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The Bayh-Dole Act and Incentives for the Commercialization of Government-Funded Invention in Developing Countries

Michael S. Mireles Jr.
University of the Pacific, mmireles@pacific.edu

THE BAYH-DOLE ACT AND INCENTIVES FOR THE COMMERCIALIZATION OF GOVERNMENT-FUNDED INVENTION IN DEVELOPING COUNTRIES

Michael S. Mireles*

I. INTRODUCTION

Numerous developing and developed countries are considering adopting or have adopted legislation similar to the U.S. Bayh-Dole Act.[1] Enacted in 1980, the Bayh-Dole Act attempts to provide incentives for potential participants in the creation and development of government-funded technology to commercialize that technology.[2] The Act has been controversial, and whether developing and developed countries that enact similar legislation will realize the same purported impact the Act has had in the United States is questionable. This article provides an analysis of some of the provisions of the Act in light of its alleged effects in the United States since its enactment and offers some suggestions for modification of the Act for developing countries.[3] This paper also proposes that

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[1] Bayh-Dole University and Small Business Patent Procedures Act, Pub. L. No. 96-517, 94 Stat. 3015 (1980) (codified as amended at 35 U.S.C. §§ 200-212 (2000)).

[2] *See* 35 U.S.C. § 200 (identifying the statute's policy and objective).

[3] There is no universal definition of what constitutes a "developed" or "developing" country, even though those terms are used within the World Trade Organization (WTO) system. *See* Sungjoon Cho, *The WTO's Gemeinschaft*, 56 ALA. L. REV. 483, 487 n.18 (2004) ("There is no official definition of 'developing countries.'"); Leah Granger, *Explaining the Broad-Based Support for WTO Adjudication*, 24 BERKELEY J. INT'L L. 521, 521 n.3 (2006) ("There is no universally accepted definition for a 'developing' or 'developed' country, and this is a very rough division. Developing countries are a diverse group, varying in physical size, population, and resources."); Doris Estelle Long, *"Democratizing" Globalization: Practicing the Policies of Cultural Inclusion*, 10 CARDOZO J. INT'L & COMP. L. 217, 222 n.13 (2002) ("Admittedly, the terms 'developed' and 'developing' lack clear definitions and suffer from being both over- and under-inclusive."); Eugenia McGill, *Poverty and Social Analysis of Trade Agreements: A More Coherent Approach?*, 27 B.C. INT'L & COMP. L. REV. 371, 373 n.2 (2004) ("Classifications of countries as 'developed,' 'developing,' and 'least developed' are similarly contested and fluid and can vary from one context to another."); World Trade Organization, Who are the developing countries in the WTO?, http://www.wto.org/english/tratop_e/devel_e/d1who_e.htm [hereinafter WTO Developing Countries] ("There are no WTO definitions of 'developed' and 'developing' countries.") (last visited Dec. 27, 2007). In fact, countries within the WTO may designate themselves as developing and other countries may challenge that designation. *See* Cho, *supra*, at 487 n.18 ("Countries often declare themselves to be developing countries, in which case other countries can challenge that declaration. Within the WTO system, developing countries are treated more favorably than developed countries under certain circumstances."); WTO Developing Countries, ("Members announce for themselves whether they are 'developed' or 'developing' countries. However, other members can challenge the decision of a member to make use of provisions available to developing countries."). An additional category, "least developed country," has been created by the United Nations and is also used by the WTO. *See* Cho, *supra*, at 487 n.18 ("In the case of Least

the adoption of the Act in developing countries could lead to an increased focus on commercializing technology directed to the local needs of developing countries. However, enactment of similar legislation in a developing country is unlikely to have the same purported impact on a similar scale in that developing country as the Bayh-Dole Act has had in the United States—substantially increased patenting and licensing and other related economic activity.

Commentators in the United States have been debating the merits of the Bayh-Dole Act, which allows recipients of government funding to take title to inventions developed with that funding, and its purported consequences since the Act's inception. Some argue that the Act has a deleterious impact on the creation, direction and dissemination of basic scientific research, particularly in the biotechnology field,[4] and that it facilitates the development of conflicts of

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Developed Countries (LDCs), the UN officially designated 50 countries as the LDCs."); World Trade Organization, Least-developed countries, http://www.wto.org/english/thewto_e/whatis_e/tif_e/org7_e.htm (identifying the thirty-two designated LDCs that are WTO members) (last visited Dec. 27, 2007); UN Office of the High Representative for the Least Developed Countries, Landlocked Developing Countries and Small Island Developing States, http://www.unohrlls.org/ [hereinafter UN Office for LDCs] (last visited Dec. 27, 2007). The criteria for LDC status includes:

> a low-income criterion, based on a three-year average estimate of the gross national income (GNI) per capita (under $745 for inclusion, above $900 for graduation);
> a human capital status criterion, involving a composite Human Assets Index (HAI) based on indicators of: (a) nutrition . . . ; (b) health . . . ; (c) education . . . ; and (d) adult literacy rate; and an economic vulnerability criterion, involving a composite Economic Vulnerability Index (EVI) based on indicators of: (a) population size; (b) remoteness; (c) merchandise export concentration; (d) share of agriculture, forestry and fisheries in gross domestic product; (e) homelessness owing to natural disasters; (f) instability of agricultural production; and (g) instability of exports of goods and services.
> To be added to the list, a country must satisfy all three criteria. In addition, since the fundamental meaning of the LDC category, i.e. the recognition of structural handicaps, excludes large economies, the population must not exceed 75 million. To become eligible for graduation, a country must reach threshold levels for graduation for at least two of the aforementioned three criteria, or its GNI per capita must exceed at least twice the threshold level, and the likelihood that the level of GNI per capita is sustainable must be deemed high.

UN Office for LDCs, Least Developed Countries: Criteria for identification of LDCs, http://www.unohrlls.org/en/ldc/related/59/ (last visited Dec. 27, 2007).

In this article, the term "developed countries" includes the United States, European Union countries, Japan, South Korea, Canada, and Australia. It is the author's belief that countries designated as "least developed countries" by the United Nations may receive little benefit from the passage of legislation similar to the Bayh-Dole Act. Though those countries that are not developed and are not categorized as "least developed" by the United Nations may receive some benefit from legislation similar to the Bayh-Dole Act, generalizations are difficult to make because of the diversity among those countries in terms of size, resources, and political stability.

[4] See Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698 (1998).

interest, which may impact public health.[5] Thus far, there is insufficient and somewhat conflicting empirical evidence of whether a tragedy of the anticommons—the inability to aggregate the patents covering various technologies needed to develop a product or process—exists in the biotechnology sector.[6] Some posit that the Federal Circuit's decision in *Madey v. Duke University*,[7] which narrowly interprets the common law experimental use exception to patent infringement, may contribute to the development of an anticommons.[8] There is also conflicting empirical evidence on whether the Bayh-Dole Act has affected the direction of academic research from basic to applied science. However, some specific examples of conflicts of interest have arisen, which cause concern about the effect the Act has had on the integrity of academic research. Supporters of the Act point to an upswing in universities' patenting and licensing government-funded inventions, along with other related economic activity (such as the creation of new companies and jobs) since passage of the Act.[9] Others argue that those effects would have occurred without passage

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[5] See Michael S. Mireles, *States as Innovation System Laboratories: California, Patents, and Stem Cell Technology*, 28 CARDOZO L. REV. 1133, 1174 (2006); Joshua B. Powers, *Between Lab Bench and Marketplace: The Pitfalls of Technology Transfer*, CHRON. HIGHER EDUC., Sept. 22, 2006, at B18; DEREK BOK, UNIVERSITIES IN THE MARKETPLACE: THE COMMERCIALIZATION OF HIGHER EDUCATION 215 (2003).

[6] *See, e.g.*, Charles McManis & Sucheol Noh, Impact of the Bayh-Dole Act on Genetic Research and Development: The Empirical Evidence to Date (reviewing empirical evidence concerning anticommons) (unpublished manuscript, on file with author); STEPHEN HANSEN ET AL., THE EFFECTS OF PATENTING IN THE AAAS SCIENTIFIC COMMUNITY 7 (2006), *available at* http://sippi.aaas.org/survey/AAAS_IP_Survey_Report.pdf [hereinafter AAAS REPORT] (last visited Dec. 27, 2007); NAT'L INSTITUTES OF HEALTH, REPORT OF THE NATIONAL INSTITUTES OF HEALTH (NIH) WORKING GROUP ON RESEARCH TOOLS (1998), *available at* http://www.nih.gov/news/researchtools/ (last visited Dec. 27, 2007); NAT'L RESEARCH COUNCIL, REAPING THE BENEFITS OF GENOMIC AND PROTEOMIC RESEARCH: INTELLECTUAL PROPERTY RIGHTS, INNOVATION, AND PUBLIC HEALTH (2006) [hereinafter REAPING THE BENEFITS]; John P. Walsh et al., *Effects of Research Tool Patents and Licensing on Biomedical Innovation*, *in* PATENTS IN THE KNOWLEDGE-BASED ECONOMY 285 (Wesley M. Cohen & Stephen A. Merrill eds., Nat'l Research Council 2003); Fiona Murray & Scott Stern, *Do Formal Intellectual Property Rights Hinder the Free Flow of Scientific Knowledge? An Empirical Test of the Anti-Commons Hypothesis* 6 (Nat'l Bureau of Econ. Research, Working Paper No. 11465, 2005), *available at* http://www.nber.org/papers/w11465 (last visited Dec. 27, 2007); Bhaven N. Sampat, *Genomic Patenting by Academic Researchers: Bad for Science?* 5-6 (2004), http://mgt.gatech.edu/news_room/news/2004/reer/files/sampat.pdf.

[7] 307 F.3d 1351 (Fed. Cir. 2002).

