on the corresponding provision in the Paris Convention for the Protection of Intellectual Property.[220] If, within three years of the patent's being issued, the patent holder has neither worked an application relevant to food security nor made licenses readily available to those who seek to do so, a party could apply to a designated authority for a nonexclusive license authorizing use for such purpose(s). Applications would be approved unless the patent holder immediately implemented a plan to use the invention for the relevant purposes.

A working requirement along these lines would improve access by ensuring that patented tools of biotechnology would be available within a reasonable amount of time for research addressing food security. It would not significantly undercut incentives to innovate, for licenses would be available only when patent holders elect not to apply their inventions to the specific developing-country food security needs at issue. There is no threat to the domestic cash streams that finance innovation. Much like the compulsory license scheme above, the proposal is more modest than traditional working requirements. Most apply generally and limit all patent exclusivity to applications actually worked. We instead propose a narrower working requirement that specifically targets applications of biotechnology for research to improve food security.

Exercise U.S. Eminent Domain Authority — Under this policy alternative, the U.S. government would exercise its existing statutory eminent domain authority[221] to authorize the use of patented tools of biotechnology for research seeking to increase food security in developing countries. A designated authority would establish and adminis-

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216. *See* TRIPS art. 31, 33 I.L.M. 95 (1994), *available at* http://docsonline.wto.org/DDFDocuments/t/UR/FA/27-TRIPS.doc.

217. *See supra* note 140 and accompanying text.

218. 42 U.S.C. § 7608 (2000).

219. *See supra* note 144 and accompanying text.

220. Paris Convention, *supra* note 144, art. 5(A)(4). The provision permits working requirements, but does not mandate them. *Id*. Unlike most other signatories, the United States has not adopted any such limitation on the rights of patentees.

221. *See* 28 U.S.C. § 1498 (2000).

ter a mechanism under which a researcher seeking to apply patented technology for such purposes could seek a ruling that the efforts are on behalf of the United States. The government would then be liable for any damages that the patent holder established in court.

This use of existing eminent domain authority would improve global food security by creating a mechanism that would afford developing countries access to all relevant U.S.-patented technology without fear of liability for infringement. It would not significantly undercut invention incentives given the right of patent holders establishing economic loss to obtain compensation from the government. Moreover, the option would not be available to those seeking to compete domestically.

Make Available U.S. Government-Funded or -Owned Biotechnology — Still another alternative would be to establish as a matter of policy that all tools of agricultural biotechnology developed by the USDA and other U.S. government agencies, whether patented or not, shall be freely available (without the need for a license or other permission) for efforts to enhance food security in developing countries. This would not entail any change to existing law. In the case of government patents, even an ostensibly exclusive license extends only to the limits of the specific practical application that the licensee negotiated.[222] As for patents not owned by the government but developed with government funding, this proposal requires that the government exercise its retained licenses under the Bayh-Dole Act[223] and allow contractors to use government-patented technology for research related to food security. Thus, this proposal would provide ready access to any necessary technology that the government funded in whole or in part; the identity of the patent holder is irrelevant. It would not significantly undercut invention incentives for government agencies, because agencies presumably do not make research decisions based on anticipated marketplace returns. As for the fruits of CRADAs, private patent holders could rest assured that use of their technologies would be limited to applications beyond the scope of their business plans.

2. Preserving Flexibility for Developing Countries

The key issue in U.S. policy concerning foreign patent systems is the government's willingness to preserve the flexibility that develop-

222. *See* 35 U.S.C. § 209 (2000). There are also a number of other restrictions, including the equivalent of a working requirement. *See* 35 U.S.C. § 209(d) (2000); *see also* 37 C.F.R. § 404.7(a)(2)(i) (2003) (preserving the government's right to "practice and have practiced" even exclusively licensed technology "pursuant to any existing or future treaty or agreement" with foreign nations or international organizations).

223. *See* 35 U.S.C. § 202(c)(4) (2000).

ing countries now have under the TRIPS Agreement. The United States has been ambivalent at best on this question, supporting TRIPS in general and touting its flexibility in dealing with access to drugs for HIV/AIDS, while at the same time pushing a harmonization agenda through other trade negotiations and WIPO.[224] To help ensure access to biotechnology for developing-country food security purposes without undercutting invention incentives, the United States could support preservation and use of developing-country flexibility in several ways.

