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Michael Taylor

Dr. Jerry Cayford PhD

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Biotechnology Patents and African Food Security: Aligning America's Patent Policies and International Development Interests*

Michael R. Taylor & Jerry Cayford**

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

Patent policy is but one example of U.S. policies and government programs that affect food security and poverty reduction in developing countries and that deserve scrutiny. The United Nations' Millennium Development Goals aim to eradicate extreme poverty and hunger, and they recognize the importance of developing country agriculture in achieving that objective.¹ The United States has embraced these goals,² but

* This article is partly an encapsulation of some of the concepts and arguments presented in an article published by the Harvard Journal of Law & Technology. Michael R. Taylor & Jerry Cayford, *American Patent Policy, Biotechnology, and African Agriculture: The Case for Policy Change*, 17 HARV. J.L. & TECH. 321 (2004).

** Mr. Michael R. Taylor is a Senior Fellow at Resources for the Future (RFF). Dr. Jerry Cayford is a Washington-based philosopher, public policy analyst, and former research associate at RFF.

1. The World Bank Group, *Millennium Development Goals*, at <http://www.developmentgoals.org> (last updated Sept. 23, 2003).

many policies of the United States are not fully aligned with the goals or with the critical need to improve developing country agriculture.³ This includes U.S. policies concerning agricultural subsidies, trade barriers, development assistance, and food aid.⁴ Nor does U.S. patent policy appear to be fully aligned with the goal of achieving global food security.⁵

The U.S. government is a strong promoter of biotechnology as a tool for improving food security,⁶ and the U.S. patent system has enthusiastically embraced plant biotechnology through the issuance of thousands of patents.⁷ The United States is also a proponent of strong patent protection

2. President Bush told a World Bank audience early in his term that a "world where some live in comfort and plenty, while half of the human race lives on less than \$2 a day is neither just, nor stable." 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>.

Undersecretary of State for Business, Economic, and Agricultural Affairs, Alan Larson recently declared that "[f]ood security is a serious foreign policy concern that profoundly threatens human health, economic prosperity and political stability." 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. For a recent and accessible overview of how agricultural, trade, and food aid policies of the United States and Europe adversely affect developing country agriculture and food security, see generally 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.

4. *See generally id.*

5. *See id.* at 84-85 (noting that the U.S. is seen to favor biotechnology and to represent the interests of multinational corporations).

6. At a June 2003 biotechnology conference in Washington, DC, for example, President Bush said, "For the sake of a continent threatened by famine [Africa], I urge the European governments to end their opposition to biotechnology. We should encourage the spread of safe, effective biotechnology to win the fight against global hunger." BBC News, *US in New Global GM Push*, at <http://news.bbc.co.uk/1/hi/sci/tech/3013394.stm> (last updated June 23, 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.

7. *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 Minnesota Journal of Law, Science & 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/afinalbbkk.pdf>.

worldwide.⁸ It is thus important to explore how the U.S. stance in these three connected areas—biotechnology, patent policy, and the need for progress in developing country agriculture—can be reconciled, and how food security and the broader international interests of the United States can be advanced through patent policy change.

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

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

This article aims to stimulate thinking among policymakers and stakeholders about how U.S. patent policies affect the broader U.S. interest in poverty reduction and food security in Africa. It suggests how patent policies might be changed 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 investment 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

8. PTO, *A New Organization for a New Millennium: Performance and Accountability Report*, Forward to 2000 PTO PERFORMANCE & ACCOUNTABILITY REP. 17, [hereinafter *A New Organization for a New Millennium*], at <http://www.uspto.gov/web/offices/com/annual/2000> (last visited Sept. 21, 2004).

answer on the ideal mix of policies in this complex area, but we find the case for policy change convincing.

I. FOOD SECURITY, AGRICULTURAL PRODUCTIVITY, AND THE PATENTING OF BIOTECHNOLOGY

A common reality in many developing and food-insecure countries is that a large majority of the people depends on agriculture for their livelihood, directly or indirectly. In sub-Saharan Africa, seventy percent of the people are rural and largely agriculture-dependent.⁹ Although industrialization has fueled growth and hunger reduction in some Asian economies, it is generally recognized among experts that the poor countries of sub-Saharan Africa must improve their agriculture and food systems to achieve economic growth and food security.¹⁰ Moreover, according to the World Bank, global food production will have to double by 2025 to meet rising demand.¹¹

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

Within this context, improving the productivity of farmers

9. AFRICAN DEVELOPMENT BANK GROUP, GENDER, POVERTY AND ENVIRONMENTAL INDICATORS ON AFRICAN COUNTRIES tbl. 3.1 (2002-2003), at http://www.afdb.org/knowledge/statistics/statistics_indicators_gender/environment/indicators_environment.htm.

10. Advances in agricultural science and technology will be an important factor in improving nutritional security and stimulating economic growth. See WORLD BANK, AN INTERNATIONAL ASSESSMENT ON THE ROLE OF AGRICULTURAL SCIENCE AND TECHNOLOGY IN REDUCING HUNGER AND IMPROVING RURAL LIVELIHOODS 4 (2002), at <http://www.agassessment.org/pdfs/roleofag.pdf> (last visited Nov. 16, 2004).

