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Academia to Industry Technology Transfer: An Alternative to the Bayh-Dole System for Both Developed and Developing Nations

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Abstract

Renewed efforts to bring science and technology to the center of economic revival in developing nations recognize the centrality of the university in the creation and promotion of science and innovation. Many developed nations, following the paradigmatic U.S. technology transfer system, transfer their academic innovations to industry—through licensing intellectual property—for eventual commercialization. While conventional wisdom places the Carter era Bayh-Dole legislation at the center of that successful American system, this Article argues that the U.S. biotechnology and high tech booms are more likely attributable to the confluence of unique and propitious conditions, and that Bayh-Dole played a marginal role in the commercialization of American academic ingenuity and the resulting socioeconomic prosperity. Instead, this Article suggests that Bayh-Dole's legacy is chiefly the ubiquitous university technology transfer office, at best a drain on limited university resources, but potentially a major impediment in the innovation and commercialization process. After reviewing Bayh-Dole and similar efforts in other nations, the author advocates an alternative system for those developing (and even developed) nations seeking to grow their economies through the commercialization of academic inventions. In contrast to the inefficient local technology transfer office, this Article suggests a centralized and independent office that would have the infrastructure, informatics and incentives necessary to take advantage of economies of scale in the patenting, licensing and marketing of academic research. With recent studies now suggesting that patents woefully under-incentivize academic researchers, this system would provide a more relevant incentive to promote the commercialization of academic research. This streamlined and efficient process would allow researchers to trade their intellectual property rights, forgoing unlikely future royalty streams, for a more enticing and less risky research grant with a value tied to the expected value of the patented innovation. The innovation, once acquired and patented by the central technology office, would then be offered to industry via a flat rate non-exclusive license, relieving the current debilitating and inhibitory transaction costs, and diffusing the technology efficiently, rapidly and broadly throughout society.

KEYWORDS: biotechnology, Bayh-Dole, Academic research

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After reviewing Bayh-Dole and similar efforts in other nations, the author advocates an alternative system for those developing (and even developed) nations seeking to grow their economies through the commercialization of academic inventions.

In contrast to the inefficient local technology transfer office, this Article suggests a centralized and independent office that would have the infrastructure, informatics and incentives necessary to take advantage of economies of scale in the patenting, licensing and marketing of academic research. With recent studies now suggesting that patents woefully under-incentivize academic researchers, this system would provide a more relevant incentive to promote the commercialization of academic research. This streamlined and efficient process would allow researchers to trade their intellectual property rights, forgoing unlikely future royalty streams, for a more enticing and less risky research grant with a value tied to the expected value of the patented innovation. The innovation, once acquired and patented by the central technology office, would then be offered to industry via a flat rate non-exclusive license, relieving the current debilitating and inhibitory

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INTRODUCTION

Representatives of the fifty-three member African Union gathered recently in Ethiopia to discuss one of the most critical issues in Africa and the developing world: Science.[1] At the summit, keynote speaker Calestous Juma emphasized the importance of "[b]ringing science and technology to the centre of Africa's economic renewal," and underscored the centrality of universities and research institutions in the creation of science and technological innovation.[2] Although Africa made scientific growth a priority earlier in the century, "[t]hroughout the 1980s and 1990s, science and technology investments were not prioritised despite considerable empirical evidence . . . showing

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1 8th African Union Summit, Addis Ababa, Eth., Jan. 22–30, 2007, http://www.africa-union.org/root/AU/Conferences/Past/2007/January/summit/summit1.htm (last visited Jan. 30, 2009).

2 Calestous Juma, Professor of the Practice of Int'l Dev., Belfer Ctr. for Sci. and Int'l Affairs, Kennedy Sch. of Gov't, Harvard Univ., The New Culture of Innovation: Africa in the Age of Technological Opportunities, Keynote Address at the 8th African Union Summit (Jan. 29, 2007), http://belfercenter.ksg.harvard.edu/files/juma_au_summit_keynote_jan_29_2007.pdf; *see also* Kofi Annan, *Science for All Nations*, 13 SCIENCE 925, 925 (2004). Other groups have also highlighted the importance of science and innovation in achieving the Millennium Development Goals (or "MDGs"): "The role that science and technology play in the attainment of the MDGs is implicit in the Millennium Declaration adopted by the Heads of States." AFRICAN MINISTERIAL COUNCIL ON SCI. & TECH. ("AMCOST"), AFRICA'S SCIENCE AND TECHNOLOGY CONSOLIDATED PLAN OF ACTION 9 (2006), *available at* http://www.nepadst.org/doclibrary/pdfs/ast_cpa_2007.pdf. The eight United Nations Millennium Development Goals can be found at http://www.un.org/millenniumgoals (last visited Jan. 30, 2009).

that investment in science and technology yields direct and indirect benefits to national economies."[3]

Developing nations, now intent on integrating themselves into the global knowledge economy, becoming self-reliant, and fostering sustainable development, have only recently revisited the connection between promoting local scientific innovation and a strong economy. Many nations are now working toward harnessing and applying science and innovation within their borders.

Historically, scientific innovation has been an integral component to national development and growth.[4] Postwar success stories in Europe, and more recently in Asia, are often touted as proof of concept.[5] Externalities from scientific innovation also extend beyond pure economic development: indigenous science and technology can help create solutions to specific regional and local problems that themselves impede innovation, such as health or agricultural issues. Further, basic research innovations often have consequences and ramifications beyond their specific and particular goals, eventually becoming part of a feedback loop that fuels the engine of local innovation and productivity.[6]

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[3] AMCOST, *supra* note 2, at 8 ("In many countries infrastructure for R&D has been neglected and is decaying. Institutions of higher education, particularly universities and technical colleges, are in urgent need of renewal after many years of neglect and disorientation from local and national priorities.").

[4] "Since the Industrial Revolution, the growth of economies throughout the world has been driven largely by the pursuit of scientific understanding, the application of engineering solutions, and continual technological innovation." NAT'L ACAD. OF SCI. & NAT'L ACAD. OF ENG'G, RISING ABOVE THE GATHERING STORM: ENERGIZING AND EMPLOYING AMERICA FOR A BRIGHTER ECONOMIC FUTURE 41 (2006).

[5] There is a substantial body of literature on the nature and causes of Asian postwar success. *See generally* Robert Wade, *East Asia's Economic Success: Conflicting Perspectives, Partial Insights, Shaky Evidence*, 44 WORLD POL. 270 (1992). "Over the past two decades a literature big enough to fill a small airplane hangar has been produced on the causes of East Asian economic success." *Id.* Note that, like the rise of American science, there are numerous factors that have led to the success of science in Japan as well as Hong Kong, Singapore, South Korea and Taiwan. *See generally* Boris Holzer, *Miracles with a System: The Economic Rise of East Asia and the Role of Sociocultural Patterns*, 15 INT'L SOC. 455 (2000).

[6] It also is thought to limit the brain drain to more developed nations. *See, e.g.*, David Dickson, *Turning The Brain Drain From A Threat To Opportunity*, SCI. & DEV. NETWORK, Nov. 2, 2007, *available at* http://www.scidev.net/en/science-and-innovation-policy/editorials/turning-the-brain-drain-from-threat-to-opportunity.html (discussing how

Striving to recreate the prior successes in now-developed nations, many developing nations, often with unrealistic expectations,[7] look to re-enact the American technology transfer successes, linked by many to the Carter era Bayh-Dole legislation.[8] With the growing appreciation of the university's function as the central scientific and technological innovator—particularly in developing nations with little to no appreciable technological infrastructure[9]—many scholars, non-governmental organizations (or "NGOs"), and local politicians in both developed and developing nations have suggested importing Bayh-Dole-like

a recurring brain drain may induce developing nations to limit their investment in science education and noting that developing countries need to provide their scientists with the proper incentives to continue their research in developing nations).

[7] *See, e.g.*, A.D. Heher, *Implications of International Technology Transfer Benchmarks for Developing Countries*, 4 INT'L J. TECH. MGMT. & SUSTAINABLE DEV. 207, 207 (2005).

[8] Bayh-Dole Act of 1980, 35 U.S.C. §§ 200–212 (2006); *see* ORG. FOR ECON. COOPERATION & DEV. (OECD), A NEW ECONOMY? THE CHANGING ROLE OF INNOVATION AND INFORMATION TECHNOLOGY IN GROWTH 9 (2000) (noting that many OECD nations see Bayh-Dole as a major factor in the success of science in the United States). In the United States, the Bayh-Dole Act (1980), which extended patent protection to publicly funded research, helped to strengthen the role of science in the innovation process and was an early step in facilitating industry-university collaboration. Since then, further policy reform in this area has facilitated innovative performance. A recent analysis of United States patent citations found, for example, that more than 70% of citations in biotechnology were to papers originating solely at public science institutions, while a study of scientific publications in the United Kingdom showed that the proportion of articles authored by industry scientists with an academic co-author rose from 20% in 1981 to 40% in 1991. *Id.*; *see also* COMM. ON UTILIZATION OF TECHS., NAT'L RESEARCH COUNCIL, RUSSIAN ACAD. OF SCI., TECHNOLOGY COMMERCIALIZATION: RUSSIAN CHALLENGES, AMERICAN LESSONS 85 (Nat'l Acad. Press 1998) ("A joint working group could be established to consider the relevance of the provisions of the Bayh-Dole Act to Russian conditions."); Ken Howard, *Global Biotech Expansion Taking Cues from Bayh-Dole*¸ BIOENTREPRENEUR, May 20, 2004, http://www.nature.com/bioent/bioenews/052004/full/bioent811.html.

[9] *See, e.g.*, GARETH WILLIAMS, JAMES ROBERTSON & MIKE GILBERT, MARKS AND CLERK BIOTECHNOLOGY REPORT 2007, at 17–20 (2007) (noting that most of the influential patents, as measured by citations, come from universities, and that American universities tend to be domestic patent leaders in terms of sheer numbers of patents). *But see* David Mowery, *The Bayh-Dole Act of 1980 and University-Industry Technology Transfer: A Policy Model for Other Governments?* 2, http://www.merid.org/bayh-dole/BDRF paper_Mowery.pdf (noting that most industries look to open science).

legislation, to help promote the transfer of knowledge and technical know-how from the university to industry.[10]

Further, regional scientists in developing nations are quickly learning that joint ventures and collaborations with more affluent labs, and the access to knowledge and technical knowhow which comes with such interactions, is indispensible in growing local science.[11] But these interactions require that those labs in developing nations provide similar levels of intellectual property protection as their developed brethren to alleviate much of the unfortunate mistrust and suspicion.[12] These and other requirements necessary to interact in the modern academic science world necessitate the incorporation of intellectual property laws into the everyday workings of the developing world's science laboratories.

Notwithstanding this global interest in promoting university to industry transfer, there is a shortage of scholarly work on the promotion of innovation and scientific advancement in developing nations, and, in particular, the effect of Bayh-Dole-like legislation on developing nations' economies and academies. The lack of a

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[10] *See, e.g.*, Press Release, Arizona State University, Innovate or Perish? Helping Developing Countries Fight Neglected Diseases (Oct. 25, 2005), http://www.eurekalert.org/pub_releases/2005-10/asu-iop102405.php (discussing the exportation of Bayh-Dole to other countries); *see also* Goldie Blumenstyk, *Turning Research—Slowly—Into Riches*, CHRON. OF HIGHER EDUC., Oct. 7, 2005 (discussing Bayh-Dole-like legislation in Europe). *See generally* SARA BOETTIGER & ALAN BENNETT, THE BAYH-DOLE ACT'S EFFECTS ON DEVELOPING COUNTRIES: TOPICS FOR DISCUSSION, http://www.merid.org/bayh-dole/Boettiger%20BDRF%20Paper%20v3%20_final_.pdf (draft report for The Rockefeller Foundation); Karim Maredia, Frederic Erbisch & Maria Sampaio, *Technology Transfer Offices for Developing Countries*, 43 BIOTECH. & DEV. MONITOR 15 (1997); Jerry Thursby & Marie Thursby, *University Licensing Under Bayh-Dole: What are the Issues and Evidence?*, May 2003, http://opensource.mit.edu/papers/Thursby.pdf. Ironically one of the many criticisms of Bayh-Dole has been the resulting shift by research institutions away from unprofitable developing nation-oriented research—i.e., tropical diseases—to more profitable diseases of affluence. Note, however, that many developing nations may also be suffering with these diseases. *See* Majid Ezzati et al., *Rethinking the "Diseases of Affluence" Paradigm: Global Patterns of Nutritional Risks in Relation to Economic Development*, 2 PLOS MED. 0404 (2005), *available at* http://medicine.plosjournals.org/perlserv?request=get-document&doi=10.1371/journal.pmed.0020133.

[11] *See generally* Clemente Forero-Pineda, *The Impact of Stronger Intellectual Property Rights on Science and Technology in Developing Countries*, 35 RES. POL'Y 808 (2006).

[12] *Id.*

rigorous empirical analysis has resulted in this aforementioned inadvertent promotion of misinformation regarding the ability of developing nations to mimic American and Western European successes in innovation simply through importing Bayh-Dole like legislation.[13]

Much of the current conversation on optimal methodologies for promoting innovation in developing nations suggests a misunderstanding of the role of the Bayh-Dole legislation in the current success of science and innovation in the United States. Simplistically, other potentially more important factors are often overlooked: a great deal of Bayh-Dole's purported successes in the United States must be credited to a preexisting strong and expansive intellectual property regime, a recognition of the market's importance in promoting innovation and development, preexisting interactions and collaborations between industry and academia, an emerging culture of academic patenting, a pre-existing academic entrepreneurial spirit, extensive venture capital markets, and an exceedingly well-funded high quality research system.

Nevertheless, developing nations on the cusp of innovation—i.e., many of those nations that fall within the World Bank's Middle Income Developing Nation categorization[14]—need to implement some form of system to promote the transfer of their academic basic research to the private sector for further development and commercialization. "Corporate America is increasingly moving academic research programs to schools overseas, particularly to the developing world, where results are outstanding, costs are low and arguments over IP are nonexistent."[15] Now is the time to take advantage of these newly

[13] *See, e.g.*, Frank Rothaermel, Shanti Agung & Lin Jiang, *University Entrepreneurship: a Taxonomy of the Literature*, 16 INDUS. & CORP. CHANGE 691 (2007) (providing an exhaustive review of the relevant literature), *available at* http://olympus.cs.cmu.edu/links/rothaermel-4002-3-T.pdf.

[14] *See, e.g.*, Country Classification Definitions, The World Bank Group, http://www.worldbank.org/data/countryclass/classgroups.htm (last visited Nov. 23, 2008).

[15] Thomas K. Grose, *A Challenging Matchup: Time Consuming Wrangling Over Intellectual Property Issues is Affecting the Relationship Between Academia and*

developing collaborations and institutionalize some form of academia to industry technology transfer schema. This Article suggests a promising new methodology for developing nations, allowing them to simultaneously reap potential pecuniary gains from their growing research sectors and to promote local science and innovation.

The first half of the Article delves into an analysis of the current state of university to industry technology transfer within the United States. The Article provides a critical analysis of the Bayh-Dole Act[16] and the historic developments leading up to its conception. This historical review attempts to establish the centrality of some particular extrinsic factors, including concurrent scientific developments, market driven forces, and other legislation that were relevant for the boom in American innovation. By highlighting these factors, the Article hopes to diminish the perceived relevance and importance of the Bayh-Dole legislation itself within the rapid expansion of American innovation.[17]

In particular, this Article will first review the basic history of United States technology transfer between universities and industry, starting from the Morrill Act of 1862[18] and culminating in the passage of the Bayh-Dole Act. Through establishing the unique nature of the historical and academic environment in the development of the U.S. technology transfer phenomenon, this Article would hope to dissuade other nations from thinking that creating a similar piece of legislation would guarantee similar results.

The following section will establish the contention that the Bayh-Dole Act, while not directly responsible for the present state of affairs vis-à-vis technology transfer in universities, can be

Industry, 15 AM. SOC'Y FOR ENGINEERING EDUC. ("ASEE") PRISM 18, 20 (2006), *available at* http://www.prism-magazine.org/feb06/feature_IntellectualProperty.cfm.

16 Bayh-Dole Act of 1980, 35 U.S.C. §§ 200–212 (2006).

17 *But see generally* Nat'l Acads. Bd. on Sci., Tech. & Econ. Policy, Comm. on Intellectual Prop. Rights in the Knowledge-Based Econ., Workshop on Academic IP: Effects of University Patenting and Licensing on Commercialization and Research (2001), http://www7.nationalacademies.org/step/ipwkshp_PDF.pdf (unedited verbatim transcript of the conference of Apr. 17, 2001, "Intellectual Property Rights: How Far Should They Be Extended?").

18 Morrill Act of 1862, 7 U.S.C. §§ 301–308 (2006).

shown to be the impetus for the ubiquitous technology transfer office (or "TTO")—a consistent thorn in the side of many researchers and businesses alike—and an actual bottleneck in the innovation process. Any implementation of Bayh-Dole-like legislation would necessitate the creation of a local equivalent to the United States technology transfer office—an ineffectual and ultimately undesirable result.

The next section looks to the particular effects of academia-industry technology transfer on universities in the United States, noting both positive and negative effects, including potentially limiting the extent of research fraud, and the growth of material transfer agreements. Any developing nation interested in implementing its own system of technology transfer should be aware of the strengths and limitations of the American system of technology transfer. Determining where the American system has resulted in positive and negative externalities will allow developing nations the opportunity to cherry-pick the superior aspects of the United States system while leaving behind the flawed components.

The second half of this Article—a proposed alternative to Bayh-Dole-like legislation—is directed primarily at developing nations. With the understanding that Bayh-Dole-like regulations—particularly the granting of intellectual property rights to universities and not the inventing academic researchers, and the regulatory hoops that Bayh-Dole requires in order for the university to retain that intellectual property[19]—are encumbrances rather than impetuses to innovation. This Article suggests reforming or preventing the creation of the technology transfer office—the most significant result of the Bayh-Dole Act. As the

[19] *See* April L. Butler, *Stealing Thunder from Government Contractors: Thwarting the Intent of The Bayh-Dole Act in* Campbell Plastics v. Brownlee, 31 U. DAYTON L. REV. 477, 477–78 (2006) ("Government contractors: proceed with caution—if you make one wrong move, the Government may steal your invention. Now, the tough part is . . . making sure you immediately document it on an exact form, within the exact time frame, and with significant detail. The Bayh-Dole Act . . . has turned into an opportunity for the Government to take advantage of small business firms who require its support. The effect of the Bayh-Dole Act has become hazy by the recent decision of *Campbell Plastics v. Brownlee*, which has done little to guide future claims and has left government contractors with paperwork anxiety.").

primary implementer of commercialization of academic research, much of the failures attributed to Bayh-Dole can be traced back to these offices, each arguably an unfortunate necessity for the university's implementation of its side of the Bayh-Dole bargain.

A central tenant of this Article's proposed solution lies in the abolishment of technology transfer offices, as we know them, and a reformulating of the ideas that necessitated their creation. Simplistically, this solution would look to a centralized organization or government agency to essentially buy out a scientist's intellectual property (or "IP") risk—her future and perhaps somewhat unlikely revenue streams from her innovations. This entity would then non-exclusively license out that academic scientific research at a flat rate to industry for commercialization. Notably, as opposed to the current system in the United States and many other developed nations, this proposal would require the implementation of a *Hochschullehrerprivileg*, i.e., an academic exception to the common patent regulation that automatically transfers ownership of an employee's innovation to the employer.[20]

As this Article will point out, many of the particular issues with local technology transfer offices can be remedied through the use of a regional or national office that deals with the inventors, not the administrators at the university. Of particular interest is the possibility that a centralized system could remove encumbering conflicts of interest and take advantage of economies of scale, reducing transaction costs and broadening the target audience for each piece of innovation. Nonetheless, technology transfer offices may still be necessary in some research universities; these offices would simplify the proposed system by evaluating and prosecuting the patents prior to transferring the IP rights to the centralized agency. Note that these offices would be treated as core facilities by the university—not-for-profit components of a research facility

[20] *See* Christian Kilger & Kurt Bartenbach, *New Rules for German Professors*, 298 SCIENCE 1173, 1173 (2002).

designed only to support the research endeavors without the need to financially justify their existence or maximize revenue.[21]

Inevitably, some academic innovations will require an exclusive license in order to fully incentivize industry involvement. In these instances, licensees would be able to take an exclusive license, although with a viral clause requiring the reasonable and non-discriminatory licensing of the IP and possibly even the derivative innovations back to academia.[22]

With many scientists generally uninterested in the commercialization of their research, this particular system would provide novel and appreciable incentives in the form of grants for researchers to hand over the IP rights in their developments, without the need for obtrusive and pushy technology transfer officers. The system would also allow, and potentially even encourage, scientists to hold on to their intellectual property rights when the researchers feel that they can better license the science or technology themselves—a proven strategy when commercializing early innovations, and a promising approach to inculcate an entrepreneurial culture into developed and developing nations' academic research and, according to many, the next step in the evolution of academia.

Imposing a new system of technology transfer may not even be that radical and, as such, more likely to be implemented in the context of developing nations. Recent research into the status of technology transfer in developing nations indicates that most universities are currently woefully under-equipped to handle the complexities of patenting and licensing of basic science research.[23] As such, this proposed system might be just as easily implemented as any other system currently available to developing nations.

[21] *See* Howard Hughes Med. Inst. ("HHMI"), *Core Facilities at Medical Schools Help Power Biomedical Research*, HHMI SCI. EDUC. NEWS, Oct. 15, 1997, http://www.hhmi.org/news/core.html.

[22] *See, e.g.*, Phil Albert, *GPL: Viral Infection or Just Your Imagination?*, LINUXINSIDER, May 25, 2004, http://www.linuxinsider.com/story/33968.html (offering a layman's explanation of the GPL viral copyright license).

[23] *See* Julie Stackhouse & Rachel Day, *Global and Regional Practices in University Research Management: Emerging Trends*, 4 INT'L J. TECH. MGMT. & SUSTAINABLE DEV. 189, 190–99 (2005).

Notwithstanding this focus on developing nations, the proposed system of university-to-industry technology transfer may also be relevant for developed nations as well, including the United States. Still, it is less likely to be adopted in the United States as it requires a fundamental overhaul of the current entrenched system.[24] Nevertheless, supporting the contention that such a system could be introduced, even in the United States, a recent survey of more than 1,800 U.S. life scientists suggests that the vast majority of researchers had little to no interaction with industry and few if any patents, with only 8% of the respondents ever receiving any form of patent royalties;[25] the current system may not be as ingrained into the research process as conventional wisdom might imply.

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[24] The proposed system would look to inventors themselves as the primary owners of the innovation—passing the proposed benefits of the system to the inventor and circumventing the academic institution. Under Bayh-Dole, "although title still vests in the named inventor, the inventor remains under a legal obligation to assign his interest either to the government or the nonprofit contractor . . . ." Bd. of Trustees of the Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc., 487 F. Supp. 2d 1099, 1118 (N.D. Cal. 2007) (interpreting Bayh-Dole to give the government the right of first refusal and the academic institution the right of second refusal, ahead of the named inventor); *see also* Fenn v. Yale Univ., 184 Fed. App'x 21, 23 (2d Cir. 2006) (denying the National Institutes of Health's ability to allow the named inventor to retain the rights to his invention if the academic institution has yet to elect to retain the rights to the same invention); FilmTec Corp. v. Hydranautics, 982 F.2d 1546, 1553 (Fed. Cir. 1992) (noting that Bayh-Dole divests the patentee of all interests in her invention, by operation of law, then the academic institution can acquire those interests by satisfying the regulatory requirements in the Bayh-Dole Act). Note, additionally, that failure to follow these regulations results in the forfeiture (automatic or otherwise is subject to debate) of the academic institution's right to the patented invention, and the rights revert back to the Federal Government. *But see* Campbell Plastics Eng'g & Mfg. Inc. v. Brownlee, 389 F.3d 1243, 1250 (Fed. Cir. 2004) (noting that the government has discretion in determining whether or not to invoke forfeiture of the patent rights following the failure to properly follow the regulatory requirements of Bayh-Dole); TM Patents, L.P. v. IBM Corp., 121 F. Supp. 2d. 349, 368 (S.D.N.Y. 2000) ("Failure to comply with the conditions of § 202 [Bayh-Dole] results in the Government's acquiring title."); Cent. Admixture Pharmacy Serv. Inc. v. Advanced Cardiac Solutions, P.C., No. CV-00-2430, 2006 U.S. Dist. LEXIS 95833, at *21–22 (N.D. Ala. Jan. 10, 2006) (criticizing the *TM Patents* decision, stating that the forfeiture of rights to a patent is automatic upon failure to follow the regulatory requirements of Bayh-Dole).

[25] *See* Press Release, University of Wisconsin-Madison, Basic Research Robust in Face of More University Patenting (Sept. 14, 2007), http://www.eurekalert.org/pub_releases/2007-09/uow-brr091407.php.