Support Incorporating TRIPS Flexibility Provisions in Any New WIPO Agreement and in Any Bilateral or Regional Trade Agreements — As discussed in Section IV, the TRIPS Agreement provides significant flexibility for developing countries to devise patent regimes that serve their local technology and development needs. It also explicitly recognizes their rights to adopt special nutrition-related measures[225] and to grant exceptions to patent rights to address defined needs when the interests of the patent holder will not be adversely affected.[226] The United States could support efforts to include these same general flexibility provisions in the drafted SPLT and oppose any attempt under the WIPO process to reduce the patent policy flexibility granted developing countries in the TRIPS Agreement.[227] Similarly, the U.S. government could accept analogous provisions when negotiating trade agreements with developing countries, reversing the trend against flexibility evident in recent agreements with Singapore and Chile.[228] Perhaps more simply, the United States could refrain from incorporating any intellectual property provisions at all in new trade agreements with countries already bound by TRIPS.

Support Preservation and Use of the Flexibility Provisions in TRIPS — The TRIPS Council is reviewing the TRIPS Agreement in the context of the Doha Round of WTO trade negotiations.[229] The United States could make clear that it supports maintaining the current flexibility provisions in the TRIPS Agreement. There are many such provisions: the broad authority to grant benign exceptions to patents,[230] the explicit right to define patentable subject matter so as to

224. *See supra* notes 154–74 and accompanying text.

225. *See supra* notes 157–62 and accompanying text.

226. *See supra* note 142 and accompanying text.

227. This includes ensuring that the technical advice WIPO offers to developing countries as they implement their TRIPS obligations takes full account of the flexibility provisions of TRIPS so they can be applied appropriately to meet the developing country's particular needs. *See* COMM'N ON INTELLECTUAL PROP. RIGHTS, *supra* note 11, at 155, 160–61.

228. *See supra* note 171 and accompanying text.

229. WTO Ministerial Conference, *Ministerial Declaration*, WT/MIN (01)/DEC/1, ¶ 19 (Nov. 20, 2001), *at* http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm.

230. TRIPS art. 30, 33 I.L.M. 95 (1994), *available at* http://docsonline.wto.org/DDFDocuments/t/UR/FA/27-TRIPS.doc.

exclude plants and animals,[231] the right to grant compulsory licenses,[232] and many others.[233] The United States could make clear that it considers these provisions broad enough to enable developing countries to adopt all the same provisions for access to patented technologies that we propose above for domestic patent policy. It could also work within TRIPS and through WIPO to ensure that the flexibility provisions are used in a way that promotes food security in developing countries without significantly undercutting invention incentives.[234]

3. Full Implementation of Article 66.2 of the TRIPS Agreement

Article 66.2 of the TRIPS Agreement[235] speaks directly to the disparity in innovation capacity and access to technology between developed and developing countries. This was part of a compromise in the TRIPS negotiations: developing countries were promised assistance with technology transfer in exchange for establishing the patent systems that developed countries sought to protect their intellectual property. The general perception in developing nations is that developed countries have not honored their end of the bargain.[236]

The American report on compliance with Article 66.2 lends some credence to this view. The document recites several statutes and programs that relate generally to technology transfer and trade development. However, most predate the TRIPS agreement.[237] The report likewise identifies some capacity-building programs, but only in areas

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231. *Id*. art. 27.3(b).

232. *Id*. art. 31.

233. The COMM'N ON INTELLECTUAL PROP. RIGHTS, *supra* note 11, has a thorough discussion of these flexibility options in chapter 6.

234. By their terms, TRIPS Articles 8 and 30 allow developing countries to devise intellectual property approaches to agricultural biotechnology that best serve local food security needs. *See* TRIPS arts. 8, 30, 33 I.L.M. 95 (1994), *available at* http://docsonline.wto.org/DDFDocuments/t/UR/FA/27-TRIPS.doc. The United States could specifically endorse the use of these provisions for that purpose and support efforts to craft implementation schemes for these provisions that comply with TRIPS, meet food security needs, and preserve invention incentives. Further, Article 27.3(b) of TRIPS explicitly allows countries to exclude plants from patentability provided that there is an effective *sui generis* alternative in place for protecting plant varieties. This provides vital flexibility for countries that rely on publicly-funded plant breeding programs and on the saving and reuse of seed by farmers to develop and disseminate new seed varieties. However, the provision is under review by the TRIPS Council. The United States could endorse retaining the flexibility and support its use in ways that promote food security needs without undercutting invention incentives.

235. *Id*. art. 66.2 ("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.").