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

is not by itself the solution to food security. It is, however, an important part of the picture, especially in sub-Saharan Africa. African farmers often face difficult growing conditions, and better access to the basic Green Revolution tools can play an important role in improving their productivity. The Green Revolution promoted the use of irrigation, fertilizers, pesticides, high-yield varieties, and the greater efficiencies of monoculture and large farm size. While the result was dramatic increases in productivity, this was accompanied by fertilizer and pesticide runoff into surface waters, greater soil erosion, and other environmental costs. With the environmental lessons of the Green Revolution in mind, many agricultural experts also believe that the tools of modern biotechnology (including the use of recombinant DNA technology to produce genetically modified plants) can play a role in solving developing country agronomic problems and increasing productivity.¹² By building into the seed itself traits for drought and disease resistance, insect and other pest control, and improved yield under specific local growing conditions, biotechnology may enable farmers to increase their productivity without as much reliance on the external inputs that characterized the Green Revolution.

Biotechnology cannot benefit African farmers, however, if they and those who would develop the technology specifically for developing country purposes cannot gain access. This article focuses on the problem of access to biotechnology for developing country purposes. The access problem arises from the recent shift of investment in agricultural innovation from the public sector to the private and the use of the patent system by biotechnology companies to protect their investments.

Research breakthroughs in the use of recombinant DNA techniques to modify plants, coupled with the 1980 U.S. Supreme Court decision in *Diamond v. Chakrabarty*¹³ sanctioning the patenting of living organisms made by humans, have spawned substantial investment in biotechnology by large agricultural chemical companies and small biotech startup

12. See GORDON CONWAY, *THE DOUBLY GREEN REVOLUTION: FOOD FOR ALL IN THE 21ST CENTURY* (1999); see also ISMAIL SERAGELDIN & G.J. PERSLEY, *PROMETHEAN SCIENCE: AGRICULTURAL BIOTECHNOLOGY, THE ENVIRONMENT, AND THE POOR* (2000), at www.ifpri.org/themes/biotech/sergeldi.pdf (last visited Nov. 16, 2004).

13. 447 U.S. 303 (1980); see also *Ex parte Hibberd*, 227 U.S.P.Q. (BNA) 443, 444-47 (1985) (expanding the scope of what the PTO considered patentable biotechnologies from microorganisms to genetically modified plants).

companies, primarily in the United States and Europe.¹⁴ Increased private investment in and patenting of biotechnology are producing significant changes in how agricultural innovation occurs, how it is paid for, and who controls it.

For most of history, innovation in seed technology has been a freely shared or public good.¹⁵ Farmers developed higher yielding, better performing varieties and shared them with neighbors. From its founding in 1862, the U.S. Department of Agriculture (USDA) has invested in research to develop improved seed.¹⁶ Until 1925, the USDA's largest budget item was a program that provided the latest seed free to farmers.¹⁷ Only in the years following World War II did a large-scale private-sector seed industry develop in the United States and other industrialized countries based on hybridization technology.¹⁸

In most developing countries, seed innovations remain largely a public good. Farmers produce, save, and share improved seed, and national and international agricultural research laboratories produce innovations in seed technology that are commonly distributed through public channels. There are fledgling seed industries in developing countries that are marketing privately developed hybrids and serving as distribution channels for publicly developed seed innovation, but in many areas, such as sub-Saharan Africa, innovation remains largely a public enterprise and a public good.¹⁹ Internationally, the Consultative Group on International Agricultural Research (CGIAR), which is sponsored by the World Bank and funded largely by donor countries in the industrialized world, has played a leading role in seed innovation, and many of its laboratories are exploring the use of modern biotechnology to solve developing country agronomic

14. See Graff, *supra* note 7; Bradford 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>.

15. See Nathan A. Busch, *Jack and the Beanstalk: Property Rights in Genetically Modified Plants*, 3 MINN. INTELL. PROP. REV. 1, 10 (2002) (discussing the centralization of control of the germplasm base by the government which allowed for distribution of new varieties of seeds for all farmers).

16. *Id.* at 12-13.

17. *Id.* at 14.

18. *Id.* at 31.

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

problems.²⁰

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.²¹ Generally, public-sector plant breeding expenditures for field crops have been relatively flat for decades but “appear to have started to decline in real terms from the mid-1990s In contrast, private-sector plant breeding investment appears to have grown extremely rapidly” (perhaps by a factor of ten since 1960).²² Depending on what one measures, private expenditures appear to have passed public expenditures around 1990.²³ Measured in scientist years, though, private sector effort was more than double public effort by 1994.²⁴

The privatization of research affects the kinds of research done and products developed. Private companies have invested heavily in the technology and seed companies required to bring new products to market.²⁵ To capture a return on this investment, they have focused their commercial efforts, including product development, on applications with mass appeal to farmers who can afford the technology.²⁶ This economic reality creates a problem, however, because private-sector holders of biotechnology patents have little or no

20. For background on the CGIAR system, see Future Harvest, at <http://www.futureharvest.org> (last visited September 21, 2004); see also AGRICULTURAL BIOTECHNOLOGY AND THE POOR: AN INTERNATIONAL CONFERENCE ON BIOTECHNOLOGY (G.J. Persley & M.M. Lantin eds., 1999), available at www.cgiar.org/biotech/rep0100/contents.htm; Applied Biotechnology Ctr. at the Int'l Maize and Wheat Improvement Ctr., *Reaching inside the Genome, Reaching Farmers* (2002), at www.cimmyt.org/ABC/map/about/BROCHURE97ABC/BROCHURE97ABC.htm (last visited Dec. 1, 2004).