As a general industry disgust with American academic technology transfer methods becomes more pervasive,[26] more and more companies are looking to offshore sources for research and innovation, in particular to universities that are less protective of their intellectual property and less likely to involve themselves in protracted negotiations.[27] To stem this tide and the subsequent potential loss of foreign graduate students and postdocs to these foreign universities, flush with cash and technology from foreign investors, American universities need to reassess and possibly drastically change their current technology transfer procedures and mindsets.[28] Meanwhile developing nations ought to take advantage of this situation, implementing the streamlined transfer policies suggested in this Article that will benefit the universities, their researchers, and the licensors who are eagerly looking for alternatives to the dysfunctional American system.

[26] The current stagnation and forecasted decline in industry investment in American academic research, a decline in academia-industry collaborations, and fewer citations of academic articles in industry invented patents may be partially attributable to these poor interactions. *See generally* Alan I. Rapoport, *Where Has the Money Gone? Declining Industrial Support of Academic R&D*, INFOBRIEF: SCI. RESOURCES STATS., Sept. 2006, *available at* http://www.nsf.gov/statistics/infbrief/nsf06328/nsf06328.pdf.

[27] *See* THOMAS K. GROSE, AM. SOC'Y FOR ENG'G EDUC., INTELLECTUAL PROPERTY: UNIVERSITIES, CORPORATIONS AND FINDING A COMMON GROUND 3 (2006), http://www.asee.org/activities/organizations/councils/edc/2006-IP-White-Paper/IPWhite Paper-WEB.doc ("Frustrated by the hassles endemic in negotiating sponsored research contracts, many American companies are taking a growing amount of their research work to foreign academic labs—often in the developing world—where costs are not only low, but there's no desire on the part of most schools to own the IP. And, as Wisconsin's Dean Peercy says, the companies get excellent results. . . . [A]cross the developing world, these burgeoning schools are using faculty educated and trained in the United States, 'and they are top-notch,' Peercy says. Taking research to foreign schools is decidedly a growing trend among many *Fortune 500* companies . . . . 'The levels of talent and domain expertise are extremely high, and you very often have outright access to the IP that gets created.'. . . '[M]any high-quality foreign universities are very eager to work with American companies, and by keeping attorneys out of the discussion completely, they have streamlined the processes.' . . . [I]t typically takes three weeks to negotiate a sponsored-research contract with a foreign school, as opposed to the six months it takes in the United States. . . . [T]hat time savings is a cost savings, too. . . . I can easily envision a time when we actually encourage our (in-house) researchers' to seek overseas research partners. . . . 'American universities will either have to modify their behavior or lose their industrial customers.'").

[28] *Id.* at 25.

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I. THE AMERICAN SYSTEM OF UNIVERSITY TO INDUSTRY TECHNOLOGY TRANSFER

A. The Current State of American Academic Technology Transfer

Although dubbed "[p]ossibly the most inspired piece of legislation to be enacted in America over the past half-century,"[29] the Bayh-Dole Act[30] does not suffer for lack of detractors.[31] Bayh-Dole, and its potential effects on science, have been examined, praised, and derided in the months leading up to, and following, the recent 25th anniversary of its enactment.[32]

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29 *Innovation's Golden Goose*, ECONOMIST, Dec. 12, 2002, at 3-3. *But see Bayhing for Blood or Doling Out Cash?*, ECONOMIST, Dec. 24, 2005, at 50.

30 Bayh-Dole Act, 35 U.S.C. §§ 200–212 (2006).

31 *See, e.g.*, Sara Boettiger & Alan Bennett, *Bayh Dole: If We Knew Then What We Know Now*, 24 NATURE BIOTECH. 320 (2006) (reviewing the various opinions regarding Bayh-Dole); *see also* MICHAEL CRICHTON, NEXT 422–23 (2006) (discussing his opposition to Bayh-Dole); *A Conversation with Michael Crichton: The Charlie Rose Show* (television broadcast Feb. 19, 2007), *available at* http://www.charlierose.com/shows/2007/02/19/1/a-conversation-with-michael-crichton (communicating a less extreme opinion).

32 *See, e.g.*, H.R. Con. Res. 319, 109th Cong. (2005) (observing a biased view of the success of the legislation).

> [T]he 96th Congress enacted Public Law 96-517, entitled "An Act to amend the patent and trademark laws" . . . in 1980 . . . before 1980, only 5 percent of patents owned by the Federal Government were used by the private sector—a situation that resulted in the American people being denied the benefits of further development, disclosure, exploitation, and commercialization of the Government's patent portfolio . . . the Bayh-Dole Act established a "single, uniform national policy designed to . . . encourage private industry to utilize government financed inventions through the commitment of the risk capital necessary to develop such inventions to the point of commercial application", and eliminated the 26 different Federal agency policies that had existed regarding the use of the results of federally funded research and development . . . . Bayh-Dole Act fundamentally changed the Federal Government's patent policies by enabling inventors or their employers to retain patent rights in inventions developed as part of federally funded research grants, thereby promoting licensing and the leveraging of contributions by the private sector towards applied research, and facilitating the transfer of technology from the laboratory bench to the marketplace . . . Bayh-Dole . . . ha[s] played a vital role in enabling the United States to become renowned as the world leader in scientific research, innovation, ingenuity, and collaborative research that involves

Anecdotal evidence has suggested, and numerous studies have attempted to prove, how Bayh-Dole has created the biotechnology revolution, or distorted the academic mission of American universities, or has brought incredible untapped wealth through licensing fees to universities, or has reallocated scarce research resources away from basic science research, or has turned white-coated, pure-hearted curious scientists into money-grubbing corporate shills.[33]

> institutions of higher education and the private sector . . . [and] has made substantial contributions to the advancement of scientific and technological knowledge, fostered dramatic improvements in public health and safety, strengthened the higher education system in the United States, served as a catalyst for the development of new domestic industries that have created tens of thousands of new jobs for American citizens, strengthened States and local communities across the country, and benefitted the economic and trade policies of the United States . . . .

Id. ("[T]he Bayh-Dole Act has stimulated two of the major contemporary scientific trends of the last quarter century—the development of the biotechnology and information communications industries—and the Act is poised to continue playing a central role in new fields of innovative activities, including nanotechnology . . . .").

33 *See, e.g.*, Wesley Cohen, *Patents and Appropriation: Concerns and Evidence*, 30 J. TECH. TRANSFER 57 (2005); Pierre Azoulay et al., The Impact of Academic Patenting on the Rate, Quality and Direction of (Public) Research Output (Nat'l Bureau of Econ. Research, Working Paper No. 11917, 2006); Fiona Murray & Scott Stern, Do Formal Intellectual Property Rights Hinder the Free Flow of Scientific Knowledge? An Empirical Test of the Anti-Commons Hypothesis (Nat'l Bureau of Econ. Research, Working Paper No. W11465, 2005), http://ssrn.com/abstract=755701; *see also* Mark A. Lemley, *Are Universities Patent Trolls?*, 18 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 611 (2008) (noting that universities sometimes are more focused on maximizing licensing revenue than on maximizing the overall social impact of technologies). *But see* D. Blumenthal, *Academic-Industry Relationships in the Life Sciences. Extent, Consequences, and Management*, 268 J. AM. MED. ASS'N 3344, 3344 (1992) (noting that the interaction overall has been good) ("The balance of known benefits and risks suggests that academic-industry relationships should be permitted and even selectively promoted. However, there is also a need for enhanced vigilance on the part of academic institutions and government to reduce risks posed by certain types of arrangements. . . ."); 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 RES. POL'Y 99, 99 (2001) ("The evidence suggests that Bayh-Dole was only one of several important factors behind the rise of university patenting and licensing activity. Bayh-Dole also appears to have had little effect on the content of academic research at these universities. A comparison of these three universities reveals remarkable similarities in their patent and licensing portfolios 10 years after the passage of the Bayh-Dole Act."); James Stuart, Comment, *The Academic-Industrial Complex: A Warning to Universities*, 75 U. COLO. L. REV. 1011, 1040–41 (2004).

The debate is based on the arguably faulty assumptions that Bayh-Dole has been primarily responsible for the phenomenal growth in science and technology in the United States during the past quarter century, and, concurrently, that Bayh-Dole has been responsible for the growing prioritization-shift among academic research and a parallel devaluation of academic ideals within the university.[34] This Article argues that history proves otherwise. While the encroachment of a proprietary mindset in science, blamed on Bayh-Dole, has been argued by scholars to be either a boon or a bust for innovation and advancement,[35] historically, Bayh-Dole has only been a small player in the introduction of a patent culture into the science lab. While the commodification of research and the corporatization of the university may have been somewhat spurred along by Bayh-Dole, the current state of American university research programs and U.S. science, in general, cannot be wholly attributed to the Act.[36]

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[34] *See generally* Timothy Caulfield et al., *Evidence and Anecdotes: An Analysis of Human Gene Patenting Controversies*, 24 NATURE BIOTECH. 1091 (2006) (discussing some of the effects of commercialization, patenting and licensing on academia).

[35] The *Economist* Technology Quarterly claims that "[m]ore than anything, this single policy measure helped to reverse America's precipitous slide into industrial irrelevance." *Innovation's Golden Goose*, *supra* note 29; *see also Rep. Sensenbrenner Makes Statement Supporting H. Con. Res. 319, the Bayh-Dole Resolution*, AUTM NEWS, March 15, 2006, *available at* http://web.archive.org/web/20071219033045/http://autm.net/news/dsp.newsDetails.cfm?nid=81.

> The Bayh-Dole Act transformed research and development in America. The technology boom that daily changes our lives arises from a combination of basic research, applied research, and ultimately, the commercialization of innovation. The passage of the Bayh-Dole Act obliged U.S. universities, hospitals and research institutions to invest significantly in the process of managing the intellectual property that emerges from research. The revenues arising from these commercial and licensing activities are all directed back into the university community.

Id.

[36] *See, e.g.*, David Mowery & Bhaven Sampat, The Bayh-Dole Act of 1980 and University-Industry Technology Transfer: A Model for Other OECD Governments?, Seminar at The Center on Employment and Economic Growth, Stanford University 18 (May 12, 2004), http://siepr.stanford.edu/programs/SST_Seminars/HBSemulationtalk.pdf ("[W]e believe that much of the growth in licensing and university-based 'spinoffs' that has occurred since the passage of the Bayh-Dole Act almost certainly would have occurred in the absence of this piece of legislation . . . . [W]e believe that the Bayh-Dole

Current research in fact suggests that patenting in academia (i.e., the goal of Bayh-Dole) does not impede research, alter the research goals of universities toward more commodifiable research directions, or promote a veil of secrecy over research.[37]

Moreover, independent of the veracity of the above allegations, the infusement of corporate ideals into scientific research is not the paradigm shift it is claimed to be. Classical Mertonian ideals,[38] while noble, were merely ideals,[39] the modern science establishment has long had the anti-Mertonian vices of secrecy,[40]

Act was neither necessary nor sufficient for the post-1980 growth in university patenting and licensing in the United States.").

[37] *See generally* John P. Walsh & Wesley M. Cohen, *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., 2003).

[38] *See generally* S. Shapin, *Mertonian Concession*s, 259 SCIENCE 839 (1993) (providing a short discussion of Mertonian ideals).

[39] ROBERT MERTON, SOCIAL THEORY AND SOCIAL STRUCTURE (Free Press 1968) (1949). "The right to search for truth implies also a duty; one must not conceal any part of what one has recognized to be true." Einstein Memorial, The Nat'l Acad. of Science Bldg., http://www.nasonline.org/site/PageServer?pagename=ABOUT_building_einstein_memorial (last visited Jan. 30, 2009) (quoting inscription on the Albert Einstein Memorial Statue located on the Academy grounds).

[40] Note however, that while secrecy has been a "fact of life in academic science" due to priority or cost concerns, secrecy is on the rise. Additionally, researchers have found that a researcher's association with industry increases her propensity to withhold data. A decade ago, David Blumenthal and his colleagues found that "[w]ithholding of research results is not a widespread phenomenon among life-science researchers." David Blumenthal, Eric G. Campbell, Melissa S. Anderson, Nancyanne Causino & Karen Seashore Louis, *Withholding Research Results In Academic Life Science—Evidence From a National Survey of Faculty*, 277 J. AM. MED. ASS'N 1224 (1997). More recently they came to a different conclusion: "Data withholding is common, takes multiple forms, is influenced by a variety of characteristics of investigators and their training, and varies by field of science." Blumenthal et al., *Data Withholding in Genetics and the Other Life Sciences: Prevalence and Predictors*, 81 ACAD. MED. 137, 137 (2006). *See generally* Eric Campbell et al., *Data Withholding in Academic Genetics; Evidence from a National Survey*, 287 J. AM. MED. ASS'N 473 (2002). Note, though, that John P. Walsh and Wei Hong found that while "[s]ecrecy is strongly predicted by scientific competition . . . the focus on commercialization as the cause may be misplaced." John P. Walsh & Wei Hong, *Secrecy is Increasing in Step with Competition*, 422 NATURE 801, 802 (2003); *see also* Arti Rai, *Open and Collaborative Research: A New Model for Biomedicine*, *in* INTELLECTUAL PROPERTY RIGHTS IN FRONTIER INDUSTRIES 136 (Robert W. Hahn ed., 2005), *available at* http://aei-brookings.org/admin/authorpdfs/redirect-safely.php?fname=../pdffiles/phpWC.pdf ("Indeed, in the biological sciences, such calls for access may even create a Mertonian sphere more robust than that which existed before 1980.").

rivalry, and inducements outside of noble curiosity and concern for social welfare.[41]

Ironically, the Act may now serve to actually weaken the alliances between academia and industry. There is an intensified need by industry for academic basic science research as a source of new innovation, but, with all the hurdles that Bayh-Dole and the technology transfer offices enforce,[42] access to basic innovation is impeded by the technology transfer gatekeepers that protract negotiations, demand excessive fees and royalties, or write overly restrictive material transfer agreements. Further, evidence from Japan indicates that when researchers are faced with complicated and time consuming hurdles to transfer technology, they will choose to either transfer the knowledge surreptitiously to a single corporation without disclosing the knowledge to the industry as a whole (e.g., through a patent or a publication), or will withhold disclosure altogether.[43]

B. The Technology Transfer Office

If Bayh-Dole is not responsible for either destroying academia or bolstering the economy, what then has Bayh-Dole accomplished over the past twenty-five years? If nothing else, Bayh-Dole ought to be credited with bringing the legal and scientific universes closer together, although not in the most obvious sense. For example, scientists, for the most part, continue to ignore intellectual property rights,[44] infringing with impunity and relying on an ephemeral research exemption to use proprietary research

[41] As this Article's author has learned through personal experience in academic labs.

[42] The productivity costs resulting from administrating is non-trivial and is thought to be an important factor in reducing the effectiveness of Japanese researchers, inhibiting their innovative capacity.

[43] *See generally Not Invented Here*, ECONOMIST, Dec. 1, 2007, at 68 (exploring business in Japan).

[44] *See generally* Kara Moorecroft, *Scofflaw Science: Avoiding The Anticommons Through Ignorance*, 7 TUL. J. TECH. & INTELL. PROP. 71 (2005).

tools,[45] confident that no right-minded company would sue an academic establishment.[46]

This Article posits that Bayh-Dole does have a true academic legacy, albeit somewhat more mundane than those suggested by Congress in their rush to praise the legislation: Bayh-Dole brought science and the law, two very different worlds, together through the establishment of the now relatively ubiquitous technology transfer office.[47]

Academic scientists typically lack the market knowledge and the resources to successfully commercialize their own innovations: "New firms created [independently by] scientists may lack critical resources such as technological resources, human capital and finance [and] typically lack industry experience."[48] To help the academe promote and commercialize innovations, universities have universally invested in the creation of technology transfer offices or offices of technology licensing ("OTLs") to help academics "exploit knowledge-based business ideas" and lower barriers to commercialization.[49]

On paper, technology transfer offices seem like a great idea—an in-house institution designed and devoted to bridge the science, law and business goals of the research institution in the encouragement of technology, information, and knowledge transfer to promote social welfare and, on the side, provide some revenue to cash-strapped research departments reeling from recent funding cuts. Regrettably, the result has been an unexpected culture clash. Research scientists are often reluctant or, at best, accidental

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45 *See* John R. Thomas, *Scientific Research and the Experimental Use Privilege in Patent Law*, CRS Report for Congress, Congressional Research Service, Oct. 28, 2004.

46 Note, however, there are conflicting opinions about the integration of law into science. *See, e.g.*, STEVEN GOLDBERG, CULTURE CLASH: LAW AND SCIENCE IN AMERICA 104 (1994) ("Doing research today without concern for the ultimate legal consequences is like doing a high wire act without the wire.").

47 Note that Bayh-Dole is often credited with bringing together industry and academia, but these were well on their way to finding each other—it is law and science that truly make strange and uncomfortable bedfellows.

48 Colm O'Gorman, Orla Byrne & Dipti Pandya, *How Scientists Commercialise New Knowledge Via Entrepreneurship*, 33 J. TECH. TRANSFER 23, 24 (2006), *available at* http://www.springerlink.com/content/fhm16744j0577243.

49 *Id.* at 25.

entrepreneurs, typically only interested in commercializing their research either to supplement their grant funding or to validate their research by proving its commerciability. There is a definite lack of scientists interested in spending the time and effort to patent and license what will be a wholly university-owned invention.

Technology transfer offices, on the other hand, are interested in proving their usefulness to their home institution, preferably by licensing the next big blockbuster technology.[50] These offices tend to focus on the distant secondary effect of technology transfer—revenue generation, at the expense of the primary purpose—the transfer of knowledge for the benefit of society. However, technology transfer offices often either just break even or are outright money-losing ventures for the universities:

> [M]any schools earn only enough from IP royalties to cover the costs of running a technology transfer office, and a significant number don't even manage to do that: They're in the red. "There is a lot of mythology out there" concerning royalties, says Don Giddens, dean of Georgia Insistute of Technology's engineering school. And even if a tech transfer office's overhead is only just covered by royalty revenues, "What are the benefits of that?" asks Nino A. Masnari, dean of the College of Engineering at North Carolina State University.[51]

Nonetheless, this pervasive inability to prioritize between the secondary and primary goals is not the only reason for the problems that this Article associates with technology transfer offices: Bayh-Dole legislation mandates that each university patent all academic patentable innovation or risk losing the right to patent that particular innovation.[52] With this overwhelming responsibility looming over their heads, technology transfer

[50] The fact that *Nature Biotechnology* published a three page piece on getting along with technology transfer offices is indicative of the poor relationship between technology transfer offices and scientists. *See* O. Prem Das, *Building Relationships With Technology Transfer Officers*, 23 NATURE BIOTECH. 781 (2005).

[51] Grose, *supra* note 15, at 20.

[52] 35 U.S.C. § 202(d) (2006).

officers need to constantly hound and pester researchers for information relating to anything patentable.[53] This strained interaction is somewhat understandable: the technology transfer office may be one of the only sources of interaction between scientists and law and business interests. Unfortunately, a quantitative and qualitative assessment of the interaction between scientists and technology transfer personnel is non-trivial. While a comparison of technology transfer regulations and material transfer agreements may be somewhat enlightening, such an analysis would have to account for differences between regulation and actual practice in the technology transfer office, as well as those scientists who avoid technology transfer rules by working around them.[54]

Previous studies focusing on technology transfer offices may not be as reliable, nor as valuable, as direct conversations with scientists in determining the extent of the impediments imposed by technology transfer offices on basic science research. This Article will later suggest a potential system to measure this interaction and determine the extent to which research is actually being inhibited. Through quantifying and qualifying the interactions between scientists and licensing professionals, Congress, and those developing nations interested in implementing Bayh-Dole, locally, may be persuaded to reassess the success of Bayh-Dole and potentially implement a new and better system. A retrospective analysis questioning conventional wisdom's understanding of the historical role of Bayh-Dole may further help this cause.

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[53] *See* David Schwartz, *Long-term Tech Transfer Success Depends on Strong TTO-Researcher Relationships*, TECH. TRANSFER TACTICS, Dec. 10, 2007, http://www.technologytransfertactics.com/content/2007/12/10/long-term-tech-transfer-success.

> [I]n the daily crush of work most TTOs experience, the focus is on their invention disclosures, potential partners for their technologies, legal documents, valuation, market analysis, seed funding . . . . And in the context of the daily grind, it's easy to forget that these researchers are more than the financial value of their ideas—they are people; individuals, or clients, who must be courted, cajoled, pampered, communicated with, assisted, and educated.

Id.

[54] *See* Moorecroft, *supra* note 44.

II. HISTORICAL ANALYSIS OF TECHNOLOGY TRANSFER IN AMERICAN UNIVERSITIES

A. Pre-World War II

Although Bayh-Dole is often credited for spawning the patent culture within American universities, patenting and commercialization within the Ivory Tower considerably predates the United States government's interventions in the early 1980s. "The phenomenal innovation and job creation that America produced during the 1990s sprang from significant investments in education, infrastructure and research and development—that began in the 1960s,"[55] if not earlier. Arguably, American academia had been transferring technology and knowhow to the private sector from its very inception through the publication of papers, private consulting activities,[56] and presentations at conferences.[57]

The Morrill Acts of 1862 and 1890 established the land grant university system.[58] In 1862, legislation sponsored by Congressman Justin Morrill of Vermont granted every state in the Union 30,000 acres of public land for every representative that the state had in Congress.[59] Over seventy land grant institutions of

55 Editorial, *Job Losses: The Wrong Debate; Look to the Future: Preparing American Workers for the Next Wave is the Key*, SAN JOSE MERCURY NEWS, Mar. 21, 2004, at 4.

56 "The best way to send information is to wrap it up in a person." J. Robert Oppenheimer, *The Eternal Apprentice*, TIME, Nov. 8, 1948, *available at* http://www.time.com/time/magazine/article/0,9171,853367,00.html.

57 In a 1997 study, the National Science Foundation found that 73% of all papers cited in industry patents were from academic and public sources. Bruce P. Mehlman, Assistant Sec'y for Tech. Policy, U.S. Dep't of Commerce, Testimony on the Virtues of the Bayh-Dole Act, Opening Statement to the President's Committee of Advisers on Science and Technology (May 9, 2002), *available at* http://patapsco.nist.gov/ts/220/external/tech%20transfer/testimony%20on%20virtues.htm.

58 The act's express reasoning was to "promote the liberal and practical education of the industrial classes in the several pursuits and professions in life" through "the endowment, support, and maintenance of at least one college where the leading object shall be, without excluding other scientific and classical studies, and including military tactics, to teach such branches of learning as are related to agriculture and mechanic arts." 7 U.S.C. § 304 (2006).

59 Thus under the Constitution every state received a minimum of 90,000 acres because each state has at least three representatives in Congress (two senators and one congressman). U.S. CONST. art. I., § 2, cl. 3; *id.* art. I, § 3, cl. 1.

engineering, agriculture and military science were set up under the act. The 1890 Act further extended the land grants to the sixteen southern states.[60] Given the obvious technical nature and vocational orientation of these land grant universities, there were powerful incentives within the universities to create close relationships with industry,[61] and potentially to patent and to license to industry.[62]

In 1912, Frederick Cottrell, a faculty member at the University of California, Berkeley, established the Research Corporation,[63] in an effort to manage his,[64] and other's,[65] scientific patents, and allocate the surplus income from those patents back into research.[66]

By the 1920s there were already a handful of universities that were involved in transferring basic science research to industries.[67] Despite the fact that several academics supported patenting university research,[68] there were many in academia who felt that

60 Backgrounder on the Morrill Act, http://web.archive.org/web/20070824033550rn_1/usinfo.state.gov/usa/infousa/facts/democrac/27.htm (last visited Oct. 1, 2008).

61 DAVID MOWERY ET AL., IVORY TOWER AND INDUSTRIAL INNOVATION, UNIVERSITY-INDUSTRY TECHNOLOGY TRANSFER BEFORE AND AFTER THE BAYH DOLE ACT 13 (2004).

62 *Id.* at 39.

63 Cottrell later acknowledged that patenting within public institutions was more trouble than it was worth. Moreover, he felt that with the exception of a few discoveries, society would be better off if researchers just published promptly. *See* Charles Weiner, *Patenting and Academic Research: Historical Case Studies*, 12 SCI. TECH. & HUM. VALUES 55 (1987).

64 For example, his electrostatic precipitator for cleaning smokestack emissions. Research Corporation for Science Advancement—About RSCA, http://www.rescorp.org/about-rsca/ (last visited Jan. 21, 2009).

65 The Research Corporation was integral in providing funds for numerous projects prior to extensive government funding of research after World War Two. These included the development of the cyclotron by Ernest Lawrence, R.H. Goddard's experiments with rockets, and organic synthesis experiments conducted by Robert Burns Woodward. *See, e.g.*, Chem. Heritage Found.—Chemical Achievers: The Human Face of the Chemical Sciences, http://www.chemheritage.org/classroom/chemach/environment/cottrell.html (last visited Jan. 30, 2009).

