THE BAYH-DOLE ACT: IMPLICATIONS FOR DEVELOPING COUNTRIES

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I. INTRODUCTION

The Bayh-Dole Act[1] of 1980 was intended to facilitate the commercialization of inventions resulting from U.S. federally-funded research. By designing incentives for universities, faculty inventors, and private industry to engage in the commercialization process, the Act's proponents hoped to foster the creation of new products and services from research that might otherwise remain early-stage and undeveloped. Clear ownership of intellectual property, and the ability to negotiate exclusive licenses, were seen as necessary elements in a policy striving to stimulate private sector investment in the development of government-funded innovations.[2]

The Bayh-Dole Act created default ownership of patent rights for universities[3] and allowed for exclusive licensing. In addition, the Act contained requirements for universities to favor licensing contracts with domestic and small businesses and to take reasonable steps to ensure commercialization of their inventions. Under very limited circumstances, the Act also allowed for

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1 Throughout the paper, "Bayh-Dole" or "the Act" refers to the Bayh-Dole Act, Pub.L. No. 96-517, 98 Stat. 3015 (1980) (The Patent and Trademark Act of 1980) (amendments included in Pub.L. No. 98-620, 98 Stat. 3335 (1984)).

2 Prior to Bayh-Dole, U.S. universities could seek patent rights through the negotiation of an Institutional Patent Agreement ("IPA") with the appropriate government funding agency. Bayh-Dole was intended to replace the IPA system with a simpler mechanism and reduce the uncertainty surrounding patent ownership and the ability to license exclusively.

3 The original legislation allowed for any university, small business, or non-profit institution receiving government grants to retain patent rights on inventions developed with federal funding. The scope of the legislation was later expanded to include *any* institution receiving a federal grant, regardless of size.

"march-in" rights, under which the government can require the compulsory licensing of a patent.

Twenty-five years after becoming law, the effects of the Bayh-Dole Act in the U.S. remain controversial. Some regard it as a catalyst for economic growth, fundamental to the transfer of technology from university to industry. Others argue that the legislation has the potential for unintended and deleterious consequences for the innovation system. Even though the debate involves issues of particular relevance to developing countries, remarkably little has been written about the Bayh-Dole Act in relation to the needs of the poor and underserved. Empirical evidence is lacking to answer concerns about whether the Act has changed developing countries' access to U.S. publicly-funded research or whether the focus of research in U.S. universities has shifted away from fundamental research, that targets applications to developing country agriculture and health, in order to focus on research targeted to commercial applications for the most developed countries. Neither has the recent international trend to emulate the Bayh-Dole Act received considerable attention in relation to developing countries' interests.

The analysis here is limited both by the lack of a foundation of empirical literature on the topic, and by difficulties inherent in considering an extraordinary diversity of economies under one rubric, "developing countries." While we identify important considerations in the debate on Bayh-Dole's implications for developing countries, the issues we raise should be considered in the context of specific situations; appropriate policy options will depend on regional, national and sectoral analyses of conditions and objectives.

II. Bayh-Dole in the U.S. and Developing Countries' Access to Technology

A. Access to Basic Research

North-South partnerships are a key element in developing countries' access to technology. The North's concentrated ownership and control of technologies necessary for research in agriculture and health creates the potential for the needs of the poor and underserved to remain unmet by technological advances.[4] Recent growth in U.S. patenting and the debate about proprietary ownership of research tools are, therefore, particularly relevant to developing countries' research. Whether access to enabling technologies has been impeded, *per*

4 Léa Velho, *Agricultural Biotechnology Research Partnerships in Sub-Saharan Africa: Achievements, Challenges and Policy Issues*, 3 Tech. Policy Briefs 1 (2004).

se, by the Bayh-Dole Act is not clear. However, it is clear that, since 1980, universities have increasingly used the patent system as a tool to commercialize their research results. David Mowery[5] cautions against attributing increased university patenting solely to the Bayh-Dole legislation, citing university patenting trends that began before 1980 and many other influences to a widespread rise in patenting, but the trends in universities acquiring proprietary rights to technologies are undisputed. As a consequence, there are reasons to highlight the importance of the role of U.S. universities and non-profit institutions in managing their intellectual property ("IP") so as to provide greater access to developing countries. In their patent portfolios, U.S. universities and non-profit institutions hold a valuable resource to which developing country access may be increasingly limited. While the U.S. public sector owns roughly 2.5% of patents across all technology fields, in agriculture the story is quite different; almost a quarter of patents are owned by universities and non-profit research institutions.[6] In health, too, patents central to developing country needs are held by universities. Kapczynski *et al.*[7] cite major HIV treatment drug patents held by Yale University, University of Minnesota, Emory University and Duke University.[8]

Given that the strategic management of U.S. universities' IP portfolios involves daily patenting and licensing decisions made by technology transfer staff that are crucial to defining future access to a technology, it is worth considering the incentive structure surrounding these decisions. While technology transfer offices ("TTOs") typically perform a wide range of services beyond patenting and licensing,[9] the offices are held to performance standards based on numbers of patents and licenses, and revenue generated. In a survey of technol-

5 David C. Mowery, Richard R. Nelson, Bhaven N. Sampat & Arvids A. Ziedonis, *The Growth of Patenting and Licensing by U.S. Universities: An Assessment of the Effects of the Bayh-Dole Act of 1980*, 30 Research Policy 99, 100 (2001).

6 Gregory D. Graff, Susan E. Cullen, Kent J. Bradford, David Zilberman & Alan B. Bennett, *The Public−Private Structure of Intellectual Property Ownership in Agricultural Biotechnology,* 21 Nat. Biotechnology, 989-95 (2003).