[8] REAPING THE BENEFITS, *supra* note 6; *see also* FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY 35 (2003), *available at* http://www.ftc.gov/os/2003/10/innovationrpt.pdf ("[T]he . . . [Madey decision] could unsettle expectations regarding the availability of an experimental use defense and could have a chilling effect on university research.").

[9] *See* W. Mark Howell, *Message from the President* in ASS'N OF UNIV. TECHNOLOGY MANAGERS, AUTM U.S. LICENSING SURVEY: FY 2004 (2005), *available at* http://www.autm.net/events/File/04AUTMSurveySum-USpublic.pdf (last visited Dec. 27, 2007);

of the Act.[10] At least one commentator argues that the fundamental decision to allow universities to take title to government-funded inventions was a mistake because of the subsequent mismanagement of government funding and abuse of licensing position and income by universities.[11]

Notwithstanding these debates and the lack of conclusive empirical evidence concerning the impact of the Act, other countries, developed and developing, are considering adopting legislation similar to the Bayh-Dole Act in order to achieve the same purported benefits of the Act.[12] Some commentators have argued that the Bayh-Dole Act may not achieve the same purported level of success—success defined as increased patenting and licensing of government-funded inventions and related economic activity—in developed, Organisation of Economic Co-operation and Development [OECD] countries for several reasons. Those reasons focus on the existence of factors in the United States not always present in other developed countries: the close link between universities and the private sector; the structure and scale of the university system; the existence of technology transfer offices well before the passage of the Act; and the presence of the demand from industry for technology transfer because of "venture capital, labor mobility between university and industry, large scale public funding for biomedical research, competition between universities for faculty and research money, lack of central government control and administrative autonomy of universities in addition to a comprehensive patent system."[13] In a recent essay, I

U.S. DEP'T OF COMMERCE, THE ADVANCED TECHNOLOGY PROGRAM: REFORM WITH A PURPOSE 11 (2002), *available at* http://www.atp.nist.gov/secy_rept/report.pdf (last visited Dec. 27, 2007).

[10] DAVID C. MOWERY ET AL., IVORY TOWER AND INDUSTRIAL INNOVATION: UNIVERSITY-INDUSTRY TECHNOLOGY TRANSFER BEFORE AND AFTER THE BAYH-DOLE ACT 1 (2004).

[11] Lorelei Ritchie de Larena, *The Price of Progress: Are Universities Adding to the Cost?*, 43 HOUS. L. REV. 1373, 1390-91 (2007).

[12] See Michael S. Mireles, *Adoption of the Bayh-Dole Act in Developed Countries: Added Pressure for a Broad Research Exemption in the United States?*, 59 ME. L. REV. 259 (2007); Ken Howard, *Global Biotech Expansion Taking Cues from Bayh-Dole*, 22 NATURE BIOTECH. 919 (2004). South Africa, Malaysia, and the Philippines are considering or have adopted legislation similar to the Bayh-Dole Act. *See* Chris Bull, *Managing Intellectual Assets at Universities: The South African Government is Considering the Introduction of Legislation Similar to the US Bayh-Dole Act Governing IP Arising from University R&D*, MANAGING INTELL. PROP., Apr. 1, 2005, *available at* http://www.accessmylibrary.com/coms2/summary_0286-6541410_ITM (last visited Dec. 28, 2007); *South Africa: Should SA Follow US Lead on Patent Laws?*, AFRICA NEWS, Jan. 13, 2004; *Local Scientists Hope to Reap Benefits via New Research Law*, MALAYSIA ECON. NEWS, Oct. 29 2004.

[13] Howard, *supra* note 12, at 919-20; *see also* David C. Mowery & Bhaven N. Sampat, *The Bayh-Dole Act of 1980 and University-Industry Technology Transfer: A Model for Other OECD Governments?*, 30 J. TECH. TRANSFER 115, 118-19 (2005) (identifying the unique structure of the U.S. higher educational system and its effect on academic patenting). For additional discussion of differences between market structure and other factors in the United States and other developed countries, *see* Michael R. Darby & Lynne G. Zucker, *Star Scientists, Institutions, and the Entry of Japanese Biotechnology Enterprises* (Nat'l Bureau of Econ. Research, Working Paper No. 5795, 1996), *available at* http://www.nber.org/papers/w5795 (last visited Dec. 28, 2007) ("Some authors have also specifically discussed the various differences between the United States and Japanese systems concerning 'higher education and research funding, the venture-capital and IPO markets, cultural characteristics and incentive systems which impact scientists' entrepreneurialism, and tort-

described how OECD countries are attempting to address some of those issues in order to improve the rate of commercialization of government-funded inventions and to encourage related economic activity by attempting to facilitate collaborations between industry and universities, changing university structure and incentives for researchers, and providing venture capital support.[14] I propose that OECD countries will achieve some level of success in the form of increased patenting and licensing of government-funded inventions, which may result in pressure on the United States for the adoption of a more robust experimental use exception.[15] Negative consequences of the Act in the form of the development of an anticommons may be avoided in some OECD countries because of the presence of an experimental use exception to patent infringement that is broader than its counterpart in the United States.[16]

The chance for success of legislation similar to the Bayh-Dole Act in developing countries seems to be bleak, particularly considering that similar success may not occur in developed countries that have access to far more resources than developing countries. In addition to the lack of a history of technology transfer and collaboration between industry and academia, a similar scale of university systems, and analogous mobility among personnel between universities and industry, developing countries may also not have access to other resources necessary to establish a successful innovation system that utilizes legislation similar to the Bayh-Dole Act to encourage commercialization. An innovation system that includes a grant of title to a government-funded invention, as the Bayh-Dole Act is premised upon, likely requires at least a substantial level of government funding to support research and development; a well-established and functioning patent system; qualified technology transfer personnel and researchers; favorable corporate formation, initial public offerings, and competition laws; and ample venture capital. The presence of these factors may be fundamental to the success of an innovation system predicated on capturing the supposed benefits of a Bayh-Dole scheme, although it is very difficult to make generalizations about developing countries at various levels of economic growth and political stability.[17] This article first provides some lessons from the

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liability exposures.'"); ANNA S. NILSSON ET AL., COMMERCIALIZATION OF LIFE-SCIENCE RESEARCH AT UNIVERSITIES IN THE UNITED STATES, JAPAN AND CHINA 27 (2006), *available at* http://www.itps.se/Archive/Documents/Swedish/Publikationer/Rapporter/Allmänna/A2006/A2006_006%20webb.pdf (last visited Dec. 28, 2007) ("Japanese pharmaceutical companies tend to do more in-house basic research and to a lesser extent rely on alliances with biotechnology companies or universities" than their European or U.S. counterparts); and Thomas J. Siepmann, *The Global Exportation of the U.S. Bayh-Dole Act*, 30 U. DAYTON L. REV. 209, 218 (2004) (indicating that European researchers may be more risk adverse in commercializing research because of the small number of positions in European universities and that there may be a greater incentive in the United States to commercialize because of the lack of government price controls on pharmaceuticals).

[14] Mireles, *supra* note 12, at 265.

[15] *Id.* at 273-76.

[16] *Id.*

[17] Some additional impediments to the success of legislation similar to the Bayh-Dole Act in developing countries could include corruption, conflicts of interest, the lack of a contracting culture and negotiation skills, the lack of markets within the developing country, and the lack of interest in commercialization.

United States experience with the Bayh-Dole Act and proposes some suggestions for change based on those lessons. It then sets forth one possible consequence to developing countries of passage and implementation of legislation similar to the Bayh-Dole Act.

II. THE BAYH-DOLE ACT AND ITS PURPORTED CONSEQUENCES: LESSONS FOR DEVELOPING COUNTRIES

Commentators have provided suggestions for reform of the Bayh-Dole Act based on its purported impact on biotechnology innovation. Commentators have also proposed reform to general patent law principles, in part in response to the Bayh-Dole Act's impact. One timely and excellent article by Sara Boettiger and Alan Bennett examines the possible implications for developing countries of the adoption of the Bayh-Dole Act in the United States and also the possible ramifications of the adoption of legislation similar to the Bayh-Dole Act in developing countries.[18] This paper discusses and analyzes that paper, along with other scholarship concerning the impact of the Act and proposals for its reform, including best practices for licensing government-funded technology.

A. The Bayh-Dole Act

The Bayh-Dole Act provides incentives for parties to engage in the commercialization of government-funded research. The primary incentive provided by Bayh-Dole is the ability of grant recipients, usually universities, to take title to government-funded inventions, subject to certain conditions.[19] Some of these conditions on obtaining title to government-funded inventions include accepting reporting requirements, a grant-back license, and march-in rights.[20] The Act gives inventors an incentive to disclose patentable inventions through the possibility that they will receive some royalties from the successful license of patented technology.[21] This prospect of royalties also gives inventors an incentive to continue to work on commercializing the technology with industry. The Act's implementing regulations require that the university develop a policy to encourage disclosure of patentable inventions by its researchers.[22] The university has an incentive to create and monitor that policy and facilitate

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[18] Sara Boettiger & Alan Bennett, *The Bayh-Dole Act: Implications for Developing Countries*, 46 IDEA 261 (2006).

[19] COUNCIL ON GOVERNMENTAL RELATIONS, UNIVERSITY TECHNOLOGY TRANSFER, QUESTIONS AND ANSWERS 1 (1996), *available at* http://206.151.87.67/docs/bayhdoleqa.htm (last visited Jan. 4, 2008). "When a university elects title to an invention, it assumes responsibility for taking certain actions to properly manage the invention." University of California Technology Transfer, The Bayh-Dole Act, A Guide to the Law and Implementing Regulations, http://www.ucop.edu/ott/faculty/bayh.html (last visited Jan. 4, 2008).

[20] ALINE C. FLOWER, INTELLECTUAL PROPERTY TECHNOLOGY TRANSFER 17-18 (2006) (citing 37 C.F.R. § 401.14(f)(2) (2005)).