66 Research Corporation for Science Advancement, *supra* note 64.

67 COUNCIL ON GOVERNMENTAL RELATIONS, THE BAYH-DOLE ACT: A GUIDE TO THE LAW AND IMPLEMENTING REGULATIONS 2 (1999), *available at* http://www.cogr.edu/docs/Bayh_Dole.pdf; *see also* MOWERY ET AL., *supra* note 61, at 57 (noting that inter-institutional competition, administrative structure of universities and the need for more funding helped push universities towards stronger ties with industry).

68 Elihu Thomas, President of MIT, stated in 1920:

patenting was not the appropriate method to transfer knowledge to industry or to the public.[69]

With uncertainty as to what ought to be the appropriate level of university patenting, many universities in the early part of the 20th century set out to devise guidelines for patenting academic research. Yale University, although formally against patenting, created policies allowing for some patents to be granted under specific circumstances.[70] Harvard, in 1934 adopted a similar policy.[71] Other universities, such as the University of Wisconsin,

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> I have known some well-meaning scientific men . . . to look askance at the patenting of inventions, as if it were a rather selfish and ungracious act, essentially unworthy. The answer is very simple. Publish an invention freely, and it will almost surely die from lack of interest in its development. It will not be developed, and the world will not be benefited. Patent it, and if valuable, it will be taken up and developed into a business.

Nicholas H. Steneck, Priorities For Federal Innovation Reform Making Ethical Dialogue a Part of the National Innovation System 1–2 (issue paper submitted to the NSTC Committee on Technology), *available at* http://clinton4.nara.gov/media/doc/steneck2.doc.

69 *See, e.g.*, Weiner, *supra* note 63, at 50. George and Gladys Dick, at the McCormick Institute in Chicago developed an antitoxin to Scarlet Fever. After publishing their results, the market was flooded with antitoxins, many of them substandard. In an effort to retain quality control, it was suggested that the Dicks patent their antitoxin. The Public Health Service, citing the patenting of insulin at the University of Toronto, noted that the ethical barriers to academic patenting were crumbling and suggested that the Dicks also patent. The Dicks offered to donate their patent to the American Medical Association, who turned down the offer as there was significant dissention within the AMA as to the propriety of patenting medical cures. Although the Dicks were nominated for a Nobel Prize in 1925, the Nobel committee did not award a prize for medicine that year, reinforcing the criticism that was already rampant in the medical community both stateside and abroad. *Id.* at 52–53.

70 Yale AIDS Network, *University-Industry Relations: Historical Perspective*, Apr. 19, 2003, http://www.yale.edu/aidsnetwork/Spring%202003%20Univ%20IP%20History.ppt.

> [I]t is, in general, undesirable and contrary to the best interests of medicine and the public to patent any discovery or invention applicable in the fields of public health or medicine; but if, at any time, any member of the faculty deems it necessary solely for the protection of the public, without profit to himself or the University, to control any invention or discovery by means of a patent, he shall bring the matter before the Prudential Committee.

Id.

71 "No patents primarily concerned with therapeutics or public health may be taken out by any member of the University, except with the consent of the President and Fellows; nor will such patents be taken out by the University itself except for dedication to the

were more aggressive in their patent policies. The Wisconsin Alumni Research Foundation ("WARF"), founded by Harry Steenbock and other alumni of the University of Wisconsin, was set up in 1925 to manage the licensing of the research coming out of the University of Wisconsin at Madison.[72] By the 1930s WARF was so successful that other universities, principally other land grant institutions, began to emulate it.[73] By the late 1940s most American universities had developed some sort of patent policy.[74]

B. Post War University Research

Following the success of the Manhattan Project, Vannevar Bush launched the postwar science era with the seminal report *Science-The Endless Frontier*.[75] In arguably one of the most important science pronouncements of the 20th century, Bush called for, among other things, the establishment of a centralized government funding source for research, stimulating the formation of the National Science Foundation ("NSF") and the National Institutes of Health (or "NIH"), and establishing the notion of significant government funding for basic research.[76] Bush highlighted the importance of basic science research as an impetus

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public." *Id.* In fact, Harvard, in 1926 refused to patent a medical therapy for anemia, deciding that it was unethical to patent medical therapies. *Id.*

72 Wisconsin Alumni Research Foundation—Steenbock and WARF's Founding, http://www.warf.org/about/index.jsp?cid=26&scid=33 (last visited Jan 30, 2009).

73 MOWERY ET AL., *supra* note 61, at 39–40.

74 *Id.* at 42. Although in summarizing the history of university patenting prior to the end of World War II, Weiner notes that in most instances patenting did not pay off and even when it did, universities also had to deal with credibility issues, general public disgust, and conflicts of interests arising out of the patents. *See* Weiner, *supra* note 63, at 57; *see also* Bhaven N. Sampat & Richard Nelson, *The Emergence and Standardization of University Technology Transfer Offices: A Case Study of Institutional Change* 6–12, Prepared for the 1999 Conference of the International Society for the New Institutional Economics ("ISNIE"), in D.C. (Sept. 16–18, 1999), http://www.isnie.org/ISNIE99/Papers/nelson.pdf (noting a number of scholars in the '30s and '40s who commented on the trajectory of most universities toward patent polices).

75 VANNEVAR BUSH, SCIENCE THE ENDLESS FRONTIER: A REPORT TO THE PRESIDENT 3 (1945).

76 AAAS made similar pronouncements a decade earlier, stating "that aggressive governmental support of scientific work is essential to any sound program of building for the future national welfare." AAAS RESOLUTION: GOVERNMENT SUPPORT OF SCIENTIFIC WORK (Dec. 31, 1934), *available at* http://archives.aaas.org/docs/resolutions.php?doc_id=199.

for American innovation and success.[77] Still, Bush cautioned that much of the success of basic science research was contingent on the differences between academia and industry, particularly those positive aspects of academic research that distinguished academia from industry.[78]

The eventual surge in federal funding, particularly in more recent decades for biomedical research, cemented ties between basic science researchers and those participating in its clinical applications. This promoted rapid innovation in the biomedical fields.[79] With this increased funding, academic research in the United States dwarfed all other industrialized economies in much of the postwar period.[80]

Prior to 1950, there was no uniform United States government policy as to the intellectual property status of research produced via government funds; each agency created and followed their own guidelines.[81] In 1955, the precursor to the Department of Health

77 "The information, the techniques, and the research experience developed . . . by the thousands of scientists in the universities and in private industry, should be used in the days of peace ahead for the improvement of the national health, the creation of new enterprises bringing new jobs, and the betterment of the national standard of living." BUSH, *supra* note 75, at 3.

78 "It is chiefly in these institutions that scientists may work in an atmosphere which is relatively free from the adverse pressure of convention, prejudice, or commercial necessity. . . . Industry is generally inhibited by preconceived goals, by its own clearly defined standards, and by the constant pressure of commercial necessity. Satisfactory progress in basic science seldom occurs under conditions prevailing in the normal industrial laboratory. . . . [I]t is rarely possible to match the universities in respect to the freedom which is so important to scientific discovery." *Id.* at 19.

79 MOWERY ET AL., *supra* note 61, at 25.

80 *Id.* at 26.

81 PETER BARTON HUTT & THOMAS MAYS, GOVERNMENT AND INDUSTRY COLLABORATION IN AIDS DRUG DEVELOPMENT: HISTORICAL PERSPECTIVES ON GOVERNMENT TECHNOLOGY TRANSFER POLICY AND PHARMACEUTICAL INDUSTRY 3 (1994), *available at* http://books.nap.edu/openbook.php?record_id=9196&page=3. Interestingly, government policy towards the patenting of federally funded projects generally ignored issues relating to universities during this time period (1940s and 1950s), as universities, at this point, were only a fraction of federal research and development spending. Bhaven N. Sampat, *Recent Changes in Patent Policy and the "Privatization" of Knowledge: Causes, Consequences, and Implications for Developing Countries*, *in* 1 KNOWLEDGE FLOWS, INNOVATION, AND LEARNING IN DEVELOPING COUNTRIES 39, 54 (2003), *available at* http://www.cspo.org/home/cspoideas/know_flows/CSPO_Rockefeller_Vol1.pdf.

and Human Services, the Health, Education and Welfare Department ("HEW"), promulgated regulations, noting that in most circumstances, inventions derived from federally funded research ought to be made available freely to the public, and, if patented, should be made available to the public royalty-free and with non-exclusive licenses. Eventually, in 1968, the NIH granted universities the right to freely patent and license the innovation.[82] For the most part, these allowances were limited to those exceptional circumstances where commercial development was integral to social welfare. In these instances the institution requesting to license out their research had to request an Institutional Patent Agreement (or "IPA") from the Surgeon General, or, alternatively, petition for title from the granting agency.[83] These IPAs, (typically few and far between) gave the research institution the right to determine and define the ownership of the invention.[84]

In 1963, President Kennedy (and later Nixon[85] and Carter[86] as well, but to lesser degrees) issued a memorandum that attempted to harmonize the government's patent policy, creating government-wide criteria and objectives for the distribution of inventor's rights

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82 The National Science Foundation followed shortly after in 1973. Ken Howard, *Tech Transfer's Living Legacy*, BIOENTREPRENEUR, Oct. 24, 2004, http://www.nature.com/bioent/2004/041001/full/bioent832.html.

83 Sampat, *supra* note 81, at 54.

84 HUTT & MAYS, *supra* note 81, at 4; *see also* William Broad, *Patent Bill Returns Bright Idea to Inventor*, 205 SCIENCE 473, 473 (1979) (noting that scientists often complained of the 'bureaucratic knots' resulting from HEW's policies and that it was common for years to "slip by before a funding agency decide[d] whether or not to return the patent rights to an inventor's organization").

85 President Nixon's 1971 memorandum invoked the Harbridge Report and was later endorsed by the Bayh-Dole Act. *See* Lawrence Rudolph, *Overview of Federal Technology Transfer*, 5 RISK 133, 134 (1994). "The thrust of [that memo]: 'A single presumption of ownership of patent rights to government-sponsored inventions either in the government or its contractors is not a satisfactory basis for government patent policy and, that a flexible, government-wide policy best serves the public interest.'" Howard W. Bremer, *The First Two Decades of the Bayh-Dole Act as Public Policy*, Presentation to the National Association of State Universities and Land-Grant Colleges ("NASULGC"), Nov. 11, 2001, at 6, http://www.lsuhsc.edu/no/administration/otd/Bayh_Dole_Act.pdf.

86 ANDREW Z. MICHAELSON, THE LAW OF THE LAB: USING ZERIT TO INFORM TECHNOLOGY TRANSFER 21, 22 (2002), *available at* http://leda.law.harvard.edu/leda/data/512/michaelson.pdf.

in government funded research.[87] In spite of these memoranda, government agencies continued to act independently and inconsistently.[88] HEW, in particular, refrained from assigning further IPAs until the General Accounting office reported that HEW's policies were deterring industry cooperation with basic research.[89] In 1968, the executive branch commissioned a report from Harbridge House which noted that commercial utilization of government funded research and development was low.[90] Interestingly, the report also found that "the evidence does not indicate that either title or nonexclusive licensing is uniformly the best way to promote utilization" of academic research.[91]

As the decade progressed, the uncertainty regarding the government's views on patenting research and development grew as well.[92] Nevertheless, even without a coherent government wide policy,[93] university patenting grew significantly during this period and into the 1970s.[94] But, without a clear, coherent patent policy on government-funded research, many in industry were reluctant to fund research in educational institutions, fearing that a comingling of even a de minimus amount of federal funds with their private funds would contaminate the private funds and limit industry's ability to claim ownership to commercialize an invention.[95]

87 Memorandum of October 10, 1963 [Government Patent Policy], 28 Fed. Reg. 10943, 10944 (Oct. 12, 1963) (following an analysis by Dr. Jerome Weisner, President Kennedy's science advisor).

88 HUTT & MAYS, *supra* note 81, at 4. "Despite numerous congressional hearings on this issue, no legislation was adopted during the 1950–75 period, because of the inability of supporters of opposing positions outlined above to resolve their differences." Sampat, *supra* note 81, at 54.

89 HUTT & MAYS, *supra* note 81, at 4–5.

90 MICHAELSON, *supra* note 86, at 21.

91 *Id.*

92 Bob Dole famously stated that "rarely have we witnessed a more hideous example of overmanagement by the bureaucracy." BHAVEN N. SAMPAT, PRIVATE PARTS: PATENTS AND PUBLIC RESEARCH IN THE TWENTIETH CENTURY 17 (2003), *available at* http://www.card.iastate.edu/research/stp/papers/SAMPAT-Nov-03.pdf.

93 Rudolph, *supra* note 85.

94 MOWERY ET AL., *supra* note 61, at 50, 57 (noting that federal fund dispersion increased negotiations of IPAs, changing content of research, and noting a greater trend by federal agencies towards allowing institutions to patent).

95 *See, e.g.*, *Bayh-Dole: The Next 25 Years: Hearing Before H. Comm. on Science and Technology, Subcomm. on Technology and Innovation*, 110th Cong. (2007). These concerns were somewhat lessened by Bayh-Dole where the government's retained rights

C. Bayh-Dole

In September of 1978, Senators Dole and Bayh introduced Senate Bill 414, the University and Small Business Patent Act, which attempted to harmonize the government's policies towards patenting of federally funded research, changing the presumption as to who ought to own a patent resulting from academic research.[96] Interestingly, while much of the rhetoric surrounding the bill focused on losing the innovative edge to Japan and other foreign countries,[97] there was no mention of the idea within the bill itself.[98]

On July 1, 1980, a lame duck Congress, against all odds, passed the Bayh-Dole Act.[99] The legislation gave universities and small businesses (and later by executive order, large businesses[100]) the ability to maintain title to their federally sponsored innovations,[101] if a number of regulations are adhered to.[102] These

in the patent are limited to instances where the funds were used in either the conception of the invention or in the first actual reduction to practice. *See* John H. Raubitschek, *Responsibilities Under the Bayh-Dole Act*, 87 J. PAT. & TRADEMARK OFF. SOC'Y 311, 313 (2005).

[96] *See, e.g.*, David C. Mowery, The Bayh-Dole Act and High-Technology Entrepreneurship in U.S. Universities: Chicken, Egg, or Something Else?, Presented at the Colloquium on Entrepreneurship Education and Technology Transfer 11 (Jan. 21–22, 2005), *available at* http://entrepreneurship.eller.arizona.edu/docs/conferences/2005/colloquium/D_Mowery.pdf. Note also that prior to Bayh-Dole there were 20 statutes governing the United States policy towards patents. *See, e.g.*, Clifton Leaf, *The Law of Unintended Consequences*, FORTUNE, Sept. 19, 2005, at 250.

[97] *See, e.g.*, Broad, *supra* note 84, at 476.

[98] MICHAELSON, *supra* note 86, at 24.

[99] *See, e.g.*, Ashley Stevens, *The Enactment of Bayh-Dole*, 29 J. TECH. TRANSFER 93 (2004) (a compelling narrative of the events immediately preceding the passage of Bayh-Dole).

[100] *See* Exec. Order No. 12,591, 52 Fed. Reg. 13,414 (Apr. 10, 1987).

[101] "Bayh-Dole clearly and decisively answered the question whether academic researchers can own and commercialize government-sponsored research. According to Bayh-Dole, they not only can but are also obligated to do so." Steneck, *supra* note 68, at 3.

[102] Note however that these requirements have changed a couple of times over the years. *See generally* Raubitschek, *supra* note 95, at 311. In exchange for title, receivers of federal funds can claim title to the invention if they: (1) report each disclosed invention to the funding agency, (2) elect to retain title in writing within a statutorily prescribed timeframe, (3) file for patent protection, (4) grant the federal government a non-exclusive, non-transferable, irrevocable, paid-up license to practice or have practiced on its behalf throughout the world, (5) actively promote and attempt to commercialize the

included: (i) the university must "disclose each subject invention to the Federal agency within a reasonable time (i.e., two months)[103] after it becomes known to contractor personnel responsible for the administration of patent matters;"[104] (ii) once disclosed the university must opt in to retain title and patenting rights to the invention within two years;[105] (iii) the government "shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world;"[106] (iv) the government also retains the right "to require periodic reporting on the utilization or efforts at obtaining utilization that are being made by the contractor or his licensees or assignees;"[107] (v) the government can require that the patenting university "include within the specification of such application and any patent issuing thereon, a statement specifying that the invention was made with Government support and that the Government has certain rights in the invention;"[108] (vi) the government also granted itself 'march in rights'[109] that is, a grant of either "a nonexclusive, partially

invention, (6) do not assign the rights to the technology, with a few exceptions, (7) share royalties with the inventor, (8) use any remaining income for education and research, (9) give preference to U.S. industry and small business. 35 U.S.C §§ 200–212 (2006). While typically lax in enforcing these requirements, the government has on at least one occasion refused to grant title when disclosure was not timely and piecemeal. *See* Campbell Plastics Eng'g & Mfg., Inc. v. Brownlee, 389 F.3d 1243, 1248 (Fed. Cir. 2004) (finding that while policy considerations behind the Bayh-Dole Act "clearly intended 'to promote the commercialization and public availability of inventions made in the United States by United States industry and labor,' and 'to encourage maximum participation of small business firms in federally supported research and development efforts,' [Congress] also provided the government with certain aforementioned rights to the inventions and sought to ensure the safeguard of those rights by requiring government contractors to disclose subject inventions." (citing 35 U.S.C. § 200 (2000)).

[103] *See, e.g.*, Cent. Admixture Pharmacy Serv., Inc. v. Advanced Cardiac Solutions, P.C., No. CV-00-2430, 2006 U.S. Dist. LEXIS 95833, at *16 (N.D. Ala. Jan. 10, 2006) (citing 48 C.F.R. § 52.227-11(c)(1) (2007)).

[104] 35 U.S.C. § 202(c)(1) (2006).

[105] Or sixty days prior to the expiration of the one year grace period granted to inventions that have been publicized, e.g., through a scholarly publication or conference. 35 U.S.C. § 202(c)(2) (2006).

[106] *Id.* § 202(c)(4).

[107] *Id.* § 202(c)(5).

[108] *Id.* § 202(c)(6).

[109] Note, however, that march-in rights have been part of the government's university patenting policy since the 1960s. *See* Raubitschek, *supra* note 95, at 312.

exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances;"[110] (vii) universities cannot transfer ownership of a patented innovation developed in whole or in part with university funds to a third party; and (viii) all exclusive licensees must substantially manufacture the commercialized product in the United States.

Although there is some flexibility in these regulations,[111] failure to conform could result in the forfeiture of the intellectual property rights to the invention, even if the government was in no way harmed.[112] Additionally, failure to comply limits the ability of the patent owner to enforce her patent against putative infringers.[113]

Bayh-Dole provisions apply only to inventions conceived or first introduced into practice as a result of a project funded either in whole or in part by the federal government.[114] When this is the case, Bayh-Dole gives the named inventor the right to acquire the patent rights to her invention in the relatively unlikely event that the contractor, i.e., the academic institution, does not elect to retain its title, and provided that the federal funding agency has consulted

[110] 35 U.S.C. § 203(1). The application of these rights are thoroughly noted in the Federal Register, Rights To Inventions Made By Nonprofit Organizations And Small Business Firms Under Government Grants, Contracts, And Cooperative Agreements, 37 C.F.R. § 401.6 (2006). Note that the idea of march-in rights dates back to at least Vanaver Bush, who thought that "[t]he public interest will normally be adequately protected if the Government receives a royalty-free license for governmental purposes under any patents resulting from work financed by the [National Science] Foundation." *See* BUSH, *supra* note 75, at 38.

[111] *See, e.g.*, 35 U.S.C. § 202(c)(2) (2006) (allowing for the contractor to request additional time from the funding source to complete the regulatory requirements).

[112] "[N]oncompliance with a patent rights clause may have serious consequences on enforcing rights in any invention made with Government funding. Although I doubt that agencies will start exercising forfeiture rights, I expect that contractors and universities, in particular, will be more careful in meeting their obligations under Bayh-Dole." Raubitschek, *supra* note 95, at 318; *see, e.g.*, Campbell Plastics Eng'g & Mfg. v. Brownlee, 389 F.3d 1243, 1250 (Fed. Cir. 2004). *But see* Narda Microwave v. Gen. Microwave Corp., 201 U.S.P.Q. (BNA) 231, 232 (E.D.N.Y. 1978) (allowing the contractor to rectify its oversight).

[113] *See* Filmtec Corp. v. Allied Signal, Inc., 939 F.2d 1568 (Fed. Cir. 1991); TM Patents L.P. v. Int'l Bus. Machs. Corp., 58 U.S.P.Q.2d (BNA) 1171 (S.D.N.Y. 2000).

[114] Raubitschek, *supra* note 95, at 313.

with the contracting academic institution at the request of the inventor and prior to granting the rights to the inventor.[115]

Bayh-Dole had numerous policy objectives in addition to simply promoting innovation resulting from federally funded research. Bayh-Dole legislation encourages the participation of small businesses in federally funded research and promotes collaboration between commercial and non-profit organizations, not just universities.

President Jimmy Carter, in his signing statement on Bayh-Dole anticipated that the legislation would provide "some real benefits to the Nation's economic health by stimulating our people's innovative activity."[116] Although one cannot know for sure if Bayh-Dole provided any immediate stimulation to innovation, we can look to concurrent scientific advancements to see that biotechnology, in particular, was already well on its way to its 1980s era boom, even without Bayh-Dole.

D. Concurrent Events in Science

Much of academic patenting and licensing is in the area of life sciences. In order to assess the actual impact of Bayh-Dole on universities, it is important to put the legislative act within the historical context of the science at the time. Molecular biology was going through its own paradigm shift concurrent with the events leading up to and following the passage of Bayh-Dole.[117]

Modern understanding of molecular biology usually begins in 1953 with the discovery of the structure of DNA.[118] Watson and

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[115] 35 U.S.C. § 202(d).

[116] President James E. Carter, Patent and Trademark System Reform Statement on Signing H.R. 6933 Into Law (Dec. 12, 1980), *available at* http://www.presidency.ucsb.edu/ws/index.php?pid=44398.

[117] Eric Campbell calls the convergence of Bayh-Dole, molecular biology, and other events in this time period the "science and technology version of the Perfect Storm." *See* Alan Dove, *When Science Rides the MTA,* 110 J. CLINICAL INVESTIGATION 425, 425 (2002).

[118] J.D. Watson & F.H.C. Crick, *Molecular Structure of Nucleic Acids*, 171 NATURE 738 (1953). Note, however, that there were numerous other earlier discoveries that led to many of the techniques commonly used today in biotechnology. *See, e.g.*, J. Lederberg & E.L. Tatum, *Gene Recombination in Escherichia Coli*, 158 NATURE 558 (1946) (describing transfer of bacterial genes); S.E. Luria et al., *Electron Microscope Studies of*

Crick's determination of the double stranded helical structure of DNA[119] led to an understanding of how DNA replicates and serves as a template for the production of all the proteins in the cell. In the early 1970s much of the Nobel Prize winning technology and knowledge that would be integral to the coming biotechnology revolution began to be discovered by academic research labs in quick succession. This massive expansion of our understanding of the basic molecular nature of the cell helped create the biotechnology revolution. Further, with many of these scientists in academia, this helped propel universities—now owners of these blockbuster innovations—into prosperous relationships with industry.

The seventies began with the discovery of retroviruses by Nobel Laureates Drs. Temin and Baltimore in 1970.[120] In 1972, Paul Berg determined how to isolate genes from one organism and recombine them with DNA from a different organism *in vivo*.[121] In 1973, Cohen and Boyer created functional organisms that were able to recombine DNA from other cells and replicate that DNA as their own.[122] Drs. Hedges and Jacob discovered transposons in bacterial genomes in 1974, transferring amipicillin resistance from one plasmid to another.[123] In 1975, Edward Southern created the

Bacterial Viruses, 46 J. BACTERIOLOGY 57 (1943) (describing the mechanism of viral infection); Arne Tiselius, *A New Apparatus for Electrophoretic Analysis of Colloidal Mixtures*, 33 TRANSACTIONS OF THE FARADAY SOC'Y 524 (1937) (describing the technique of electrophoresis).

119 Watson & Crick, *supra* note 118.

120 D. Baltimore, *RNA-Dependent DNA PolymeraseIin virions of RNA Tumour Viruses*, 226 NATURE 1209 (1970); H.M. Temin & S. Mizutani, *RNA-Dependent DNA Polymerase in Virions of Rous Sarcoma Virus* 226 NATURE 1211 (1970).

121 J.F. Morrow & P. Berg, *Cleavage of Simian Virus 40 DNA at a Unique Site by a Bacterial Restriction Enzyme*, 69 PROC. NAT'L ACAD. SCI. USA 3365 (1972).

122 S.N. Cohen et al., *Construction of Biologically Functional Bacterial Plasmids in Vitro*, 70 PROC. NAT'L ACAD. SCI. USA 3240, 3240 (1973). The famed Cohen-Boyer discovery brought in over 200 million dollars in royalties, with the bulk going to the University of California, San Fransisco and Stanford Universities. Interestingly, the inventors themselves plowed their third of the revenue back into research, declining to take any of the money for their personal use. *See* Baruch Brody, *Intellectual Property and Biotechnology: The US Internal Experience—Part I*, 16 KENNEDY INST. ETHICS J. 1.6, 6 (2006).