21. For a discussion on how amounts of research can be calculated many different ways, see Paul W. Heisey et al., *Public Sector Plant Breeding in a Privatizing World*, AGRIC. INFO. BULL. NO. 772, Mar. 2001, available at <http://www.ers.usda.gov/publications/aib772/>; see also Robbin Shoemaker, et al., *Economic Issues in Agricultural Biotechnology*, AGRIC. INFO. BULL. NO. 762, Mar. 2001, at 38–39, available at <http://www.ers.usda.gov/publications/aib762/>.

22. Heisey et al., *supra* note 21, at 6–8.

23. *Id.* at 7.

24. *Id.* at 8; see also K.J. Frey, *National Plant Breeding Study-I: Human and Financial Resources Devoted to Plant Breeding and Development in the United States in 1994*, SPECIAL REPORT 98 IOWA AGRICULTURAL AND HOME ECONOMICS EXPERIMENT STATION (1996), available at <http://www.ers.usda.gov/data/plantbreeding/Plant%20Breeding.pdf>.

25. Heisey et al., *supra* note 21, at 1.

26. *Id.* at 2.

economic incentive to use the laboratory tools or gene traits they own to develop solutions to developing country agricultural problems.²⁷ 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.²⁸

Consequently, the finite capital resources of biotechnology companies will, for the foreseeable future, continue to be focused on meeting the needs of farmers in Western industrialized countries and will not be deployed in substantial measure to meet the needs of developing country farmers.

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

II. U.S. DOMESTIC AND FOREIGN POLICY ON PATENTS

It is important to distinguish conceptually between “domestic” and “foreign” patent policies. Domestic patent policy includes the rules governing what gets patented in the United States and how non-patentholders might gain access to patented technology. The Constitution of the United States establishes the mandate for, 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.”²⁹ The requirements and conditions for granting patents reflect the terms of the deal between the inventor and society. Congress defined patentable subject matter in 35 U.S.C. § 101: “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent

27. *Id.* at 4; see also Michael R. Taylor & Jerry Cayford, *American Patent Policy, Biotechnology, and African Agriculture: The Case for Policy Change*, 17 HARV. J.L. & TECH. 321, 334 (2004).

28. Taylor & Cayford, *supra* note 27, at 334.

29. U.S. CONST. art. 1, § 8.

therefore, subject to the conditions and requirements of this title.”³⁰ These terms ensure that the inventor’s contribution to society has value. Hence, there is a utility requirement, so society will receive a useful invention.³¹ There is a novelty requirement, so inventors cannot offer something that society already has.³² There is a nonobviousness requirement, so inventors cannot offer what society would likely soon have in any case:

A patent may not be obtained . . . if the differences between the subject matter . . . and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.³³

There is also a disclosure or specification requirement, so that society actually receives the invention, in the sense that it becomes part of the common knowledge, usable by others.³⁴

Domestically, access to patented technology is also governed by the operation of the patent law, which gives the inventor a time-limited monopoly right to exploit the invention for economic gain.³⁵ Patent holders typically transfer patented technology and reap economic gain through licensing or sale. However, access to patented technology may be hampered by the “patent thicket” problem: “an overlapping set of patent rights requiring that those seeking to commercialize new technology obtain licenses from multiple patentees.”³⁶

Domestic patent policy attempts to ease restrictions through such tools as research exemptions and compulsory license provisions.³⁷ First, the utility patent statute does not

30. 35 U.S.C. § 101 (2000).

31. *See id.*

32. *See id.*

33. *Id.* § 103(a).

34. *See id.* § 112 (“The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the same . . .”).

35. *See id.* § 154(a)(2) (“[S]uch grant shall be for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed in the United States . . .”).

36. Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting*, in 1 *INNOVATION POL. AND THE ECON.* 119, in executive summary (Adam Jaffe et al. eds., 2001).

37. *See* JAMES LOVE AND MICHAEL PALMEDO, *EXAMPLES OF COMPULSORY LICENSING OF INTELLECTUAL PROPERTY IN THE UNITED STATES*, at ch. III (2001) available at <http://www.cptech.org/ip/health/cl/us-cl.html> (last visited Sept. 21, 2004).

explicitly allow researchers to use patented inventions freely in their research. Courts have interpreted the law as implicitly exempting from infringement the use of patented inventions in non-commercial research.³⁸ However, this exemption is narrow in that it does not permit the use of patented technology in the research and development of new technologies for use in commercial research or nonresearch settings.³⁹ Second, compulsory licenses, like research exemptions, are tools for adjusting the balance between the private interests of the patent holder and a broader public interest by providing an exception from the exclusive rights normally provided by a patent. U.S. law provides for compulsory licenses to make a technology available to ameliorate anticompetitive practices by patent holders.⁴⁰

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

The ways in which U.S. patent policy affects developing countries are complex and multifaceted. They include domestic policies on what gets patented under U.S. patent law, including the direct and indirect effects of the patent thicket that has

38. *Id.*

39. *Id.* The judicially-created research exemption was narrowed even further, perhaps to the point of eliminating it for practical purposes, by a recent decision of the U.S. Court of Appeals for the Federal Circuit holding, in a case involving university researchers, that there was no protection from an infringement claim if the research was “in keeping with the alleged infringer’s legitimate business, regardless of commercial implications.” *Madey v. Duke Univ.*, 307 F.3d 1351 (Fed. Cir. 2002).