[21] *See id.* at 19-20.

[22] *Id.*

licensing of patentable inventions because of the opportunity to recover licensing fees and royalties. The university is also likely the party best positioned to front patent prosecution costs, as an inventor is unlikely to have the resources (although the licensee of government-funded technology tends to reimburse the university for costs expended).[23] The market actor/licensee has an incentive to obtain technology that has been developed through government funding because it may be able to acquire technology, including a possible exclusive license, without having to invest in the creation of that technology. The Bayh-Dole Act eliminated the ability of individual government grantor entities to develop their own policy for the ownership of government-funded technology and provided a uniform policy for the treatment of that technology.[24]

The basic provisions creating these incentives are likely to be adopted by developing countries that adopt legislation similar to the Bayh-Dole Act. Some provisions that may be modified by developing countries include a research exemption to increase access to government-funded inventions, expanded and specific march-in rights, and the right to a royalty stream to the government that is providing the funding. Other issues include the adoption of mandatory licensing best practices, which may be included in the developing country Bayh-Dole Act legislation, and structuring technology transfer offices as regional or national offices instead of having institutional offices. Still other concerns include attempts to learn from and avoid the possible negative impacts of the Bayh-Dole Act seen in the United States, such as the effect of the Act on the direction and dissemination of research and the creation of conflicts of interest in academia. Some of these concerns are addressed by Sara Boettiger and Alan Bennett's article and the work of other commentators, which are reviewed and analyzed below.

B. Lessons from the Bayh-Dole Act and Its Purported Impact

This section reviews and analyzes issues concerning access to government-funded technology that have arisen since passage of the Bayh-Dole Act in the United States, and potential issues that may develop because of the adoption of similar legislation in other developed countries and in developing countries. This section also analyzes the question of whether developing countries should adopt national, regional or institutional technology offices or some combination, and

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[23] *See* INTELLECTUAL PROPERTY STUDY GROUP, CALIFORNIA COUNCIL ON SCIENCE AND TECHNOLOGY, POLICY FRAMEWORK FOR INTELLECTUAL PROPERTY DERIVED FROM STEM CELL RESEARCH IN CALIFORNIA: INTERIM REPORT TO THE CALIFORNIA LEGISLATURE, GOVERNOR OF THE STATE OF CALIFORNIA, CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE 10 (2005), *available at* http://www.ccst.us/publications/2005/IPinterim.pdf (last visited Jan. 4, 2008) [hereinafter CCST INTERIM REPORT] (suggesting that California should adopt Bayh-Dole Act policies which place patenting costs with the entity most likely able to bear them).

[24] *See The University and Small Business Patent Procedures Act: Hearing on S. 414 Before the S. Comm. on the Judiciary*, 96th Cong. 2 (1979) (statement of Sen. Birch Bayh); *id.* at 30 (statement of Sen. Robert Dole); *id.* at 33 (statement of Sen. Orrin G. Hatch).

other issues related to technology transfer that may impact the success of legislation similar to the Bayh-Dole Act in developing countries.

1. Access to Government-Funded Technology

Some of the most controversial issues concerning the Bayh-Dole Act include access to government-funded technology by third parties who either need to access the technology to continue to innovate and create a product, or require the technology for an end use purpose such as use of the technology to treat a disease (which may include access to a pharmaceutical that has been developed in part with government funding or with technology created with government funding). One potential issue involves whether grant recipients under the Bayh-Dole Act or similar legislation in developed countries will create licensing policies and practices that take into account the needs of developing countries to have access to government-funded technology in both cases described above. Second, the rise in patenting and licensing as a possible result of passage of the Bayh-Dole Act and similar legislation in other developed countries could result in an anticommons in the United States, other developed countries, and developing countries. Third, provisions in the U.S. Bayh-Dole Act designed to ensure access to government-funded technology have likely not been used as frequently as expected by policymakers and those provisions could be used more effectively to ensure access to government-funded technology for developing countries—in the Bayh-Dole Act and in similar legislation in developed and developing countries. Fourth, access to research materials covered by material transfer agreements is a problem that apparently has risen in the United States and may develop in developing countries. Finally, the decision to grant exclusive versus non-exclusive licenses by grant recipients under the Bayh-Dole Act or similar legislation in other developed or developing countries may result in problems with access to government-funded technology for developing countries.

Boettiger and Bennett's article addresses some of the major issues concerning the Bayh-Dole Act and access to government-funded technologies for developing countries. The article recognizes the difficulties in making generalizations concerning developing countries, which have widely differing economic conditions.[25] Boettiger and Bennett assert that issues concerning access to research tools and other basic research in biotechnology may have negative implications for developing countries, particularly in the agricultural field.[26] A potential problem for developing countries is that university technology transfer offices in the United States may not be considering the interests of developing countries in accessing basic research, and undoing existing licenses to allow access may be difficult if not impossible. Boettiger and Bennett point to licensing language developed by the Public Intellectual Property Resource for Agriculture and Universities Allied for Essential Medicines designed to ensure that universities and other research institutions reserve rights

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[25] Boettiger & Bennett, *supra* note 18, at 262.
[26] *Id.* at 265-66.

to allow access for "humanitarian commercial development, that benefits the poor and underserved."[27] Developing countries adopting Bayh-Dole Act legislation should consider creating licensing rules that reserve the right to provide access specifically for humanitarian reasons. This reservation may in some cases undercut the value of the patent rights because the only commercial market for some patents may be other developing countries that have humanitarian needs and want to access the technology. However, some basic research conducted in developing countries may have broad applicability and there may be demand in developed countries for patents covering that basic research. Moreover, some developing countries may have the resources to pay at least reduced prices to use the technology.[28]

The next issue Boettiger and Bennett address concerns the creation of an anticommons and whether the *Madey v. Duke University*[29] decision, which narrowly interprets the U.S. experimental use exception to patent infringement, will contribute to the development of an anticommons.[30] Commentators have argued that an anticommons may develop because of the *Madey* decision, and many such commentators have also argued for the adoption of a broader exception.[31] The empirical evidence of an anticommons is unclear.[32] I recently

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[27] Boettiger & Bennett, *supra* note 18, at 265 (citing the Public Intellectual Property Resource for Agriculture website, http://www.pipra.org/ and Universities Allied for Essential Medicines, Model Provisions for an Equitable Access and Neglected Disease License, http://www.essentialmedicine.org/EAL.pdf). Boettiger and Bennett also raise the open licensing approaches proposed by Amy Kapczynski, Samantha Chaifetz, Zachary Katz & Yochai Benkler. *See Id.* (citing Amy Kapczynski, Samantha Chaifetz, Zachary Katz & Yochai Benkler, *Addressing Global Health Inequities: An Open Licensing Approach for University Innovations*, 20 BERKELEY TECH. L. J. 1021 (2005)).

[28] Some developing countries have negotiated lower fees for patented drugs with pharmaceutical companies. *See* Kaisernetwork.org, Kaiser Daily HIV/AIDS Report, Drug Access, Brazilian Official at Latin American Conference on AIDS Calls for Countries to Break Patents, Self-Produce ARVs, Jan. 13, 2006, http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=34778 (last visited Jan. 4, 2008).

[29] 307 F.3d 1351 (Fed. Cir. 2002).

[30] Boettiger & Bennett, *supra* note 18, at 268.

[31] See Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017 (1989); Rochelle Dreyfuss, *Protecting the Public Domain of Science: Has the Time for an Experimental Use Defense Arrived?*, 46 ARIZ. L. REV. 457 (2004); Janice M. Mueller, *The Evanescent Experimental Use Exemption from United States Patent Infringement Liability: Implications for University and Nonprofit Research and Development*, 56 BAYLOR L. REV. 917 (2004); Janice M. Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1 (2001); David L. Parker, *Patent Infringement Exemptions for Life Science Research*, 16 HOUS. J. INT'L L. 615 (1994); Katherine J. Strandburg, *What Does the Public Get?: Experimental Use and the Patent Bargain*, 2004 WIS. L. REV. 81 (2004); *but cf.* Jordan P. Karp, Note, *Experimental Use as Patent Infringement: The Impropriety of a Broad Exception*, 100 YALE L.J. 2169, 2179-83 (1991) ("A system with a broad experimental use allowance would have a disparate impact on less well-financed inventors whose ability to conduct R&D may be limited in the short term when they are not able to convince possible investors of the potential commercial success of their patented inventions."); Heather Hamme Ramirez, Comment, *Defending the Privatization of*

argued that adoption of the Bayh-Dole Act in developed countries may lead to increased patenting and licensing in the United States, which could lead to an anticommons effect and subsequent pressure to adopt a broad experimental use exception in the United States similar to that existing in some other developed countries.[33] Whether adoption of Bayh-Dole Act legislation in developing countries will contribute to an anticommons in those countries or in developed countries is unclear and will likely depend on the breadth of the experimental use exception to patent infringement in each of those countries, as well as the presence and exercise of specific provisions in their Bayh-Dole legislation concerning access. One solution to overcoming a potential anticommons within a particular developing country would be to adopt a proposal recently made by Professor Gary Pulsinelli to require that "[a]ll researchers whose work is supported by federal funds should have a limited, royalty-free license to make and use for research purposes all inventions developed with federal funds."[34] This proposal would create a research exemption that would include all recipients of government funding in the developing country and might mitigate an anticommons effect. Another option to possibly avoid an anticommons is to adopt a broad research exemption to patent infringement. This may undercut the value of the patent and create uncertainty as to the scope of the patent. However, a broad research exemption within the Bayh-Dole Act type legislation seems to be more justified than a general research exemption because the government has already funded the creation of the invention, at least to a stage where it is protected by patent law.[35]

While the Bayh-Dole Act in the United States attempts to take into account the interests of all the relevant parties—the taxpayers who provide the funding, the government, the researcher, the licensee and the licensor—the Act arguably does not sufficiently protect the interests of the public in the United States. For example, an "exceptional circumstances" provision designed to leave certain

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Research Tools: An Examination of the "Tragedy of the Anticommons" in Biotechnology Research and Development, 53 EMORY L.J. 359, 372-74 (2004); Richard J. Bauer, Comment, *Why Not Try the Experiment and Stop Pointing the Finger? Modern University Research Unaffected by a Narrow Experimental Use Exception*, 24 TEMP. J. SCI. TECH. & ENVTL. L. 121, 135 (2005) ("Yet in practice, industry is not aggressively suing universities for patent infringement despite both a university's greater than before vulnerability to patent infringement claims, and academic scientists' pervasive and routine disregard for intellectual property rights." (citations omitted)); Elizabeth A. Rowe, *The Experimental Use Exception to Patent Infringement: Do Universities Deserve Special Treatment?*, 57 HASTINGS L.J. 921, 954 (2006) ("The *Madey* court's narrow interpretation of the experimental use exception is consistent with precedent, consistent with public policy, and appropriate for university research.").