123 R.W. Hedges & A.E. Jacob, *Transposition of Ampicillin Resistance from RP4 to Other Replicons*, 132 MOLECULAR GEN. GENETICS 31 (1974).

Southern Blot, the precursor of today's high throughput genomic chips and other technologies.[124] Kohler and Milstein created the first monoclonal antibodies in 1975.[125] Harold Varmus and J. Michael Bishop later received the Nobel Prize for their discovery of the cellular origin of retroviral oncogenes in 1976.[126] In 1977, Maxam and Gilbert,[127] concurrently with Sanger in the U.K.,[128] developed modern methods for sequencing strands of DNA—a necessary innovation for the eventual decoding of the entire human genome, as well as other genomes,[129] and Itakura et al. first synthesized a human protein by bacterial transformation.[130] In 1980, the first transgenic mouse was created.[131] In 1986, the polymerase chain reaction (PCR) methodology was introduced by Kary Mullis.[132]

Note that this list of important biotechnology inventions is merely illustrative, and is far from an exhaustive list, of all the major accomplishments that occurred during the period leading up to and directly following the enactment of Bayh-Dole, in 1980. Science in general was experiencing a phenomenal and unprecedented growth spurt during this period: during the '70s there was, on average an annual 2% increase in the number of

[124] E.M. Southern, *Detection of Specific Sequences Among DNA Fragments Separated by Gel Electrophoresis*, 98 J. MOLECULAR BIOLOGY 503 (1975).

[125] G. Kohler & C. Milstein, *Continuous Cultures of Fused Cells Secreting Antibody of Predefined Specificity*, 256 NATURE 495 (1975).

[126] D. Stehelin et al., *DNA Related to the Transforming Gene(s) of Avian Sarcoma Viruses is Present in Normal Avian DNA*, 260 NATURE 170 (1976).

[127] Allan M. Maxam & Walter Gilbert, *A New Method for Sequencing DNA*, 74 PROC. NAT'L ACAD. SCI. USA 560 (1977).

[128] Frederick Sanger et al., *DNA Sequencing with Chain-Terminating Inhibitors*, 74 PROC. NAT'L ACAD. SCI. USA 5463 (1977).

[129] Maxam, *supra* note 127, at 561.

[130] Keiichi Itakura et al., *Expression in Escherichia Coli of a Chemically Synthesized Gene for the Hormone Somatostatin*, 198 SCIENCE 1056 (1977).

[131] Jon W. Gordon et al., *Genetic Transformation of Mouse Embryos by Microinjection of Purified DNA*, 77 PROC. NAT'L ACAD. SCI. USA 738 (1980).

[132] K. Mullis, et al., *Specific Amplification of DNA In Vitro: The Polymerase Chain Reaction*, 51 COLD SPRING HARBOR SYMP. ON QUANTITATIVE BIOLOGY 263 (1986). Dr. Mullis was awarded the Nobel Prize in Chemistry for this discovery. Press Release, Royal Swedish Acad. of Sci., The 1993 Nobel Prize in Chemistry (Oct. 13, 1993), *available at* http://nobelprize.org/nobel_prizes/chemistry/laureates/1993/press.html ("With PCR it is possible to replicate several million times, in a test tube, an individual DNA segment of a complicated genetic material.").

scientific publications.[133] Starting in the late 1970s and continuing on through the '80s science saw a jump to an annual increase of 4 or 5% in the publication of papers.[134] By 1990 biomedical science was pumping out 85% more papers annually than it had produced in 1970.[135] With much of the basic technology of the biotechnology revolution produced, published, and freely available long before Bayh-Dole passed, it seems difficult to ascribe even a large part of the current biotechnology boom to Bayh-Dole.

E. *Concurrent Biotechnology Industry Growth*

Wall Street was also very interested in biotechnology at this time, with equity investments in biotechnology companies increasing from $50 million to over $800 million between 1978 and 1981.[136] Genentech, which preceded Bayh-Dole, exemplified Wall Street's early passion for biotech. Long before the dawn of huge IPOs, the value of Genentech stock, a pioneer biotechnology company founded by University of California, San Fransisco professors Herbert Boyer and Robert Swanson, went from $35 million to $89 million in the first 20 minutes of public trading.[137] Cetus (founded in Berkeley, California in 1971) successfully went public around the same time.[138] Cetus's initial public offering pulled in over 100 million dollars, making it the largest IPO on the American stock market at the time.[139]

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[133] Data compiled by the author from PubMed, http://www.ncbi.nlm.nih.gov/pubmed/.

[134] *Id.*

[135] *Id.*

[136] Biotech Stock Letter—Investors History of the Biotech Industry, *available at* http://web.archive.org/web/20070202171703/http://biotechstock.com/en-us/pg_10.html (as the page appeared on Feb. 2, 2007).

[137] Brody, *supra* note 122, at 7.

[138] *Id.* at 8–9.

[139] Michael Rosen, *The Birth of Biotech: San Francisco, Boston, Geneva or Chicago?*, WIS. TECH. NETWORK NEWS, Aug. 25, 2004, http://wistechnology.com/article.php?id=1118. In October of 1979, *Business Week* was already gushing about the future of biotechnology in industry:

> As recently as three years ago, predictions of a future technology based on bacteria sounded at best like science fiction . . . . [E]xcitement over industrial applications is building rapidly . . . . [T]he promise is nothing less than "the possibility of building a sustainable future based on renewable resources" . . . . In the area of synthetic organic chemicals alone, J. Leslie Glick, president of Genex

By 1987, the San Francisco Bay Area's biotech industry, benefiting from the quality and quantity of surrounding universities, a local agricultural biotechnology sector, and favorable non-compete laws that promoted cross-fertilization among companies, had grown to 112 companies, from 84 a decade earlier.[140] These companies had revenues exceeding 2 billion dollars and created at least 19,400 San Francisco Bay Area jobs. The market only got hotter as the decade wound down, with 81 new companies being formed in the Bay Area between 1987–1990.[141] Although exemplified in the Bay Area, innovation and productivity were also up nationwide, setting the stage for a competitive and robust biotechnology industry that would feed off of academic research.[142]

F. Concurrent Events in Patent Law

In addition to the incredible advancements made in molecular biology, Bayh-Dole was enacted just as important changes in the United States patent regime—vis-à-vis the biotechnology industry—were taking effect. Throughout the 1970s, patent eligibility requirements were confusing and contradictory,[143] and

> Corp., has identified existing markets worth $12.4 billion annually in which he is convinced that bacteria have a high probability of being more efficient and economical than present technology. . . . And Glick sees another group of markets worth $20 billion annually where less substantial inroads are possible, including the manufacture of such products as plastics, synthetic rubber, and pesticides. Seeing the potential, a growing number of industrial companies are buying in to gain what Charles L. Ruby, Corporate planning manager at Standard Oil Co. of California (Socal), calls "a window on this technology."

Where Genetic Engineering Will Change Industry, BUS. WEEK, Oct. 22, 1979, at 160.

140 BayBio—History of the Industry, http://www.baybio.org/wt/home/Industry_Statistics (last visited Jan. 30, 2009).

141 *Id.*

142 *See, e.g.*, Stephen A. Merrill, Executive Dir. Sci., Tech., & Econ. Policy Bd., The Nat'l Acads., Remarks at the Conference on IPR, Innovation, and Economic Performance (Aug. 28, 2003). For slides of the presentation see http://www.oecd.org/dataoecd/3/51/12040024.pdf.

143 Rebecca S. Eisenberg, *Biotech Patents: Looking Backward While Moving Forward*, 24 NATURE BIOTECH. 317, 317 (2006).

standards for utility, novelty, non-obviousness, and written description were in flux.[144]

In 1980, the Supreme Court's landmark decision in *Diamond v. Chakrabarty*,[145] solidified the expanded scope of patentable subject matter, proclaiming that the patent act will protect "anything under the sun that is made by man" including living organisms and other biological matter.[146] This decision gave biotechnology firms and research institutions the opportunity to patent their biotechnology discoveries.

Diamond v. Diehr[147] set the stage for the patenting of computer software, an integral component of the growing fields of bioinformatics and computational biology, and necessary for the high throughput analysis revolution. In 1990, the California Supreme Court in *Moore v. Regents of the University of California*[148] ruled that the cell line derived from an unwitting patient could be patented, with the patient himself having no claim to those derived cells.[149] "[T]he use of excised human cells in medical research does not amount to a conversion."[150]

The U.S. Patent and Trademark Office (or "USPTO"), in an interference decision, explicitly expanded the scope of patentability to include plants,[151] and later more complex

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144 *See generally id.*

145 Diamond v. Chakrabarty, 447 U.S. 303 (1980) (ruling that a genetically engineered bacteria that consumed oil could be patented).

146 *Id.* at 309.

147 Diamond v. Diehr, 450 U.S. 175 (1981).

148 Moore v. Regents of the Univ. of Cal., 793 P.2d 479 (Cal. 1990).

149 *Id.* at 492–93.

> Human cell lines are patentable because long-term adaptation and growth of human tissues and cells in culture is difficult—often considered an art . . . . It is this *inventive effort* that patent law rewards, not the discovery of naturally occurring raw materials. Thus, Moore's allegations that he owns the cell line and the products derived from it are inconsistent with the patent, which constitutes an authoritative determination that the cell line is the product of invention.

Id. (emphasis in original) (internal quotes omitted).

150 *Id.* at 493. "Moore's allegations that he owns the cell line and the products derived from it are inconsistent with the patent, which constitutes an authoritative determination that the cell line is the product of the invention." *Id.*

151 *Ex parte* Hibberd, 227 U.S.P.Q. 443, 444 (1985).

organisms[152]—eventually even issuing a patent for a transgenic mouse.[153] During this time the Patent Office announced that it considered all "non-naturally occurring non-human multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. [§] 101."[154] There were large institutional changes as well: The Federal Circuit, which is largely perceived as pro-patent[155] and has been actively involved in shaping patent policy to support the biotechnology industry, was established in 1982.[156] The Hatch Waxman Act of 1984[157] allowed pharmaceutical patentees to hold onto their patent monopoly a little longer, making up for time lost during the FDA approval process, further promoting the biotechnology industry.[158]

G. *Concurrent Legislative Efforts*

Even if one were to ascribe a significant portion of the responsibility for the biotechnological and high tech revolutions to Bayh-Dole, the act was only one piece of a larger set of relatively concurrent legislative acts that attempted to promote the transfer of technology. Each of the other pieces of legislation focused on a particular niche, but together they helped set the stage for the biotechnological boom.

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152 *Ex parte* Allen, 2 U.S.P.Q.2d 1425, 1427 (1987) (allowing the patenting of polyploid oysters).

153 Transgenic Non-Human Mammals, U.S. Patent No. 4,736,866 (filed June 22, 1984) (issued Apr. 12, 1988).

154 Brody, *supra* note 122, at 14.

155 *See* Cohen, *supra* note 33, at 58 (discussing perception of CAFC granting large awards); Matthew D. Henry & John L. Turner, *The Court of Appeals for the Federal Circuit's Impact on Patent Litigation*, 35 J. LEGAL STUDS. 85, 114 (2006) (noting that "[i]n sum, we find that the CAFC has been pro-patent, but only with respect to validity."). *But see* John R. Allison & Mark A. Lemley, *How Federal Circuit Judges Vote in Patent Validity Cases*, 27 FLA. ST. U. L. REV. 745, 767 (2000) ("[T]he outcome of patent validity cases in the Federal Circuit has depended on the facts of the case, and not on the composition of the panel.").

156 U.S. Court of Appeals for the Federal Circuit—About the Court, http://www.cafc.uscourts.gov/about.html (last visited Jan. 30, 2009).

157 Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98. Stat. 1585 (1984) (codified as amended at 15 U.S.C. §§ 68b–68c, 70b, 21 U.S.C. §§ 301, 355, 360cc, 28 U.S.C. § 2201, 35 U.S.C. §§ 156, 271, 282).

158 *See generally* Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD & DRUG L.J. 187 (1999) (providing a history and the effects of the act).

In 1976, President Ford, in an effort to revive the presidential science advisory system ("PSAC"), signed the National Science and Technology Policy Organization and Priorities Act of 1976[159] which established an executive office of Science and Technology Policy (or "OSTP"). The act gave the OSTP a

> broad mandate to advise the President and others within the Executive Office of the President on the effects of science and technology on domestic and international affairs . . . [and] authorizes OSTP to lead an interagency effort to develop and to implement sound science and technology policies and budgets and to work with the private sector, state and local governments, the science and higher education communities, and other nations toward this end.[160]

The OSTP has had a significant influence on national innovation policies. During the Carter presidency, the OSTP worked to influence the president to stimulate or remove barriers to innovation, promoted close industry-university relations, and created a close working relationship with the Office of Management and Budget effectuating a pro-science policy.[161]

In 1978 the National Science Foundation started a pilot project to promote university-industry cooperation—something that had

[159] National Science and Technology Policy Organization and Priorities Act of 1976, Pub. L. No. 94-282, 90 Stat. 549 (1976) (codified as amended at 42 U.S.C. § 6614(a)(2), 6615, 6618). The law stipulated that the U.S. government

> adhere to a national policy for science and technology which includes the following principles: (1) the continuing development and implementation of a national strategy for determining and achieving the appropriate scope, level, direction, and extent of scientific and technological efforts . . . (2) the enlistment of science and technology to foster a healthy economy in which the directions of growth and innovation are compatible with the prudent and frugal use of resources . . . and (3) the development and maintenance of a solid base for science and technology in the United States.

Id. at § 102.

[160] Office of Science & Technology Policy—About OSTP, http://www.ostp.gov/cs/about_ostp (last visited Jan. 30, 2009).

[161] *See* Frank Press, *Science and Technology in the White House, 1977 to 1980: Part 1*, 211 SCIENCE 139, 142 (1980).

been on the decline since the exponential growth of government research funds in the 1950s.[162]

In 1980 Congress passed the Stevenson-Wydler Technology Innovation Act[163] which promoted the patenting and licensing of federal laboratory research and development. Like later technology transfer offices set up in universities in response to Bayh-Dole, Stevenson-Wydler required that federal labs set up Offices of Research and Technology Applications and set aside a portion of their funding for the explicit goal of transferring technology to the private sector.[164]

The act also established the National Medal of Technology,[165] an honor "given annually to individuals, teams, and/or companies/divisions for their outstanding contributions to the Nation's economic, environmental and social well-being through the development and commercialization of technology products, processes and concepts, technological innovation, and development of the Nation's technological manpower."[166] "By highlighting the national importance of technological innovation, the Medal also seeks to inspire future generations of Americans to prepare for and pursue technical careers to keep America at the forefront of global technology and economic leadership."[167]

The Tax Reform Act of 1986[168] allowed universities that had financed the construction of their facilities with tax exempt bonds to conduct industry-sponsored research in those facilities without

162 *See generally* Richard C. Atkinson & William A. Blanpied, *Research Universities: Core of the US Science and Technology System*, 30 TECH. IN SOC'Y 30 (2008).

163 Stevenson-Wydler Technology Innovation Act of 1980, Pub. L. No. 96-480, 94 Stat. 2311 (codified as amended at 15 U.S.C. §§ 3701–14) ("[T]he Federal Government shall strive where appropriate to transfer federally owned or originated technology to State and local governments and to the private sector.").

164 15 U.S.C. § 3719 (2006).

165 *Id.* § 3711. Note, however, that the first medal was not awarded until 1985. *See* U.S. Patent & Trademark Office—The National Medal of Technology and Innovation, http://www.uspto.gov/nmti (last visited Jan. 30, 2009).

166 National Medal of Technology and Innovation Nomination Application, 73 Fed. Reg. 57337 (Oct. 2, 2008).

167 U.S. Patent & Trademark Office—The National Medal of Technology and Innovation, http://www.uspto.gov/nmti (last visited Jan. 30, 2009).

168 Tax Reform Act of 1986, Pub. L. No. 99-514, 100 Stat. 2085.

losing their tax exempt status.[169] In order to retain this status, the resulting research had to fall within one of two safe harbors for basic research activities;[170] either a corporate-sponsored research agreement—which required that the sponsor pay a fair market price for the intellectual property rights in the resulting research, or a joint industry governmental cooperative research agreement—which required that the "[t]itle to any patent or other product incidentally resulting from the basic research lies exclusively with the university and that the cooperating corporations would be entitled to no more than a nonexclusive, royalty-free license to use the product of any of that research."[171]

The Orphan Drug Act,[172] with a particular focus on rare diseases, passed in 1983. This act was designed to provide incentives for drug companies to invest in research and development,[173] focusing primarily on classes of unprofitable

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[169] IRS Rev. Proc. 97-14, 1997-5 I.R.B. 20 (IRB 1997). This was superseded only recently on June 26, 2007 by Revenue Procedure 2007-47 that clarifies exactly how Bayh-Dole rights fit within the safe harbor parameters. *See, e.g.*, Mintz-Levin, *Public Finance Advisory: IRS Clarifies Sponsored Research Limitations*, July 13, 2007, http://www.mintz.com/newsletter/2007/Pub-Fin-Adv-Sponsored-Research-07-07/index.htm.

[170] Mintz-Levin, *Public Finance Advisory: IRS Clarifies Sponsored Research Limitations*, July 13, 2007, http://www.mintz.com/newsletter/2007/Pub-Fin-Adv-Sponsored-Research-07-07/index.htm.

[171] *Id.*

[172] Orphan Drug Act, Pub. L. No. 97-414, 96 Stat. 2049 (1983) (defining "rare" as any disease or condition which (A) affects less than 200,000 persons in the United States, or (B) affects more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will be recovered from sales in the United States of such drug).

[173] Orphan Drug Act, § 1(b)(4)–(6), 96 Stat. at 2049.

> [B]ecause so few individuals are affected by any one rare disease or condition, a pharmaceutical company which develops an orphan drug may reasonably expect the drug to generate relatively small sales in comparison to the cost of developing the drug and consequently to incur a financial loss; . . . [Thus] there is reason to believe that some promising orphan drugs will not be developed unless changes are made in the applicable Federal laws to reduce the costs of developing such drugs and to provide financial incentives to develop such drugs . . . [and] it is in the public interest to provide such changes and incentives for the development of orphan drugs.

Id.

drugs.[174] The Act has helped build biotechnological science, create large and small pharmaceutical firms, and promote the type of research that might be conducted in an academic setting—research on niche diseases with little prospect of financial payback.[175]

The Federal Technology Transfer Act[176] was enacted in 1986 to amend Stevenson Wydler. This act attempted to institutionalize technology transfer in government laboratories by, among other things, making technology transfer a component of employee evaluation. To further promote technology transfer, the Act chartered the Federal Laboratory Consortium (or "FLC") to actively "promote and strengthen technology transfer nationwide."[177]

Other legislation contributing to the technological boom include: the Small Business Innovation Development Act of 1982,[178] Cooperative Research Act of 1984,[179] Trademark Clarification Act of 1984,[180] Japanese Technical Literature Act of

174 By most accounts the Orphan Drug Act has been a success. *See* 21 U.S.C. § 360ee note (a)(5) (2006) ("Before 1983, some 38 orphan drugs had been developed. Since the enactment of the Orphan Drug Act [Jan. 4, 1983], more than 220 new orphan drugs have been approved and marketed in the United States and more than 800 additional drugs are in the research pipeline.").

175 *See, e.g.*, Steve Seget, *Orphans Join European Pharma Family*, PHARMAFOCUS.COM, July 5, 2005, http://www.pharmafocus.com/cda/focusH/1,2109,22-0-0-JUL_2005-focus_feature_detail-0-353040,00.html ("Orphan drug legislation in the US is often cited as a major factor in the biotech boom of the 1980s."); *see also* Beverly Goodman, *The Biotech Boom: Big Money in Orphans*, RED HERRING, July 27, 2001, http://www.redherring.com/Home/1396.

176 Federal Technology Transfer Act, Pub. L. No. 99-502, 100 Stat. 1785 (1986).

177 Federal Laboratory Consortium for Technology Transfer, http://www.federallabs.org/home/about (last visited Jan. 30, 2009). Over 250 federal laboratories and centers and their parent departments and agencies are members of the FLC. *See id.*

178 Small Business Innovation Development Act of 1982, 15 U.S.C. § 638 (2006) ("It is the policy of the Congress that assistance be given to small-business concerns to enable them to undertake and to obtain the benefits of research and development in order to maintain and strengthen the competitive free enterprise system and the national economy.").

179 Cooperative Research Act of 1984, 15 U.S.C. § 69 (2006) (establishing that cooperative research is not a per se antitrust violation).

180 Trademark Clarification Act of 1984, 15 U.S.C. § 1064(c) (2006) (amending the Lanham Trademark Act).

1986,[181] the Executive Order Facilitating Access to Science and Technology,[182] and the Omnibus Trade and Competitiveness Act of 1988.[183]

III. EFFECTS OF A CULTURAL SHIFT TOWARDS TECHNOLOGY TRANSFER

A. Revisiting the Technology Transfer Office

While the previous section noted numerous other forces at work that drove universities to their current patent culture and helped to promote the current U.S. technology industry successes, the significant consequence of the Bayh-Dole Act arguably has been primarily the expansion of technology transfer offices into hundreds of universities.[184] The Association of University

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[181] Japanese Technical Literature Act of 1986, 15 U.S.C. § 3704 (2006); *see* Ronald Reagan, Statement on Signing the Japanese Technical Literature Act of 1986 (Aug. 14. 1986), http://www.reagan.utexas.edu/archives/speeches/1986/081486f.htm (explaining that the Act will "increase the availability in the United States of scientific and technical literature published in the Japanese language").

[182] Exec. Order No. 12,591, 52 Fed. Reg. 13,414 (Apr. 10, 1987) (promoting technology transfer by establishing the Technology Share Program whereby "scientists and engineers in the private sector may take temporary assignments in Federal laboratories, and scientists and engineers in Federal laboratories may take temporary assignments in the private sector").

[183] Omnibus Trade and Competitiveness Act of 1988, Pub. L. No. 100-418, 102 Stat. 1107.

[184] *See, e.g.*, *National Institutes of Health: Moving Research from the Bench to Bedside: Health Subcommittee of the House Energy and Commerce Committee: Hearing Before the Subcomm. on Health of the H.Comm. on Energy and Commerce*, 108th Cong. 60 (2003) (statement of Jonathan Soderstrom, Managing Director, Office of Cooperative Research, Yale University, noting that Yale set up its licensing office as a direct response to Bayh-Dole); *see also* COUNCIL ON GOVERNMENTAL RELATIONS, *supra* note 67 ("With the passage of the Bayh-Dole Act, colleges and universities immediately began to develop and strengthen the internal expertise needed to effectively engage in the patenting and licensing of inventions. In many cases, institutions that had not been active in this area began to establish entirely new technology transfer offices, building teams with legal, business, and scientific backgrounds. These activities continue to accelerate nationally as the importance of the Bayh-Dole Act becomes fully appreciated."). *But see* Sampat & Nelson, *supra* note 74, at 20 (noting that the inability of the Research Corporation to handle all of the licenses may have been an impetus to set up technology transfer offices and citing a 1974 Research Corporation report that found that every major institution was considering setting up a technology transfer office); *id.* at 20, 31 (noting

Technology Managers (or "AUTM") lists over 700 university and research institute technology transfer offices in the United States.[185]

During the last decade (between 1990 and 2000), invention disclosures to these technology transfer offices have increased by 79%, patent applications by 253%,[186] patents granted by 131%, and start-up companies evolving out of university research by 92%.

While many of these offices share similar goals and responsibilities,[187] differences remain regarding the extent of their involvement in non-licensing related activities.[188] In general, the offices are responsible for patenting university-created inventions, licensing faculty innovation, and helping faculty license in outside technology. Many offices work with faculty to identify, evaluate, and determine commercial potential for patentable faculty inventions. The offices also work to promote a patent-friendly culture among the faculty, foster contractual and business relationships between faculty and industry, and mediate complex negotiations between faculty, other academic institutions, and industry.

that only 20 technology transfer offices were set up by 1980 and Bayh-Dole induced the proliferation of technology transfer offices).

185 Association of University Technology Managers—Technology Transfer Offices, http://www.autm.net/directory/search_org_results.cfm?searchby=all (last visited Nov. 6, 2008).

186 Academics with industry support are more likely to apply for a patent. In 1980, 240 Patents were granted to universities—by 2004, the annual number had reached 3800. *See* ASS'N OF UNIV. TECH. MANAGERS, AUTM U.S. LICENSING SURVEY: FY 2004, at 2 (2004).

187 In general, there are four types of TTO's nationwide: (1) Centralized Licensing Offices: MIT's technology transfer office is a centralized unit that coordinates all technology transfer activities university-wide; (2) Decentralized Licensing Offices: John Hopkins has three different offices for technology transfer—one for the medical school, one for the Applied Physics Laboratory and one for the rest of the university; (3) Foundations: The University of Wisconsin has a separate and independent foundation (WARF) that was specifically set up to handle all activities related to technology transfer; and (4) Contractors: Research Corporation Technologies Inc. has handled technology transfer activities for many universities. *See generally* U.S. GEN. ACCOUNTING OFFICE, TECHNOLOGY TRANSFER: ADMINISTRATION OF THE BAHY-DOLE ACT BY RESEARCH UNIVERSITIES, GAO/RCED 98–126 (May 7, 1998).