40. *Id.*

grown up around biotechnology in the United States,⁴¹ and the rules governing non-domestic access to U.S.-patented technology. Developing countries are also affected by U.S. foreign policy on patents, which is grounded in a different set of interests and values arising outside the traditional confines of domestic patent law and policy. It rests on the conviction that strong intellectual property protection is important to the economic success of U.S.-based technology companies, but it does not involve balancing the competing interests that are central to domestic patent policy. The effects of domestic and international patent policies are difficult to measure, but in the view of many well-informed stakeholders, they can be substantial; and, in the future, developing country access to biotechnology for food-security purposes may be affected even more substantially by patent-related policies the U.S. government pursues in the international arena than by its domestic patent policies. U.S. foreign policy on patents manifests itself in three main contexts: implementation of the TRIPS Agreement,⁴² international harmonization of patent laws through the World Intellectual Property Organization (WIPO),⁴³ and use of bilateral trade relationships to strengthen patent protections.⁴⁴ We focus here on the TRIPS and WIPO arenas.

The TRIPS agreement is, as its name implies, a trade

41. See Shapiro, *supra* note 36.

42. See 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 33 I.L.M. 81 (1994) [hereinafter TRIPS], available at http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm (last visited Oct. 14, 2004).

43. WIPO is the international standards setting group for patent and intellectual property matters. World Intellectual Property Organization Website, at <http://www.wipo.int> (last visited Nov. 16, 2004).

44. For example, in negotiating a free trade agreement with Singapore, the U.S. won provisions that require Singapore to adopt intellectual property protections that go beyond Singapore's WTO and TRIPS obligations, including giving up the explicit flexibility in Article 27.3(b) of TRIPS to choose not to grant utility patents for plants. TRIPS, *supra* note 42. According to a statement issued by the Singapore government: "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 Nov. 16, 2004).

agreement.⁴⁵ It was negotiated as part of the Uruguay Round of trade negotiations that concluded in 1994 and created the WTO. Its primary objective was to reduce impediments to trade, taking into account the need both to “promote effective and adequate” intellectual property rights, and to ensure that such rights do not themselves become barriers to trade.⁴⁶ With respect to patents, a core requirement of TRIPS is that members provide for the patenting of all forms of technology in accordance with widely accepted principles of novelty, nonobviousness, and usefulness.⁴⁷ Further, “national treatment” shall be accorded to all members; that is, member countries must permit nationals of other countries to obtain patents on terms no less favorable than those accorded to their own nationals.⁴⁸

The TRIPS Agreement explicitly recognizes the need of developing countries for “maximum flexibility” in implementing their patent laws in ways that enable them to create “a sound and viable technological base.”⁴⁹ It contains several provisions that give countries the flexibility to grant exceptions to patent rights under certain circumstances, including broad authority in Article 30 to grant exceptions when the interests of the patent holder will not be adversely affected⁵⁰ and authority in Article 31 to provide for compulsory licenses, subject to some conditions, when the patent holder’s interests are affected.⁵¹

45. TRIPS, *supra* note 42.

46. *Id.* p.mbl.

47. *See id.* art. 27.1 (“patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application”).

48. *Id.* art. 3.1.

49. *Id.*

50. TRIPS, *supra* note 42, art. 30. “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.” *Id.*

51. Article 31 provides in part:

Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder . . . the following provisions shall be respected: . . .

. . .

(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. . . .

(h) the right holder shall be paid adequate remuneration in the

Furthermore, Article 27.3(b) permits countries to exclude plants and animals from patentability altogether, if an alternative *sui generis* system of protection is provided.⁵² This flexibility is important for countries that might judge it in their interest to adopt a system of plant variety protection that allows for the use of protected plants for breeding of new varieties and for farmers to save their seed for planting the next year. These provisions reflect the reality documented by expert commissions and commentators that the patent and other intellectual property needs of developing countries vary and can be sharply different from the needs of industrialized countries.⁵³

Nevertheless, the United States and other Western industrialized nations are leading a concerted effort through WIPO⁵⁴ to achieve international harmonization of patent law beyond that provided for in TRIPS. TRIPS only established minimum standards for adoption of patent systems by WTO

circumstances of each case, taking into account the economic value of the authorization; . . .

. . .

(k) . . . Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur

Id. art. 31.

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

53. For a broad overview of this topic, see Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy* (London, September 2002), at <http://www.iprcommission.org> (last visited Sept. 8, 2004). For an analysis specifically addressing issues concerning TRIPS and development, see CARLOS M. CORREA, INTELLECTUAL PROPERTY RIGHTS AND THE USE OF COMPULSORY LICENSES: OPTIONS FOR DEVELOPING COUNTRIES (South Centre, Working Paper No. 5, 1999) at <http://www.southcentre.org/publications/complicence/toc.htm> (last visited Sept. 8, 2004).