236. *See* WTO Comm. on Trade & Dev., *Special and Differential Treatment Provisions: Joint Communication from the African Group in the WTO*, TN/CTD/W/3/Rev.1, ¶3 (June 24, 2002), *at* http://docsonline.wto.org/DDFDocuments/t/tn/ctd/W3R1.doc.

237. *See id*.

of technology unrelated to agriculture and food security.[238] The United States has not taken steps specifically designed to provide incentives for U.S. companies to transfer agricultural technologies to developing countries for food security purposes. Also, it has yet to promote the transfer of patented technology, including relevant research tools.[239]

The United States could work to fulfill its obligation under Article 66.2 in multiple ways with respect to agricultural biotechnology and food security. It might be tempting to provide incentives, perhaps in the form of tax credits or other economic subsidies, for companies to develop and commercialize applications of biotechnology that may reduce hunger in developing countries. However, the existing market incentives for such commercial investment are woefully inadequate, and there is likewise little commercial infrastructure for the actual delivery of seeds needed to improve food security.[240] Government incentives on any reasonably foreseeable scale are thus not likely to have a significant or sustainable effect. Moreover, subsidizing private industry in developed nations is not likely to advance Article 66.2's objective of enabling developing countries "to create a sound and viable technological base"[241] of their own.

A course more likely to achieve the goal is to provide incentives for U.S. companies to transfer the tools of biotechnology and other agricultural technologies to public- and private-sector researchers in developing countries. The researchers, in turn, would apply them to local food security problems, building a local technological base that would support the search for long-term solutions. This approach would help support both the public and public-private channels of innovation in African agriculture we posited in Section II.

One possible model for the public-private channel is the newly founded, nonprofit African Agricultural Technology Foundation ("AATF"). With start-up funding from the Rockefeller Foundation and the U.S. Agency for International Development ("USAID"),[242]

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238. *See* WTO Council for Trade-Related Aspects of Intellectual Prop. Rights, *Implementation of Article 66.2 of the TRIPS Agreement: Information from Developed Country Members, Addendum: United States*, IP/C/W/388/Add.7 (Feb. 4, 2003), *at* http://docsonline.wto.org/DDFDocuments/t/IP/C/W388A7.doc.

239. Although Article 66.2 does not explicitly state that the developed countries must encourage their private sectors to transfer *patented* technology, this requirement is implicit in the reality that the underlying accord concerns the protection of intellectual property. Moreover, the Doha negotiations reaffirmed that "each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement." WTO Ministerial Conference, *Declaration on the TRIPS Agreement and Public Health*, WT/MIN(01)/DEC/2, ¶ 5(a) (Nov. 20, 2001), *at* http://docsonline.wto.org/DDFDocuments/t/WT/min01/DEC2.doc.

240. *See supra* Section II.

241. TRIPS art. 66.2, 33 I.L.M. 95 (1994), *available at* http://docsonline.wto.org/DDFDocuments/t/UR/FA/27-TRIPS.doc.art.

242. *See* AATF, Links, *at* http://www.aftechfound.org/links.php (last visited Feb. 16, 2004).

the AATF describes itself as "a public-private partnership to serve smallholder farmers in sub-Saharan Africa."[243] It seeks "to identify and facilitate the royalty-free transfer of proprietary technologies that meet the needs of resource-poor African farmers, in ways that address and resolve the concerns of technology providers," including issues related to intellectual property, protection of commercially important markets, and liability.[244]

To discharge its responsibilities under Article 66.2, the United States could encourage and support the transfer of technology from U.S.-based patent holders to organizations like the AATF that can make good use of the techniques to combat hunger in developing countries. The USAID support for the formation of the AATF is one such effort. In addition to covering some of the costs of the intermediary services provided by the AATF, USAID provides an official imprimatur that may enhance the willingness of companies to participate. The United States could also provide direct economic incentives for companies to make royalty-free transfers to the AATF. These mechanisms could take the form of tax deductions or credits, but also might involve direct subsidies to defray at least the out-of-pocket expense of collaborating on technology transfer projects.

In addition to economic inducements, technology-transfer schemes must afford patent holders some protection from liability for harms associated with use of the product. There is always the possibility that someone downstream could use the technology improperly or without the required regulatory approval, creating liability that potentially could fall on the developer of the technology. The U.S. government's ability to protect companies is limited in that it cannot preclude lawsuits or regulatory actions in other countries. However, Congress could adopt measures that insulate non-negligent donors from liability in U.S. courts for any harms resulting from the use or misuse of the technology by another.[245] The United States could also indemnify companies for legal fees and judgments regardless of the forum. Thus, diplomatic efforts to address the liability issue might encourage the royalty-free transfer of technology to meet food security and development needs.