188 For example, while many offices handle material transfer agreements between researchers and outside entities, the University of California does not.

Some offices are also involved in creating start-up firms based on faculty innovation, educating the faculty regarding intellectual property (IP) and licensing issues, and holding regular seminars to discuss IP issues with faculty. Outside of a university's general counsel, the officers of the technology transfer offices are possibly the only attorneys that most academic scientists regularly interact with.[189]

Unfortunately, "[a]cademic researchers and the technology transfer office at their universities have had a prickly relationship . . . ."[190] Not only do the two professions deal with two very different subject matters very differently, scientists and technology transfer officers—and particularly those with legal training—also think differently, in vastly different time frames, and with different goals in mind. For example, scientists, in their drive towards progressive approximations of the truth, unhurriedly seek out and attempt to solve universal problems. Time is on the side of scientists, and they can afford to wait for the best answer. Meanwhile, in the short term, scientists are often satisfied with unknowns, unsolvables, and impossibles. In contrast, even with the tacit acknowledgement that many complex issues cannot themselves be resolved, lawyers attempt to, nevertheless, resolve the questions brought before them now, not in some specified or indeterminate future.[191] Having technology transfer offices and scientists working together on the same project with—often unstated but typically implicit—different processes, goals and timelines, can be somewhat harrowing for both the technology transfer professional and the scientist.[192]

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189 See, for example, varied documents on technology transfer websites outlining their missions and goals, including Yale University Office of Cooperative Research, http://yale.edu/ocr (last visited Jan. 30, 2009) and University of California Technology Transfer, http://www.ucop.edu/ott (last visited Jan. 30, 2009).

190 Editorial, *More than Money; Technology Transfer Offices are Learning from Their Mistakes*, 440 NATURE 845, 845 (2006).

191 While "no generalization is wholly true—not even this one," scientists, unlike lawyers, tend to think in the long term. *See* THE YALE BOOK OF QUOTATIONS 368 (Fred R. Shapiro ed., Yale University Press 2006) (attributing quote to Oliver Wendell Holmes, Jr.).

192 Typical comments include these by Chris Johnson, a computer science professor at the University of Utah:

Notwithstanding this Article's aversion to the technology transfer office in its current form, there remains substantial sympathy for the plight of the technology transfer officers. The job of a technology transfer officer is not easy. Patent prosecution, maintaining patent portfolios, and licensing are non-trivial, often complex, tasks, and these responsibilities frequently stress the systems that are often not designed or funded to carry anything approaching such loads or expenses.[193] Additionally, Bayh-Dole imposes considerable regulatory requirements and restrictions that require technology transfer officers to constantly coax and convince uncooperative and uninterested faculty members to complete invention disclosures for their discoveries.[194] It's not

> The tech transfer office saw inventions as a way to augment the shrinking university budget and [was] overly aggressive in trying to make money," says Johnson. "For us, the better research opportunity was to make it open-source, but they didn't want to do that. It was all very frustrating. My philosophy was that, yes, I could make money, but I wanted to do it in a way that benefited more than just me, but also my research and my lab, and allow the software to get into real-world situations. Money wasn't the primary motivation. The whole process was so onerous. Since then, in the last year or so, the tech transfer office has been completely reformulated. Thankfully.

Ed Silverman, *The Trouble with Tech Transfer: Fighting Tech Transfer—and Winning*, 21 SCIENTIST 40, 43 (2007); *see also* O. Prem Das, *Building Relationships with Technology Transfer Officers*, BIOENTREPRENEUR, May 23, 2005, *available at* http://www.nature.com/bioent/2005/050501/full/bioent861.html (noting how effective technology transfer is enhanced by a strong relationship between technology transfer personnel and the researcher).

193 For example, in 2004, most technology transfer offices had less than five full time employees and spent at least 250 thousand dollars on legal fees, with six institutions spending at least four million dollars. *See* AUTM U.S. LICENSING SURVEY: FY 2004, *supra* note 186, at 24.

194 The Bayh-Dole Act requires universities to set patent policies that encourage patenting and inventing. Other Bayh-Dole obligations include: (i) the filing of a patent on any inventions that the university wishes to claim; (ii) written agreements signed by the faculty that acknowledges that faculty must disclose all inventions and assign ownership to the institution; and (iii) technology transfer offices must use any excess revenue from royalties and fees to support research. *See, e.g.*, *Implementation of Proposition 71: Options for Handling Intellectual Property Associated with Stem Cell Research Grants, at the J. Informational Hearing of the S. Health Comm. Subcomm. on Stem Cell Research Oversight Assemb. Health and Assemb. Judiciary Comms.* (Cal. 2005), *available at* http://www.senate.ca.gov/ftp/SEN/COMMITTEE/STANDING/HEALTH/_home/PROP_71_IP_BENNETT.doc (testimony of Alan Bennett, Associate Vice Chancellor for Research, UC Davis).

hard to understand why interactions with technology transfer offices by faculty are often strained and seen in a negative light by both sides.[195]

Not only do academics feel harassed by technology transfer officers, but technology transfer offices are criticized by academics for not doing enough to commercialize their inventions. Some faculty members feel that their inventions are ignored or undervalued by the technology transfer office and take up valuable time insisting that their disclosures be transformed into applications and licensed at unreasonable fees.[196]

Nonetheless, notwithstanding this empathy for the technology transfer offices, the implementation of patent and licensing policies by these technology transfer offices is seen by many as the source of many of the negative consequences of Bayh-Dole.[197]

1. The Technology Transfer Office's Effect on Research

While only a small minority of these offices is actually profitable,[198] their near-ubiquity in universities continues—possibly because of alumni pressure, the administration, or

[195] *See generally* Jason Owen-Smith & Walter Powell, *To Patent or Note: Faculty Decisions and Institutional Success at Technology Transfer*, 26 J. TECH. TRANSFER 99 (2001) (noting that faculty dissatisfaction with technology transfer offices translates into independent faculty startups—which are increasing in frequency—indicating a growing unhappiness with the technology transfer offices and, further, that because many technology transfer offices are overworked, they delay applications, miss deadlines and drag on license negotiations, all creating uneasiness between faculty and technology transfer professionals).

[196] *See, e.g.*, Silverman, *supra* note 192, at 40 ("[T]he TTO failed to recognize the potential value, balked at the cost of filing a patent application, and didn't pursue any leads, which ended up scuttling a chance to cut a licensing deal with a company." (quoting a genetics researcher at UCLA)).

[197] Boettiger & Bennett, *supra* note 31, at 320 ("Many of the issues that are identified today as negative consequences of Bayh-Dole can be traced to the institutional policies . . . rather than to the Act itself."). *Contra* Sheila Kirschenbaum, *Patenting Basic Research Myths and Realities*, 5 NATURE NEUROSCIENCE 1025, 1026 (2002) (noting that technology transfer offices are invaluable for advancing research objectives and patenting).

[198] Returns on academic research hover around an average of 5%, at most 10%, for the most profitable institutions. It is unlikely that licensing can adequately subsidize new research. *See, e.g.*, Gregory K. Sobolski, John H. Barton & Ezekial J. Emanuel, *Technology Licensing; Lessons from the US Experience*, 294 J. AM. MED. ASS'N 3137 (2005).

regional politician's expectation that the office will find, patent, and license the next big thing.[199] But, while some licenses may be a boon for universities and some academic inventors, the majority of income derived from licensing of academic innovation nationwide comes out of a handful of licensing offices, most of which predated Bayh-Dole, and even those take relatively little revenue home relative to the costs necessary to generate those innovations.[200] Further, those offices that are profitable typically rely on one or two innovations to maintain that profitability.

More often than not, technology transfer offices drain university resources, promising the sky but delivering little. Further, they drain the resources and time of the researchers who must cooperate with the TTOs to draft and license patents. With their monopolistic hold on all licensing efforts in the university, technology transfer offices may also inhibit many entrepreneurial efforts by the researchers themselves—stunting the growth of a patent-friendly environment in academia and hampering independent academia-industry collaborations. Finally, with their indiscriminate and invariably slow efforts to license any potential research innovation, they create a bottleneck in the dissemination of academic science and innovation. Further, technology transfer offices, through their common practice of publishing all possible provisional patent applications, as promoted by the Bayh-Dole

[199] *See, e.g.*, *id.* at 3139 ("[T]he chance to generate significant revenue, however slight tends to create a distorted perception . . . ."); *see also* Rochelle Dreyfuss, *Protecting the Public Domain of Science: Has the Time for an Experimental Use Defense Arrived?*, 46 ARIZ. L. REV. 457, 464 (2004); Kristen Osenga, *Closing In On Open Science: Trends In Intellectual Property & Scientific Research: Rembrandts In The Research Lab: Why Universities Should Take A Lesson From Big Business To Increase Innovation*, 59 ME. L. REV. 407, 418 (2007); The Lemelson-MIT Intel Prop. Workshop, How Does Intellectual Property Support the Creative Process of Invention? 10, http://web.mit.edu/INVENT/n-pressrelease/downloads/ip.pdf (Rochelle Dreyfuss notes that technology transfer has become the "new football").

[200] *See* Leaf, *supra* note 96; *see also* Wayne C. Johnson, Changing Interfaces Between the Research University and Industry, Presentation at the 2005 Engingeering Research Council Workshop and Forum (Feb. 27, 2005), *available at* http://www.asee.org/asee/conferences/erc/2005/upload/wayne-c-johnson.pdf ("Of 3200 universities, perhaps 6 have made significant amounts of money from their intellectual property rights. IP rights should be pursued as a means for interaction with industry rather than as a means for raising revenue from commercialization."(quoting John C. Hurt of the National Science Foundation)).

legislation,[201] waste university funds and researchers' time in drafting patents that may never get anywhere, or languish in the TTO as the office works feverishly to promote those developments that seem to be the most profitable.

While individually small, the combined interruptions caused by technology transfer officers on individual labs quickly adds up, taking away precious time and resources from research.[202] Further, many common practices in technology transfer offices serve to limit outside access to the underlying scientific data, often for an extra year.[203]

Few successful technology transfer offices win the metaphorical technology transfer lottery: successfully licensing one or, rarely, two blockbuster innovations.[204] The obsession with winning the technology transfer lottery is somewhat contagious, and technology transfer offices note that some faculty also become too invention-focused, demanding that every invention disclosure end up as a high profile licensed patent.[205]

With the growing realization that they are often a drain on tight university resources, the technology transfer offices are perversely incentivized to aggressively ramp-up their search for the next big thing in an effort to show their worthiness to the university administration. Recent scholarship from the Kauffman

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201 35 U.S.C. § 202(c)(1) (2006) (disposition of rights).

202 *See, e.g.*, Leaf, *supra* note 96; *see also* Margo A. Bagley, *Academic Discourse and Proprietary Rights: Putting Patents in their Proper Place*, 47 B.C. L. REV. 217, 228 (2006) ("Encroachment of traditional sharing norms now often comes from university intellectual property policies codified in faculty handbooks and in the instructions of TTO personnel . . . .").

203 *See, e.g.*, Bagley, *supra* note 202, at 248 (noting that in fiscal year 2004, 75% of the applications filed by universities, hospitals and institutes were provisional).

204 "Most universities have not earned much money from royalties; the odds of making anything substantial from patenting a new discovery are extremely small. Still, the extraordinary success of a few patents and the many millions of dollars in royalties earned each year by a small minority of schools are enough to keep scores of institutions scouring their labs for commercially valuable innovations." DEREK BOK, UNIVERSITIES IN THE MARKETPLACE: THE COMMERCIALIZATION OF HIGHER EDUCATION 77 (2003).

205 *See, e.g.*, Sean M. O'Connor, Wash. Univ., Opening the Bottleneck: Statutory and Regulatory Reforms for Tech Transfer, Presentation at the DePaul University College of Law Center for Intellectual Property Law and Information Technology, 2004 Intellctual Property Scholars Conference (Oct. 2004).

Foundation highlights these issues, finding that the current system's "home run" mentality works to inhibit rather than promote commercialization of scientific and technological research.[206] This attitude produces a monopolistic approach to revenue maximization and places that ideal ahead of potentially greater social goods related to university output maximization.

Although acknowledging that the probability of licensing that next blockbuster patent is slim, nevertheless, given that the potential payoffs can be in the hundreds of millions of dollars, the technology transfer office and its home university can still rationally choose to chase every potential patent. In order to overcome this drive, the alternative opportunity has to be substitutable—equally valued in the eyes of the university.[207]

2. Material Transfer Agreements

Another overburdening document to come out of the technology transfer office explosion is the relatively recent phenomenon of material transfer agreements. These may arguably have directly resulted from, or at least have been facilitated by, the introduction of technology transfer offices.[208]

Simplistically, material transfer agreements (or "MTAs") are contracts delineating the terms of use for a shared resource, most often concerning the transfer of material (typically biological) and/or data, principally for research purposes. Material transfer agreements exist between inter-industry collaborations, university-university collaborations, and in industry-university collaborative

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[206] *See generally* Robert E. Litan, Lesa Mitchell & E.J. Reedy, *Commercializing University Innovations: Alternative Approaches*, 8 INNOVATION POL'Y & ECON. 31, 31 (2007); *see also Intellectual Property: Universities, Corporations and Finding a Common Ground* 1, 9 (Am. Soc. for Eng'g Educ., White Paper, 2006), *available at* http://www.asee.org/activities/organizations/councils/edc/2006-IP-White-Paper/IPWhitePaper-WEB.doc ("MIT's Preston agrees that too many tech transfer offices are overly preoccupied with elusive licensing revenues.").

[207] Although, note that such calculations would not take into account the expected utility to society resulting from the patenting of each and every innovation.

[208] *See* Wendy D. Streitz & Alan B. Bennett, *Material Transfer Agreements: A University Perspective*, 133 PLANT PHYSIOLOGY 10, 11 (2003) (noting that the UC system executed 2000 MTAs in 2002 and that MTAs can have a significant impact on careers of student scientists, limiting their ability to publish).

efforts. Many in academia find the agreements to be burdensome and tedious at best.

MTAs are also particularly useful at restricting access to patented technologies that could not be restricted without potentially being held liable for patent misuse.[209] Without the MTAs, patented technology might still be accessible to researchers who are enabled by the patent or subsequent publications. MTAs may potentially also be considered prior art and invalidate any subsequent resulting patents.[210]

"Even researchers who routinely accept such conditions . . . bemoan the tangled web that MTAs have become. . . . [I]t's 'a horrendous problem' . . . ."[211] They generally dissuade cooperation with future collaborators that do not want to be hampered by third party contracts. MTAs can also hamper follow-on innovation by allowing the contracting parties to assert ownership over the subsequent innovations resulting from the original material transferred. With limited rights in any subsequent innovations, researchers may be dissuaded from conducting productive research. Unfortunately, a large majority of published research will require access to physical materials from the patent holder, the transfer of which will trigger an MTA resulting in restriction of use of the technology.

One of the main goals of an MTA is to outline the rights of the provider and the users with regard to the materials, themselves, and any derivative data or materials derived from experiments with the initial material. Limitations on material and data typically involve issues of confidentiality, publication embargoes, and limitations on the type of research that can be conducted. In extreme cases MTAs may even demand reach-through intellectual property rights.[212] Reach-through rights guarantee either that the

[209] Patent misuse refers to an impermissible attempt to expand either the scope of the patent or to exact monopoly protections beyond its temporal scope. *See* Mallinckrodt, Inc. v. Medipart, Inc., 976 F.2d 700, 704 (Fed. Cir. 1992). Patent misuse will often parallel the anticompetitive goals of antitrust law. *See, e.g.*, *id.* at 708.

[210] *See generally* Victor Rodriguez, *Material Transfer Agreements: Open Science vs. Proprietary Claims*, 23 NATURE BIOTECH. 489 (2005).

[211] Elliot Marshal, *Need a Reagent? Just Sign Here*, 278 SCIENCE 212, 212 (1997).

[212] "At the same time that the numbers of MTAs are increasing, so is their complexity, with restrictions and obligations potentially reaching far beyond the material itself, to

provider of the material is granted an automatic license to use any discoveries arising out of her material, or that the owner of the material gets royalty payments for any revenue brought in by discoveries made with the material. These agreements go against many of the basic customs of science, and apply to material that would have, in the past, been shared freely and without much inhibition. MTAs also tend to require complex legal and time-consuming negotiations.

Given the contractual (and non-IP) nature of MTAs, they often dispense with the fair use and whatever research exceptions are available under patent and copyright law: fair uses may be contractually overridden, and the future attempts to reinvigorate the research exemption in patents,[213] or other flexibilities directed at academic research, will be moot if academic institutions and corporations contract around them anyway with their MTAs.[214]

Efforts by the National Institutes of Health, and the introduction of the Uniform Biological Material Transfer Agreement (or "UBMTA"), have attempted to simplify and harmonize the MTA process through creating a straightforward and streamlined MTA to be used by all academic institutions.[215] Nevertheless, in spite of the original interest in UBMTAs, many technology transfer offices do not use them at all or use them only as starting, alterable templates.[216] But, even when they are used as

data or inventions made using the material and to derivative materials. Because MTAs are contractual agreements between two parties, they typically do not have the geographic or temporal limitations of patented technologies and can, consequently, be much farther reaching than the scope of patent rights." Streitz & Bennett, *supra* note 208, at 11.

213 *See, e.g.*, Boettiger & Bennett, *supra* note 31, at 321; Kenneth Neil Cukier, *Navigating the Future(s) of Biotech Intellectual Property*, 24 NATURE BIOTECH. 249, 251 (2006); Paulette Walker Campbell, *Pacts Between Universities and Companies Worry Federal Officials; Research Agencies Fear that the Restrictions in Some Agreements May Impede Scientific Progress*, CHRON. HIGHER EDUC., May 15, 1998, at A37.

214 *See, e.g.*, Bagley, *supra* note 202, at 273–74 (calling for extended grace periods for scientific researchers).

215 *See* Uniform Biological Material Transfer Agreement: Discussion of Public Comments Received; Publication of the Final Format of the Agreement, 60 Fed. Reg. 12,771 (Mar. 8, 1995).

216 *See, e.g.*, Arti Rai & Rebecca Eisenberg, *The Public Domain: Bayh-Dole reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289, 305–06 (2003); *see also*

initially intended, UBMTAs present some of the same problems to academic research.[217] They still allow for the delay of publications, are often customized through time-consuming negotiation, are still perceived to be too complex, limit the use of materials, sometimes create overburdening confidentiality requirements, and are an additional step that must be completed in order to conduct scientific research.[218]

Without a local technology transfer office to facilitate and negotiate MTAs, one could expect them to become too burdensome for even the owner of the MTA and eventually a more simplistic academic model may arise.

3. Joint Research Agreements

Joint Research Agreements are another outgrowth of the legal and business environment created by technology transfer offices and can, like MTAs, pose a substantial roadblock to scientific innovation. Joint research agreements (or "JRAs") have become more important subsequent to the passing of the Cooperative Research and Technology Enhancement Act ("CREATE"),[219] another effort by Congress to promote industry-academia interactions.[220]

Megan Ristau Baca, *Barriers To Innovation: Intellectual Property Transaction Costs In Scientific Collaboration*, 4 DUKE L. & TECH. REV. ¶¶ 28–29 (2006).

[217] The growing concern over MTAs and their effect on research is growing as indicated by AUTM's creation of an interest group on MTAs in 2003. *See* Rodriguez, *supra* note 210, at 489.

[218] Recent results suggest that MTAs may cause significant friction in the transfer of materials and information, even between academic scientists. *See* JOHN P. WALSH, CHARLENE CHO & WESLEY M. COHEN, PATENTS, MATERIAL TRANSFERS AND ACCESS TO RESEARCH INPUTS IN BIOMEDICAL RESEARCH (Sept. 20, 2005), *available at* http://www2.druid.dk/conferences/viewpaper.php?id=776&cf=8 (noting that while patenting did not have a major effect on research projects, MTAs, which made up 40% of all research transfers, do pose threats to researchers).

[219] 35 U.S.C § 103(c) (2006).

[220] *See* Bagley, *supra* note 202, at 237.

> This bill makes a narrow but important change in our patent laws to ensure that the American public will benefit from the results of collaborative research efforts that combine the erudition of great public universities with the entrepreneurial savvy of private enterprises. . . . [W]e must encourage—not discourage—public institutions and private entrepreneurs to combine their respective

The Federal Circuit in *Kimberly-Clark*,[221] following precedent set by its predecessor court in *In re Clemens*[222] and *In re Bass*,[223] ruled that a strict interpretation of the obviousness standard in 35 U.S.C. § 103 would include secret prior art—i.e., prior art that is not yet publicly known or available—as a type of prior art that could invalidate a patent for obviousness.[224] Importantly for cooperating researchers, this even included instances where that secret prior art was only discussed among research collaborators.

Realizing that this might chill communication between collaborators during the inventive process, Congress amended the Patent Act in 1984 to, among other things, create a safe harbor for some forms of secret prior art by excluding materials that were passed among collaborators and co-inventors, excluding these from the definition of invalidating prior art.[225] "New technology often is developed by using background scientific or technical information known within an organization but unknown to the public. The bill, by disqualifying such background information from prior art, will encourage communication among members of

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> talents in joint research efforts. Indeed Congress committed itself to this principle when it passed the Bayh-Dole Amendments to the Patent Act.

Id. (quoting Senator Orin Hatch during his introduction of the CREATE Act).

221 Kimberly-Clark Corp. v. Johnson & Johnson, 745 F.2d 1437 (Fed. Cir. 1984).

222 *In re* Clemens, 622 F.2d 1029 (C.C.P.A. 1980).

223 *In re* Bass, 474 F.2d 1276 (C.C.P.A. 1973).

224 *Kimberly-Clark*, 745 F.2d 1437, 1444–46. The patent law requires that the invention not be obvious to a person having ordinary skill in the art at the time of the invention's conception in light of the teaching of the prior art. *See* 2-5 CHISUM ON PATENTS § 5.01 ("The general purpose behind the requirement of nonobviousness . . . serves to limit patent monopolies to those innovations that in fact serve to advance the state of the useful arts. New problems arise and call for new solutions. A patent monopoly may issue only for those literally new solutions that are beyond the grasp of the ordinary artisan who had a full understanding of the pertinent prior art.").

225 Patent Law Amendments Act of 1984, Pub. L. No. 98-622, 98 Stat. 3383, § 103 (codified as amended at 35 U.S.C. § 103) ("Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.").

research teams, and patenting, and consequently public dissemination, of the results of "team research."[226]

Nevertheless, despite Congressional efforts, the law remained unclear on the issue of collaborators from different organizations, i.e., collaborators in different universities,[227] and, in 1997, was narrowly construed by the Federal Circuit in *OddzOn Products, Inc. v. Just Toys, Inc.*[228] to be limited to instances wherein the collaborators were actually both in the same organization.[229] The *OddzOn* ruling created the potential for a substantial chilling effect for open discussion among collaborators, particularly the many public-private research and development collaborations. Apportionment of patents rights between collaborators would not get around the problem of invalidating secret prior art because federal granting agencies required that the granted university retain sole ownership of the invention, only licensing the rights to the private-sector research partners.[230]

The CREATE act was designed to overrule this narrow interpretation of §103 in an effort to promote greater collaboration among researchers in different organizations: "Congress intends to extend this exemption [from the 1984 Patent Law Amendments] to 'joint research agreement' inventors, who may represent more than one organization . . . ."[231]

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226 Legislative History of the Patent Law Amendments Act of 1984, Section-By-Section Analysis of H.R. 6286, Patent Law Amendments Act of 1984, 130 Cong. Rec. H10525–529 (Oct. 1, 1984) (inserted by Representative Kastenmier, chairman of the Subcomm. on Courts, Civil Liberties and the Administration of Justice of the Comm. on the Judiciary), *available at* http://ipmall.info/hosted_resources/lipa/patents/Legislative_History1984.pdf.

227 *But see, e.g.*, *Patent Law and Non-Profit Research Collaboration: Hearing Before the Subcomm. on Courts, the Internet and Intellectual Property and the H. Comm. on the Judiciary*, 107th Cong. (2002) (statement of Carl E. Gulbrandsen, Ph.D., Wisconsin Alumni Research Foundation and the Council on Government Relations) ("The legislative history of the 1984 amendment clearly establishes that subsection 103(c) was [designed to help encourage teamwork at least] *within* organizations"). Given the text of subsection 103(c) and its legislative history, it is clear that the enactment of subsection 103(c) sought to encourage teamwork among researchers, rather than stifle team research. 35 U.S.C. § 103(c) (2006).

228 Oddzon Prods., Inc. v. Just Toys, Inc., 122 F.3d 1396(Fed. Cir. 1997).

229 *Id.* at 1403 (ruling that private and confidential material between collaborators at different institutions may be seen as prior art for finding obviousness).

230 *See* H.R. Rep. No. 108-425 (2004).

231 *Id.* at 6.