54. WIPO evolved out of two 19th century international conventions on intellectual property: the Paris Convention for the Protection of Intellectual Property, Mar. 20, 1883, <http://www.wipo.int/clea/docs/en/wo/wo020en.htm> [hereinafter Paris Convention], and the Berne Convention for the Protection of Literary and Artistic Works, Sept. 9, 1886, <http://www.wipo.int/clea/docs/en/wo/wo001en.htm>. It became a United Nations agency in 1974. WIPO administers two main treaties. One is the Patent Cooperation Treaty (PCT), which seeks to harmonize standards for obtaining patents. PCT, June 19, 1970, <http://www.wipo.int/pct/en/texts/pdf/pct.pdf>. The other is the Patent Law Treaty, which aims to integrate the paperwork for obtaining patents and promote mutual recognition of patents among the treaty parties by ensuring that one international patent filing will have effect in all signatory countries. Patent Law Treaty, June 1, 2000, at <http://www.wipo.int/clea/docs/en/wo/wo038en.htm>.

members and left considerable flexibility to tailor the system to local needs. WIPO is focusing on a more standardized “one size fits all” approach to patents that would support the move toward a single patent application establishing patent rights to an invention worldwide. WIPO’s strategic goals are similar to those of the PTO, including “maintenance and further development of the respect of intellectual property throughout the world” and ensuring that acquiring and enforcing patents “should be simpler, cheaper and more secure.”⁵⁵ 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). 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:

[A]pplicants, 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.⁵⁶

If successful, WIPO’s approach to harmonization could hinder developing countries in adopting patent regimes tailored to their particular needs, including the need to foster dissemination of biotechnology for food-security purposes. Specifically, 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.⁵⁷ As one commentator observed:

[O]ne of the most significant issues on which some developing countries expressed their position . . . was whether an invention

55. 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 Sept. 8, 2004).

56. 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> (last visited Sept. 8, 2004).

57. See Carlos Correa, *WIPO’s Patent Agenda: For Whom*, S. BULL. 48, available at <http://www.southcentre.org/info/southbulletin/bulletin48/bulletin48-01.htm> (last visited Sept. 8, 2004).

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 endeavour, 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”⁵⁸

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.”⁵⁹

III. THE CASE AND OPPORTUNITY FOR POLICY CHANGE

The United States cannot solve the world’s technological and economic problems by itself, but the United States has a national security interest in reducing global poverty and hunger. It also has a duty, as the richest and most powerful country in the world, to avoid actions and policies that have unnecessary and avoidable adverse impacts on progress elsewhere. This includes patent policies that adversely affect food security in developing countries. Indeed, U.S. patents and patent policy contribute to the difficulties researchers face in applying biotechnology to the solution of food security problems in developing countries. Enforcement of U.S. patents can *directly* block U.S. researchers’ access to a technology either as a legal bar to unlicensed use of a patented technology or through the proliferation of upstream patents on research tools described above as the “patent thicket.”⁶⁰ It can also directly impede researchers working in developing countries on applications of biotechnology to crops intended to be exported to

58. *Id.*

59. *Id.* “The process of harmonizing “the rules and procedures of a wide majority of countries with the practices and legislation of a small number of countries . . . [c]ould represent, in reality, a step-backwards from the limited aspects of flexibility stipulated in the TRIPS agreement.” *The WIPO Patent Agenda Must Promote Development*, S. BULL. 48 (adapted from the statement of the Egyptian delegation at the 37th series of Meetings of the Assemblies of Member States of WIPO), at <http://www.southcentre.org/info/southbulletin/bulletin48/bulletin48-02.htm> (last visited Sept. 8, 2004).

60. See Shapiro, *supra* note 36.

the U.S. If such crops are produced with unlicensed U.S.-patented technology, importing these crops into the U.S. would constitute an infringement of the patent.

Because researchers and research institutions in developing countries frequently cannot navigate through the patent thicket, the possibility that the crop will be exported to the U.S. acts as a legal obstacle and disincentive for developing country researchers to use U.S.-patented technologies. For researchers working outside the U.S. on crops with little or no export potential, use of a U.S.-patented tool for such an improved plant is not directly blocked by U.S. patents which are binding only in the U.S. Nevertheless, there are several ways U.S. patents may have an *indirect* impact on the use of patented technology by these researchers. First, the U.S. government pushes hard for foreign countries and institutions to protect the intellectual property rights of U.S. companies, and systematic violation of U.S. patents may jeopardize funding by the U.S. government and international financial institutions. Further, developing country research institutions using unlicensed patented technology may find that the Western biotechnology companies unwilling to provide much needed cooperation. These Western biotechnology companies jealously guard their patents and are less likely to cooperate with institutions that do not respect their patents.⁶¹ Finally, if foreign researchers desire to form partnerships with patent-holders to gain access to enabling technologies and necessary know-how, they generally must enter material transfer agreements (MTAs) that place strict restrictions on the use of the technology.⁶² The leverage to impose strict MTA conditions can operate as a *de facto* extension of the patent to the country where the researcher works: to the extent the researcher was legally free to use the invention outside the U.S., that freedom is usually lost in the material transfer agreement.

If the United States believes biotechnology can help improve agriculture and food security in developing countries,

61. See John Komen, *International Collaboration in Agricultural Biotechnology*, in *MANAGING AGRICULTURAL BIOTECHNOLOGY: ADDRESSING RESEARCH NEEDS AND POLICY IMPLICATIONS* 110, 117-19, (Joel I. Cohen ed., 1999), available at ftp://ftp.cgiar.org/isnar/ibs/III_10.pdf.