[32] Boettiger & Bennett, *supra* note 18, at 270-71; Mireles, *supra* note 5, at 1165-68.

[33] Mireles, *supra* note 12, at 276-82.

[34] Gary Pulsinelli, *Share and Share Alike: Increasing Access to Government-Funded Inventions Under the Bayh-Dole Act*, 7 MINN. J. L. SCI. & TECH. 393, 442-43 (2006). Boettiger and Bennett also argue that "[d]evelopment of new policies should consider the inclusion of a well-reasoned research exemption for university researchers' use of proprietary IP." *See* Boettiger & Bennett, *supra* note 18, at 278.

[35] *See* Michael S. Mireles, *An Examination of Patents, Licensing, Research Tools, and the Tragedy of the Anticommons in Biotechnology Innovation*, 38 U. MICH. J.L. REFORM 141, 211-16.

government-funded inventions in the public domain[36] and "march-in rights"[37] exist in the present Bayh-Dole Act, but these provisions have been used infrequently.[38] The exercise of those provisions might also be used to prevent an anticommons from forming in the United States or in other countries that adopt similar legislation to the Bayh-Dole Act. Boettiger and Bennett also argue that while there are protections in the Bayh-Dole Act for access to patented technologies, such as march-in rights, similar compulsory licensing in legislation adopted by developing countries may deter investment by the private sector.[39] However, because of the scarcity of funding resources in developing countries, the argument for access to government-funded technology has more force, and ensuring that access through march-in rights or a similar provision (such as the grant-back clause) is critical to ensuring that a government-funded technology is available to the public. Furthermore, the prospect of compulsory licensing already exists in developing countries as a result of provisions in TRIPS. Moreover, march-in rights could be tailored to industry concerns and are also helpful for ensuring that government-funded inventions are commercialized.

Another potentially troubling problem involves access to research materials covered by material transfer agreements (MTAs).[40] Some studies have found that researchers are having trouble accessing materials covered by those agreements in the United States.[41] In one study, 47% of researchers surveyed reported difficulties in accessing data and materials held by other researchers.[42] If researchers are reporting difficulties accessing materials covered by MTAs in the United States, it is probable that researchers in developing countries will have similar problems in obtaining materials from researchers in their country or other countries. The solution to this problem for a particular country could be an agreement by researchers receiving government funding from that country to allow other researchers receiving government funding from that country to have

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[36] The government may determine that "exceptional circumstances" exist where the policies and objectives of the Act are better served by the "restriction or elimination of the right to retain title to any subject invention will better promote the policy and objectives" of the Act. 35 U.S.C. § 202(a)(ii) (2000). For additional discussion of the exceptional circumstances provision and a proposal to modify that provision, see Arti K. Rai & Rebecca S. Eisenberg, *The Public Domain: Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289, 293-94, 310-13 (2003).

[37] The government has the power to compel an owner of a patent on a government-funded invention to license that invention when "(1) action is necessary because the [grantee] has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use; [or] (2) action is necessary to alleviate health or safety needs which are not reasonably satisfied by the [grantee]." 35 U.S.C. § 203(a).

[38] Mireles, *supra* note 5, at 1155-56, 1159. Boettiger and Bennett argue that "the inclusion of 'march in' rights has the potential for creating uncertainty in IP rights ownership and therefore may discourage industry involvement." Boettiger & Bennett, *supra* note 18, at 279.

[39] Boettiger & Bennett, *supra* note 18, at 276.

[40] *See* Mireles, *supra* note 5, at 1170-74.

[41] *Id.*

[42] Eric G. Campbell, et al., *Data Withholding in Academic Genetics: Evidence from a National Survey*, 287 J. AM. MED. ASS'N 473, 473 (2002).

access to materials or data created during government-funded research. This proposal is somewhat similar to that offered by Professor Pulsinelli,[43] but it is not limited to government-funded patented inventions, including also research materials and data that may not be covered by patents.

Another concern is the use of exclusive licenses, which would allow a single licensee to control the exploitation of a government-funded invention. The Bayh-Dole Act allows the recipient of government funding to grant exclusive licenses in technology created with that funding.[44] Exclusive licenses in government-funded technology are particularly troublesome when examined in light of the lack of use of the "march-in" and the general reluctance to use the "exceptional circumstances" provisions in the Bayh-Dole Act designed to ensure access to that technology. Instead of leaving the decision to the recipient of government funding, the decision to patent and whether to grant a non-exclusive or exclusive license could be left with the grantor of funding.[45] However, as discussed by Professor Pulsinelli, there are intractable issues with attempting to determine ex ante whether something should be patented or not, thus making provisions like the "exceptional circumstances" provision in the Bayh-Dole Act very difficult to use.[46] Given the uncertainty that exists in research, particularly biotechnology research, it may also be difficult to determine ex ante at the time of funding whether an exclusive license may be necessary to commercialize a government-funded invention. The National Institutes of Health's *Best Practices for the Licensing of Genomic Inventions* and *Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources* take a different approach and recommend that research tools should be subject to non-exclusive licenses; however, these policies are voluntary and not mandatory.[47] If the determination of whether to grant a non-exclusive or exclusive license remains with the university, exclusive licenses should only be granted when necessary to secure funding for commercialization. As Professor Lemley has recently suggested, universities could use exclusive licenses with field-of-use restrictions to minimize the impact of the exclusive license.[48] The use of negative milestones would also be helpful to ensure that technology that is exclusively licensed will be commercialized.

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[43] *See supra* text accompanying note 34.

[44] 35 U.S.C. § 207(a)(2) (2000).

[45] *See* Rai & Eisenberg, *supra* note 36, at 304-05, 310-11.

[46] Pulsinelli, *supra* note 344, at 441.

[47] Best Practices for the Licensing of Genomic Inventions: Final Notice, 70 Fed. Reg. 68 (Apr. 11, 2005); Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice, 64 Fed. Reg. 246 (Dec. 23, 1999).

[48] Mark A. Lemley, *Are Universities Patent Trolls*? 14-16 (Stanford Public Law, Working Paper No. 980776, 2007), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=980776 (last visited Jan. 5, 2008).

2. National, Regional, and/or Institutional Technology Transfer Offices

Professor Lorelei Ritchie de Larena advocates that a national technology transfer office should be created and given control over management of government-funded technologies.[49] She is critical of universities in the United States and asserts that they are incompetent stewards of government-funded invention.[50] She points to universities' failure to adhere to Bayh-Dole Act mandates, such as reporting inventions,[51] university researchers misusing government funding,[52] and universities abusing their licensing position and resulting revenue.[53] A study by the Inspector General indicated that approximately 23% of the federally-funded inventions were not reported to the government as required by Bayh-Dole.[54] According to Professor Ritchie de Larena, this "means that federal taxpayers are not even getting basic governmental access to many of the inventions they fund."[55] Given these issues, developing countries should ensure that if they require reporting requirements, which they should require in order to track inventions developed by university researchers with government funding, they should enforce compliance by universities. This enforcement is particularly important for the government to be able to exercise "march-in" rights whenever necessary.

Professor Ritchie de Larena further describes numerous instances of universities and their researchers misusing government funding.[56] These abuses include six major research universities in the United States that have "paid civil fees to the government to settle charges of improper diversion of federal research funds."[57] She argues that, "[t]he lack of oversight over faculty, coupled with the pressures on them to compete for grants and produce exciting results, leads to a culture where hard-core cheating as well as softer ambiguities in interpretation and presentation are common."[58] To address similar situations that may arise, developing countries should also create ethics rules concerning the use of government funding for research and the licensing of government-funded inventions to mitigate issues concerning cheating.

Finally, Professor Ritchie de Larena points to the abuse of licensing position and revenue by universities under the Bayh-Dole scheme.[59] Some of this abuse includes favoring faculty start-ups with licenses with inadequate

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[49] Ritchie de Larena, *supra* note 11, at 1339-44.
[50] *See id.* at 1389-91.
[51] *Id.* at 1396-99.
[52] *Id.* at 1402-10.
[53] *Id.* at 1412.
[54] *Id.* at 1399 (citing U.S. GEN. ACCOUNTING OFFICE, TECHNOLOGY TRANSFER: REPORTING REQUIREMENTS FOR FEDERALLY SPONSORED INVENTIONS NEED REVISION 12-13 (1999)).
[55] *Id.* at 1398.
[56] *Id.* at 1401-10.
[57] *Id.* at 1406.
[58] *Id.* at 1409.
[59] *Id.* at 1412.

consideration in return and attempting to extract overreaching payments for licensing government-funded technology.[60] Universities may also attempt to use patents on basic science to garner high licensing fees,[61] may over-patent possibly contributing to an anticommons,[62] and may engage in "socially conscious licensing"—licensing at low rates to organizations serving third world countries, but reserving rights to industrialized countries—while still requiring those organizations to pay patent expenses.[63] Moreover, as discussed supra, to avoid the possibility of the development of an anticommons, developing countries should consider a research exemption similar to that proposed by Professor Pulsinelli.[64] This exemption may also allow for "socially conscious" licensing and help mitigate the impact of the possible development of an anticommons generally. In addition, developing countries should consider legislating licensing best practices to avoid some of the problems raised by Professor Ritchie de Larena.