7 A. Kapczynski, E.T. Crone & M. Merson, *Global Health and University Patents*, 301 Sci. 1629 (2003).

8 "[S]tavudine (Yale University), abacavir (University of Minnesota), lamivudine (Emory University), and enfuvirtide (Duke University)." *Id.*

9 The TTOs mandate may include, for instance: assisting joint ventures, consortia, startups, and contracted research related to the commercializing university inventions; undertaking publicity and information campaigns to promote new research; assessing technologies for commercial potential; arranging prototype development funding; and advising faculty on intellectual property issues.

ogy transfer offices, Jerry Thursby *et al*.[10] found that licensing revenue was the TTO's most important measure of success.

Arti Rai and Rebecca Eisenberg[11] consider incentives governing the decisions of patenting and licensing in conjunction with the preservation of the public domain. They argue that Bayh-Dole may have created incentives that undermine the representation of the public interest in the calculus of determining which technologies should be patented and how they are licensed. Focusing on access to research tools, they note that the benefits of proprietary ownership of research tools flow to the TTOs, but the cost is borne by the university's scientists as their access to appropriate technologies becomes more likely to be impeded. While the debate about access to research tools most often centers on the access of U.S. researchers, not developing countries, to U.S. university patents, the arguments highlight the exigency of making prudent patenting and licensing decisions and the challenges of misaligned incentives.

The International Rice Research Institute ("IRRIs") experience with the Xa21 rice gene illustrates how university patenting and licensing strategies can limit developing countries' access to technology.[12] IRRI identified a bacterial blight resistance gene and bred it, by conventional techniques, into cultivated rice varieties. University of California, Davis acquired one of the IRRI varieties, then mapped, sequenced, and cloned the gene (called Xa21). The resulting patented technology was then licensed exclusively, which had the potential of blocking IRRI's use of a gene that they had themselves characterized. Eventually the difficulties were overcome, and, in fact, a "Genetics Resource Recognition" fund was established for research fellowships for students from Mali where the gene originated, but the process took several years of negotiation. Patenting and licensing decisions at technology transfer offices are often difficult or impossible to change, after the fact, and can have consequences that last decades. The University of California's experience with IRRI illustrates the value of a well-informed and discerning technology transfer office staff.

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10 Jerry G. Thursby, Richard Jensen & Marie Thursby, *Objectives, Characteristics and Outcomes of University Licensing: A Survey of Major U.S. Universities*, 26 J. Tech. Transfer 59, 65 (2001).

11 Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 L. & Contemp. Probs. 289, 310 (2003).

12 *See* Ronald P. Cantrell, Gene P. Hettel, Gerard F. Barry & Ruaraidh Sackville Hamilton, *The Impact of Intellectual Property on Nonprofit Research Institutions and the Developing Countries They Serve*, 6 Minn. J.L. Sci. & Tech. 253 (2004).

The Public Intellectual Property Resource for Agriculture ("PIPRA"),[13] was developed in response to concerns about IP impediments to research and development on subsistence crops for the developing world. PIPRA uses the structure of IP-ownership that Bayh-Dole facilitated, and recognizes that the patent system provides an important tool to promote commercialization of technology. But PIPRA has also created a mechanism for its members to collaboratively manage their agricultural IP with goals that focus on both individual universities' interests as well as public interests.

A new trend in licensing language, aimed at the reservation of access rights for research and for humanitarian commercial development, that benefits the poor and underserved, provides an example of how the patenting and licensing discretion allowed by Bayh-Dole can be used strategically. The Equitable Access License[14] for health technologies and PIPRA's humanitarian use reservation of rights language for agriculture[15] are two examples. The groups promoting these licensing clauses hope that university technology transfer offices will begin to routinely include them in exclusive licenses.

III. THE U.S UNIVERSITY RESEARCH AGENDA AND THE BAYH-DOLE ACT

Commercial development of agriculture and health technologies leaves developing countries' needs largely unmet. Less than 10% of health research funding is targeted at diseases that account for 90% of the global disease burden.[16] In agricultural biotechnology, too, investment remains focused on a small number of crops and traits of very limited relevance to developing country agricultural challenges. Public research, therefore, remains pivotal to the development of technologies in health and agriculture that do not have commercial markets. This is not a new situation, since advances in subsistence crops and neglected diseases have historically depended on research in the public sector. What is new, is that while these targeted research results have been historically

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13 *See* The Public Intellectual Property Resource for Agriculture, http://www.pipra.org (accessed Nov. 6, 2005).

14 Universities Allied for Essential Medicines, *Model Provisions for an Equitable Access and Neglected Disease License*, http://www.essentialmedicine.org/EAL.pdf (accessed Nov. 6, 2005).

15 Public Intellectual Property Resource for Agriculture, *Draft Definition of Humanitarian Use*, http://www.pipra.org/docs/HumResLanguagePIPRA.doc (accessed Nov. 6, 2005).

16 These statistics have been used to coin the phrase "10/90 Gap." *See* Global Forum for Health Research, *The 10/90 Report on Health Research: 10/90 Report 2003/2004*, http://www.globalforumhealth.org (accessed Nov. 6, 2005).

treated as public goods, today they are increasingly proprietary and have the potential to be diverted from their intended recipients to commercial applications. Thus, the Bayh-Dole Act's effects on the research agenda of U.S. university faculty are an appropriate concern for developing countries' needs. Two areas of concern deserve attention. The first is whether Bayh-Dole has influenced university faculty toward research with more commercial applications and second, whether the general increase in patenting has created impediments to research and to humanitarian applications of new technologies.