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243. AATF, Index, *at* http://www.aftechfound.org/index.php (last visited Feb. 16, 2004).

244. *The African Agricultural Technology Foundation*, 48 BIOLINES 3 (2003), *at* http://www.africabio.com/biolines/48.pdf.

245. Since there has not yet been a liability suit over biotechnology, it is too early to judge the significance of this concern. However, the experience of biomaterials suppliers offers a plausible analogy. So long as the materials meet the contract specifications, suppliers are not liable under the common law for what people do after delivery. *See* Gary Marchant et al., *Regulatory and Liability Considerations*, 6 B.U. J. SCI. & TECH. L. 5, ¶¶ 51–84 (2000), *at* http://www.bu.edu/law/scitech/volume6/Panel3.htm. Even though companies rarely if ever lose cases, the high volume of suits imposes a considerable burden in legal fees. Congress accordingly gave the industry a variety of relief measures in the Biomaterials Access Assurance Act of 1998, 21 U.S.C. § 1601 (2000). *See id.* ¶¶ 74–76.

Implementation of Article 66.2 in these focused ways would address the technology access problem directly. The proposals would complement policy changes that reduce obstacles to access, but they are not adequate substitutes for reform. Developing countries need the flexibility to develop intellectual property systems that strike an appropriate balance between inducing invention and ensuring that inventions are put to practical uses that meet local needs. Honoring the promise in Article 66.2 can help, but developing countries should not be dependent solely on decisions made in Washington or by biotechnology companies when it comes to achieving basic food security.

VII. CONCLUSION

While the countries of sub-Saharan Africa face a number of daunting social, economic, and medical challenges, achieving basic food security is the central concern for many countries and individuals in that region. If basic nutritional needs are not being met, neither individuals nor societies can thrive. Food security, economic development, and poverty reduction are thoroughly intertwined. Likewise, U.S. leaders are becoming increasingly aware that U.S. interests in maintaining security within its own borders are well served through working to alleviate food insecurity outside the United States.

There is also an increasing recognition in American media and policy circles that many U.S. policies complicate the efforts of developing countries to address food security and other basic development problems. These include U.S. agricultural and trade policies, development assistance and food aid policies, and the approaches that the country takes in the international arena to address trade and other development-related issues. Indeed, the "development round" is an appropriate name for the current cycle of WTO trade negotiations that began at Doha in 2001. As a precondition for trade liberalization, developing countries are demanding that industrialized nations reform policies and programs adversely affecting third-world development, especially with respect to agriculture.

Patent policy is an important part of this picture. This Article documents the relationship between U.S. patent policy and the ability of developing countries to apply the latest technology in their efforts to address food security needs. The relationship is enormously complex due to (1) complications inherent in how patents work and are used by their owners to control access, and (2) the multitude of exogenous factors that affect whether and how developing-country farmers can make good use of any new technology. We conclude that the relationship, though murky in some respects, is real and important, and that there is a strong case for examining and changing U.S. patent policy with an eye toward the food security needs of developing coun-

tries. Based on our analysis, the United States could make changes in both its domestic and foreign policies that would improve developing-country access to the patented tools of biotechnology while preserving the core invention incentives of the patent system. These changes deserve consideration as the United States grapples with its heightened national interest in global food security and works to build a harmonized global patent system that fairly embraces the needs of developed and developing countries alike.

APPENDIX: THE NUMBER AND PATTERN OF BIOTECHNOLOGY PATENTS

Graff has compiled a unique dataset of agricultural plant biology patents[246] 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, indicate that a large number of biotechnology-related patents have been issued at an ever-increasing rate. The patents cover traits, transformation tools, and modified plants. The majority of the patents are in private hands.

A. The Number of Biotechnology Patents

Graff's dataset of patents granted from 1975 through 1998 comprises thirty categories of "biology-based agricultural technology." Graff used both the U.S. Patent Classification system and the International Patent Classification system to identify candidate patents. He then read each patent to identify ones relating to biology-based agricultural technology. Of Graff's thirty categories,[247] we focus on twenty-three, including specific genetic traits potentially useful in plants; tools used to modify the genome of plants through recombinant DNA techniques and other techniques of modern molecular biology, such as marker-assisted selection ("MAS") of desirable gene traits; and the germplasm of plants. The Graff dataset includes patents on other technologies that do not involve genetic modification of plants, such as the use of biological control agents for plant pests and diseases. We exclude these (numbers one to seven in Table 1) from our discussion.[248]

246. *See* Graff, *supra* note 32.