Professor Ritchie de Larena has proposed the development of a national technology-transfer center in the United States.[65] This center would provide management services for all government-funded intellectual property and require any commercial licensing entities to pay patent prosecution costs.[66] Under this scheme, inventors would receive a portion of the licensing fee in exchange for finding licensees, while "a smaller percentage [of licensing income] would go to the school or department and a nominal amount to the university."[67] Moreover, funding normally held under Bayh-Dole by university administrators for "indirect costs" would go to the national technology-transfer center for further investment in research.[68] "[T]he center would have a Board of Advisors consisting of university, government, legal and industry experts who would review technology-specific portfolios quarterly and make suggestions on commercialization"; in addition, "the center would maintain a public, Internet database of all inventions and their licensing status [that] every government contractor would have access to. . . ."[69] "Any technology patented but not licensed within a reasonable period, would be dedicated to the public domain, so as not to unduly encumber future research."[70] However, moving away from an atomistic institutional scheme to a more centralized approach would create certain concerns. For example, one of the benefits of the Bayh-Dole Act is that it

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[60] *Id.* at 1416.
[61] *Id.* at 1418.
[62] *Id.* at 1422-25.
[63] *Id.* at 1421. Professor Ritchie de Larena further argues that "the very fact of having patent rights in [third-world] countries provides a bar to entry for potential competitors that might offer lower-cost options on the university technology and improvements thereto." *Id.*
[64] *See supra* text accompanying note 344.
[65] Ritchie de Larena, *supra* note 11, at 1439.
[66] *Id.* at 1440.
[67] *Id.* at 1441.
[68] *Id.*
[69] *Id.* at 1443.
[70] *Id.* (citation omitted).

provides incentives for individual researchers to disclose their inventions and continue involvement in the commercialization of the invention through the promise of a royalty. The involvement of the inventor in the commercialization of government-funded research is critical in many cases.[71] The Act also provides incentives for universities to encourage researchers to engage in technology transfer. Professor Ritchie de Larena's scheme may leave insufficient incentives to prompt universities to encourage researchers to disclose inventions. However, this problem could be cured by improved oversight by the grantor of the government funding, which is also part of Professor Ritchie de Larena's proposal.

Professor Kristen Osenga argues that Professor Ritchie de Larena's approach fails to "suggest an intellectual property management strategy" for universities, "provide [universities] with hows and whys of patent acquisition and exploitation," or "provide the vital infrastructure necessary to create an effective technology transfer office."[72] According to Professor Osenga, adopting an approach that addresses these concerns will help alleviate problems concerning access and funding for research and development.[73] Professor Osenga advocates that universities should embrace patenting and, importantly, decide on an intellectual property strategy that includes focus on a particular strategy for what inventions to patent and attempt to license.[74] For developing countries, as discussed infra, this could include focusing on creating inventions directed to solving local problems. She also highlights the importance of having a well-trained staff to understand technology and commercialization trends to implement the intellectual property strategy.[75] The structure proposed by Professor Osenga includes at least one patent attorney, personnel with technical skill, and personnel with business expertise.[76] However, as discussed infra, access to qualified personnel may be difficult for some, if not most, developing countries.

Depending on the resources in a developing country, the country may or may not attempt to create technology transfer offices in each university. A regional approach, similar to the one proposed by Jennifer Washburn,[77] or the

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[71] Mireles, *supra* note 5, at 1198.

[72] Kristen Osenga, *Rembrandts in the Research Lab: Why Universities Should Take a Lesson from Big Business to Increase Innovation*, 59 ME. L. REV. 407, 429 (2007).

[73] *Id.* at 436-37.

[74] *Id.* at 429.

[75] *Id.* at 433-34.

[76] *Id.*

[77] Jennifer Washburn, UNIVERSITY INC.: THE CORPORATE CORRUPTION OF HIGHER EDUCATION 228-230 (2005).

> [T]he federal government should take the initiative by establishing a series of nonprofit technology-transfer hubs, located in different regions of the country, which would handle the patenting and licensing needs of all the nation's universities and colleges. These offices . . . would operate under a federal mandate to carry out the provisions of the Bayh-Dole Act. They would probably function best if they were

national approach set forth by Professor Ritchie de Larena,[78] may be helpful in lowering the costs of funding a technology transfer office, and fewer technology transfer offices would require fewer knowledgeable personnel to manage them. "[A regional or national] structure also has the potential to sustain a 'commons' of technologies in specific areas by aggregating IP and managing unified portfolios of technologies under a common set of objectives."[79] National or regional offices would reduce competition between institutional technology transfer offices.[80]

Developing countries could experiment and utilize regional or national offices to manage and license the intellectual property created in individual institutions. Regional or national offices might be able to provide the benefits of tracking the government-funded intellectual property, providing oversight over all use of the government-funded intellectual property, and also managing any revenues that may result from licenses from the government.[81] A royalty for the

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chartered, pseudogovernmental organizations that enjoyed considerable independence and flexibility.

Id. at 229.

[78] *See* Boettiger & Bennett, *supra* note 18, at 275. Boettiger and Bennett caution that there may not be enough well-trained IP technology transfer professionals and that "[r]egional, rather than institutional management of government-funded patents affords economies of scale in sustaining the large costs and limited revenues of patent portfolios" and technology transfer offices. *Id.*

[79] *Id.*

[80] *See id.* at 280.

[81] Technology transfer offices, whether at the institutional, regional, or national level, can provide the following benefits:

> *Protection of intellectual property.* TTOs review new inventions by an institute's research staff and assist them in determining the patent status of the technology. Assigning a financial value to the research is important for approaching industry with the aim of licensing the technology.
>
> *Revenues through licensing of intellectual property.* TTOs can assess the commercial potential of intellectual properties and market these technologies through licensing, so as to generate new revenues for the institute. Licencing [sic] of technology involves promotion and marketing, negotiation, implementation and execution of the actual license agreement, including royalty payments.
>
> *Education and awareness.* TTOs can conduct educational programmes to make scientists and research administrators aware of the correct ways to handle new inventions, including issues such as official lab books for record-keeping, confidential disclosures, publication guidelines and agreements.
>
> *Networking.* TTOs can stimulate networking by maintaining a database of new technologies with commercial potential and sharing this with other institutes under conditions of confidentiality. The office may also facilitate networking with technology transfer associations, training and service organizations.
>
> *Creation of new start-up companies.* TTOs can help in the establishment of new start-up companies through links with venture capital firms in countries where these are available. Office staff can help to address any conflicts of interest which may arise between researchers' duties to their parent institutes and their spin-off company.
>
> *Institutional policies related to technology transfer.* TTOs can help develop and enforce policies dealing with inventions, discoveries and intellectual properties that are generated by the institute.

university and researcher would be required by legislation and negotiable by the parties to the license. Regional or national offices might also be helpful in promoting collaborations of institutions within their region or the nation and in coordinating research and development.[82] For some developing countries, technology transfer offices might also be able to track and catalogue indigenous knowledge and biodiversity resources, creating a repository of prior art to prevent patenting in other countries.

3. Additional Issues Concerning Adoption of the Bayh-Dole Act in Developing Countries

This section discusses additional issues concerning the adoption of the Bayh-Dole Act in developing countries, including the possible impact of the Act on the direction of academic research in the United States and elsewhere; the historical lack of cooperation between industry and academia in developing countries and the presence of other resources, such as a large amount of government funding; the possible modification of provisions of the Bayh-Dole Act for adoption in developing countries, including the manufacturing clause; and the addition of new provisions concerning a royalty stream to the government or contributors of indigenous knowledge or biodiversity resources, and consequences for noncompliance with the legislation. Moreover, this section analyzes issues concerning the ability of governments in developing countries to use the prospect of government funding for research to leverage favorable pricing for products developed with government-funded technology and the creation of performance metrics for technology transfer that take into account factors besides revenue generation and numbers of patents and licenses.

Boettiger and Bennett point out that "[l]ess than 10% of health research funding is targeted at diseases that account for 90% of the global disease burden" and that public research has historically been very important to the development of inventions in the "health and agriculture [fields] that do not have commercial

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> *Service to society.* Society supports public institutes indirectly through the payment of state and local taxes. TTOs may stimulate access to the knowledge and biotechnologies developed in the institutes for the benefit of society.

Karim M. Maredia et al., *Technology Transfer Offices for Developing Countries*, 43 BIOTECH. & DEVELOPMENT MONITOR 15, 16-17 (2000).

[82] Halla Thorsteinsdóttir et al., Commentary, *Conclusions: Promoting Biotechnology Innovation in Developing Countries*, 22 NATURE BIOTECH. DC48, DC50 (2004) ("By encouraging collaborations and resource sharing among different institutions in its innovation system, Cuba has been able to succeed in health biotechnology, despite its very limited financial resources."). Brazil has been successful in creating a virtual institute wherein researchers from thirty-four biology laboratories and a bioinformatics research institute across Brazil were able to sequence "the genome of a plant pathogen, *Xylella fastidiosa*, a bacterium that attacks citrus fruits." Marcela Ferrer et al., *The Scientific Muscle of Brazil's Health Biotechnology*, 22 NATURE BIOTECH. DC8, DC10 Box 1 (2004) (citation omitted). However, Brazil has struggled with developing relationships between universities and private industry, and between private companies. *See id.* at DC11 ("The Minister of Science and Technology . . . [stated], 'Brazilians get lost between basic research and its transformation into technology, between academic life and the manufacturing system.' A major contributor to this problem is the lack of linkages among biotechnology firms.").

markets."[83] Boettiger and Bennett express concern about the impact the Bayh-Dole Act may have had upon the direction of academic research and whether an increase in patenting is creating "impediments to research and humanitarian applications of new technologies" or an anticommons effect.[84] First, empirical evidence concerning whether the direction of academic research has been affected by the opportunities to commercialize research is unclear.[85] The lure of potential royalties and other economic rewards would seem to provide an incentive for academic researchers to orient their research toward applied research to solve problems where there are commercial markets,[86] and therefore whether the Bayh-Dole Act has had an impact on the direction of research should

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[83] Boettiger & Bennett, *supra* note 18, at 265.