62. See Steven C. Price, *Public and Private Plant Breeding*, 17 *NATURE BIOTECH.* 938 (1999), available at http://www.biotech-info.net/public_private.html (last visited Sept. 23, 2004); Charles Benbrook, *Who Controls and Who Will Benefit from Plant Genomics?*, Feb. 19, 2000, at <http://www.biotech-info.net/AAASgen.pdf> (last visited Sept. 8, 2004).

and if U.S. patent policy can impede such improvement, policy change should be considered. The case for policy change is well grounded in the fundamental social purpose of the patent system, which grants patents to serve society's interests in both the invention and dissemination of innovative technology. The theoretical underpinnings of the U.S. patent system codified in 35 U.S.C. §§ 101, 103, and 112 have been discussed above in the beginning of Part II.⁶³ The patent system is an instrumental social construct intended to benefit society by fostering useful innovation. This understanding of the system requires us to evaluate its performance from a social outcome perspective. From this perspective, the success of the patent system and possible changes in patent policy are fairly judged on the basis of whether and to what extent the societal benefits of the system, in terms of useful innovation, exceed the societal costs of the patent monopoly, in terms of higher prices to consumers or constraints on access to new inventions by those not holding patents.⁶⁴ If the patent system is not achieving this objective or could achieve it better, it is fair and appropriate to consider policy change. Patent policies should be changed if the changes will improve dissemination for food security or other important social purposes without significantly undercutting incentives for invention.

While some may argue that it is unfair to maintain that an international concern—food security in developing countries—is a societal interest against which U.S. patent policy is fairly judged, 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 policy making. As previously noted, U.S. patents and patent policy have extraterritorial aspirations and impacts, including practical impacts on access to technology in other countries. Furthermore, it is the declared objective of the PTO to promote adoption of U.S.-like patent systems in other countries, including developing countries.⁶⁵

63. See *supra* notes 30-34 and accompanying text.

64. See Lester C. Thurow, *Needed: A New System of Intellectual Property Rights*, Sep.-Oct. 1997 HARV. BUS. REV. 95; Rebecca S. Eisenberg, *Patents: Help or Hindrance to Technology Transfer*, in BIOTECHNOLOGY: SCIENCE, ENGINEERING, AND ETHICAL CHALLENGES FOR THE TWENTY-FIRST CENTURY 161, (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 (2000).

65. See James E. Rogan, Remarks at the Hearings on Competition and

A set of possible changes in U.S. patent policy that appear to meet the social outcome balancing test is outlined below. They fall into three categories: changing U.S. law and policy to improve access to patented technologies; preserving the flexibility developing countries have in the current TRIPS Agreement to tailor their patent systems to their local needs; and more fully implementing Article 66.2 of TRIPS regarding support for technology transfer.⁶⁶ Most of the changes to U.S. law considered are designed to improve access to patented technology specifically for developing country food security purposes. This narrow focus limits special access to cases in which that benefit is achieved without directly competing with the patent holder in the market (the United States) for which the patent was granted.

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

Intellectual Property Law and Policy in the Knowledge-Based Economy, Feb. 6, 2002, at <http://www.uspto.gov/web/offices/com/comm06feb2002.html> (last visited Sept. 8, 2004). “[T]he United States has made it a key part of its trade policy to create international frameworks for recognizing intellectual property rights.” *Id.*; see also *A New Organization for a New Millennium*, *supra* note 8, at 15. “Many developing countries were also provided technical assistance by the USPTO to help them implement their obligations under the Trade Related Aspects of Intellectual Property Agreement (TRIPs).” *Id.*

As the largest intellectual property office in the world, the PTO is at the forefront of developing and strengthening intellectual property protection, both at home and abroad. The Undersecretary and Director is the organization’s standard-bearer of intellectual property 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.

66. “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.” TRIPS, *supra* note 42, art. 66.2.

IV. IMPROVING ACCESS TO PATENTED TECHNOLOGIES

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

A. CREATE A STRONG RESEARCH EXEMPTION

Under this policy alternative, Congress would enact a statutory limitation on the scope of the patent monopoly such that the use of a patented tool of biotechnology in the research and development of new applications for developing country food-security purposes would not constitute infringement of the patent. The proposal would improve access to patented biotechnology by freeing both U.S. and foreign-based researchers to work on applying patented technology to developing country food-security problems without concern about infringement claims. Such a research and development exemption as envisioned would not be limited to non-commercial users or uses of patented technology. The exemption is, however, only for research. If that research produces new products that contain the original patented invention or that cannot be exploited without infringing the original patent, the patent holder would retain full control of the original invention. Accordingly, the exploitation of such dependent products would still require permission from the patent holder.

B. ESTABLISH A COMPULSORY LICENSE REQUIREMENT FOR AGRICULTURAL BIOTECHNOLOGY

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

could be used for developing country food-security purposes without risk of patent infringement. But it would not significantly undercut invention incentives because the royalty provision would make the patent holder economically whole to the extent it would lose economic value from its own application of the technology for developing country food-security purposes.

C. ESTABLISH A “WORKING” REQUIREMENT FOR AGRICULTURAL BIOTECHNOLOGY PATENTS

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

This provision is modeled on the “working” provision in the Paris Convention for the Protection of Intellectual Property. Article 5(A)(4) of the Paris Convention states:

A compulsory license may not be applied for on the ground of failure to work or insufficient working before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last; it shall be refused if the patentee justifies his inaction by legitimate reasons. Such a compulsory license shall be non-exclusive and shall not be transferable, even in the form of the grant of a sub-license, except with that part of the enterprise or goodwill which exploits such license.⁶⁷

The TRIPS Agreement requires compliance with the Paris Convention, first enacted in 1883, which permits, but does not demand, a working requirement. The United States is a signatory of the Paris Convention, but, unlike most other countries, it has not adopted a working requirement. A working requirement along these lines would improve access by ensuring that, after a certain waiting period, patented tools of biotechnology would be available for developing country food-

67. Paris Convention, *supra* note 54, art. 5(A)(4).

security purposes without risk of patent infringement. Again, it would not significantly undercut invention incentives, because it would limit access to cases in which the patent holder chose not to apply the invention to the specific developing country food-security need in question.