Investigations into whether the Bayh-Dole Act has caused university research to move toward more commercial applications have produced mixed empirical evidence. Henderson *et al.* found a decreasing trend in the quality of university patents, [17] where innovative merit was based on the number of forward citations. This evidence was taken as a harbinger of a future trend toward more applied research. However, further investigations by David Mowery[18] indicated that the trend in "poorer quality" patents likely resulted from an increased number of new and inexperienced technology transfer offices, not a systemic change in the nature of academic research. Case studies by Colyvas *et al.*,[19] Thursby and Thursby,[20] and Mowery *et al.*[21] also provide empirical evidence that faculty research has not been markedly affected by the changes brought about in the Bayh-Dole legislation. Some authors (for example, Jason Owen-Smith[22]) propose that a shift in the relationship between academic research and commerce, catalyzed in part by the Bayh-Dole Act, has brought about changes in the environment of faculty research. Still others consider the possibility of applied and basic research as complements rather than substi-

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17 Henderson et al. suggested the trend in citations per patent was due to an increased "propensity to patent" at TTOs. *See* Rebecca Henderson, Adam B. Jaffe & Manuel Trajtenberg, *Universities as a Source of Commercial Technology: A Detailed Analysis of University Patenting, 1965-1988*, 80 Rev. of Econ. & Statistics, 119, 119 (1998).

18 *See* Mowery, *supra* n. 5; David C. Mowery, Bhaven N. Sampat & Arivds A. Ziedonis, *Learning to Patent: Institutional Experience, Learning, and the Characteristics of U.S. University Patents After the Bayh-Dole Act, 1981-1992*, 48 Mgt. Sci. 73 (2002); David C. Mowery & Arvids A. Ziedonis, *Academic Patent Quality and Quantity Before and After the Bayh-Dole Act in the United States*, 31 Research Policy 399 (2002).

19 Jeannette Colyvas, Michael Crow, Annetine Gelijns, Roberto Mazzoleni, Richard R. Nelson, Nathan Rosenberg & Bhaven N. Sampat, *How Do University Inventions Get Into Practice*, 48 Mgt. Sci. 61, 63 (2002).

20 Jerry G. Thursby & Marie C. Thursby, *University Licensing and the Bayh-Dole Act*, 301 Sci. 1052,1052 (Aug. 22, 2003).

21 Mowery, *supra* n. 5.

22 *See* Jason Owen-Smith, *Trends and Transitions in the Institutional Environment for Public and Private Science*, 49 Higher Educ. 91, 93 (2005).

tutes.[23] One perspective is that the source of funding is more important in the determination of a researcher's agenda than potential commercial activities or licensing revenues. Given that more than 93% of academic funding comes from non-industry sources,[24] this may be a larger driver determining faculty's predilection for basic or applied research. Whether, and how, increased commercialization of university research has changed faculty behavior is important for developing countries considering emulating Bayh-Dole, as well as for gauging continued interest for research scientists' work on developing countries' crops and diseases without the promise of commercial rewards. Overall, there is a need for more research examining the effects of Bayh-Dole on faculty behavior.

Another potential effect of increased patenting on the U.S. university research agenda concerns the "anticommons," a term coined by Heller and Eisenberg[25] to describe how technologies owned by multiple parties may impose daunting transaction costs and delays in accessing research inputs which ultimately may lead to an underutilization of proprietary technologies.[26] The "patent thickets,"[27] that can create anticommons, result from a widespread increase in patenting, by both firms and universities, and therefore we cannot attribute anticommons effects directly to increased university patenting, let alone to Bayh-Dole. However, the Bayh-Dole Act may have an effect on the range of possible remedies for anticommons.[28] For this reason and because the commercialization of technologies relevant to developing countries is particularly prone

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23 Marie Thursby, Jerry Thursby & Swastika Mukherjee, *Are There Real Effects of Licensing on Academic Research? A Life Cycle View* 4 (Natl. Bureau of Econ. Research Working Paper No. 11497 June 2005).

24 National Science Board, 1 Science and Engineering Indicators,, National Science Foundation (Arlington, VA) (2004).

25 *See* Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 Sci. 698, 698 (May 1, 1998).

26 In discussing the effects of anticommons on university research, it is important to segregate the problems caused by material transfer agreements ("MTAs") from those caused by access to patented technology. Delays in research due to the negotiation of MTAs for the transfer of tangible property have been identified as a significant problem. *See e.g.* National Institutes of Health, *Report of the National Institutes of Health (NIH) Working Group on Research Tools*, *Presented to the Advisory Committee to the Director June 4, 1998*, http://www.nih.gov/news/researchtools/ (accessed Sept. 15, 2005). Here we restrict our focus specifically to problems concerning access to intellectual, not tangible, property.

27 The term "patent thicket" was coined by Carl Shapiro. *See* Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting*, 1 Innovation Policy and the Economy 119, 119 (2001).

28 *See* Sections 2 and 4.2 for discussion of PIPRA and BiOS as examples.

to anticommons impediments, we include a review of current anticommons literature here.

Until recently, universities often incorrectly considered their use of proprietarily-owned technology to be exempt from infringement. The *Madey v. Duke University*[29] decision, however, made clear that effectively no research exemption exists in U.S. law and thereby created a precarious legal situation for U.S. universities. There has not yet been a trend toward commercial firms suing universities for the infringement of patents used by their faculty in research,[30] but there has been increasing pressure for universities to license research tools on behalf of their researchers.[31] Neither have universities begun to sue each other for infringement. In fact, there exists an informal code of conduct among universities discouraging challenges of researchers' infringement of patents in the course of fundamental research.[32] However, behavior such as the recent demands from Basel University to enforce an enabling technology patent used for research purposes at U.S. universities[33] brings into question the robustness of the university-to-university code of conduct. Universities' vulnerability to infringement suits, highlighted by *Madey v. Duke University* and the increasing trend in requests for licenses, indicate that it may only be a matter of time before the U.S. university system is forced to face a difficult problem. Insight into the magnitude of the problem can be gained from a recent project at the University of Iowa. Here, an investigation to determine the ownership of IP used in a single lab involved contacting seventy-one different people and an expenditure of

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29 *See Madey v. Duke Univ.*, 307 F.3d 1351, 1362 (Fed. Cir. 2002).