(c)(1) Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title [35 U.S.C. § 102], shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person.
(2) For purposes of this subsection, subject matter developed by another person and a claimed invention shall be deemed to have been owned by the same person or subject to an obligation of assignment to the same person if—

(A) the claimed invention was made by or on behalf of parties to a joint research agreement that was in effect on or before the date the claimed invention was made;

(B) the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and

(C) the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement.

(3) For purposes of paragraph (2), the term "joint research agreement" means a written contract, grant, or cooperative agreement entered into by two

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> Oddzon represents a significant potential threat to inventors who engage in collaborative research and development projects. Put another way, the decision created a situation where an otherwise patentable invention may be rendered nonpatentable on the basis of confidential information routinely exchanged between research partners. Thus, parties who enter into a clearly defined and structured research relationship, but who do not (or cannot) elect to define a common ownership interest in or a common assignment of inventions jointly developed, can unwittingly create an obstacle to patent protection by simply exchanging secret information among themselves.

Id. at 5.

> or more persons or entities for the performance of experimental, developmental, or research work in the field of the claimed invention.[232]

Although CREATE intended to promote further collaboration among public and private institutions, it has the dubious distinction of incorporating further bureaucracy and uncertainty into the commodification process. It forces putative collaborators to first carefully structure a written collaboration agreement—i.e., a joint research agreement—prior to sharing information and their current research—effectively requiring scientific collaborations to initially practice at arm's length and, through their technology transfer personnel, increasing the initial costs of beginning a collaboration. These JRAs cannot be written off the cuff; they need to be written broad enough such that the resulting product, and eventual field of research fall within the scope of the JRA. "The Act thus places a premium on well documented collaborative research activities."[233] Often they are written following substantial time-consuming negotiations between academics and their technology transfer offices.

Further, the legislative history suggests that in order to claim the safe harbor exemption of the CREATE act, the relevant parties need to be publicly disclosed—which may further chill public-private collaborative research that benefits from anonymity.

Some have suggested that the increased usage of JRAs will also result in more IP litigation focused on infringing academics. JRAs create joint responsibilities and interests in the intellectual property. These interests are protected by all the partners in the JRA—unifying their resources and strengthening their ability to target anyone they want and potentially scaring off risk-averse users of the technology.[234] Further, there are concerns that the lag time resulting from the need to negotiate the agreement up front

[232] 35 U.S.C. § 103(c) (2006).

[233] Kenneth Meyers, *Joint Research Agreements and the CREATE Act 2004: IP Value in the Life Sciences Industries*, Feb. 2006, http://www.finnegan.com/files/PDFs/200812110431237535804news914.pdf.

[234] Ann E. Mills, Donna T. Chen, John Gillon, Jr. & Patti M. Tereskerz, *The CREATE Act: Increasing Costs Associated with the Biotech Industry?*, 24 NATURE BIOTECH. 785, 786 (2006).

prior to any potentially fruitful collaboration with another institution may further hamper scientific innovation.

Technology transfer offices are typically not staffed by lawyers, and, as such, some JRA experts warn technology transfer staff to be especially aware of the number of pitfalls and traps in the CREATE act.[235] Like MTAs, JRAs have become more complicated and time-consuming because of the availability of technology transfer professionals. As long as universities have technology transfer offices, there is little incentive for universities and academics to lobby to change the current state of the CREATE Act.

4. General Issues in University Industry Relationships

If nothing else, universities' licensing offices, set up after Bayh-Dole in the hopes of patenting the next blockbuster drug, have created a mechanism for increasing and maintaining relationships between academia and industry[236] that could potentially be exploited by either or both parties. Public-private partnerships are considered critical elements for the future of basic and clinical research.[237] And, public-private partnerships, while more difficult and subject to additional delays, often are less likely to abort prematurely than their homogenous counterparts.[238]

[235] *See* Nixon Peabody LLP, *Technology & Intellectual Property Alert*, Jan. 2005, http://www.nixonpeabody.com/linked_media/publications/TIPA_01282005.pdf.

[236] These relationships have been very beneficial to industry. *See, e.g.*, David Blumenthal, Nancyanne Causino, Eric Campbell & Karen Louis, *Relationships Between Academic Institutions and Industry in the Life Sciences—An Industry Survey*, 334 NEW ENG. J. MED. 368, 373 (1996) (suggesting "that research ties with academic institutions have demonstrable benefits for sponsors, that these benefits persist over time, that life-science companies remain financially committed to university research, and that universities are well positioned to compete for industry funds"). Note also that the U.S. government has a vested interest in promoting these types of relationships as indicated by the recent effort by Congress in legislating the CREATE act of 2004.

[237] *See generally* David Hill et al., *Academia-Industry Collaboration: An Integral Element for Building "Omic" Resources*, 14 GENOME RES. 2010 (2004); *see also* Joshua Newberg & Richard Dunn, *Keeping Secrets in the Campus Law: Law, Values and Rules of Engagement for Industry-University R&D Partnerships*, 39 AM. BUS. L.J. 187, 187 (2002).

[238] Bronwyn H. Hall, Albert Link & John T. Scott, *Universities as Research Partners*, 85 REV. ECON. & STATS. 485, 487 (2003).

Overall estimates have shown industry supporting thousands of projects[239] during the nineties.[240]

Universities are beginning to realize that many of their industry relationships are now more important than ever: Science funding has had an unprecedented ride over the last few years, particularly in the United States. Inexplicably, while other United States government agencies regularly get budget cuts, science funding has been growing at a steady clip until recently. Total research and development spending for 2004 was $41.25 billion, up from $38.5 billion in 2003,[241] but this will not last forever. Already the budget for government funding of biomedical science seems to be stagnating, barely keeping up, if at all, with inflation.[242] While industry's contribution to public R&D funding is still, for the most part, in the single digit billions,[243] it may grow in the near future and will be particularly important, if and when the nation's science budget begins to decline.[244] Those institutions that have strong industry ties will probably benefit the most as industry's role in science funding grows.[245] A number of forward-looking technology transfer offices have actually begun to focus more on creating fruitful partnerships than on controlling technology transfer, often prioritizing one over the other during negotiations with industry.[246]

239 Eric Campbell et al., *Inside the Triple Helix: Technology Transfer and Commercialization in the Life Science*, 23 HEALTH AFF. 64, 66 (2004).

240 *Id*. (noting that it was at a cost of $1.5 billion).

241 *See* AUTM U.S. LICENSING SURVEY: FY 2004, *supra* note 186, at 24.

242 *See, e.g.*, J. Michael Bishop & Harold Varmus, *Re-Aim Blame for NIH's Hard Times*, 312 SCIENCE 499, 499 (2006) (noting that NIH will have 11% less spending power in 2007 than it had in 2004).

243 Industry funded research is growing but not substantially. Industry funding towards academic R&D was $2.8 billion in 2004 and $2.8 billion in 2003. *See* AUTM U.S. LICENSING SURVEY: FY 2004, *supra* note 186, at 24.

244 *But see* Blumenthal et al., *supra* note 236, at 372 ("[A]cademic institutions may not be able to depend heavily on industrial support to maintain their intellectual vitality. . . . [A]lthough it is a substantial complement to federal support, industrial sponsorship remains small as compared with NIH funding. It therefore seems unlikely that industrial funding could make up for any appreciable reduction in funding from the NIH.").

245 Although, note that "most research contracts with industry are small and short-lived." *Id.*

246 From author's personal conversations with technology transfer officers.

There are many positive components to such interactions including, (i) opportunities for industry jobs for graduate students or postdocs, (ii) availability of high-end instrumentation that may be beyond the budget of an academic institution but available through industry contacts, (iii) new approaches and directions to research, and (iv) industry funding. Unfortunately, though, many industry collaborations have been of short duration and with minimal monetary input from industry.[247]

However, a focus on fostering industry-academia partnerships may also end up hurting science, as technology transfer offices may be more inclined to license to industry at favorable terms and conditions to industry, with less than optimal terms for researchers or for society. Some argue that the technology transfer offices are actually straining the relationship between industry and academia. Industry representatives recently told a subcommittee of the House of Representatives Committee on Science and Technology, headed by Representative David Wu of Oregon, that technology transfer offices are typically overly concerned with money and are insensitive to the needs of industry.[248] Frustrated companies told stories of prolonged lengthy negotiations with uncompromising technology transfer officers.[249] As opposed to enhancing relationships, these offices may be hurting and hampering productive relationships, sending disgruntled corporate academic liaisons to other universities and potentially other countries in search of better collaborators.[250]

[247] *See* Virginia Gewin, *The Technology Trap*, 437 NATURE 948, 948 (2005) (noting that many companies are now backing away from dealing with academia and the flow of research dollars from industry to academia has slowed).

[248] *The Bayh-Dole Act (P.L. 96-517, Amendments to the Patent and Trademark Act of 1980): The Next 25 Years: Hearings Before the H. Comm. on Science and Technology, Subcomm. on Technology and Innovation*, 110th Cong. (2007).

[249] *Id*.

[250] *See, e.g.*, Bernadette Tansey, *The Building of Biotech 25 Years Later, 1980 Bayh-Dole Act Honored as Foundation of an Industry*, S.F. CHRON., June 21, 2005, *available at* http://www.sfgate.com/cgi-bin/article.cgi?f=/c/a/2005/06/21/BUG6JDBOSP1.DTL&hw=the+BUilding+of+biotech&sn=001&sc=1000 ("The companies that are in a position to actually translate academic research into useful therapies or products have trouble negotiating with financially strapped universities who want to recover as much money as they can from their scientists' inventions." (quoting Professor Michael Eisen)).

B. Effect on Science Fraud

In addition to the possibility of enhanced relationships with industry, another possible positive secondary effect of technology transfer offices—and the growing number of industry relationships fostered by them—might be a reduction of fraud in academic science. While many fear that the basic ethos of science is under attack by its corporatization, corporatization has also propelled science to a new level of professionalism.[251] At this level of professionalism, fraud and misconduct are less tolerated than they were in the past. Additionally, with the influx of corporate culture into science, formerly laissez faire scientists are considerably more vigilant in weeding out fraud, particularly in the work of competitors. In contrast to previous circumstances, where competing labs could publish similar results simultaneously and receive equal degrees of credit and prestige for their work, patents are often a winner-take-all game, and only one lab can be the winner.

Historically, science was a gentleman's pursuit. Those who were independently wealthy, or had a wealthy patron, could afford to tinker. This was the case even up to the Second World War when some of the best physics research was conducted at Alfred Loomis' sprawling estate in the upscale Manhattan suburb of Tuxedo Park.[252] With the onset of government funding, however, science started to become more professional. This continued with greater vigor following Bayh-Dole and the advent of universal university technology transfer offices.

For decades, the scientific community has been struggling to deal with a growing realization that misconduct in basic science research may be more endemic than previously thought.[253] While

[251] The author's personal experience has shown even the influx of corporate terminology like "action items" into science.

[252] *See generally* JENNET CONANT, TUXEDO PARK: A WALL STREET TYCOON AND THE SECRET PALACE OF SCIENCE THAT CHANGED THE COURSE OF WORLD WAR II (2002).

[253] "There's a lot to worry about." Donald Kennedy, *Research Fraud and Public Policy*, 300 SCIENCE 393, 393 (2003) (noting that hard sciences are not the only sciences that suffer from fraud; in fact, often social scientists have political incentives to commit fraud, something that exists to a lesser degree in basic science research); *see also* Kenneth Ryan, *Scientific Imagination and Integrity*, 273 SCIENCE 163, 163 (1996) ("The

the three cardinal sins of fabrication, falsification and plagiarism[254] are committed by a relatively small number of scientists,[255] studies have found that nearly a third of all scientists have been involved in some misconduct in their research over the course of their careers.[256] Ethics courses do not seem to help.[257] Neither fear of

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current research environment seems to foster cynicism about simple virtues such as honesty and fairness, and it clearly fosters hostility toward anyone who makes claims about misconduct."); David. S. Oderberg, *The Unholy Lust of Scientists: It May Be Time to Curtail Public Financing of Scientific Research*, S.F. CHRON., Jan. 15, 2006, *available at* http://www.sfgate.com/cgi-bin/article.cgi?file=/chronicle/archive/2006/01/15/INGMDGMDSV1.DTL ("I venture to suggest that contemporary science is now so corrupted by the lust for loot and glory that nothing less than root-and-branch reform can save it. . . . How could the millions thrown at scientists be anything other than a veritable inducement to misconduct? When you combine it with the innumerable honors and awards that await the next would-be secular savior of humanity, one wonders that fraud is not even more common than it appears to be."). *But see* Gerald Holton & Frederick Grinnell, *Defining Misconduct*, 273 SCIENCE 858, 858 (1996) (arguing against these accusations).

254 *See* 42 C.F.R. § 50.102 (2001) ("Misconduct or Misconduct in Science means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data."). The National Academy of Science suggested limiting misconduct to just fabrication, falsification and plagiarism. *See, e.g.*, Charles Walter & Edward P. Richards, *Defining Scientific Misconduct for the Benefit of Science*, http://biotech.law.lsu.edu/IEEE/ieee23.htm#fn2. *But see* Jocelyn Kaiser, *NSF Stakes a Position on Misconduct*, 276 SCIENCE 1779, 1779 (1997) (citing the National Science Foundation's ethics enforcer, Inspector-General Linda Sundro, explaining that the "serious deviation" clause in the definition of misconduct: "fabrication, falsification, plagiarism ("FFP"), or other serious deviation from accepted practices," is the core of the definition). The NSF is alone in this regard and many other science groups wanted the term "serious deviation" removed because many scientists found it too vague. As a result, the White House interagency Committee on Fundamental Science suggested the term be removed. *Id.*

255 *See, e.g.*, Georg W. Kreutzberg, *The Rules of Good Science*, 5 EMBO REP. 330, 330 (2004) ("When scientists hear about scientific fraud, they quickly denounce the culprits as not being 'true' scientists. The true scientist, they argue, is only interested in unveiling step by step the countless enigmas of nature. He or she labours long hours and weekends at a desk or in the laboratory to find the truth, not to invent it."). *But see* K.J. Breen, *Misconduct in Medical Research: Whose Responsibility?*, 33 INTERNAL MED. J. 186 (2003) (noting that these few are far from normal).

256 *See, e.g.*, Brian C. Martinson, Melissa S. Anderson & Raymond de Vries, *Scientists Behaving Badly*, 435 NATURE 737, 738 (2005).

257 *See, e.g.*, Charles E. Deutch, *A Course in Research Ethics for Graduate Students*, 44 COLLEGE TEACHING (1996); *see also* Caroline Whitbeck, *Teaching Ethics to Scientists and Engineers: Moral Agents and Moral Problems*, 1 SCI. & ENG'G ETHICS 229 (1995).

criminal penalties,[258] nor of civil suits,[259] has in any way lessened the incidence of fraud.

While archaic yet noble Mertonian ideals arguably still drive some of the science in this country,[260] it is becoming clearer, particularly with the significant increase in reports of fraud in science, that other incentives, particularly monetary, are also involved in driving academic science, in general, and potentially driving academic science to fraudulent activity. Thus, while the lure of patents may drive scientists to work harder, hit more deadlines, and strive towards potentially lucrative results more efficiently than the reward of publishing alone, unfortunately the potential to make money in addition to publishing may push more scientists to fudge and cheat.

Patents and other imports from industry can be seen as a strong force against fraud in science. The recent upsurge in ferreting out fraud, discussing fraud in journals, and teaching about misconduct in graduate programs may be part of the cultural shift to a more responsible corporate ideology represented by the culture of technology transfer offices. Note however that this new zealousness in finding misconduct may unfortunately, and all too often, lead to unfounded accusations[261]—the fear of which could

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258 *See, e.g.*, Susan Kuzma, *Criminal Liability for Misconduct in Scientific Research*, 25 U. MICH. J.L. REFORM 357, 381 (1992); *see also* Bratislave Stankovic, *Pulp Fiction: Reflections on Scientific Misconduct*, 2004 WIS. L. REV. 975, 978 (2004).

259 For example, under the False Claims Act. *See, e.g.*, Franklin Hoke, *Novel Application Of Federal Law To Scientific Fraud Worries Universities and Reinvigorates Whistleblowers*, 9 SCIENTIST 1, 1 (1995); *see also* Keith D. Barber, David. B. Honig & Neal A. Cooper, *Prolific Plaintiffs or Rabid Relators? Recent Developments in False Claims Act Litigation*, 1 IND. HEALTH L. REV. 131 (2004); Dan L. Burk, *False Claims Act Can Hamper Science With 'Bounty Hunter' Lawsuits*, SCIENTIST, Sept. 4, 1995, at 12.

260 ROBERT K. MERTON, THE SOCIOLOGY OF SCIENCE (1973). Mertonian Norms include: (1) Communalism; (2) Universalism; (3) Disinterestedness; (4) Originality; and (5) Skepticism. *See* Wikipedia—Robert K. Merton, http://en.wikipedia.org/wiki/Robert_K._Merton; *see also* Sheila Jasanoff, *Contested Boundaries in Policy-Relevant Science*, 17 SOC. STUD. SCI. 195, 196 (1987) (noting that science does its best to at least show to the public that the norms are still in effect).

261 In the United States, the Office of Research Integrity received 267 allegations of research misconduct in 2006. Research misconduct was found in only 15 of the 28 cases that it actually closed that year. OFFICE OF RESEARCH INTEGRITY, ANNUAL REPORT 2006, at 5 (2007) ("Most Federal agencies win most of their cases before hearing offices in their own agencies. In most cases, the batting average is over 70 or 80 percent."); Gina

strain relationships with collaborators, principle investigators, students, and postdoctoral fellows.[262]

Still, there are many positive aspects, with regard to science misconduct, that have resulted from the technology transfer culture. Whereas in the past fabrication of results may have helped a scientist get a prestigious paper published—and that was all she wanted, itself enough incentive to commit fraud—fraud cannot help one's chance of practically applying one's research with a patent, suggesting the incentives for science misconduct are diminished. Moreover, while it is now clear that results are rarely reproduced by independent laboratories, companies licensing a patent will want to reproduce results. With the possibility of more research licensed out to industry, there may be stronger countervailing forces not to cheat, than to cheat, in research. Additionally, the technology transfer offices' common suggestion that researchers keep meticulous notebooks and records, albeit for patent-related reasons, can only help prevent fraudulent recording activity. The licensing professional is also another set of eyes in her examination of the required invention disclosure and the documents leading up to a patent, lessening the chance that a fraudulent result will get past science's gatekeepers.

Some issues relating to misconduct in science, however, may not benefit from a greater trend towards patenting and commercial culture—specifically, the growing issue of conflicts of interest among researchers, journal reviewers, grant reviewers, institutional review boards, and institutions.[263] Nowhere is this a

Kolata, *Inquiry Lacking Due Process*, N.Y. TIMES, June 25, 1996 at C3. The inability to make the charges stick even in internal hearings may indicate an even smaller number of instances of true fraud than the numbers of claimed fraudulent activities indicates and that most claims of fraud are unfounded.

262 *See, e.g.*, Laura Bonetta, *The Aftermath of Scientific Fraud*, 124 CELL 873, 875 (2006) (noting the data from the Office of Research Integrity ("ORI"): Of the 2700 allegations of fraud submitted to ORI, there have been to date only 160 findings of actual fraud).

263 *See generally* David Blumenthal, *Biotech in Northeast Ohio Conference: Conflict of Interest in Biomedical Research*, 12 HEALTH MATRIX 377 (2002).

greater concern than in the interactions between research labs and corporations.[264] Others disagree completely.[265]

IV. SIGNIFICANT LIMITATIONS WITH THIS ARTICLE—LACK OF EMPIRICAL DATA

Much of this Article has been written in a speculative fashion. That is intentional. In fact some of the historical information has been hyper-cited to draw out an important distinction: the paucity of empirical information with regard to some of the effects of Bayh-Dole and technology transfer offices on academic scientific research.

There is a dearth of hard data on the effect of Bayh-Dole on basic research, and much of what is available is contradictory. While some claim that the 'legal frenzy' created by Bayh-Dole has significantly diverted scientists from doing their research,[266] others have found no indication that the nature of academic research has changed.[267] "It is too easy for academics and others to raise alarms when the bases for arguments are conjectural and understanding of the institutions and behaviors involved so limited."[268]

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[264] *See, e.g.*, Press Release, Federation of American Societies for Experimental Biology, FASEB Calls on the Scientific Community to Endorse Guideline for Conflicts of Interest—Unveils COI Toolkit (July 20, 2007), *available at* http://opa.faseb.org/pdf/July%20-%20Dec%202007/COIPressRelease.07.20.07.pdf (describing the recent guidelines for conflicts of interest created by the Federation of American Societies for Experimental Biology recently promulgated in July of 2007).

[265] *See, e.g.*, JENNIFER WASHBURN, UNIVERSITY INC. (2004).

[266] *See* Leaf, *supra* note 96; *see also* Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons In Biomedical Research*, 280 SCIENCE 698, 698 (1998).

[267] *See, e.g.*, Lori Pressman et al., *The Licensing Of DNA Patents By U.S. Academic Institutions: An Empirical Survey*, 24 NATURE BIOTECH. 31 (2006); Jerry Thursby & Marie Thursby, *University Licensing and the Bayh-Dole Act*, 301 SCIENCE 1052 (2003); *see also* WALSH, CHO & COHEN, *supra* note 218; John P. Walsh, Charlene Cho & Wesley M. Cohen, *View From The Bench: Patents and Material Transfers*, 309 SCIENCE 2002 (2005). *Contra* ECONOMIST, *supra* note 29 ("[T]here is ample evidence that scientific research is being delayed, deterred or abandoned due to the presence of patents and proprietary technologies."); *see also* Ted Agres, *Tying Up Science: Are Intellectual Property Protections Slowing Progress?*, SCIENTIST, Jan. 2006, at 77.

[268] Cohen, *supra* note 33.

Under the pervasive patent culture in universities, more basic science research tools are now being licensed and sold. In a post-*Madey*[269] world, where the courts have emphatically stated that no one, not even academics, are above the intellectual property laws, many corporations and universities are more willing to request, threaten, and/or sue to get universities to license the proprietary technologies they are using.[270] Although academics are, at best, typically oblivious to intellectual property issues and potentially even knowing violators, risk adverse institutions that receive such cease-and-desist threats have, in the past, shut down research projects or forced labs to consider alternatives.[271]

In an attempt to determine the extent of the effect Bayh-Dole had on the patent culture (although not the technology transfer office), empirical studies have tried to quantify both the number of threatening actions and their effect on academia.[272] University concerns about image and lawsuits have, thus far, impeded the collection of a sample size large enough for robust statistical analysis.[273] Those that have provided information to researchers create a self-selecting sample that may understate or overstate the nature of Bayh-Dole and technology transfer offices on research.

Inadequate record keeping and lack of faith in the anonymity of studies make university legal counsels the wrong source of information for an analysis on the effects on research resulting from such cease and desist actions.[274] An alternative is to have the researchers themselves submit this type of information as they

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269 Madey v. Duke, 307 F.3d 1351 (Fed. Cir. 2002) (holding that an academic research exemption does not exist for research tools).

270 *See* NAT'L ACADS., FIFTH MEETING OF THE COMMITTEE ON INTELLECTUAL PROPERTY RIGHTS IN GENOMIC AND PROTEIN-RELATED INVENTIONS (2005), *transcript available at* http://www7.nationalacademies.org/step/Genomics_Committee_Meeting_6_transcript.pdf.

271 *See* Cukier, *supra* note 213, at 249 (noting that patent law never anticipated many of the issues arising out of patenting research tools and genomics data—principally the inability to work around the patent).

272 *Id.*

273 *Id.*

274 Additionally, as opposed to patent data, licensing information and practices are typically viewed as proprietary and, thus, universities are often unwilling to divulge information. *See, e.g.*, Pressman et al., *supra* note 267.

receive and react to it. Moreover, with regard to issues like MTAs, sometimes a student or postdoctoral fellow may be the best source of information. Surveys typically poll only the principle investigators who may be woefully uninformed about the true facts on the ground.

V. PROPOSED TECHNOLOGY TRANSFER PARADIGM FOR DEVELOPED AND DEVELOPING NATIONS

This Article argues that the American system ought not be seen as a paradigm for developing nations intent on setting up their own technology transfer mechanisms between academia and industry. In fact, other developed nations somewhat vary from the U.S. in implementation of technology transfer. This section will provide a brief overview of some other national mentalities and mechanisms for transferring knowledge and innovation to industry. This Article suggests that there are some very useful components and ideas in other systems of technology transfer that can be imported into the American system or, alternatively, incorporated into a novel system implementable both in developed and developing nations.

Implementation in the U.S. would require a complete overhaul of the current system. Its execution in a developing nation, however, might be easier and more efficient than implementing a comprehensive Bayh-Dole-like system from scratch. This comprehensive option for both developed and developing nations would serve to promote scientific research in their universities, and at the same time, advance innovation throughout the country. Although the solution presented herein is framed in the context of revamping the American system, and while the implementation of this system might be radically different in the context of a developed country, the overall structure of this solution can be applied equally well to developing nations. Nevertheless, it is helpful to present the solution within the framework of the current U.S. system, as it allows for comparison.