D. EXERCISE U.S. EMINENT DOMAIN AUTHORITY

Under this policy alternative, the U.S. government would exercise its existing statutory eminent domain authority under 28 U.S.C. § 1498 to authorize the use of patented tools of biotechnology for developing country food-security purposes. Eminent domain authority has existed in U.S. patent law since 1910.⁶⁸ Under the government's eminent domain authority, government authorization of the use of a patented technology insulates a user from any patent infringement claim by the patent holder. There are no subject matter, purpose, or other substantive restrictions on the uses of the technology for which eminent domain authority may be exercised, and there is no requirement for formal action by the government to invoke it.⁶⁹ 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.⁷⁰ Eminent domain authority has not been exercised with respect to patents on the tools of agricultural biotechnology.

A designated authority within the U.S. government could establish an administrative mechanism under which a technology developer who wanted to use the patented technology could make application and then be deemed to be using the technology for the United States. The U.S. government, rather than the technology developer, would then be liable for any compensation to which the patent holder could prove entitlement in court.

E. MAKE AVAILABLE U.S. GOVERNMENT-FUNDED OR

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

69. See, e.g., *Bereslavsky v. Esso Standard Oil Co.*, 175 F.2d 148, 150-51 (4th Cir. 1949).

70. See Consumer Project on Technology, *Ciprofloxacin: the Dispute over Compulsory Licenses* (noting recent publicity in international media concerning the use of eminent domain power over the CIPRO patent), at <http://www.cptech.org/ip/health/cl/cipro> (last visited Nov. 16, 2004).

GOVERNMENT-OWNED BIOTECHNOLOGY

This alternative would establish as a matter of policy that all tools of agricultural biotechnology developed by the U.S. Department of Agriculture (USDA) and other U.S. government agencies, whether patented or not, would be made available by the government, without the need for a license or other permission, when used for developing country food-security purposes. 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 Act⁷¹ encourages the patenting of government-funded research as a means of fostering its dissemination and use, and USDA's current patent policy is based on the goal of making government-developed technology available for development and application.⁷²

This is consistent with the patent law, which declares:

It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development . . . to ensure that the Government obtains sufficient rights to federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions . . .⁷³

This declaration of policy is backed up by restrictions on the granting of exclusive or partially exclusive licenses on government-owned inventions, including requiring that "the Federal agency finds that the public will be served by the granting of the license . . . and that the proposed scope of exclusivity is not greater than reasonably necessary."⁷⁴ 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 "[a]s necessary for meeting the obligations of the United States under any treaty, international agreement, arrangement of cooperation, memorandum of understanding, or similar arrangement."⁷⁵ The Rome Declaration issued at the

71. Act of Dec. 12, 1980, Pub. L. No. 96-517, 94 Stat. 3015-28 (1980) (codified as amended at 35 U.S.C. §§ 200-212 (2000) (commonly known as the "Bayh-Dole Act").

72. USDA, TECHNOLOGY TRANSFER IN ARS, 141.2-ARS (Sept. 11, 2000), at <http://www.afm.ars.usda.gov/ppweb/141-2.htm> (last visited Nov. 16, 2004).

73. 35 U.S.C. § 200 (2000).

74. 35 U.S.C. § 209(a)(2) (2000).

75. 35 U.S.C. § 202(c)(4) (2000).

World Food Summit of 1996 and signed by the United States, says, "We pledge our actions and support to implement the World Food Summit Plan of Action."⁷⁶ 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.

IV. PRESERVING FLEXIBILITY FOR DEVELOPING COUNTRIES

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

A. SUPPORT INCORPORATING TRIPS FLEXIBILITY PROVISIONS IN ANY NEW WIPO AGREEMENT AND IN ANY BILATERAL OR REGIONAL TRADE AGREEMENTS

The TRIPS Agreement provides significant flexibility for developing countries to devise patent regimes that serve their local technology and development needs. The United States could support the inclusion of these same general flexibility provisions in the draft WIPO Substantive Patent Law Treaty and oppose any efforts through the WIPO process to reduce the patent policy flexibility granted developing countries in the TRIPS Agreement. Similarly, it could accept the inclusion of these flexibility provisions in any trade agreements it negotiates with developing countries, reversing the trend against flexibility set in its recent agreements with Singapore and Chile.⁷⁷ Perhaps more simply, the United States could

76. Rome Declaration on World Food Security, Nov. 13-17, 1996, at www.fao.org/docrep/003/w3613e/w3613e00.htm.

77. See Singapore Ministry of Trade and Industry, at

refrain from incorporating any intellectual-property provisions at all in new trade agreements with developing countries already bound by TRIPS.

B. SUPPORT PRESERVING THE TRIPS FLEXIBILITY PROVISIONS

The TRIPS Council is reviewing the TRIPS Agreement in the context of the Doha Round of WTO trade negotiations.⁷⁸ The United States could make clear in this review that it supports maintaining the current flexibility provisions in the TRIPS Agreement. There are many such provisions, including: the broad authority in Article 30 to grant benign exceptions to patents; the Article 27.3(b) explicit right to exclude plants and animals from patentable subject matter; the implicit right to set patentability standards (novelty, inventive step, utility, disclosure) so as to maximize disclosure, minimize patenting of discoveries, and narrow patent breadth; and the right to grant compulsory licenses.⁷⁹

C. ENDORSE APPLICATION OF ARTICLES 8 AND 30 TO FOOD SECURITY NEEDS

By their terms, Articles 8 and 30, as well as other flexibility provisions in TRIPS, are available to allow developing countries to devise intellectual property approaches to agricultural biotechnology that best serve local food-security needs.⁸⁰ The United States could specifically endorse the use of these provisions for that purpose and support efforts to craft implementation schemes for these provisions that comply with TRIPS, meet the food-security need, and preserve invention incentives.