30 The *Madey v. Duke Univ.* case was based on a dispute between employer and employee, rather than a commercial firm's decision to sue a university. Duke contended that Madey managed his lab ineffectively and eventually removed him from director of the lab in 1997. Madey contended that Duke sought contracts for unwarranted use of the lab's equipment and that his objection to that cost him his job as lab director. Madey resigned from Duke in 1998 and when continued to operate the lab equipment, Madey brought a patent infringement suit. Therefore the case, while it gained landmark status, is somewhat of an anomaly in terms of its origin.

31 *See* Eliot Marshall, *DuPont Ups Ante on Use of Harvard's OncoMouse*, 296 Sci. 1212 (2002). But Walsh et al. finds that the pressure for universities to in-license patented technologies is largely restricted to clinical research, based on diagnostic tests. *See* John P. Walsh, Ashish Arora & Wesley M. Cohen, *Research Tool Patenting and Licensing and Biomedical Innovation*, 10 Pats. in the Knowledge-Based Econ., 285, 317 (2003).

32 *See* Walsh, *supra* n. 31.

33 E-mail from Thomas Bauer, Transfer Specialist, Office of Technology Transfer, University of Basel, stating that University of Basel had acquired from BASF Aktiengesellschaft, Germany, a worldwide exclusive license to produce, offer, sell and use the TEF2-Promoter and Terminator System and requesting that other universities take a license for the patented technology (Mar. 2005).

$24,000 to do background checks and send letters to patent owners.[34] None of the patent owners required the university to take licenses for the technologies involved. The figures here, then, represent transaction costs involved in auditing the IP used by faculty and ascertaining ownership of the IP. Were in-licensing required, significant further transaction costs would be incurred. The *Madey v. Duke University* decision and the commercial value of research tools have the potential to make the effects of an anticommons considerably worse and serve to draw attention to the benefits for other countries, including clearly defined research exemptions in their innovation policies.

Even when research at universities can be pursued without the need to in-license, intellectual property rights ("IPR")-related difficulties can arise at the point when university research leaves the academic environment and moves toward commercialization. Leaving the examination of freedom-to-operate[35] ("FTO") until this later stage, perhaps after years of research, can create a situation where proprietarily-owned technologies are embedded and re-engineering the innovation to use other technologies may be financially or technically infeasible. As a consequence, there are fewer options for achieving freedom-to-operate and a higher likelihood of IPR-related impediments to commercialization. Unlike universities, commercial firms often evaluate promising research projects early on for IPR considerations,[36] a practice that provides greater flexibility and allows freedom-to-operate information to be accounted for in weighing the costs and benefits of commercializing a particular path of research. Because this early-stage assessment of IPR does not occur at universities,[37] the

34 Bernard Wysocki Jr., *Cutting Edge: A Laser Case Sears Universities' Right to Ignore Patents: Court Narrows an Exemption in Suit Over Device at Duke and a Spurned Physicist*, Wall Street Journal A1 (Oct. 11, 2004).

35 A freedom-to-operate examination entails an evaluation of whether the making, using, or selling of a particular technology is likely to infringe a third party's patent. Once the potentially infringed patents are identified, they may be invented around, licensed, or simply ignored, depending on the assessed risks of infringement and other constraints.

36 "We start very early on . . . to assess the patent situation. When the patent situation looks too formidable, the project never gets off the ground. . . . Once you are well into development, you get patent issues, but not the show stopper that you would identify early on." Walsh, *supra* n. 31, at 303.

37 Freedom-to-operate assessment is a time-consuming and expensive process. While a commercial firm can weigh these costs against its future profits, neither the university inventor, nor the technology transfer office is in a position to invest in FTO research. In addition, the academic focus on publishing, rather than commercialization, means that inventors may seek out the most technically superior set of research tools, regardless of whether they are patented, in an effort to achieve the desired results. In the area of agriculture, PIPRA serves to address FTO issues, delivering services individual universities are not designed to provide.

commercialization of university research can be particularly prone to IPR impediments. Indeed, anecdotal evidence suggests that in practice researchers are experiencing problems in this respect; research is being re-directed, delayed, or shelved altogether because of the impossibility or high cost of accessing the necessary permissions to incorporate patented technologies into a research program that has a potential commercial outcome.[38]

In developing countries' agricultural research, this effect was famously illustrated by the story of Golden Rice™.[39] Little attention was paid to IPRs in the research stage; only when the crop was headed for commercialization were the many pieces of technical and intellectual property identified. After some delay, licenses were negotiated and the development of the crop progressed. But it is unclear whether this would have been the case had there not been a high level of publicity[40] and significant investment in the IP audit and license negotiation process.[41] The successful clearance of Golden Rice™ through a set of IPR hurdles serves to highlight the hurdles themselves and identify a central problem in the commercialization of university research.

Two new papers find evidence of anticommons effects by examining how citations of a technology in published literature change over time. Murray and Stern show that forward citations on papers drop off after a patent issues on the technology and interpret this as indicative of a "modest anticommons effect."[42] Sampat, citing several authors documenting the use of disease gene pat-

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PIPRA analyzes the freedom-to-operate of commonly-used research tools and works to identify technologies with clear FTO that researchers can substitute for patented research tools.

38 In agriculture, examples of holdups due to intellectual property include the University of California's long shelf-life tomato, Michigan State University's transgenic turfgrass, CLIMA's (Australia's) herbicide tolerant lupin and University of California's herbicide tolerant barley. *See* Brian D. Wright, *Public Germplasm Development at a Crossroads: Biotechnology and Intellectual Property*, 52 Cal. Agric. 8 (1983).

39 Investigations revealed 70 pieces of intellectual property and 15 pieces of technical property. These properties were owned by 31 different institutions. *See* R. David Kryder, Stanley P. Kowalski & Anatole F. Krattiger, *The Intellectual and Technical Property Components of Pro-Vitamin A Rice (Golden Rice™): A Preliminary Freedom-To-Operate Review*, International Service for the Acquisition of Agri-biotech Applications (ISAAA), i, vi (2000).