247. *See id.* (providing the data used in Table 1).

248. Some of the patents in the Graff dataset cover more than one category of technology. As a result, the 2,428 patents he compiled cover 3,003 inventions across the thirty categories. Of these 3,003 inventions, 2,247 fall in the twenty-three categories we summarize.

Table 1: Patents for Biology-Based Agricultural Technologies Granted from 1975 Through 1998, by the Organizational Types of the Patent Assignees[249]

NOTE: Proportions can sum to more than one because single patents can be granted to multiple assignees.

Technology Area	Total patents	University or public institution	Small firm, startup, or individual	Corporation
Total patents in sample and proportion by patenting organization type	**2,428**	**645**	**893**	**955**
		27%	**37%**	**39%**
Beneficial microorganisms linked to health and performance of plants	96	34	43	22
		35%	45%	23%
Behavior of plant insect pests: sex attractants and integrated insect pest management	86	51	23	14
		59%	27%	16%
Molecular biology, genetics, and genetic modification of plant insect pests	39	31	3	5
		79%	8%	13%
Biological control of plant pathogens	179	66	53	66
		37%	30%	37%

249. Gregory Graff, The Sources of Biological Technologies for Agriculture: Public and Private Innovation and Patenting (Apr. 10, 2000) (presented at the AAEA NC208 Conference on "R&D Policies and Impacts," Univ. of California-Berkeley, Mar. 30–31, 2001) (on file with the Harvard Journal of Law and Technology).

Technology Area	Total patents	University or public institution	Small firm, startup, or individual	Corporation
Bt bioinsecticides and Bt-based biological control of plant insect pests (but not genetic modification of plants)	130	17	79	35
		13%	61%	27%
Other (not Bt-based) bioinsecticides and biological control of plant insect pests	164	55	60	56
		34%	37%	34%
Bioherbicides and biological control of weeds	62	39	16	10
		63%	26%	16%
Plant genetic markers	66	18	32	20
		27%	48%	30%
Plant genetic transformation vectors and systems	151	45	67	50
		30%	44%	33%
General plant gene expression	81	25	29	27
		31%	36%	33%
Controllable or inducible plant gene promoters	108	28	35	47
		26%	32%	44%
Antisense suppressor technology	37	15	6	18
		41%	16%	49%
Plant cell, tissue, and embryo culture techniques	73	15	31	28
		21%	42%	38%

Technology Area	Total patents	University or public institution	Small firm, startup, or individual	Corporation
In vitro selection, somaclonal, and gametoclonal variation	57	16	26	17
		28%	46%	30%
Genetic traits and modification for plant nutrition, metabolism, and growth	64	23	17	24
		36%	27%	38%
Genetic traits and modification for plant pathogen resistance	166	62	27	86
		37%	16%	52%
Bt genetic traits and modification for plant insect resistance: Bt only	138	7	102	29
		5%	74%	21%
Other (not Bt) genetic traits and modification for plant insect resistance	67	20	27	28
		30%	40%	42%
Genetic traits and modification for plant herbicide tolerance: for all herbicides	122	34	16	72
		28%	13%	59%
Genetic traits and modification for stress tolerance	55	24	18	13
		44%	33%	24%
Genetic traits and modification for control of plant reproduction	97	23	35	42
		24%	36%	43%

Technology Area	Total patents	University or public institution	Small firm, startup, or individual	Corporation
Genetic traits and modification controlling plant amino acid or protein profile	39	12	14	15
		31%	36%	38%
Genetic traits and modification controlling plant fatty acid or oil profile	92	28	25	39
		30%	27%	42%
Genetic traits and modification controlling plant carbohydrate profile	55	9	27	20
		16%	49%	36%
Genetic traits and modification controlling plant fruit ripening process, shelf life	44	15	10	19
		34%	23%	43%
Genetic traits and modification for other quality enhancements	61	24	26	18
		39%	43%	30%
Genetic traits and modification for plant production of biomolecules	14	29	46	47
		25%	40%	41%
Maize germplasm: breeding and hybridization methods, hybrid parental lines, inbred lines, hybrid varieties	298	2	42	254
		1%	14%	85%

Technology Area	Total patents	University or public institution	Small firm, startup, or individual	Corporation
Soybean germplasm: breeding, hybridization, and improvement methods, varieties	117	15	84	18
		13%	72%	15%
All other germplasm: breeding, hybridization, and improvement methods, plant varieties	145	36	70	39
		25%	48%	27%

