Symposium Introduction*

Intellectual Property Rights for the Public Good: Obligations of U.S. Universities to Developing Countries

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I. BACKGROUND

According to the recent National Research Council report entitled "A Patent System for the 21st Century," "the patent system, like other important innovation policy tools, merits periodic examination to help ensure the vitality of the national innovation system."[1] Universities must ensure that their participation in the patent system does not cause a "social disservice." This symposium, "Intellectual Property Rights for the Public Good: Obligations of U.S. Universities to Developing

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1. NATIONAL RESEARCH COUNCIL OF THE NATIONAL ACADEMIES, A PATENT SYSTEM FOR THE 21ST CENTURY 19 (Stephen A. Merrill, et al. eds., 2004).

Countries,"[2] seeks to achieve the following goals:

(1) To better understand the forms of intellectual property rights.

(2) To identify limitations that intellectual property places on technology transfer.

(3) To facilitate the sharing of patented technologies for humanitarian reasons.

(4) To evaluate the role of American universities in delivering new technologies and products to developing nations.[3]

My interest in sponsoring such a symposium was spurred by a 2001 visit to the International Rice Research Institute (IRRI) in the Philippines as a Scientific Liaison Officer for the U.S. Agency for International Development. After my arrival, I heard the exciting news: scientists Ingo Potrykus from Switzerland and Peter Beyer from Germany were flying in the next day with "golden rice" germplasm. The event was even more exciting because I had known Ingo Potrykus as a fellow scientist for many years. What a thrill it was to be on site when the seed was handed over to one of the best international research institutes. To think that the vitamin A deficiency, a problem that causes blindness in 500,000 children every year and malnutrition of millions of adults, could be reversed in the future by simply changing the variety of rice in their diet.[4] Yet it took a year and a half to present golden rice to IRRI. The technology underlying its development was divided between seventy patents held by thirty-two organizations. Ever since that day, I've thought, "What about the next product—one that has the potential of benefiting 800 million malnourished people who live on less than a dollar a day and often cannot afford proper diets?"

A later event honed my interest in this topic. I attended the meeting at the Donald Danforth Plant Science Center in St.

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2. *See generally Intellectual Property Rights for the Common Good: Obligations of U.S. Universities to Developing Countries*, Consortium on Law and Values in Health, Environment & the Life Sciences, http://www.lifesci.consortium.umn.edu/conferences/ip.php.

3. *See id*.

4. Golden rice has the potential to reduce much of the blindness that is so prevalent in poor, rice-dependent countries. *See* Kristen Hessler, et al., *Golden Rice*, *in* LIFE SCIENCE ETHICS 307, 307-10, 358-68 (Gary L. Comstock ed., 2002); Mark Chong, *Acceptance of Golden Rice in the Philippine 'Rice Bowl'*, 21 NATURE BIOTECHNOLOGY 971, 971 (2003).

Louis, Missouri at which the Board of Directors adopted a policy on conditioning intellectual property rights on fulfilling humanitarian purposes. The policy called for the Danforth Center to attempt to negotiate the terms of a worldwide license, the goal of which would be to make intellectual property available for meeting the needs of developing countries.[5] An editorial by Roger Beachy[6] and a "Policy Forum"[7] piece in *Science* magazine encouraged all academic and not-for-profit research institutions to include similar terms in licensing agreements pertaining to technologies with potential benefits for poor and developing countries.

Finally, the serious doubt cast on the "research exemption" by the *Madey v. Duke University*[8] decision threatens to expose university research programs to allegations of patent infringement. The United States Patent Office issues approximately 710 patents every working day (170,000 per year) from among 360,000 applications per year.[9]

II. AGRICULTURE AS A FOCUS

This symposium examines issues affecting universities, especially issues concerning intellectual property and technology transfer. The fate of the developing world clearly hinges on a life-saving technology or product that is beyond the financial reach of the poorest of the poor. One example involving the University of Minnesota is the anti-HIV/AIDS drug, Ziagen.[10] There is a critical need for a clear-cut set of guidelines defining relationships among educational institutions, industry, and developing countries. This

5. *See* Press Release, Donald Danforth Plant Science Center, Danforth Center Joins With Leading Public Sector Research Institutions In New Effort To Make Patented Agricultural Technologies More Widely Available To Improve Farm Productivity and Fight Global Hunger (Jul. 11, 2003), *available at* http://www.danforthcenter.org/newsmedia/NewsDetail.asp?nid=88.