40 Inventor Ingo Potrykus recounts: "[p]ublicity sometimes can be helpful: Only a few days after the cover story about "golden rice" had appeared in *Time*, I had a phone call from Monsanto offering free licenses for the company's IPR involved." Ingo Potrykus, *Golden Rice and Beyond,* 125 Plant Physiology 1157, 1159 (2001).

41 Both the Rockefeller Foundation and Zeneca (Fernhurst, UK) were instrumental in achieving freedom-to-operate. *Id*.

42 Fiona Murray & Scott Stern, *Do Formal Intellectual Property Rights Hinder the Free Flow of Scientific Knowledge? An Empirical Test of the Anti-Commons Hypothesis* 1 (Natl. Bureau of Econ. Research Working Paper No. W11465 July 2005).

ents to limit future research and clinical testing,[43] finds support for this argument in his empirical work with genomic patents. He interprets his results as "evidence that academic genomic patents can hinder subsequent scientific research."[44] Interestingly, Sampat finds the effect in a particular category of genomics patents known to be frequently exclusively licensed, but the effect is absent in a different type of genomics patent known to be widely, non-exclusively licensed.[45] His research also suggests that the effect has worsened over time.

Walsh *et. al.*,[46] in contrast to much of the work cited above, find that proprietary ownership of research tools "rarely precluded the pursuit of worthwhile projects." This conclusion may not be relevant to developing countries' perspectives, however. If "worthwhile projects" are equated with research that has commercial potential, then products with limited commercial markets and insufficient potential profitability to overcome IP impediments may suffer disproportionately from anticommons problems.

IV. EMULATING BAYH-DOLE IN DEVELOPING COUNTRIES

Implementing national science and technology policies for the developing world has become a top priority in the effort to alleviate poverty (for example, Kofi Annan's opinion piece in *Science*[47]). Policy analysts argue that effective innovation policies require strategically-placed intellectual property rights

43 Michelle R. Henry, Mildred K. Cho, Meredith A. Weaver & Jon F. Merz, *Policy Forum: Genetics: DNA Patenting and Licensing*, 297 Science 1279, 1279 (2002); Michelle R. Henry, Mildred K. Cho, Meredith A. Weaver & Jon F. Merz, *A Pilot Survey on the Licensing of DNA Inventions*, 31 J.L., Med. & Ethics 442, 442-49 (2003); Mildred K. Cho, Samantha Illangasekare, Meredith A. Weaver, Debra G. B. Leonard & Jon F. Merz, *Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services*, 5 J. Molecular Diagnostics 3, 3 (2003); Jon F. Merz, Antigone G. Kriss, Debra G. B. Leonard & Mildred K. Cho, *Diagnostic Testing Fails the Test: The Pitfalls of Patents are Illustrated by the Case of Haemochromatosis*, 415 Nature 577, 577-79 (2002).

44 Bhaven N. Sampat, *Genomic Patenting by Academic Researchers: Bad for Science?*, 1, 26 Mimeo (2004).

45 According to Sampat, gene sequence patents are often exclusively licensed, *see* Henry, 31 J.L., Med. & Ethics at 442-49, while non-sequence genomic patents, "techniques," are non-exclusively licensed. *See* David C. Mowery, *Ivory Tower and Industrial Innovation: University-Industry Transfer Before and After Bayh-Dole*, 1, 158-59 (2004) (discussing non-exclusive licensing of the Axel cotransformation patent and the Cohen-Boyer patents).

46 John P. Walsh, Ashish Arora & Wesley M. Cohen, *Working Through the Patent Problem*, 299 Science 1021, 1021 (2003).

47 Kofi Annan, *Science for All Nations*, 303 Science 905 (Feb. 13, 2004).

as incentives and that the role of universities in developing countries may need to change.[48] These issues are of interest not only at national and international levels, but at the institutional level as well. Wolson,[49] for example, discusses the changing nature of technology transfer at West African universities where partnerships between government, university, and industry are becoming more common. She notes a trend toward contracts between individual university researchers and private firms, often excluding the host university from the potential benefits. For these universities, and more generally in the design of innovation policies, the ownership of, and access to, inventions created within universities is clearly an important issue.

The Bayh-Dole Act appears to be an attractive and proven solution to a growing need for technology transfer policy. However, policies modeled after the Act are unlikely to deliver the much-vaunted results reported in the press.[50] Neither the conditions that prefaced the adoption of the Bayh-Dole Act nor many of the environmental factors determining its effects in the U.S. are prevalent in developing countries. Bayh-Dole was intended to stimulate public institutions' participation in a well-established intellectual property regime, dominated by commercial interests. In contrast, IP regimes in many developing countries are nascent and provide a very different environment in which to establish a policy for the ownership of university intellectual property. The Bayh-Dole Act built on a vibrant history of university-industry collaboration[51] which, again, may be lacking in some, and emerging in other, developing countries.[52] The technology sectors in which Bayh-Dole has shown its greatest licensing successes (biomedical and biotechnology) may represent a portion of unpat-

[48] Technology, Science, and Innovation Task Force, United Nations Millennium Project, *Innovation: Applying Knowledge in Development* 1, 93, 112 (2005).

[49] Rosemary Wolson, *The Global Biodiversity Institute/International Institute of Tropical Agriculture Training Course on Biodiversity, Biotechnology, and Law 1-24 March 2000 Ibadan, Nigeria,* 1-58, 31 (2000).

[50] *See e.g. Innovation's Golden Goose*, The Economist, (Dec. 14, 2002) ("More than anything, this single policy measure helped to reverse America's precipitous slide into industrial irrelevance.").

[51] 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, 115-27 (2005).