[84] *Id.* at 266.

[85] *Id.* at 266-67; *see also* Mireles, *supra* note 355, at 168-70 (discussing recent research and potential impact of a shift in academic research from basic to applied research); McManis & Noh, *supra* note 6, at 27 (arguing empirical evidence of shift in academic research is "mixed at best"); Jerry G. Thursby & Marie C. Thursby, University Licensing Under Bayh-Dole: What are the Issues and Evidence? 5 (May 2003), *available at* http://opensource.mit.edu/papers/Thursby.pdf (last visited Jan. 5, 2008) ("We find in a study of over 3400 faculty at 6 major research universities that the basic/applied split in research did not change over the period 1983–1999 even though licsensing [sic] had increased by a factor greater than 10 . . . ."); MOWERY ET AL., *supra* note 10, at 184 ("We have uncovered little evidence that the expanded patenting and licensing activities of U.S. universities since 1980 have produced significant shifts in the orientation of academic researchers away from fundamental research toward more applied, short-term research activities that might be more easily patented and licensed."); SCOTT SHANE, ACADEMIC ENTREPRENEURSHIP: UNIVERSITY SPINOFFS AND WEALTH CREATION 282 (2004) ("While scholars of . . . technology transfer have not found any direct evidence . . . that the opportunity to found university spinoffs leads researchers to focus on more applied research at the expense of basic science or to avoid research areas with limited commercial potential, they have found indirect evidence of these effects."); *cf.* Pierre Azoulay et al., *The Impact of Academic Patenting on the Rate, Quality, and Direction of (Public) Research* 2 (Nat'l Bureau of Econ. Research, Working Paper No. 11917, 2006), *available at* http://www.nber.org/papers/w11917 (last visited Jan. 5, 2008) ("patenting has had real effects on the direction of scientific progress" by more closely tying research and development with commercial interests); David Blumenthal, *Academic-Industry Relationships in the Life Sciences: Extent, Consequences, and Management*, 268 J. AM. MED. ASS'N 3344, 3346 (1992) ("Among respondents to the Harvard project's faculty survey, 30% of biotechnology faculty with industrial support (compared with 7% without it) said that their choice of research topics had been influenced by the likelihood that the results would have commercial application.").

[86] *See* WILLIAM M. LANDES & RICHARD A. POSNER, THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW 316 (2003) ("Being able to earn substantial income from patent licensing has, it appears, induced universities to substitute away from basic research, and the result may have been a net social loss."); Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663, 1669-70 (1996); *see also* Katherine J. Strandburg, *Curiosity-Driven Research and University Technology Transfer*, *in* UNIVERSITY ENTREPRENEURSHIP AND TECHNOLOGY: PROCESS, DESIGN, AND INTELLECTUAL PROPERTY 93, 111 (Gary D. Libecap ed., 2005) ("The strongest motivation for a basic researcher to skew her research direction in an effort to obtain a patent is probably the possibility of industrial research funding.").

continue to be studied.[87] This issue can have an impact on developing countries because it might lead to a decrease in the use of research funds to support research agendas that may lack a viable commercial market but that have a substantial impact on developing countries.[88]

The authors caution that the benefits of the Bayh-Dole Act may not occur in developing countries that adopt similar legislation.[89] Some of the reasons include that "[t]he Bayh-Dole Act [was] built on a vibrant history of university-industry collaboration" that is likely absent in developing countries; biomedical and biotechnology advances that are patentable in the United States may not be patentable under the laws of developing countries; the established intellectual property system, infrastructure and investment in biotechnology research and development that exist in the United States are not likely to be present in developing countries; and "the scale of the U.S. higher education research enterprise" is much larger than that in developing countries.[90] A recent policy report by the Swedish Institute for Growth Policy Studies reviews suggestions for increasing interaction between university and industry, including: "Making use of alumni to expand networks into companies[; c]reating offices of economic development & entrepreneurship[; c]reating boards where deans are represented along with commercial actors and technology-transfer officers[; and a]rranging science presentations for commercial actors with networking opportunities."[91] Some of these suggestions might be successful, depending on the conditions of each country.[92]

Boettiger and Bennett argue that Bayh-Dole's preference for small businesses and for manufacturing to occur within the country granting the funding should be maintained in developing countries because "[e]ncouragement of local industry and a focus on innovations targeted to domestic needs are both factors that analysts identify as important for a successful developing country innovation policy."[93] Boettiger and Bennett also state that a provision focused on domestic benefit instead of a requirement of "domestic manufacture" may be "more practical . . . for countries that lack research-intensive industries or manufacturing capability."[94] The developing-country Bayh-Dole Act legislation should take a tiered approach as to where research and development and manufacturing of government-funded inventions should take place. A modification of this proposal could require first that research and development with funding from the developing country occur in the developing country for a domestic benefit, and if that is not possible, then manufacturing of any

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[87] Boettiger & Bennett, *supra* note 18, at 267.
[88] *Id.*
[89] *Id.* at 272-73.
[90] *Id.*
[91] NILSSON ET AL., *supra* note 13, at 42.
[92] Boettiger & Bennett, *supra* note 18, at 273 (raising concerns about the adoption of the Bayh-Dole Act in developing countries, although "application of these concerns may vary widely and requires further analysis at a country-specific level").
[93] *Id.* at 277.
[94] *Id.* at 281.

commercial application for a domestic benefit should happen in the developing country. If neither research and development nor manufacturing is possible in the developing country, then a substantial domestic benefit should be required. This provision would ensure that government funding is used to the greatest benefit to the population of the developing country when possible.

Boettiger and Bennett assert there should be an "[a]rticulation of performance metrics for [technology transfer offices]" and that these metrics should not be "based on revenue generation, and numbers of patents and licenses [that] distort[] the decision-making process of [technology transfer office] staff."[95] These metrics "should be integrated into the policy . . . framework."[96] The use of such metrics is particularly helpful because most revenue generated from licensing comes from a limited number of licenses.[97] In fact, "[t]he top five income-generating licenses account for 76 percent of the total income that [U.S.] universities get from licensing."[98] A system that primarily uses the amount of licensing revenue as a measure of success is problematic, given the fact that most technology transfer offices operate at a loss.[99] Moreover, a system that utilizes the number of patents obtained and licenses executed is less likely to be concerned with ensuring that some technology remains in the public domain. A new performance metrics system could include the number of publications, number of commercial products and services introduced to the public, general economic growth, and new jobs.[100]

Developing countries may also consider using the lure of government funding to obtain favorable pricing for pharmaceuticals or other inventions developed by private industry using government-funded patented inventions. This issue has been considered by a public policy study group tasked with providing recommendations for the treatment of state-government-funded inventions and rejected by the group because of the apparent failure of the National Institutes of Health to obtain favorable pricing through the use of Cooperative Research and Development Agreements.[101]

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[95] *Id.* at 280.

[96] *Id.*

[97] NILSSON ET AL., *supra* note 13, at 11.

[98] *Id.*

[99] *Id.* at 16; Powers, *supra* note 5, at B18.

[100] NILSSON ET AL., *supra* note 13, at 15 (noting that developing metrics that all interested parties, including universities, market actors, and politicians, can agree upon is difficult).

> In recognition of the long odds against discovery of a profitable product, and because getting a new product to the market often requires 10 to 15 years of development and testing, the [International Cooperative Biodiversity Group (ICBG)] programs emphasize income derived by local people from the process of exploration and discovery rather than on the promise of huge royalties that may never materialize.

J. Michael Finger, *Introduction and Overview*, *in* POOR PEOPLE'S KNOWLEDGE: PROMOTING INTELLECTUAL PROPERTY IN DEVELOPING COUNTRIES 1, 21 (J. Michael Finger & Philip Schuler ed., 2004).

[101] CCST INTERIM REPORT, *supra* note 23, at 9-10.

Another possible modification to the Bayh-Dole Act scheme is to require a revenue stream back to the government, to be used for additional research and development grants and public health needs.[102] In the case where the traditional knowledge of a particular group within a developing country is utilized to develop a commercial application, the Bayh-Dole Act scheme in the developing country could require a revenue stream to the particular group that possesses the helpful traditional knowledge. In proposing that an "International Bayh-Dole" should be established to address concerns with biopiracy and attract foreign direct investment to developing countries, one commentator has argued that,

> While advantageous to business by providing clear rights to inventions derived from indigenous knowledge and potentially advantageous to developing countries who wish to attract foreign direct investment, the Bayh-Dole system does little to acknowledge the contributions that indigenous peoples make in the derivation of the inventions and to ensure that they will receive the benefits from their [traditional knowledge].[103]

In adopting legislation similar to the Bayh-Dole Act, developing countries could overcome this problem by explicitly requiring a royalty stream to indigenous groups who possess traditional knowledge used to develop a commercial application along with an acknowledgement of the contribution of the indigenous group. However, properly allocating royalties to whoever may "possess" the traditional knowledge or biodiversity resources may prove difficult.[104]

An additional concern for developing countries is to determine how to allocate rights to inventions developed from research projects that use funding from multiple sources. Developing countries could provide different rules for allocation depending upon the sources of funding for a particular project. Developing countries should also include consequences for noncompliance with the Bayh-Dole-type reporting requirements.[105] Consequences for noncompliance could include the right of the developing country to revoke intellectual property rights in the government-funded invention through such mechanisms as "march-in rights" and to deny future funding to the particular researcher or institution.[106]

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[102] *Id.* at 39-40.