6. Roger N. Beachy, *IP Policies and Serving the Public*, 299 SCIENCE 473 (2003).

7. Richard C. Atkinson et al., *Public Sector Collaboration for Agricultural IP Management*, 301 SCIENCE 174 (2003).

8. 307 F.3d 1351 (Fed. Cir. 2002), *cert. denied*, 123 539 U.S. 958 (2003).

9. *See* U.S. Patent and Trademark Office, *U.S. Patent Statistics: Calendar Years 1963 - 2003*, *available at* http://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.pdf (last visited Nov. 1, 2003).

10. *See* Letter from Zackie Achmat et al., Officers, The Treatment Action Campaign, to Mark Yudof, President, University of Minnesota (Apr. 3, 2001), *available at* http://lists.essential.org/pipermail/ip-health/2001-April/001169.html (last visited Oct. 28, 2004).

symposium discusses how intellectual property affects efforts to facilitate access in the developing world to technologies developed at universities. Land-grant universities warrant especially close attention.

As the key to global food security and economic development in the world's poorest countries, agriculture serves as the focus of this symposium. In this journal, several emerging issues in agriculture, including the ability to feed the world, were reviewed to reveal and examine the salient points. Prominent scholars in agricultural science, intellectual property, and research policy presented informed views of the situation, and a final panel discussion focused on future pathways for research and technology transfer.

III. PUBLIC GOODS AND INTERNATIONAL COLLABORATION

International collaboration and cooperation are essential in developing new technology for food and agriculture. American participation has historically hinged upon this country's foreign aid program, which has reflected a particular bias, both among countries and in subject matter. The focus for the future should fall on truly collaborative arrangements that serve the interests of developing countries and the United States alike, including the academic community.

The mission of public universities, especially land-grant institutions, is to provide education, research, and outreach for the common good. Easy public access to university services is a key feature of the successful relationship between public needs and the university. Domestic and international agriculture has benefited dramatically from the university-public alliance. New crop varieties, a myriad of production practices, new approaches to economics and marketing, food processing techniques, and many other aspects of the food industry have resulted from freely available genetic resources and technological innovations. Agribusinesses have benefited over the years from these university-developed resources. In recent years, corporations developing new chemicals for use in agriculture have begun to recognize limitations of that technology and to view biotechnology as a way to chart a more environmentally desirable course for agriculture. The expanded ability to patent new technologies and living materials has enabled agribusinesses to incorporate new and expensive technology into their portfolios. At the same time,

the Bayh-Dole Act[11] has enabled universities to reap financial benefits from generating intellectual property and facilitating technology transfer.

The flurry of patent activity in agriculture has generated a complex web of intellectual property rights. The resulting restrictions on access and increases in cost have limited the number of organizations that can utilize these useful technologies. Developing countries lack the infrastructure needed for further technological development and the necessary capital to license or purchase products. If these countries are priced out of the market, how can they procure promising technologies and products? Universities need to develop enabling policies that will facilitate the sharing of research tools and products to serve humanitarian needs.

IV. NEW APPROACHES NEEDED

Peter Beyer and Ingo Potrykus confronted these issues when their research groups developed golden rice. Their successful genomics research produced rice that contains B-carotene, or pro-vitamin A, which promises to reduce significantly the prevalence of blindness in certain rice-dependent countries.[12] Because the technology underlying golden rice is divided among seventy patents held by thirty-two organizations, distribution of this modified rice seed to the IRRI was delayed at least one and a half years.[13] With the help of Syngenta Corporation and the development of a humanitarian board, Beyer and Potrykus were finally able to make these materials available.[14] Even though legal barriers to the availability of golden rice have been overcome, this episode exposed potential pitfalls of intellectual property. Unfortunately, this incident did not generate policies to facilitate the sharing of patented technologies with developing nations for humanitarian reasons.[15]

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11. 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").