D. SPECIFICALLY ENDORSE RETENTION AND USE OF ARTICLE 27.3(B) IN THE TRIPS AGREEMENT

Article 27.3(b) of TRIPS explicitly allows countries to exclude plants from patentability, provided they establish an

http://www.mti.gov.sg/public/FTA/frm_FTA_Default.asp?sid=36 (last visited Nov. 16, 2004).

78. 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 (last visited Nov. 16, 2004).

79. TRIPS, *supra* note 42, arts. 3.1, 27.1, 27.3, 30, 31.

80. *Id.* arts. 8, 30.

effective alternative for protecting plant varieties.⁸¹ This flexibility is vital for countries that rely on publicly funded breeding programs and on the saving and reuse of seed by farmers to develop and disseminate new seed varieties. The United States could endorse retention of this provision and support its use in ways that meet developing country food-security needs without undercutting invention incentives.

E. FULLY IMPLEMENT ARTICLE 66.2 OF THE TRIPS AGREEMENT

Article 66.2 of the TRIPS Agreement says:

Developed countries shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least developed country members in order to enable them to create a sound and viable technological base.⁸²

This provision speaks directly to the disparity in innovation capacity and access to technology between developed and developing countries. It was part of the quid pro quo in the TRIPS negotiations, in which developing countries were to be provided assistance with technology transfer in exchange for establishing the patent systems that developed countries were seeking to protect their intellectual property. The perception among many in developing countries is that, while they are working to establish patent systems, the developed countries have not met their technology transfer obligations.⁸³

The United States has not taken steps targeted specifically at providing incentives to U.S. companies to transfer agricultural technologies to developing countries for food-security purposes. Rather, the United States report to the WTO on its compliance with Article 66.2 recites several U.S. statutes and programs, most predating the TRIPS Agreement, that relate generally to technology transfer and trade development, and it identifies some capacity-building programs in areas of technology unrelated to agriculture and food security.⁸⁴ Nor has it taken any steps to provide incentives to

81. *Id.* art. 27.3.

82. *Id.* art. 66.2.

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

84. WTO, Council for Trade-Related Aspects of Intellectual Property Rights, *Implementation of Article 66.2 of the TRIPS Agreement: Information*

U.S. companies to transfer patented technology, such as the tools of biotechnology.⁸⁵ The United States could work to fulfill its obligation under Article 66.2 with respect to agricultural biotechnology and food security by providing incentives, perhaps in the form of tax credits or other economic subsidies, for companies to invest in the development and commercialization of applications of biotechnology that meet developing country food security needs. However, the market incentives for such commercial investment do not exist on a viable scale in developing countries, and there is little commercial infrastructure for the delivery of seeds where they are needed for food security purposes. Government incentives on any reasonably foreseeable scale are thus not likely to make a significant or sustainable difference in the availability of improved seeds to improve food security. Moreover, subsidizing commercial applications of biotechnology is not likely to advance Article 66.2's objective of enabling developing countries "to create a sound and viable technological base" of their own.⁸⁶

A course more likely to achieve the objectives of Article 66.2 would be to provide incentives to U.S. companies to transfer the tools of biotechnology and other agricultural technologies to public and private sector researchers based in developing countries, who can apply them to local food security problems following a public-private collaborative approach. A model for the public-private innovation 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

from *Developed Country Members, Addendum: United States*, IP/C/W/388/Add.7 (Feb. 4, 2003), at docsonline.wto.org/DDFDocuments/t/IP/C/W388A7.doc.

85. Although Article 66.2 does not explicitly state that the technology that developed countries must encourage their private sectors to transfer should be patented technology, this is implicit in its being an article within TRIPS, which is an agreement about intellectual property. This implication is strongly reinforced in the Doha Declaration on the TRIPS Agreement and Public Health, which created the obligation for developed countries to file reports on their compliance with Article 66.2, and which explicitly reminds countries that "each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement." WT 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>.

86. TRIPS, *supra* note 42, art. 66.2.

Development, the AATF was established specifically to identify and facilitate the royalty-free transfer of proprietary technologies that meet the needs of resource-poor African farmers in ways that address and resolve the concerns of technology providers, including concerns related to intellectual property, protection of commercially important markets, and liability.⁸⁷ The United States could develop an agenda of concrete actions to encourage and support the transfer of technology from U.S.-based technology owners to those who can make good use of it for developing country food-security purposes, through AATF and similar organizations.

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

CONCLUSION

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

There is also an increasing recognition in the U.S. media

87. The African Agricultural Technology Foundation, *Who We Are*, at <http://www.afttechfound.org/who.php> (last visited Sept. 8, 2004).

and policy circles that a wide range of U.S. policies affects the efforts of developing countries to address food security and other basic development problems. These include U.S. agricultural and trade policies, development assistance and food aid policies, and the approaches the United States takes in the international arena to address trade and other development-related policy issues.

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