[52] Mexico provides an example of a country that, even with a relatively advanced IPR system, lacks strong industry-university collaboration. *See* Jaime Aboites & Mario Cimoli, *Intellectual Property Rights and National Innovation Systems: Some Lessons from the Mexican Experience*, 99 Revue d'Economie Industrielle 215, 216 (2002).

entable subject matter in some developing countries[53] or areas where developing countries are lacking in infrastructure and investment. Finally, the scale of the U.S. higher education research enterprise is unique and it is complemented by a robust research-intensive industry sector which works closely in translating university inventions into products. In contrast, while a large proportion of innovation in developing countries occurs in university or government laboratories, they are often only modestly funded and may not have ready access to commercial partners with resources needed for follow-on developmental research. While not speaking directly to developing countries' concerns, the U.S. debate about Bayh-Dole does bring to light issues that may warrant consideration in the design of innovation policies in developing countries. This discussion is general in its identification of potential concerns. Given the broad diversity of conditions in developing countries regarding research and innovation policy, infrastructure, and investment, the application of these concerns may vary widely and requires further analysis at a country-specific level.

A. Economic Benefits

The focus by universities on the goal of income generation has in part shaped the functioning of the U.S. technology transfer system. For developing countries, careful consideration of the nature of potential revenues and the merits of this goal are important.

For instance, Heher[54] notes that an estimated 40% to 50% of U.S. TTOs operate at a net loss, and profitability often depends on income arising from one or more "blockbuster" patents. In addition, a portfolio of university IP can require a maturation time of many years before beginning to generate income. In examining technology transfer in South Africa, Heher stresses that the success of technology transfer is highly dependent on national investment in research: "The first and foremost requirement for success from technology transfer is a well-funded, high-quality research system, as the benefits from commercialisation of research are directly proportional to the magnitude of the invest-

53 *TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights* art. 27, sec. 5 (Apr. 15, 1994) [hereinafter TRIPS Agreement] states: "Members may also exclude from patentability: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof."

54 A.D. Heher, *Economic Modeling of Institutional Research and Innovation*, *SARIMA Project 3,* Mimeo 1, 12 (2004).

ment in research."[55] He also argues that while technology transfer offices produce an average return of 1% to 1.5% on research investment, the main benefits to technology transfer occur at a broader level, through direct and indirect economic impacts. Given the modest rate of return, the timescale involved both in building a mature patent portfolio and in generating economic impacts through, for instance, the formation of startups, the development of a formal technology transfer system may require a long-term commitment of public funding.

B. Public Domain Conservation

Along with intellectual property rights, preserving access to technologies through the public domain is a necessary component of any innovation system. While patenting provides incentives for innovation, the patenting of particular types of technologies (research tools, databases, and genomic information, for instance) has the potential to cause impediments to research. Rai and Eisenberg[56] opine that Bayh-Dole not only created incentives that discourage the dedication of knowledge to the public domain, but also restricted the role of government funding agencies in this regard by vesting discretion in patenting and licensing with universities. An example can be found in the National Institutes of Health("NIH") guidelines for preserving access to research tools.[57] The NIH guidelines support the use of non-exclusive licenses for enabling technologies and have been widely adopted by TTOs, but on a voluntary basis. Bayh-Dole has limited the NIH to an advocacy role, with no effective way to enforce its position. Rai and Eisenberg[58] maintain that leaving the decision to patent and/or determine non-exclusivity in licensing with research sponsors, rather than universities, has advantages.

The innovative "open source patenting" initiative, Biological Open Source ("BiOS"),[59] brings to light another interesting potential consequence for the adoption of a Bayh-Dole-like policy. BiOS has created a legal mechanism for preserving a protected commons of intellectual property for public use. Modeled on the open source paradigm in software, BiOS provides access to

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55 *Id.* at 3.

56 Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 91 Am. Scientist 52 (2003).

57 NIH, *Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice*, 64 Fed. Register 72090 (Dec. 23, 1999).

58 Rai, *supra* n. 56.

59 *See* Biological Innovation for Open Society, http://www.bios.net (accessed Nov. 6, 2005).

platforms of patented technologies through an "open access" license.[60] The license protects the BiOS technologies from private appropriation and ensures continued ability to use them by preventing blocking patents on improvements.

The Bayh-Dole Act, however, has precipitated institutional patent policies at universities that create impediments to U.S. faculty involvement in BiOS. For example, the terms of the BiOS license that mandate a grantback of all improvements to technologies accessed via the license make it challenging for a university to become a licensee since improvements may be made under the auspices of federal funding and trigger Bayh-Dole obligations. There are problems, too, for individual inventors accessing the BiOS commons as licensees, since their employment contracts may dictate the university's right to ownership of patentable improvements. More analysis on this question is needed.

C. Access to Technologies

In the U.S., the technology transfer industry has boomed, in part due to the Bayh-Dole Act. As a result, professional training opportunities have improved, a larger pool of experienced professionals exists, and a professional body of university technology managers ("AUTM") thrives.[61] In spite of this thriving environment, few universities have the critical mass of inventions to sustain the legal and technical expertise needed to professionally address the range of technologies resulting from a broad research base. Clearly, the situation in developing countries is likely to be even more challenging, with a scarcity of trained IP management staff and lack of access to up-to-date licensing practices. The goal of well-trained IP management professionals may be better met by a policy that creates incentives for regional, rather than institution-based patent management, or alternative structures, such as TTOs, centered on specific technology fields rather than specific institutions.[62] Regional, rather than institutional management of government-funded patents affords economies of scale in sustaining the large costs and limited revenues of patent portfolios and the ability to invest the profits from any "blockbuster" inventions in the broader technology transfer infrastructure. The 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.

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60 BiOS, *About BiOS (Biological Open Source) Licenses*, http://www.bios.net/daisy/bios/398 (accessed Sept. 15, 2005).

61 The Association for University Technology Managers ("AUTM") was founded in 1974 with seven member institutions. Membership now includes over 300 institutions.