12. *See* Quirin Schiermeier, *Designer Rice to Combat Diet Deficiencies Makes Its Debut*, 409 NATURE 551 (2001).

13. *See id.*

14. *See id.*

15. On the genetic engineering of golden rice to express beta carotene, a precursor of vitamin A, see generally Ingo Potrykus, *Golden Rice and Beyond*, 125 PLANT PHYSIOLOGY 1157, 1157-58 (2001). On one of the earlier steps in the transfer of golden rice to IRRI, see generally Dennis Normile, *Monsanto*

A number of groups are beginning to address this problem. The Rockefeller and McKnight foundations have recognized the constraints intellectual property imposes on the developing world. To advance international dialogue and to provide guidance to scientists, these foundations have formed the Public Intellectual Property Resource for Agriculture (PIPRA).[16] PIPRA has gathered data on licensing practices, developed a database on intellectual property held by the public sector, and fashioned new programs to expedite the development of new technologies.[17] The presidents or chancellors of six major American universities, the presidents of the McKnight and Rockefeller Foundations, and the president of the Donald Danforth Plant Science Center signed a "Policy Forum" piece in *Science* magazine highlighting concern over this topic.[18]

A second initiative of the Rockefeller Foundation focuses on sub-Saharan Africa and provides a mechanism to shift the liability arising from the use of patented technology from the donor organization to the newly formed African Agricultural Technology Foundation.[19]

The Donald Danforth Plant Science Center's policy of conditioning intellectual property rights on fulfilling humanitarian purposes preserves the availability of technology that meets the needs of developing countries. Roger Beachy, president of the Donald Danforth Plant Science Center, has urged "all academic and not-for-profit research institutions, in particular those engaged in biological research, to include similar terms as they negotiate licensing agreements pertaining to technologies with potential benefits for poor and developing countries."[20] Although Dr. Beachy does acknowledge the "modest financial cost of taking such a position," he argues that "the potential benefits in terms of regaining public trust, and ultimately of deploying technologies

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Donates Its Share of Golden Rice, 289 SCIENCE 843, 843 (2000).

16. For background information on PIPRA, see generally Public Intellectual Property Resource for Agriculture, *available at* http://www.pipra.org (last visited Nov. 1, 2004).

17. *See Activities*, Public Intellectual Property Resource for Agriculture, *available at* http://www.pipra.org/activities.php (last visited Nov. 1, 2004).

18. *See* Atkinson, *supra* note 7, at 174.

19. *See generally* African Agricultural Technology Foundation (providing background information on the foundation), *available at* www.aftechfound.org (last visited Nov. 1, 2004).

20. Beachy, *supra* note 6 at 473.

where they may be needed most, far outweigh the financial or opportunity costs."[21]

V. IMPACT AND OUTCOMES

Universities regularly face the problem of how to make important and life-saving discoveries widely available. Rather than simply review recent developments, the papers published in this symposium bring fresh perspectives on issues of intellectual property relating to developing countries. What is the scope of the problem? What are the underlying scientific, legal, and ethical concerns? How can we cooperate and collaborate with developing countries to develop healthy policies with regard to intellectual property? This discussion should help us to resolve those critical issues. It should reveal the ways in which universities can develop intellectual property policies that further a humanitarian cause.

VI. POINTS TO CONSIDER

Intellectual property can take many forms, each with its special purpose and requirements. Forms of intellectual property include utility patents, plant variety protection, trademarks, copyrights, and contracts such as material transfer agreements. The availability of such property represents an effective system for encouraging innovation. These legal constructs, however, do not preclude segmenting the market for humanitarian use.