Taken as a whole, the following inventor-centric proposal contrasts starkly with Bayh-Dole, whose legislative history suggests that it was not enacted for the benefit of the individual researchers. Rather, "the intended beneficiaries of the Bayh-Dole Act are the institutions themselves and the government."[275] And, unlike Bayh-Dole which mandates that researchers report and patent all patentable innovation, the proposed system would try to incentivize, but never force the commodification of, basic science research. In this sense, the system is also somewhat of a hybrid: while it suggests that academics transfer their patentable inventions to a centralized technology transfer office in exchange for further research grants, it allows for the inventor to hold on to some of her innovation, either patenting it and licensing it herself, or choosing to either let it fall into the public domain or keep it as a secret.

However, like Bayh-Dole, this Article assumes that a technology transfer system is a critical feature in the development process of new technologies both in developed and developing nations. While university researchers are often highly skilled at unearthing fundamental discoveries, they are woefully unequipped to commercially develop, manufacture, and market these innovations—and innovation and entrepreneurship are most likely to emerge from universities. There is "No better text for a History of Entrepreneurship . . . than the creation and development of the modern university."[276] With this is mind, it is essential that some form of a qualified office be set up that can evaluate, patent and market academic innovations to industry.

[275] Platzer v. Sloan Kettering Inst. for Cancer Research, 787 F. Supp. 360, 364–65 (S.D.N.Y. 1992); *see* Sara Rimer, *A Warning Against Mixing Commerce and Academics*, N.Y. TIMES, Apr. 16, 2003, at D9 ("Unlike athletics . . . commercialization of research is still relatively new, and universities are not yet bound irrevocably to indefensible policies. Only time will tell if they manage to do a better job of maintaining appropriate standards for science than they have done in upholding academic value on their playing fields." (quoting Derek Bok)). Note, however, that the case discusses instances where the inventor wants a larger percentage of the royalties and, in response, the court claims that the Bayh-Dole act was intended to funnel the money back into research, not to enrich the inventors. Arguably then, it's possible that current state of affairs frustrates the purpose of Bayh-Dole. Sending royalties back to the institution is potentially more wasteful, given the administrative costs in divvying up the royalties, initially, and then putting them back into research projects. It might be more efficient, and more in-line with the purpose of Bayh-Dole, to give the royalties directly to the researcher in the form of a grant that has to be used entirely on research. *See* Platzer, 787 F. Supp. at 368.

[276] PETER F. DRUCKER, INNOVATION AND ENTREPRENEURSHIP 22 (2006).

This Article proposes a multi-part solution. It requires the creation of a new paradigm of technology transfer offices, the licensing of all or most of academic innovation at a flat rate, and the creation of a grant system wherein the rights to patentable innovation are traded for grant money to be used for funding further research in the innovating lab. While academic scientists as a self-selecting group is not heavily populated with wealth-seeking individuals,[277] their "begging and searching for money [for research] never stops."[278] It makes sense, then, to provide incentives that are particularly focused on funding research rather than personal wealth.[279]

Note that this solution is not a government buyout or a direct reward program, as is often suggested, most recently for the American market by Senator Bernie Sanders.[280] Here, as opposed to a pure reward system wherein the government provides financial incentives and an honorary prize in exchange for placing the innovation in the public domain, this system retains the bulk of the

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[277] DANIEL S. GREENBERG, SCIENCE FOR SALE: THE PERILS, REWARDS AND DELUSIONS OF CAMPUS CAPITALISM 17, 23 (2007) ("The average laboratory scientist . . . is an unlikely exemplar of personal wealth, capitalistic instincts, or sumptuous living . . . . Moneymaking has never ranked high as a motivation for the scientific career . . . . [A]cademic science is one of the least remunerative and most uncertain career choices on the professional landscape.").

[278] *Id.* at 12.

[279] Many researchers find the insufficiency of rewards to be a barrier to technology transfer from universities to industry. *See* Donald Siegel, David Waldman, Leanne Atwater & Albert Link, *Commercial Knowledge Transfers from Universities to Firms: Improving the Effectiveness of University-Industry Collaboration*, 14 J. HIGH TECH. MGMT. RES. 111, 118 (2003).

[280] *See, e.g.*, S. 2210, 109th Cong. (2007); H.R. 417, 109th Cong. (2007) (proposing along with Senate Bill 2210 to provide incentives for investment in research and development for new medicines, to enhance access to new medicines, and for other purposes). Other similar prize proposals have been suggested recently by Senators Lindsey Graham, John Edwards and Speaker Newt Gingrich. *See* Press Release, Graham Introduces H-Prize Legislation in the U.S. Senate (Jan. 24, 2007), http://schotlinepress.wordpress.com/2007/01/25/graham-introduces-h-prize-legislation-in-the-us-senate/; John Edwards, *Making Health Care Affordable, Accountable, And Universal*, Jun. 14, 2007, http://www.johnedwards.com/news/headlines/20070614-health-care-costs-quality.pdf; William Saletan, *An Inconvenient Newt: Newt Gingrich, Environmentalist*, SLATE, Oct. 30, 2007, http://www.slate.com/id/2176957.

typical intellectual property rights-based patent system.[281] This is integral. Patents, in addition to providing direct incentives to the innovator, also provide other social goods. These include facilitating coordination among the actors in a particular technological field by providing a map of the current state of the field and dissemination of technology.

This section will present each component of the proposed solution. It will attempt to succinctly outline how each element in the system would work and raise some of the potential problems associated with each module.

A. *Centralized Technology Transfer Office*

Many of the bottlenecks in the commercialization of academic science and innovation research are, ironically, created by the Bayh-Dole Act and other similar legislation initially designed to promote innovation. In particular, as stated earlier in this Article, a major consequence of the legislation—the ubiquitous university technology transfer office—is a continual impediment.[282] It is suggested that these holdups could be alleviated through the creation of a new, alternative system to promote the commercialization of basic science research.

In this proposed system, a national or regional centralized technology transfer office—with the express goal of commercializing research—would be established. In the U.S., the National Institutes of Health or the National Science Foundation would be optimal choices to accommodate such an office, although a private government-sponsored enterprise ("GSE") could also be set up to specifically accomplish these goals.[283]

[281] *See* Michael Polanvyi, *Patent Reform*, 11 REV. ECON. STUD. 61, 65 (1943); Brian Wright, *The Economics of Invention Incentives: Patents, Prizes and Research Contracts*, 73 AM. ECON. REV. 691, 694 (1983).

[282] *See* Gewin, *supra* note 247, at 948 ("[S]ome critics of the system contend that the Bayh-Dole Act, which virtually gave birth to the [U.S.] biotechnology industry, may now be strangling it, as universities seek patent protection on nearly everything . . . . People are beginning to question whether we're using the right model.").

[283] "These enterprises were established and chartered by the Federal Government for public policy purposes. They are not included in the Federal Budget because they are private companies, and their securities are not backed by the full faith and credit of the Federal Government." OFFICE OF MGMT. & BUDGET, BUDGET OF THE UNITED STATES

While merging football teams with another university may be a hard sell, it may make economic and policy sense to merge technology transfer offices among different universities and colleges, creating larger, more objective regional offices. Like football, technology transfer offices serve the school spirit, and, thus, the offices may feel obligated to comb every invention disclosure to find the Next Big Patent, raising the morale of the school and contributing to the school's coffers. Yet, individual offices lack the funds and manpower to thoroughly assess all invention disclosures.[284] Nevertheless, individual offices often feel a need to justify their existence given a generally poor track record and, thus, aggressively attempt to garner as many disclosures as possible.

A regional licensing office may be able to deal with many of these issues. Not serving any one particular school, the licensing professionals may be able to be more objective in their assessments of a patent's value. Regional offices do not have a greater need to justify their existence, serving numerous schools. Regional offices will also have more licensing clout, giving them the ability to license better deals from and for academia. Regional offices may have less incentive to be creative on their MTAs; representing a vast array of schools, they may have to be more standardized in their approach. Regional offices will be more capable of allocating their resources towards finding and patenting marketable inventions. Regional offices, potentially with a more established hierarchical structure than a small office in a single university, may be less likely to pay for patent applications on worthless or unmarketable inventions, as decisions will probably have to be vetted through more individuals. Regional offices will be better suited to hire more professional and better qualified personnel and provide better services.[285]

GOVERNMENT: FY 2006 at 1245 (2006), *available at* http://www.whitehouse.gov/omb/budget/fy2006/pdf/appendix/gov.pdf.

284 Owen-Smith & Powell, *supra* note 195, at 99.

285 Regional technology transfer offices could be networked in a similar fashion to the Federal Laboratory Consortium network for government laboratories. *See* Federal Laboratory Consortium for Technology Transfer—About, http://www.federallabs.org/home/about (last visited Jan. 30, 2009).

Although regional offices, with their broad views, may miss some licensable technologies, scientists will still continue to publish their research, thus making sure that even those missed innovations still become part of the scientific record.

Depending on the size and infrastructure of a particular country, such an agency/office could have either a singular, central well-staffed office or multiple regional offices. Unaffiliated with any particular university and responsible primarily to the government and the regional population, this type of technology transfer office may be less inclined to simply aspire to blockbuster licensing deals.

Alternatively, an agency could be set up in the model of the U.S. Federal Reserve, with long-term appointments of technocrats who would preside over a system of regional offices. Like the Federal Reserve, the system of regional technology transfer offices could be designed to be independent of the government, meeting its operating expenses primarily from its own business. The independent nature of the technology transfer system is important. With the possibility that the patenting and licensing of some academic innovations might become politically contentious, particularly in hotly debated areas such as cloning or genetic enhancement, there may be concerns that the patenting and licensing of innovations will be directed by immediate policy concerns rather than a desire to promote science and innovation.

Independent of the exact structure of the office, what is integral is that the office be designed such that it has the infrastructure, informatics, and incentives to effectively and efficiently commercialize academic innovation.

1. Funds

These technology transfer offices might be supported fully or partially with public funding. The State of Oregon has recently introduced legislation providing a sixty percent tax credit—which, as opposed to a tax deduction, reduces the overall amount of tax owed—to taxpayers who donate to technology transfer offices.[286]

[286] *See* Press Release, Oregon University System, Oregon Introduces Unique 60% Tax Credit to Donors Supporting Commercialization of University Research (Oct. 4, 2007),

Alternatively, these centralized agencies could bundle, package, and sell off what essentially amounts to the each scientist's risk as complex financial instruments to institutional investors—patent license-backed securities. These instruments, bundled as asset-backed securities, have a potential future, but often predictable cash flows from licensing fees would be sold to institutional investors on the same or similar secondary markets that deal in mortgages or insurance policies, providing a continual flow of funds back into the central office for operating expenses.

Government subsidies or a direct line of credit with the government could make up any shortfalls. Further, like Fannie Mae (the Federal National Mortgage Association) and Freddie Mac (the Federal Home Mortgage Corporation), such an institution could be exempted from taxes and from the expensive process of registering the securities that they would sell. Although Fannie Mae and Freddie Mac securities are not guaranteed by the full faith and credit of the United States government, the central licensing offices might be, incentivizing wary investors.

2. Particular Strengths of a Large Centralized Office

Larger regional offices are more likely to have the funds to hire the necessary staff to deal with the needs of both scientists and businesses and to write consistently strong and sensible patents.[287] The impact of a skilled staff in a technology transfer office cannot be underestimated.[288] There is some research to suggest that a

available at http://www.ous.edu/news_and_information/news/100407.php ("A 60 percent income tax credit is now available to Oregon taxpayers who contribute to a new program designed to fast-track commercialization of research discoveries at Oregon's eight public universities . . . . No other state has a program where donors can receive such a generous tax credit in return for helping move research from lab to market . . . This is an important link in moving innovation to new companies and jobs for Oregon." (internal quotation marks omitted)).

[287] *See* Grose, *supra* note 15, at 22 ("Schools and companies at times wrangle over control of the patent-filing process. . . . [Stanley] Williams [director of HP Quantum Science Research] is critical of the way universities sometimes handle patent applications, saying that they're often too provisional and don't contain carefully crafted claims sections . . . and they are often too weak to defend . . . .").

[288] *See* Heher, *supra* note 7, at 221; *see also* Siegel et al., *supra* note 279 (noting that many in industry find that technology transfer offices have poor marketing, technical, and negotiating skills).

well-staffed technology transfer office could substantially increase returns on innovation. This is of particular interest to small American institutions and to institutions in developing nations that may not have the funding to fully realize the increased return on investment that comes from having a professionally-staffed technology transfer office. Further, several studies have shown that long term trust relationships between technology transfer officers and industry are integral for initiating and facilitating knowledge and technology transfer: "a high level of social capital can significantly reduce transaction and monitoring costs."[289]

A centralized agency can also deal with a common problem in IP licensing: Often a single commercial product will require the licensing of numerous patents—often owned by multiple inventors. With every research institution independently demanding their fair share of the revenues for their particular licensed innovation, it quickly becomes unfeasible to commercialize the product; revenues are overwhelmed by licensing fees.[290] A central licensing agency might effectively alleviate the problem by bundling the licenses and providing them for significantly less than licensing each patent individually. Transaction costs would also be minimized, as the licensee would negotiate with and be responsible only to the centralized agency and the multiple individual licensors. Bundling may also provide distribution for unknown and untapped patents. Creating a marketable product, industry licensees may also be incentivized to purchase somewhat tangential patents that they otherwise would have overlooked.

3. Potential and Perceived Problems with the Proposed System of Centralized Offices

A centralized and government-run agency may not be trusted in a developing nation context where corruption might be rampant

[289] Anna Nilsson, Henrik Friden & Sylvia Schwagg Serger, *Commerication of Life Science Research at Universities in the United States, Japan and China*, SWEDISH INST. FOR GROWTH POL'Y STUD., at 17.

[290] *See, e.g.*, Gewin *supra* note 247, at 948 ("[I]f a product requires dozens of patents, for example, and each university wants 5% of the profits, it soon becomes unfeasible to do the work . . . .").

or unpredictable.[291] In these instances, an international non-governmental organization ("NGO") could serve as the central clearinghouse for a particular country or an entire geographic region. Such an NGO might also have international clout and respect that it could exploit to promote the catalog of licensable innovation. Having an international body run a portion of the patenting and innovation process in a developing nation is not that novel. Many countries already look to regional intellectual property offices to patent and copyright their innovation.[292] It would not be a stretch to have a regional administration licensing out patents.

Convincing universities to farm out these offices and dismantle current in-house services might be a hard sell. Many universities in both developed and developing nations may be unwilling to lose their current technology transfer offices, optimistic that their office can still produce some blockbuster innovation and licensing deal. Further, universities might note the difficulties that local technology transfer offices have in just keeping up with local university innovation on campus. Keeping up with a number of universities may be nearly impossible.

With these concerns in mind it may be advantageous to maintain small technology transfer offices in many of the larger universities. These offices will have two primary purposes: to license in technology for the benefit of university researchers, and to evaluate early stage research to: (a) determine whether at the current stage it ought to be patented, or if it requires more research to make it a viable licensable technology; and (b) to potentially

291 *See, e.g.*, Julien Penin, *Patents Versus Ex Post Rewards: A New Look*, 34 RES. POL'Y 641, 644–45 (2005) (noting that corruption and collusion are not limited to developing nations). Scholars have posited that alternatives to the current patent system, including ex post rewards and government buyouts of intellectual property, also present issues relating to collusion between innovators and the agency buying out or rewarding the inventor and a fear that the government will not pay out the committed reward or price. *Id.*

292 Such offices include: OAPI, the African Intellectual Property Organization; ARIPO, African Regional Intellectual Property Organization; BOIP, Benelux Office for Intellectual Property; EPO, The European Patent Organisation; The GCC Patent Office, The Patent Office of the Cooperation Council for the Arab States of the Gulf.

write many of the university's patents that would then be passed on to the centralized agency for licensing.

In these instances, the technology transfer would be repositioned as a university core facility. Many research institutions already have multiple core facilities, i.e., central research tools such as microarray facilities,[293] culture laboratories,[294] light and electron microscopes[295] or proteomic facilities, that are equally used and supported by multiple departments. The technology transfer office would be a similar central tool. Arguably it may be fairer to support the university-wide tool with a slice of the patent royalties. Nevertheless, there remain justifiable concerns that granting the office any monetary stake in the revenue might lead to the same problems and conflicts that American TTOs currently face.

To further incentivize universities to use a centralized agency, the national patent office could consider relaxing patent rules and fees when filing through the centralized technology transfer office. For example, recent USPTO regulations limit the number of claims in a filing to twenty-five total, with a maximum of five independent claims.[296] The USPTO could potentially relax these restrictive rules when a university patents and licenses through a central technology transfer office.

Universities might be granted a small percentage of the licensing fees generated by the patent. These fees could be used toward administrative or infrastructure costs, or could provide

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[293] *See, e.g.*, Yale WM Keck Foundation DNA Microarray Resource in the School of Medicine, http://keck.med.yale.edu/microarrays (last visited Jan. 30, 2009).

[294] *See, e.g.*, Cell Culture Core Facility at the Yeshiva University Albert Einstein College of Medicine, http://www.aecom.yu.edu/home/hgp/cell_culture.htm (last visited Jan. 30, 2009).

[295] *See, e.g.*, Light Microscopy Core Facility at Duke University, http://microscopy.duke.edu (last visited Jan. 30, 2009); Confocal & Electron Microscopy Core Facility Laboratory at Princeton, http://www.molbio1.princeton.edu/facility/confocal (last visited Jan. 30, 2009).

[296] *See* David Schwartz, *Patent Costs, Paperwork to Spiral Under 'Complex' New USTPO Rules*, TECH. TRANSFER TACTICS, 86, Oct. 17, 2007, *available at* http://www.technologytransfertactics.com/content/2007/10/17/patent-costs-paperwork-spiral-under-complex-new-ustpo-rules. The new rules, characterized by the Commissioner for Patents John Doll as extensive and complex, will also restrict applicants to two continuations and only one request for a continued examination.

additional funding for those researchers that do not produce patentable innovations.

With the centralized office owning the patent and licensing at a relatively low flat rate there may be no incentive, if and when the time ever arises, to litigate a patent infringement case. And, with no potential enforcement by the owner of the IP, potential licensees may see no incentive to ever license the patent; infringing at will. Another concern related to the nature of the centralized office's ownership is relevant to the quality of the patent. With the responsibility to prosecute so many patents, and without any profit motive, the centralized agency lacks the incentives to create high quality patents that will stand up in litigation. Not only would such a situation quickly bankrupt the system, but it could have a potentially catastrophic effect on a fledgling patent regime if it were to be implemented in a developing nation, by degrading the strength and validity of patents in general. A possible solution to this potential problem could be to include, in the flat license, a clause requiring each licensee to pay into a legal defense fund to protect the patent should it ever be infringed. Although data is not available for most nations, data for the U.S. patent system, known to be highly litigious, indicates an overall low rate of litigation. Justice Kimberly Moore counted, for instance, only 4500 patents litigated out of a total of 180,000 patents granted that same year.[297] With only 2.5% of all patents litigated, chances are relatively slim that the licensee's particular patent will be litigated, making such a clause more amenable to the licensee.

A centralized system where the inventor is quickly bought out and divorced from the potential patent may result in researchers who, for lack of any incentives, become unhelpful in the prosecution phase of the patent. In these situations, it may be helpful to dock, or threaten to dock those researchers' grants on future patents.

B. Grant Payment System

Research scientists could be incentivized into using the centralized agency through a grant-like system. In this system,

[297] Kimberly A. Moore, *Worthless Patents*, 20 BERKELEY TECH. L.J. 1521, 1521 (2005).

researchers would have the option to exchange their intellectual property rights for a grant-like transfer payment, assessed relative to the value of their innovation. The centralized agency would, in effect, be buying the inventor's risk related to her future royalty streams. Alternatively, researchers could hold on to the intellectual property themselves.

The volume of innovation in all countries has been shown to be directly proportional to the investment in research.[298] Thus, particularly in developing nations where funding is limited, this grant system provides an important feedback loop in developing innovative technologies. In this grant system, innovative research begets guarantees of further funding and investment in research—further promoting innovation. Note, however, that as a prerequisite to this system, the intellectual property rights to the invention must belong solely to the inventor and not to the university.

Under the current Bayh-Dole regime in the United States, academic scientists often have to be prompted and cajoled by technology transfer officers to cooperate in commodifying their discoveries.[299] Many if not most scientists seem to have no interest in going through the relatively tedious patent prosecution process.[300] More often than not, faculty are more interested in funding their research through industry collaborations rather than securing entrepreneurial opportunities for their universities and themselves.[301] There are often more profitable and less irritating ways, albeit not as beneficial to society, to profit from academic

[298] Heher, *supra* note 7, at 218.

[299] Possibly recognizing the problems associated with having technology transfer officers badgering researchers for their latest developments, Austria's implementation of the technology transfer office requires the researcher to contact the technology transfer officer and not vice versa. *See, e.g.*, Graz University of Technology, *Service for Inventors at Graz University of Technology: Technology Exploitation Office Celebrates its Success*, Aug. 27, 2007, http://portal.tugraz.at/pls/portal/docs/page/Files/FTH/fth_tv/files/07_08_29_Presseaussendung_TUG_vs3_e.pdf.

[300] A university's success in patenting innovations has been tied to the faculty's perception of the benefits in patenting. *See* Owen-Smith & Walter Powell, *supra* note 195, at 105.

[301] *See* Yong S. Lee, *The Sustainability Of University-Industry Research Collaborations: An Empirical Assessment*, 25 J. TECH. TRANSFER 111, 121 (2000).

technology transfer, e.g., through consulting.[302] Recent research further suggests that academics only tend to be entrepreneurial about their innovations after the product has begun the commercialization process and remain mostly uninterested until that threshold time.

Many faculty members, particularly in developing nations where a patent culture is not yet as pervasive as it is in developed Western societies, may not share the same Western drive for a blockbuster licensing deal. This proposed regime would help to overcome that initial inertia by creating a more practical and Mertonian incentive (many academics in developing nations still officially subscribe to these classical ideals). Academics can be further enticed by the prospect of contributing directly to society through the transfer of technology and then, once licensed, their innovation would give the researcher access to the relevant industries and their assets for further investigations.[303]

Nonetheless, even with the grant component of this system, there still needs to be an active educational component directed at researchers, promoting the many positive features and assuaging the fears associated with technology transfer and patents in general.[304] A strong educational module is necessary to make the system work and universities need to be proactive in informing researchers as to the importance and benefits of technology transfer.[305]

Granting a researcher immediate cash instead of a future undefined royalty rate would also alleviate the issue commonly found throughout the lateral academic hiring process. Under

[302] William Bains, *How Academics Can Make (Extra) Money Out of Their Science*, 11 J. COM. BIOTECHNOLOGY 353, 353 (2005). Dissatisfaction with university technology transfer offices have also led academics to circumvent that method of technology transfer in favor of consulting. *See, e.g.*, Owen-Smith & Powell, *supra* note 195, at 104.

[303] *See* Elizabeth R.J Bell, *Some Current Issues in Technology Transfer and Academic-Industrial Relations: A Review*, 5 TECH. ANALYSIS & STRATEGIC MGMT 307, 308 (1993).

[304] A recent study found that a lack of understanding regarding industry norms plays a large part in creating a barrier to academic technology transfer. *See* Siegel et al., *supra* note 279, 119–20.

[305] *See, e.g.*, Mauri Laukkanen, *Exploring Academic Entrepreneurship: Drivers and Tensions of University-Based Business*, 10 J. SMALL BUS. & ENTERPRISE DEV. 372, 375 (2003) (noting the typical dysfunctional business attitudes of faculty).

Bayh-Dole and similar regimes, the university retains title to the invention and, as such, may threaten to withhold future royalty payments to those researchers who leave the institution. This impediment to academic mobility could potentially have a devastating impact on the transfer of knowledge, particularly in a developing nation.

1. Concerns with the Grant System

The grant system does create some potential concerns: By creating a real and valuable incentive[306]—grant credits with minimal restrictions in exchange for handing over the licensing process to a centralized agency—academic researchers might be even too aggressive in trying to patent their discoveries. Further concerns include the reality that universities, faced with the loss of their potential golden egg, will lobby heavily against such a system. In the United States, the bulk of the royalties brought in by patents go to the university with typically only a small portion—at the university's discretion—going to the actual inventor.

In the absence of any current norms in developing nations, there may be initial levels of distrust among researchers and their institutions in divvying up the spoils of a license or in deciding who holds IP rights. With a centralized agency holding the rights, and the grant credits going directly to the researcher, this no longer becomes as significant a concern.