62 Patenting and licensing of "dry science" and "wet science" are often performed by separate staff in U.S. TTOs.

While acknowledging arguments in favor of regional patent management, Wolson[63] argues the benefits of "pre-licensing" IP management at the institution level. University TTOs in the U.S. are responsible for many more services than supervising patent prosecution and licensing. "Pre-licensing" IP management might include, for instance, advice on disclosure and patentability, and sponsored research agreements.

In theory, the Bayh-Dole Act, through its "march-in" rights, contains important protections for access to technologies but the lack of examples where these government rights have been exercised suggests that these provisions are largely impotent. Other governments may be more amenable to exercising compulsory licensing. For instance, Zambia and Mozambique issued compulsory licenses for patent rights to antiretroviral drugs in 2004.[64] Where national legislation provides for compulsory licensing, "march-in rights" may be a moot point.[65] For industry, though, the threat of potential compulsory licensing has costs that may need to be evaluated as developing countries seek to encourage new relationships between the private and public sector; industry may be reluctant to make investments predicated on patent ownership that ultimately contains a degree of uncertainty.

D. Collaboration between Industry, Government, and Universities

In the United States, collaboration among university, government, and industry has a long history and spans many different avenues other than the patent-license channel for which Bayh-Dole provided legislative support. Developing countries that have neither the history nor the breadth of collaboration channels, may find that legislating incentives focusing heavily on the patent-licensing channel of technology transfer leave other avenues of industry-university collaboration either unexplored or impeded.

Where inventions are jointly funded by government and industry, the policy for determining patent ownership of government-funded innovations

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63 Rosemary Wolson, *Intellectual Property Tools, Innovation and Commercialisation of R&D: Options to Assist Developing Countries in Positioning Themselves to Reap the Benefits of a Stronger Intellectual Property Regime, with Special Reference to the Role of Intellectual Property Management in Research Organisations*, "Intellectual Property Rights (IPRs), Innovation, and Sustainable Development" in Eastern and Southern Africa (Cape Town, South Africa 2004).

64 *See* http://www.cptech.org/ip/health/c/zambia/zcl.html (accessed Sept. 15, 2005); http://www.cptech.org/ip/health/c/mozambique/moz-cl-en.pdf. (accessed Sept. 15, 2005).

65 *See* TRIPS Agreement, art. 31; *The Doha Declaration* sec. 5(b), 5(c) (Nov. 14, 2001).

must be crafted in tandem with a sponsored research agreement policy. Wolson[66] notes the high proportion of public sector South African inventions where the ownership of the resulting IP is pre-determined by a sponsored research agreement. A recent British report argues for the use of sponsored research agreements in determining patent ownership, and against the United Kingdom's implementation of Bayh-Dole's default university ownership of patents. It states: "When industry has made a significant contribution to the research, then business should be able to negotiate ownership of the resulting IP itself."[67] However, there are several potential problems with the dependence on sponsored research agreements in determining IP rights. First, the costs of negotiation can be high and expending these costs *ex ante* to any IP being developed may lead to unnecessary expense. Second, unequal bargaining power in the negotiations may work to the detriment of the university. The latter can occur also in an *ex post* determination of access to the IP, and remains an important element of the decision to leave the bargaining at an institutional or a regional level. Third, negotiation of formal IP rights at this stage in the innovation process may altogether deter collaborations that might otherwise thrive.

The statutory preference for small businesses as licensees, and the requirements for domestic development of products, may be elements of Bayh-Dole suited to emulation by developing countries. Encouragement 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. Thorsteinsdóttir *et al.*[68] include these among other characteristics as key to the formation of successful biotechnology sectors in developing countries.

The facilitation of university start-ups has also been linked with economic growth. While Bayh-Dole's provisions of clear patent ownership and the potential for exclusive licenses are correlated with encouraging startups,[69] other elements of the business climate are crucial to their formation and success. Along with collaboration between academia and industry, cultural entrepreneurism and available funding sources are necessary. A United Nations Development Programme report, for instance, notes the dependency of successful

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66 Wolson, *supra* n. 63.

67 Richard Lambert, *HM Treasury*, *The Lambert Review of Business-University Collaboration,* 5 http://www.hm-treasury.gov.uk/media/DDE/65/lambert_review_final_450.pdf (accessed Sept. 15, 2005).

68 Halla Thorsteinsdóttir, Uyen Quach, Abdallah S. Daar & Peter A. Singer, *Conclusions: Promoting Biotechnology Innovation in Developing Countries,* 22 Nat. Biotechnology, DC 48-52 (2004 Supp.).

69 According to AUTM data, in 2003, 94% of licenses and options to startups were exclusive.

startups on venture capital markets that are lacking in many developing countries.[70] Clearly, a policy that determines patent ownership of publicly-funded innovations is one of a much larger set of policy options intended to stimulate technology transfer (tax incentives, subsidized loans, venture capital funding, technology parks, business incubation, to name but a few) and a developing country's emulation of a Bayh-Dole-like policy must be evaluated within this larger context.

E. Summary of Considerations for Developing Country's Emulation of Bayh-Dole

In summary, we outline the issues discussed above that may deserve further investigation in the design of a policy defining ownership of university IP in developing countries.

- *The Bayh-Dole Act fundamentally served to create clarity of ownership of inventions created in the public sector with public funds. This has been the major positive effect of the Act that should be emulated in national policy.* The adoption of new policy today needs to move beyond Bayh-Dole and the question of IP ownership to provide frameworks for IP management that foster broad innovation.
- *The conditions that prefaced the adoption of the Bayh-Dole Act and many of the environmental factors determining its effects in the U.S. may not be present in developing countries.* Examination of the Act's effects in the U.S., therefore, is of limited value to countries considering an emulation of the legislation which would likely play out differently in very different economic contexts, particularly with respect to the presence of a research-intensive industry sector.
- *The Bayh-Dole Act has inadvertently contributed to restricted access to "upstream research tools."* Development of new policies should consider the inclusion of a well-reasoned research exemption for university researchers' use of proprietary IP.
- *Bayh-Dole-like statutory preferences for small businesses and the domestic development of technology may work to encourage local economic growth.* The inclusion of the concept of achieving "net domestic benefit" would broaden the scope of these provisions in the context of developing countries that lack domestic development capacity but

[70] UNDP, *Human Development Report 2001:Making New Technologies Work for Human Development,* United Nations Development Programme 1, 3 (2001).

may have other means of capturing benefit from the technology development.