[103] Heather A. Sapp, *Monopolizing Medicinal Methods: The Debate Over Patent Rights for Indigenous Peoples*, 25 TEMP. J. SCI. TECH. & ENVTL. L. 191, 212 (2006).

[104] *See* Cynthia M. Ho, *Biopiracy and Beyond: A Consideration of the Socio-Cultural Conflicts with Global Patent Policies*, 39 U. MICH. J.L. REFORM 433, 463 (2006) ("[A]lthough it is true that some Samoan people[, who are entitled to receive some compensation,] assisted Western researchers in what ultimately resulted in a patented product, the native tree, the Mamala, grows throughout tropical forests in the South Pacific, such that it is possible that other indigenous communities may feel excluded.").

[105] *See* Mireles, *supra* note 5, at 1205.

[106] *Id.*

III. A POTENTIAL CONSEQUENCE FROM ADOPTING LEGISLATION SIMILAR TO THE BAYH-DOLE ACT?

This article argues that one possible consequence that may arise from developing countries adoption of legislation similar to the Bayh-Dole Act is that research agendas at local universities may be directed to developing government-funded inventions that are focused on solving local needs through public-private collaborations. Some commentators have suggested that the Bayh-Dole Act has contributed to a skewing of research agendas to issues with commercial markets—including primarily the needs of developed countries—and away from possibly solving issues that confront developing countries.[107] Boettiger and Bennett point out that there is insufficient empirical evidence to date on this topic.[108]

This issue is critically important to understanding the impact of the Bayh-Dole Act's adoption not only in the United States, but also in developed countries throughout the world who seek to capture similar economic benefits that the Act has allegedly produced for the United States. Channeling government funding towards local needs and using private-public collaborations could provide solutions to local humanitarian issues and bridge the funding gap caused by a possible shift in focus to the needs of developed countries.[109] Universities in developing countries could also use the government funding to take advantage of local biodiversity resources[110] and indigenous medicinal knowledge[111] in

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[107] Boettiger & Bennett, *supra* note 18, at 265-67.

[108] *Id.* at 267.

[109] Private companies may have an incentive to develop technology to solve local needs. *Cf.* Finger, *supra* note 1000, at 4 (Developed country negotiators argue that "[i]f developing countries enforced IPRs as the TRIPS Agreement specifies, . . . industrial country companies would have an incentive to create products aimed at problems, such as tropical diseases, that were of particular concern to developing countries.").

[110] Brazil is one example of a developing country with tremendous biodiversity resources. *See* Ferrer et al., *supra* note 822, at DC8 ("Brazil's terrestrial biodiversity, with numerous biomes including the Cerrado, Amazon rainforest, Pantanal wetlands, Caatinga region, and Araucaria and Atlantic forests, is also unrivaled in the South American continent and probably elsewhere. This combination of natural and scientific resources gives the country great potential to promote health biotechnology.").

[111] The terms "indigenous people" and "traditional knowledge" have been defined in different ways. One source defines "indigenous peoples" as "'existing descendants of non-Western peoples who in general continue to occupy their ancestral lands even after conquest by Westerners, or who have been relocated forcibly in the process of colonization'" and "traditional knowledge" as "'the body of historically constituted knowledge instrumental in the long-term adaptation of human groups.'" Sapp, *supra* note 1033, at 195 (quoting Trevor W. Purcell, *Indigenous Knowledge and Applied Anthropology: Questions of Definition and Direction*, 57 HUM. ORG. 258, 259-60 (1998)). This same source defines "indigenous medicinal knowledge" as "a subset of [traditional knowledge] 'consisting of the medicinal and curative properties of plants in indigenous culture,' including genetic resources." *Id.* (quoting John L. Trotti, *Compensation Versus Colonization: A Common Heritage Approach to the Use of Indigenous Medicine in Developing Western Pharmaceuticals*, 56 FOOD & DRUG L.J. 367, 369 (2001)). *See also* STEPHEN A. HANSEN & JUSTIN

partnership with the local population, and to commercialize those resources if desired.[112] Interestingly, one commentator has suggested that,

> [e]ssentially, the bio-diverse developing countries are facing today the same situation that the U.S. faced in the 1970s. They possess a tremendous unexploited potential value in natural products R&D, but, without the proper legal framework needed to ensure the commercial development of actual products, their economic and health objectives will not be realized.[113]

As noted earlier, however, developing countries are widely diverse in terms of the availability of resources and their ability to commercially exploit those resources.[114] Many developing countries—especially those that have been categorized as least developed countries by the United Nations—are unlikely to benefit from legislation similar to the Bayh-Dole Act.

Some developing countries have already been successful in focusing on and addressing local needs through research and development. "For example, South Africa is responding to the HIV/AIDS pandemic by prioritizing research on the disease; it is promoting the development of a vaccine against HIV subtype C, the strain most prevalent in that country (as well as in the rest of Africa and Asia)."[115] In Brazil, researchers at the federal University at Minas Gerais and a Brazilian pharmaceutical firm "developed and patented a process for

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W. VANFLEET, AM. ASS'N FOR THE ADVANCEMENT OF SCIENCE, TRADITIONAL KNOWLEDGE AND INTELLECTUAL PROPERTY: A HANDBOOK ON ISSUES AND OPTIONS FOR TRADITIONAL KNOWLEDGE HOLDERS IN PROTECTING THEIR INTELLECTUAL PROPERTY AND MAINTAINING BIOLOGICAL DIVERSITY 3 (2003), *available at* http://shr.aaas.org/tek/handbook/handbook.pdf (last visited Jan. 5, 2008) (defining "traditional knowledge" as "the information that people in a given community, based on experience and adaptation to a local culture and environment, have developed over time, and continue to development").

[112] *See* Paul Gepts, *Who Owns Biodiversity, and How Should the Owners be Compensated?*, 134 PLANT PHYSIOLOGY 1295, 1298 (2004) ("Genetic diversity is unevenly distributed around the planet, with most of the diversity located in tropical and subtropical regions, where most developing countries are located."). The government in China has identified biotechnology as a specific target for development and "this new approach is expected to develop and commercialize indigenous health biotechnology products that are internationally competitive." Li Zhenzhen et al., *Health Biotechnology in China—Reawakening of a Giant*, 22 NATURE BIOTECH. DC13, DC15 (2004). A current example of a country utilizing biodiversity resources to produce biopharmaceutical products is Cuba. *See* Halla Thorsteinsdóttir et al., *Cuba–Innovation Through Synergy*, 22 NATURE BIOTECH. DC19, DC19 (2004) ("Cuba is developing natural products based on the island's flora. An example is the natural anticholestoral drug policosanol (PPG), an 8-alcohol extract derived from the wax of one of the country's main crops, sugarcane.").

[113] Sapp, *supra* note 1033, at 212. (quoting Susan Kling Finston, Relevance of Genetic Resources to the Pharmaceutical Industry 11 (Dec. 2, 2004) (unpublished manuscript, presented at the D.C. Bar Convention on Biological Diversity)).

[114] Cuba is an example of a country with a well-developed biotechnology sector and the ability to exploit it. Interestingly, Cuba has filed over 500 patent applications on 200 products in the health biotechnology field and "exports biotechnology products to more than 50 countries, mainly in Latin America, Eastern Europe and Asia." Thorsteinsdóttir et al., *supra* note 1122, at DC19.

[115] Thorsteinsdóttir et al., *supra* note 822, at DC48.

recombinant human insulin."[116] Researchers in Brazil at the federal FIOCRUZ institute have also developed an attenuated virus to treat yellow fever and recombinant antigens to deal with Chagas disease.[117] India has developed a hepatitis B vaccine, which it sells within India and to the United Nations Children Foundation.[118] Researchers in Cuba developed a meningitis B vaccine and created "the world's first human vaccine with a synthetic antigen for *Haemophilus influenzea* type b."[119] Researchers in Egypt were able to develop recombinant insulin[120] and diagnostics for clinical use for hepatitis C, "the fastest growing infectious disease [in Egypt]."[121] Moreover, researchers in Thailand developed a method to treat drug resistant malaria that recently received a U.S. patent.[122] Moreover, researchers tend to publish articles in scientific journals on

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[116] Ferrer, *supra* note 822, at DC8.

[117] *Id.* at DC9. FIOCRUZ was founded to develop treatments for bubonic plague, yellow fever, and smallpox. *Id.* at DC10. Notably, the FIOCRUZ institute "also runs a manufacturing plant . . . that has vaccine and diagnostics production facilities." *Id.*

[118] Thorsteinsdóttir et al., *supra* note 822, at DC48; *see* Nandini K. Kumar et al., *Indian Biotechnology—Rapidly Evolving and Industry Led*, 22 NATURE BIOTECH. DC31, DC31 (2004) ("One of the biggest successes . . . was India's first indigenously developed hepatitis B vaccine . . . .").

[119] Thorsteinsdóttir et al., *supra* note 1122, at DC19. Some current research in Cuba includes "research on recombinant Dengue vaccine, preventative and therapeutic AIDS vaccines, cholera vaccine and a cancer therapeutic vaccine." *Id.* Additional biotechnology products developed by Cuba include other vaccines, therapeutics, and diagnostics. *Id.* at DC20. Some of the vaccines are purified meningococci for meningitis B and C, and synthetic Hib for pneumonia and meningitis. *Id.* Table 1. The therapeutics include recombinant streptokinase for cardiovascular disease, recombinant IFN-α for viral infections and ocological diseases, recombinant epideral growth factor for burns and ulcer healing, recombinant granulocyte colony-stimulating factor for leukopenia and neutropenia, MAb to CD3 for organ transplant rejection, recombinant erythropoietin-α for anemia, humanized MAb against epidermal growth factor receptor for head and neck tumors, and ateromixol for anti-cholesterol application. *Id.* Diagnostics include miniaturized enzyme-linked immunosorbent assay kits for AIDS, blood certification, and prenatal diagnosis; radiolabeled mAbs targeting various cancer markers for cancer imaging; and enzyme-linked immunosorbent assays for syphilis and celiac disease. *Id.*

[120] Thorsteinsdóttir et al., *supra* note 822, at DC48.