A number of limitations on the transfer of technology are inherent within an intellectual property rights paradigm. Those limits on technology transfer include the status of the research exception, transaction costs associated with obtaining and maintaining control (known as "stewardship"), and the defensive retention of intellectual property. Corporate mergers are often prompted by the strong desire to acquire patents. The resulting licensing arrangements may cause certain inventions to sit on the shelf. The value of patenting is best determined by a risk-benefit analysis, and universities will be obliged to take risks as they actively patent their inventions. And it is clear that universities will need to commit more funding to technology transfer as patent activity continues to increase. At the same time, the public sector must be involved in producing

21. *Id.*

and distributing public goods, especially for developing countries. Many factors beyond intellectual property make it more complicated to produce public goods. For example, the Convention on Biological Diversity has changed germplasm from a global public good to national property.[22] Genetic pedigrees of new crop varieties trace back to so many entities that it is difficult to achieve fair protection for all contributors. The conflict between current intellectual property policies and the furtherance of humanitarian goals is manifest. For that reason, it is imperative that policies be developed which make it easier to share patented technologies for humanitarian reasons.[23]

One example of a policy designed to further a humanitarian goal is a proposal by the Resources for the Future (RFF) organization.[24] RFF has proposed compulsory licensing of patented technologies that have not been transferred after a specific period of time (such as three years), so that the technologies can be used for humanitarian purposes.[25]

VII. THE BOTTOM LINE

The public sector should adopt policies that facilitate technology transfer to developing countries. Since the public sector currently holds twenty four percent of the agricultural biotechnology patents[26] despite holding less than three percent of all patents[27], universities have a unique opportunity to assist developing countries. Universities need to better assess freedom-to-operate issues and to understand how the expiration of key patents will affect the transfer of technology

22. *See* United Nations Conference on Environment and Development: Convention on Biological Diversity, June 5, 1992, 31 I.L.M. 818 (1992), *available at* http://www.biodiv.org/doc/legal/cbd-en.pdf.

23. Michael R. Taylor, *Biotechnology Patents and African Food Security: Aligning America's Patent Policies and International Development Interests*, 6 MINN. J.L. SCI. & TECH. (forthcoming 2004).

24. *See generally* Resources for the Future, *available at* http://www.rff.org (last visited Oct. 20, 2004).

25. Michael R. Taylor & Jerry Cayford, *The U.S. Patent System and Developing Country Access to Biotechnology: Does the Balance Need Adjusting?* 60-61 (2002), *available at* http://www.rff.org/rff/Documents/RFF-DP-02-51.pdf (last visited Nov. 14, 2004).

26. *See id.* at 8.

27. Ronald L. Phillips, et al., *Intellectual Property Rights and the Public Good*, 18 THE SCIENTIST 8 (Jul. 19, 2004).

to developing countries. It is vital that institutional capacity in developing countries, particularly in Africa, be constructed because the resultant scientific expertise has the potential to benefit so many people suffering from poverty and malnourishment. The recent trend of providing free scientific journals to developing countries is a major step forward. The Proceedings of the National Academy of Sciences, for example, can now be accessed for free online in the more than 140 countries struggling to develop their scientific infrastructure.[28] By the end of 2004, articles from the first volume in 1915 to those published six months ago will be available at no charge.[29]

Market-based commodities do not always serve the poor and marginalized. Raising patentability standards, increasing the availability of research tools, establishing a broad research exemption, adopting specialized licensing policies to the public sector, and focusing on stewardship of intellectual property are all pressing issues. There is also concern that the increased emphasis on intellectual property at universities, with unequal distributions of royalty streams, will reduce public support for higher education and may spark divisiveness and disagreement within the academy.[30] Public institutions must ensure that intellectual property does not skew the university mission and public sector intellectual property policies should include humanitarian considerations.

28. Nicholas R. Cozzarelli, et al., *PNAS Gives Free Online Access to Developing Countries*, 99 PNAS 5751, 5751 (Nov. 14, 2004), *available at* http://www.pnas.org/cgi/reprint/99/9/5751.pdf; Frequently Asked Questions About PNAS Online, *at* http://www.pnas.org/misc/faq.shtml#developing (last visited Nov. 1, 2004).

29. Nicholas R. Cozzarelli, *An Open Access Option for PNAS*, 101 PNAS 8509, 8509 (June 8, 2004), *available at* http://www.pnas.org/cgi/reprint/101/23/8509.pdf.

30. G. Edward Schuh, *Is Intellectual Property Impeding the Achievement of Land-grant University Goals?* 6 MINN. J.L. SCI. & TECH. (forthcoming 2004).