- *Enforcement of compliance with the legislation may need to diverge from Bayh-Dole's "march-in" rights.* "March-in" rights under Bayh-Dole have not been employed as a mechanism for enforcement of compliance with the legislation. In addition, the inclusion of "march-in" rights has the potential for creating uncertainty in IP rights ownership and therefore may discourage industry involvement. New policies should carefully balance the relative strength of "march-in" rights and the uncertainty they create for technology commercialization.
- *Bayh-Dole-like policies can have consequences for the conservation of the public domain.* Conservation of the public domain and related concerns about access to technology require a careful choice of how power is vested in terms of patenting decisions and decisions on the exclusivity of licensing.
- *The patent-license channel is one of many avenues for the transfer of technology from university to industry.*[71] Particularly for early stage technologies arising from universities, successful technology transfer often involves the transfer of know-how, in addition to IP rights. Policy discussion may need to consider employing a wide range of incentives to engage faculty and industry in collaborative activities rather than limiting the focus to the patenting and licensing.

A Bayh-Dole-like policy determining the ownership of university IP operates as an integral part of a larger set of innovation policies and practices. For example, the parallel development of a sponsored research agreement policy and the development of TTOs are equally important in supporting access to university discoveries and their commercial development. In considering an integrated policy to support public sector innovation, attention should also be paid to establishing a framework to manage IP and support innovation.

- *The establishment of a TTO system will likely require a long-term commitment of financial support.* A recognition of the long time lag involved and the indirect nature of economic benefits arising from university technology transfer deserves particular attention in countries where resources are exceptionally scarce.

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[71] Other channels include, for instance: publications, conferences, visiting scholars from industry, faculty involvement in startup companies, sponsored research, consulting by faculty, university-industry consortia, etc.

- *Formal TTOs at an institutional level may not be efficient.* Patenting and licensing services may not be feasible at an institutional level. The development of regional or technology sector focused TTOs are likely to be more effective and efficient whereas other services regarding advice on disclosure, patentability, and sponsored research agreements may be locally administered. The benefits of this type of structure must be weighed against the potential problems of communication between institutions, given the complexity and time sensitivity involved in the ownership and access to intellectual property.
- *Articulation of performance metrics for TTOs should be an explicit part of a policy framework that supports innovation.* Performance metrics based on revenue generation, and numbers of patents and licenses, distorts the decision-making process of TTO staff. Metrics carefully designed to meet high level national objectives should be integrated into the policy and infrastructure framework.
- *Collaborations among TTOs can provide benefits to the system as a whole, including the strategic management of IP across institutions.* The design of a policy supporting TTOs should consider reducing the potential for isolated, and perhaps competing, institutional TTOs and facilitate mechanisms for collaboration.

V. CONCLUSION

The U.S. Bayh-Dole Act created clarity around ownership of IP resulting from federally-sponsored research and required the development of university infrastructure to manage these proprietary rights. The legislation did not mandate any particular IP management structure or philosophy, nor did it contemplate the issues regarding access to research tools or so-called “upstream” inventions that have become problematic. Because of the early focus by universities on income generation as a primary goal of IP management, each university tended to develop isolated programs and to, arguably, overprotect inventions with unproven commercial value.

From today’s perspective there are many features of Bayh-Dole that have worked well and there is also room for improvements, particularly in contemplating how similar legislation may play out in a developing country’s economy. Positive features of Bayh-Dole are that it clarified the ownership of IP resulting from university research and required the domestic manufacture of products. The lack of ambiguity around IP ownership is critical for negotiation of how these rights will be transferred to commercial partners and has allowed universities to become effective players in technology transfer transactions. Bayh-Dole’s requirement for domestic manufacture has also been generally positive but this may largely be a result of the U.S. presence of a research-intensive private sector with the capacity to develop early-stage university inventions. A provision for achieving some form of domestic benefit may be more practical than specifying "domestic manufacture" for countries that lack research-intensive industries or manufacturing capability.

Although not intrinsic to the Bayh-Dole Act, its implementation has contributed to the "anticommons" problem by establishing many independent and, indeed, competitive university TTOs which effectively fragment a national portfolio of inventions in related fields of technology. This is somewhat ironic, in that federal agencies sponsor research in strategic areas in order to develop bodies of knowledge that can propel new fields of technology forward. However, this strategic development of fields of technology is not supported by strategic management of the resulting proprietary technology. PIPRA is working to re-unite the agricultural technology portfolio through a collaborative process. National policies that provided a framework to strategically manage technologies on a sector-specific basis may obviate the need to try to pull portfolios together at a later date as well as provide a basis for more efficient technology management, particularly in countries where the national research base is relatively small.

Finally, the potential to block research because of problems in access to research tools appears to be an unintended, but actual, result of the Bayh-Dole Act. This plays out in terms of directly slowing or stopping fundamental research but may also prevent research targeted towards non-commercial or humanitarian applications of technology. In the health sciences, this has been largely addressed by the NIH policy on research tools but still only applies to NIH-sponsored research and is subject to interpretation by each institution. In other areas, there is a voluntary effort to reserve rights for humanitarian uses and to make these technologies freely available for such uses, particularly in developing countries. A well-reasoned research exemption would overcome many of the problems facing university researchers and should be a consideration in setting national policies.