[121] Basma Abdelgafar et al., *The Emergence of Egyptian Biotechnology from Generics*, 22 NATURE BIOTECH. DC25, DC25 (2004).

[122] *Thai Team Gets US Patent for Malaria Drugs Breakthrough*, BANGKOK POST, June 19, 2007. Researchers in developing countries such as "Argentina, Brazil, China, Cuba, Egypt, India, Mexico and South Africa" have been conducting research on a wide range of crops, including "banana, cassava, cowpea, plantain, rice and sorghum" and some "developing countries will soon have new [genetically modified] crops available such as virus-resistant papaya, sweet potato and cassava as well as rice tolerant to abiotic stresses (salinity and drought)." Food and Agriculture Organization of the United Nations, Biotechnology: Several Developing Countries Now Have Well-Developed Programmes , http://www.fao.org/newsroom/en/news/2005/102236/index.html (last visited Jan. 5, 2008).

local health issues.[123] In Brazil, researchers publish on tropical diseases which have a large impact on its population.[124] South African researchers publish heavily on virology, which includes HIV/AIDS.[125] Researchers in South Africa and Brazil are utilizing indigenous medicinal knowledge and biodiversity resources in the search for solutions to local problems.[126] Notably, the countries listed in these examples invented and developed technologies used to solve local problems apparently without the need for legislation similar to the Bayh-Dole Act to spur commercialization. However, passage of legislation similar to Bayh-Dole may lead to an increase of such activity as more government and private resources are diverted to developing government-funded technology. Bayh-Dole legislation may enable university researchers to utilize private expertise and funding, and may increase the likelihood of the development of products and services to address local needs. In a best-case scenario, local companies may be created to license and further develop research developed in universities utilizing government funding.

Some developing countries have also been successful in licensing government-funded technology. For example, Singapore's Agency for Science, Technology and Research is responsible for the funding and development of twelve public research institutes and its commercial licensing arm, Exploit Technologies, has "licensed more than 80 cutting edge technologies (in . . . science, engineering and biomedical sciences) to companies which cover the wide spectrum from small and medium enterprises to multinationals, thus providing them with a competitive edge to stay ahead in the global biotechnology race."[127] In Indonesia, the Kekayaan Intelektual dan Alih Teknologi [KIAT], a

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[123] "Furthermore, preliminary analysis of scientometric data suggests that some of the seven case study countries publish predominately in scientific fields relevant to the health problems within their own countries." Thorsteinsdóttir et al., *supra* note 822, at DC48 (citation omitted).

[124] *Id.*

[125] *Id.*

[126] *Id.* at DC50. Notably, India is attempting to "draw from a rich heritage of traditional knowledge, and a genetically diverse population." Kumar et al., *supra* note 11818, at DC36. A recent collaborative agreement "entails the Department of [Ayruveda, Yoga & Naturopathy, Unani, Siddha, and Homeopathy (AYUSH)] identifying traditional formulations, the [Council for Scientific and Industrial Research (CSIR)] conducting the pre-clinical toxicological studies, and the [Indian Council of Medical Research (ICMR)] carrying out clinical trials to test it." *Id.*

[127] Morley Muralitharan, *Snapshot of Singapore: Biotechnology Boom Indicators*, 10 ASIA PAC. BIOTECH NEWS 402, 402-03 (2006). Notably, Singapore is quickly establishing itself as a leader in biotechnology in Asia and is developing the needed infrastructure and human capital resources to succeed. Indeed, Singapore's biomedical services industry manufacturing output increased to $11.3 billion (U.S.) in 2005 from its initial launch in 2000. Sheo S. Rai, *Overview of the BMS Industry*, 10 ASIA PAC. BIOTECH NEWS 404, 404 (2006). Singapore also offered over $18.2 million (U.S.) in grants to research institutes and hospitals. Chan Yiu Lin, *The Buzz in Singapore's Biotech Industry*, 10 ASIA PAC. BIOTECH NEWS 407, 407 (2006). "In February 2006, Bio*One Capital and the Lonza Group announced that they are jointly building a large-scale mammalian cell culture plant in Singapore for the manufacture of commercial biopharmaceuticals, totaling an investment of US$250 million." *Id.* at 411. Moreover, local companies have even developed avian flu diagnostic kits. *Id.* Employment in the biomedical services industry in Singapore in 2006 was

technology transfer office, was formed as "part of the Indonesian Agricultural Research Foundation, a private non-profit organization established by the national government to facilitate technology transfer, licensing and commercialization of agricultural technologies."[128] The KIAT has entered into numerous negotiations for licenses to commercialize bio-fertilizer, bio-bactericide, and hybrid maize, and has licensed "Rhizobium based bio-fertilizer for soybean[s] to a private company, for production and sale throughout Indonesia."[129] India, in particular, has been successful in developing commercial applications from traditional knowledge and then transferring that technology to private companies for commercialization.[130] Development of the drug Jeevani through collaboration with the Kani serves as a particularly good example:

> The Kani are an ethnic group of some 16,000 people who live in southwestern India. Working primarily with three Kani consultants, the Tropical Botanical Garden and Research Institute (TBGRI) of India learned of the antifatigue properties of a wild plant. From this plant the TBGRI developed the drug Jeevani. When the TBGRI transferred manufacturing rights to Aryavaidya Pharmacy Coimbatore Ltd., TBGRI agreed to share 50-50 the license and royalty income with the Kani. It took a while for the various Kani clans to agree, but in time they established the Kerala Kani Samudaya Kshema Trust to manage this income.
> Through 2001, the Trust Society—fully managed by Kani—has received 1,345,000 Indian rupees (about US$30,000) of royalties and fees .... The Trust Society has funded various self-employment schemes for unemployed Kani youth and has provided special financial assistance of IRs 25,000 for the welfare of two tribal children whose mother was killed by a wild elephant. It also paid IRs 50,000 to the three Kani consultants who initially provided the knowledge to TBGRI.[131]

In another case, the San community, hunter-gathers in South Africa, will be paid a percentage of the royalties and milestone payments received by the licensor, the South African Council for Scientific and Industrial Research, from the licensee, Phytopharm, a United Kingdom-based company, for an anti-obesity drug derived from the Hoodia plant.[132] Interestingly, Cuba has engaged in

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10,200. Lionel Lau, *Boom Time for Biomedical Sciences in Singapore: A Perspective from an Educational Institute*, 10 ASIA PAC. BIOTECH NEWS 413, 413 (2006). Singapore attracted over $500 million (U.S.) in investments in its biomedical services industry in both 2004 and 2005. *Id.* at 414. Despite this success, private venture capital investment is still low. Morley Muralitharan et al., *Survey Commentaries and Analysis on Singapore Biotechnology Venture Capital, Intellectual and Property Regulatory Law*, 10 ASIA PAC. BIOTECH NEWS 442, 442-43 (2006). One reason for the low private venture capital investment is the relative lack of experienced intellectual property legal personnel. *Id.* at 443.

[128] Maredia et al., *supra* note 811, at 18.

[129] *Id.*

[130] *See* Finger, *supra* note 1000, at 20.

[131] *Id.*

[132] *See* Tamar Kahn, *Indigenous Group to Share Royalties on Anti-Obesity Drug*, SCI. & DEV. NETWORK, Mar. 26, 2003, http://www.scidev.net/News/index.cfm?fuseaction=readNews&itemid=355&language=1 (last visited Jan. 5, 2008). Notably,

commercial collaborations to manufacture and distribute its meningitis vaccine with GlaxoSmithKline in Europe and North America and manufacture its hepatitis B vaccine with an Indian firm, Panacea Biotec.[133] Cuba has also entered a joint venture with a Canadian firm to develop and market cancer therapeutics and made an agreement with the U.S. firm, CancerVax, to develop and license cancer vaccines.[134] While these examples may be atypical, they do provide evidence of the possibility of addressing local needs and other issues through the transfer of government-funded inventions developed sometimes with the aid of indigenous and biodiversity resources to private companies. Legislation similar to the Bayh-Dole Act adopted in developing countries may facilitate technology transfer that results in a redirection of research agendas toward addressing local needs and may also channel attention to the commercialization of local resources. However, for most developing countries the conditions necessary to recreate the purported impact of the Bayh-Dole Act in the United States are not present.

IV. CONCLUSION

If developing countries adopt legislation similar to the Bayh-Dole Act, they should make modifications to the Act to tailor it to their local conditions and to address potential problems identified by examining the impact of the Bayh-Dole Act in the United States. The question of whether developing countries that enact legislation similar to Bayh-Dole will receive a similar purported impact that has occurred in the United States is unclear. However, adopting that legislation may result in the direction of government funding to providing solutions to local needs.

"[o]nly after a public outcry about the lack of benefit sharing with the San was a deal brokered that pledged a percentage of the royalties to them." Talent Ngandwe, *African "Biopiracy" Debate Heats Up*, SCI. & DEV. NETWORK, Feb. 2, 2006, http://www.scidev.net/content/news/eng/african-biopiracy-debate-heats-up.cfm (last visited Jan. 5, 2008). For additional discussion of the agreement with the San concerning the Hoodia plant, *see* Marion Motari et al., *South Africa—Blazing a Trail for African Biotechnology*, 22 NATURE BIOTECH. DC37, DC38 (2004).

[133] Thorsteinsdóttir et al., *supra* note 1122, at DC23.

[134] *Id.*