B. The Distribution of Patents Among Types of Technology

The Graff data show the distribution of agricultural biotechnology patents among thirty types of technology. In Table 2, we aggregate the data from the twenty-three 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).[250]

Table 2: Summary of Graff's Data (Table 1) Aggregated to Three Categories

NOTE: Rows can sum to more than total since single patents can be granted to multiple assignees

Technology Area	Total patents	University or public institution	Small firm, startup, or individual	Corporation
Transformation Technologies	536	147	220	189
Traits	1151	325	396	470
Germplasm	560	53	196	311
Totals	2247	525	812	970

250. The germplasm patents do not all involve genetic modification through recombinant DNA 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.

C. 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 and 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 were issued or assigned to small firms or individuals, and 970 were issued or assigned to corporations. These data confirm that most of the agricultural biotechnology patents (79%) are in private hands.

D. The Increasing Rate at which Biotechnology Patents Are Being Issued

The Graff dataset does not show how the issuance of agricultural biotechnology patents has changed 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, Foltz, and Kim.[251] A rough picture of the trend in biotechnology-related patents is evident from PTO data concerning the two U.S. Patent Classification system classes from which Barham, Foltz, and Kim select their data: 435 (Chemistry: Molecular Biology and Microbiology) and 800 (Multicellular Living Organisms and Unmodified Parts Thereof and Related Processes). The number of patents in these two classes, closely related to plant biotechnology, has increased almost ninefold since 1981.[252] In the same amount of time, overall utility patents per year slightly more than doubled.[253]

This trend is corroborated by Barham, Foltz, and Kim's data, describing agricultural biotechnology patents issued to universities during a comparable period.[254] The number of agricultural biotechnology patents issued to U.S. universities was about ten per year in the early 1980s, rising to about twenty-five per year in the early 1990s. In 1996,

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251. Barham et al., *supra* note 32, at 8.

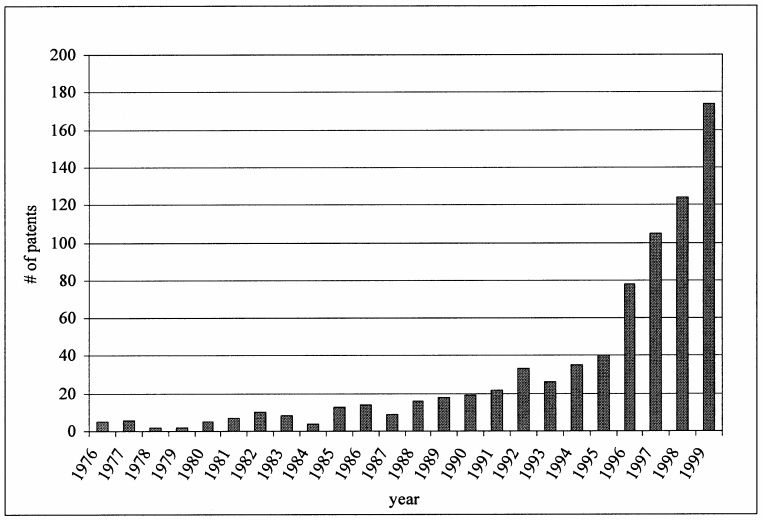
252. *See* PTO, PATENT COUNTS BY CLASS BY YEAR: JANUARY 1977–DECEMBER 2001 (2002), *available at* http://www.uspto.gov/web/offices/ac/ido/oeip/taf/cbcby.pdf. These figures are based on the original classification for each patent.

253. *See* PTO, PATENT COUNTS BY COUNTRY/STATE AND YEAR, UTILITY PATENTS: JANUARY 1, 1963–DECEMBER 31, 2001, *available at* http://www.uspto.gov/web/offices/ac/ido/oeip/taf/cst_utl.pdf. Some of this rapid growth is no doubt due to the innovations of biotechnology and novelty of utility patents being allowed on plants.

254. Barham et al., *supra* note 32, at 6–8 (generating 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).

the number rose sharply to seventy-eight and grew to 174 in 1999 (see Figure 1).

Figure 1: University Ag-Biotech Patent Production By Year[255]



As Barham, Foltz, and Kim 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 twenty 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.

255. Bradford L. Barham et al., *Trends in University Ag-Biotech Patent Production*, 24 REV. OF AGRIC. ECON. 294 (2002), *available at* http://www.biotech.wisc.edu/seebiotech/pdfs/raefinalbbkk.pdf.