Further, grant money may fail to incentivize those researchers who feel that their particular innovation is worth much more than the credits offered. In those situations, the system should allow researchers the opportunity to hold on to the intellectual property rights instead of transferring them for grant credits. In situations where the researcher thinks that her particular discovery is worth

[306] Greater rewards for faculty involvement in technology transfer are directly related to enhancing a university's technology transfer capabilities. *See* J. Friedman & J. Silberman, *University Technology Transfer: Do Incentives, Management, and Location Matter?*, 28 J. TECH. TRANSFER 17, 17 (2003); *see also* Magnus Henrekson & Nathan Rosenberg, *Designing Efficient Institutions for Science-Based Entrepreneurship: Lesson from the US and Sweden*, 26 J. TECH. TRANSFER 207, 207 (2001) (calling for stronger individual incentives in technology transfer).

her entrepreneurial skills in either starting up a company or marketing it herself, the most valuable discoveries will be aggressively brought to the marketplace by those who know the research best.[307] Technology transfer officers, in a recent survey, estimated that up to 71% of all licensed innovation could not be successfully commercialized without ongoing collaboration with the original researchers.[308] Here it is important for local technology transfer offices to promote this entrepreneurial spirit: "there is strong evidence that the entrepreneurial culture resulting from the focus on technology transfer results in many other benefits which can neither be captured nor measured by the institution but which have an impact on the local economy."[309]

C. Early IP Valuation

The proposed grant incentive system is predicated on the ability to efficiently ascertain whether the nascent innovation meets or exceeds the threshold patentability requirements set by the local patent offices. And, more importantly, the system also needs to be able to effectively determine the current and potential value of the invention such that the grant payout neither over or under incentivizes, but rather provides the optimal level of incentivization both for the inventor and for society.

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[307] Inventor cooperation and involvement is often crucial for commercial development. It is precisely the most profitable (and, possibly, important) innovations where this system would promote researchers to stay involved and cooperate with the licensor. *See, e.g.*, Richard Jensen & Marie C. Thursby, *Proofs and Prototypes for Sale: The Licensing of University Inventions*, 91 AM. ECON. REV. 240, 240–41 (2001); *see also* Brian Harmon et al., *Mapping the University Technology Transfer Process*, 12 J. BUS. VENTURING 423, 423–34 (1997) (noting the importance of strong connections in the technology transfer process). Note that studies have shown a number of entrepreneurial skills and proclivities in basic science researchers. *See, e.g.*, Karen Seashore Louis, David. Blumenthal, Michael E. Gluck & Michael A. Soto, *Entrepreneurs in Academe: An Exploration of Behaviors Among Life Scientists*, 34 ADMIN. SCI. Q. 110, 110 (1989).

[308] Jerry Thrusby & Marie Thursby, *Pros and Cons of Faculty Participation in University Licensing Introducing Technology Entrepreneurship to Graduate Education: An Integrative Approach*, *in* 16 UNIVERSITY ENTREPRENEURSHIP AND TECHNOLOGY TRANSFER: PROCESS, DESIGN, AND INTELLECTUAL PROPERTY, ADVANCES IN THE STUDY OF ENTREPRENEURSHIP, INNOVATION, AND ECONOMIC GROWTH 193 (2005).

[309] Heher, *supra* note 7, at 218–19.

As opposed to the relatively straightforward patent situation where the inventor's reward from licensing or selling the patent herself is directly correlated to the "invention's being found useful, . . . the greater the usefulness the greater the reward . . . ,"[310] this ex ante grant incentive needs to create some other fair, transparent, consistent, and reliable method of evaluating IP value at a relatively early stage in the life of the invention in order to establish a similarly incentivizing method.

There are legitimate concerns regarding the ability of any organization to fairly, and cost-effectively evaluate a patent in its earliest stages. Patent values are highly heterogeneous and are controlled by a myriad of factors. Determining and reducing a patent's valuation to a single one time payout is non-trivial. Even the current systems for IP valuation, often determining the value of the intellectual property well into the life of the invention, have been described as inappropriate, unreliable, or a series of guestimates.[311] Most banks will not use intellectual property as collateral for these very reasons.[312] But, given the time lag between the initial patentable research and commercialization, it would be impossible to properly incentivize researchers who may need to wait a decade or more before the grant value can be determined.

Notwithstanding the computational difficulties inherent in the early determination of a patent's value, there are a number of web-based services that provide tools for IP current valuation and projected revenues.[313] Further, most university innovations are

[310] JOHN STUART MILL, PRINCIPLES OF POLITICAL ECONOMY WITH SOME OF THEIR APPLICATIONS TO SOCIAL PHILOSOPHY 933 (Sir W.J. Ashley ed., 1936) (1849).

[311] Shigeki Kamiyama, Jerry Sheehan & Catalina Martinez, *Valuation And Exploitation Of Intellectual Property* 26 (The OECD Directorate for Science, Technology, Working Paper, 2006), *available at* http://www.oecd.org/sti/working-papers.

[312] *Id*. at 23.

[313] *See, e.g.*, Jiang-Liang Hou, Hseu Yen Lin & Cheng-Chuang Hon, A Web-Based Platform for IP Valuation and Trading, Presented at the 35th International Conference on Computers and Industrial Engineering (2005), http://www.umoncton.ca/cie/Conferences/35thconf/CIE35%20Proceedings/PDF/040.pdf; *see also* RoyaltySource, http://www.royaltysource.com; RoyaltyStat, http://www.royaltystat.com (containing "a subscription database of royalty rates and license agreements compiled from the US Securities and Exchange Commission ("SEC") Edgar Archive"). "In RoyaltyStat you can find comparable royalty rates for valuing (or licensing) intangible assets . . . [useful in]

licensed before they are even patented, suggesting that universities are already successfully engaged in early stage, pre-patent valuations on much of their innovations.[314]

1. Strategies for Early IP Evaluation

Early stage IP valuation can be accomplished through a number of procedures.[315] The two cost methods look to either production or replacement costs in determining the value of the IP.[316] Production costs are equal to the cost to invent and patent added to the desired profit margin. The replacement method evaluates the cost to produce a similar invention with similar utility. These methods are particularly useful for early stage technology or where there is no data on similar inventions that can be used as a comparison. Nonetheless, critics of the cost method claim that it fails to assess any real measure of value to either the owner or the potential purchaser of the patent and fails to consider any potential future markets; no projected revenue or profit data is taken into account.

The market method looks to comparable patents and their relevant historical sales data. Uniqueness of individual patents

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[f]inding reasonable or comparable royalty rates; [or] Valuing intangible property for mergers, acquisitions, divestitures, bankruptcy, or other transactions." *Id.*; SparkIP, http://sparkip.com.

314 Daniel Elfenbein, *Publications, Patents, and the Market for University Inventions*, 63 J. ECON. BEHAVIOR & ORG. 688, 693 (2007).

315 Methods are said to borrow from quantum physics, statistics, mechanics, ballistics, climatology and game theory. The Association of University Technology Managers provides some spreadsheets to help technology transfer officers determine the value of a patent. Factors listed by AUTM that affect valuation include: the potential market; how well the technology fits with the licensee in terms of technology, markets served, manufacturing capabilities, and distribution channels; whether the proposed products open up new markets for the licensee or eat into current markets of the licensee; how far along the development of the technology is—already scaled-up and tested working units, working prototype, proof of concept, analytical work; the benefits of the technology vs. the current technology within the intended markets; the strength and enforceability of the patent protection; the margins that the industry and the technology can command; the cost savings for manufacture and distribution over current technologies; who will derive value; and follow on opportunities and multiple fields of use. *See* Valuate2000 & ValBio2000, at 2 (Dec. 1, 2000), http://www.autm.net/aboutTT/ValManual.pdf.

316 David Drews, *The Cost Approach to IP Valuation: Its Uses and Limitations*, IPMETRICS, Jan. 12, 2001, at 1, http://www.ipmetrics.cc/Cost%20Approach.PDF.

makes this method speculative, at best. The method is useful only within a narrow range of patents. A proper evaluation using the market method requires an active market with sufficient publicly-available data on a sufficient number of exchanges of a similar patent. Overall, the market method is often thought to be a poor choice for IP evaluation, particularly given that individual negotiations for IP are often motivated by unknowable and unique strategic conditions that are reflected in the price.[317]

Other methods include the Industry Standards method, derived from Market Method, which looks to royalty rates in similar past transactions, and the Options Method which is based on the Black-Scholes formula for valuing stock options. The Options Method evaluates the patent/innovation through five variables, many particularly applicable to early stage research typical of an academic environment. Here the IP investment is viewed as "an option to develop the IP further or to abandon it depending on future technology and market information."[318] Relevant factors include: (a) a determination of the remaining development cost to commercialize the innovation; (b) the average market value of similar patents; (c) time until commercial utilization; (d) product value volatility; (e) risk-free rate of return; and (f) remaining time until the patent expiration date.[319]

2. Elements of a Proposed Early Evaluation System

Simplistically, however one could also imagine a more straightforward, fair and accurate approach to evaluating the intellectual property presented to the centralized technology transfer office, than those suggested above. Such a system would be a multistage process. The initial evaluation would be to determine, broadly, whether the proposed innovation is

[317] *See, e.g.*, W.H. Davidson & Donald G. McFetridge, *Key Characteristics in the Choice of International Technology Transfer Mode*, 16 J. INT'L BUS. STUD. 5, 18–19 (1985) (discussing the importance of the business status of the licensee and licensor parties in the pricing of IP).

[318] Ron Laurie, IP Valuation: Magic or Myth?, Presented at the Intellectual Property Issues in M&A Transactions (Apr. 29, 2004), *available at* http://www.ip-strategy.com/downloads/IP_Society_IP_Valuation.pdf.

[319] *Id.*

patentable—not a trivial decision. Here, an unsophisticated one-page form would provide a concise abstract of the invention, other similar patented or published research, and short answers speaking to the novelty, utility, and non-obviousness of the invention. The inventor's involvement in this procedure is imperative, as the information required at this stage is typically known best to the inventor. At this early stage, questions as to the feasibility of mass production or marketability are not relevant and, most importantly for the scientists involved, time spent on patenting innovations is time spent away from research. The faster and easier this process is, the more likely more researchers will get involved.

Typically, a vast majority of putative patents will fail at this initial patentability threshold.[320] Patent prosecutors would also determine whether a patent should be filed domestically, and internationally as well. Depending on the particular nature of the research, the costs associated with international filings may not be necessary, or justifiable.

For those patents that survive the first phase, the next level will then look to provide a basic valuation of the invention. This stage should be perceived to be as objective as possible, to prevent researchers from becoming disincentivized by what may be seen as an unfair or corrupt evaluation. Although pertinent to the discussion, the exact parameters of such an evaluation, which would probably include the maturity of the innovation and its field and the innovation's market, the degree of innovation in the invention and the general background on the specific field, are beyond the skills of the author, necessitating significantly further research into the subject matter.

It may also be helpful to consider the usage of a peer reviewing team. Often it is the scientists themselves that have the clearest vantage point as to the overall direction of any particular technology. The peer-reviewers could themselves be incentivized to participate through much smaller grant transfers. Peer-to-peer analysis of patents is not a novel idea and is currently in use on a

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[320] GREENBERG, *supra* note 277, at 24.

trial basis.[321] Patent evaluation could also be automated based on a number of important and standardized criteria.[322]

This evaluation process would also require an arbitration panel to deal with those scientists who disagree with the evaluation of their research, although the use of such a panel should be discouraged, given the resources and time needed to appeal.

Grants directly related to the evaluation of the innovation would then be provided to the researcher. These grants would be similar to a government or NGO grant for scientific research, although, unlike most grants, they should have no strings attached to further incentivize researchers to present their research to the technology transfer personnel.

The final stage of the credit evaluation would take place a few years later. Here, scientists could opt to have their innovation reevaluated based on licensing data or technological changes that would increase the value of their invention. Researchers would be credited for the increase in the value of their invention but would not be penalized for a fall in value.

D. Flat Rate Licensing

American technology transfer offices are hampered not only by the bureaucracy involved in Bayh-Dole compliance, but by the transaction costs associated with licensing of academic research. A centralized agency may be more inclined to create a flat licensing system akin to IBM standard patent licenses, or Stanford's standard licensing scheme on the Cohen-Boyer patent.[323] The creation of a flat licensing scheme, in effect, would emulate the compensatory liability regime ("CLR")[324] proposed by

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321 *See* Peer to Patent Project, http://dotank.nyls.edu/communitypatent/signup.htm (last visited Jan. 30, 2009).

322 Jiang-Liang Hou & Hsiu-Yan Lin, *A Multiple Regression Model for Patent Appraisal*, 106 INDUS. MGMT. & DATA SYS. 1304, 1305 (2006).

323 For a review of the licensing strategy, see, for example, Maryann Feldman, Alessandra Colaianni & Kang Liu, *Commercializing Cohen-Boyer 1980–1997*, at 24–26 (Danish Research Unit for Indus. Dynamics, Druid Working Paper No. 05-21, 2005), http://www.druid.dk/wp/pdf_files/Feldman_Colaianni_Liu.pdf.

324 TRACY LEWIS & J. H. REICHMAN, USING LIABILITY RULES TO STIMULATE LOCAL INNOVATION IN DEVELOPING COUNTRIES: A LAW AND ECONOMICS PRIMER, PREPARED FOR THE CONFERENCE ON INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY

Professors Reichman and Lewis as an alternative to a utility patent, creating a patent-like system based on liability rather than property rules.[325]

Professors Reichman and Lewis note how such a system would be particularly useful to a developing nation.[326] This system would alleviate the hassle and costs of negotiating and licensing each individual patent, issues that often lead to breakdowns in negotiations,[327] and the subsequent failure to commercialize an invention.[328] This initial forgoing of the significant profits present in some licensing deals is not a novel proposal. Some universities already waive license fees in an effort to create interest in their

UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME 12 (2003), *available at* http://www.earth.columbia.edu/cgsd/documents/lewisreichman.pdf

[325] *See* Guido Calabresi & A. Douglas Melamed, *Property Rules, Liability Rules and Inalienability: One View of the Cathedral*, 85 HARV. L. REV. 1089, 1092 (1972) (based on Calebresi and Melamed's distinction between liability and property rules).

[326] *See* LEWIS & REICHMAN, *supra* note 324.

[327] Wayne Johnson, Changing Interfaces Between the Research University and Industry, Presentation at the Engineering Research Council Workshop and Forum, at 16 (Feb. 27, 2005), http://www.asee.org/asee/conferences/erc/2005/upload/wayne-c-johnson.ppt.

> Typically at present, negotiating a contract to perform collaborative research with an American university takes one to two years of exchanging emails by attorneys, punctuated by long telephone conference calls involving the scientists who wish to work together. All too often, the company spends more on attorneys' fees than the value of the contract being negotiated. This situation has driven many large companies away from working with American universities altogether, and they are looking for alternate research partners.

Id. (quoting Stan Williams, Director, HP Quantum Science Research).

[328] *See* Gewin, *supra* note 247, at 949.

> At the same time, industry is tiring of disputes over intellectual property and, in some cases, withdrawing from collaboration with universities . . . . "Fewer and fewer companies want to work with universities on sponsored research because they feel it doesn't make good business sense" . . . . "Companies could disadvantage themselves if it produces inventions that they are ultimately unable to license," she adds. Industry analysts point out that the growth in the flow of industry research dollars into universities has slowed and become more volatile in the past five years.

Id. (quoting Susan Butts, External Technology Director at the Dow Chemical Company).

research and promote relationships with industry[329]—indicating a realization that complex and time-consuming negotiations may do more to hamper technology transfer between universities and industry, than they help.

The flat rate component of the proposed system would also promote many of the researchers' goals. Exclusive licensing may inhibit basic research at an academic level—universities are typically risk averse in many arenas and, with an exclusive license tying up a portion of a technological field, researchers may be unable to pursue investigations in those particular areas. Under a non-exclusive licensing plan, researchers can obtain a patent on their innovation without the fear that the patent will limit the usefulness and availability of that invention to other academics and the public at large. And, with patents increasingly becoming more popular in academia and even being used as a factor in tenure decisions,[330] it is likely that there will be a continued and strong interest in the patenting of research.

University interests would also be served by a flat-rate license. The resultant minimal level of negotiations would simplify and, importantly, speed up the commercialization of research.[331] Licensing "delays [are] antithetical to the fast product turnaround demands that many companies labor under in today's world."[332] Further, "even modest transaction costs—like the costs of hiring lawyers to write up a licensing contract, or the value of the time

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[329] *See, e.g.*, *UNMC Program Waives Research Licensing Fees*, OMAHA WORLD HERALD, Aug. 25, 2007, *available at* http://www.omaha.com/index.php?u_page+1208&u_sid+10115633 (noting the University of Nebraska's Medical center's waiver of upfront fees in return for revenue sharing later on). The University of Ottawa has a similar program. *See* Posting of David Schwartz to the Tech Transfer Blog, *Will IP License Fee Waivers Become a Trend in Tech Transfer?*, http://www.technologytransfertactics.com/enews/enews952007.htm#3 (Sept. 5, 2007).

[330] *See, e.g.*, Sara Lipka, *Texas A&M Will Allow Consideration of Faculty Members' Patents in Tenure Process*, CHRON. HIGHER EDUC., May 30, 2006, http://chronicle.com/daily/2006/05/2006053003n.htm.

[331] *See* Grose, *supra* note 15 ("Speed is a bigger issue than cost . . . GM says it is easier to merge one of its units with a company from Japan than to do IP negotiations with an American university." (quoting Paul Peercy, Dean of the University of Wisconsin's engineering school)).

[332] GROSE, *supra* note 27, at 3.

required by two parties to negotiate terms—are likely to make it unprofitable to trade many patented technologies."[333]

Cheaper and simpler flat licensing fees would also make basic science research available to even regional or state businesses, often unable to compete with national and multinational companies that have the infrastructure and the budget to negotiate and license promising academic research. Bayh-Dole expressly calls for the promotion of technology transfer to small businesses, although it provides little in the way of actualizing this goal. A system that creates an even playing field for all corporations would help governments achieve their oft-stated objective of promoting small businesses and startups.

A flat licensing rate will often incentivize the uptake of relatively non-valuable academic innovation. "All too often, the company spends more on attorneys' fees than the value of the contract being negotiated."[334] If negotiating a license costs more than the resulting profit from the innovation, industry is less likely to be interested enough to pursue commercialization in that area.[335]

Additionally, the cost of tracking royalties through product cycles presents another disincentive to licensing some innovation. Given those costs, industry will prefer to pay a lump sum licensing fee as opposed to recurring royalty payments.[336]

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[333] Elfenbein, *supra* note 314, at 691; *see also* Johnson, *supra* note 327.

> Given that negotiations with an American university can take more than a year, the idea is often valueless before an agreement can be reached, and the company often spends more in legal expenses than it would be able to pay in royalties. This can lead to a company just walking away from the negotiation, and declining to sponsor any further research at that university.

Johnson, *supra* note 327.

[334] Grose, *supra* note 15, at 20 (quoting R. Stanley Williams, director of HP Quantum Science Research).

[335] Johnson, *supra* note 327 ("The partnership between industry and universities has been weakened over difficulties associated with negotiating IP rights in research contracts in recent times.").

[336] *See id.*; *see also* Grose, *supra* note 15, at 21 (citing Joe O'Brien, University Relations Program Manager at Hewlett-Packard). "Deborah Kilpatrick, director of new ventures at Guidant Corp., a California bioengineering firm, agrees. 'Downstream royalties give us serious concern in early-stage research and technology development.' It is, she explains, very difficult to commit to them so far upstream of any commercial product." Grose, *supra* note 15, at 21.

In order to make the centralized office independently economically viable, the revenue received from licensing should cover the administrative costs, patent office expenses, and the grant money offered to those innovators that trade in their intellectual property rights. Licensing fees could be set at a global flat rate equal to the average cost of prosecuting and paying for the patent. Alternatively, the system could discriminate, setting flat rates differently for different technologies and even subsectors of those technologies—potentially charging more for patents whose technology sectors happen to be in greater demand or more profitable.

An alternative to the flat licensing may be a fee tied to the valuation of the patent plus the average prosecution costs. Licensees would probably accept such a system provided that the IP valuation methodology is transparent and conventional.

1. Exclusive Licensing Concerns

Exclusive licenses are often desired by licensees when a company must invest substantial resources to commercialize ground-breaking technology. Nonexclusive licensing programs are used when a new technology is likely to become a standard, is useful only in conjunction with other pre-existing technology, or is developed by a company that requires freedom to operate rather than an exclusive advantage over other companies.[337]

A relatively low royalty rate may also alleviate the concern that without an exclusive license companies may be unwilling to outlay the costs to develop embryonic research.[338] Arguably, if the cost to use the innovation is minimal enough, businesses might nevertheless be willing to take the risk of licensing the technology. And, with the concern that others may also be licensing the technology, businesses may be more aggressive and economical in developing that technology. The flat licensing contract might also have a sunset provision allowing either side to renegotiate the

[337] *See* ASS'N OF UNIV. TECH. MANAGERS, AUTM U.S. LICENSING SURVEY: FY 2006, at 32 (2006).

[338] *See, e.g.*, Thursby & Thursby, *supra* note 267, at 1052.

license, within certain parameters, once the research has been shown to be either a success or a dud, commercially.

Nevertheless, there may be legitimate concerns that transferring back intellectual property into the hands of the government will revert the system to its pre-Bayh-Dole years when less than 5% of government patents were licensed to industry.[339] It has been argued that much of the government's failure to license its intellectual property can be traced to the fact that it would not provide exclusive licenses to companies.[340] These arguments are not without merit. With the fear that a competitor could be simultaneously working on the same project, it often did not make good business sense to go through the hassle of licensing the innovation.

These fears are probably unfounded.[341] The National Institutes of Health also has a successful technology transfer system involving mostly non-exclusive licenses.[342] More than 60% of all IP licensed out of universities is non-exclusively licensed.[343] The most recent data from the Licensing Survey by the Association of University Technology Managers indicates that only 5% of academic inventions are currently developed into startups, even with the option for exclusive licensing.[344]

Additionally, there are reports of a licensing paradigm shift away from an earlier emphasis on protection and exclusive

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[339] U.S. GEN. ACCOUNTING OFFICE, GAO/RCED NO. 98-126, REPORT TO CONGRESSIONAL COMMITTEES: TECHNOLOGY TRANSFER, ADMINISTRATION OF THE BAYH-DOLE ACT BY RESEARCH UNIVERSITIES, at 3 (May 7, 1998).

[340] *See, e.g.*, Council on Governmental Relations, *The Bayh-Dole Act: A Guide To The Law And Implementing Regulations* (1999), *available at* http://www.ucop.edu/ott/faculty/bayh.html.

[341] *See* ASS'N OF UNIV. TECH. MANAGERS, AUTM U.S. LICENSING SURVEY: FY 2005, at 14 (2006) ("Licensing to small companies dominated total licensing; the majority of all licenses were non-exclusive.").

[342] *See* Carla Garnett, *Tech Transfer Helps NIH Breakthroughs Break Through*, NIH RECORD, May 5, 2006, http://www.nihrecord.od.nih.gov/newsletters/2006/05_05_2006/story01htm.

[343] *See* AUTM U.S. LICENSING SURVEY: FY 2005, *supra* note 341, at 33.

[344] Press Release, InnovateTech, Technology Transfer Firm Launches to Create New Startup Deal Flow Channel for DC Region (Oct. 10, 2007), *available at* http://www.prweb.com/pdfdownload/559520/pr.pdf (citing Gerard Eldering, founder and president of InnovateTech).

licensing and toward a more realistic goal of airing a simple 'right to operate', i.e., any sort of license.[345] With the fast paced nature of technology innovation, the right to exclude competitors from a particular chunk of intellectual property through an exclusive license is no longer important. A licensee now expects to extract the value of the license fees from future innovation developed from the licensed patent, not the actual patented innovation.[346]

2. Exclusive License Option

There may, nevertheless, be instances where an exclusive license is necessary to promote innovation, often in bioengineering and aerospace sectors.[347] In some instances, then, it may be worthwhile for the transfer agency to negotiate a more complex exclusive license with a company.

To prevent the exclusive licensee from impeding academic research, a clause in the exclusive license would require the licensee, and any subsequent licenses to the licensee's follow on innovation emanating from the original exclusively licensed, to license back the innovation to academic institutions at a reasonable rate. These so-called viral contracts are attempts to make "commitments run with a digital object . . . [thus attaching] the obligations regarding the content to the content itself, so that everyone who comes into possession of the content would also inherit the obligations to the initiator."[348]

345 *See* Marcia Anderegg, Joshua Thayer & Kathlen Williams, *Trendspotting: A Shift in Intellectual Property Focus*, BIOENTREPRENEUR, Apr. 24, 2006, http://www.nature.com/bioent/building/ip/042006/pf/bioent907_pf.html.

346 *Id.*

347 *See* Wendy H. Schacht, *The Bayh-Dole Act: Selected Issues in Patent Policy and the Commercialization of Technology*, Congressional Research Service, RL 32076 at CRS-10 (updated Apr. 3, 2008), *available at* http://www.italy.usembassygov/pdf/other/RL32076.pdf ("[E]xclusivity is what motivates firms to invest financial and human resources in technology development. It provides an incentive for universities to take the time and effort to pursue a patent and to license those patents in its portfolio. This has led to a significant increase in academic patenting.").

348 Margaret Jane Radin, *Humans, Computers & Binding Commitment*, 75 IND. L.J. 1125, 1132–33 (2000).

Some intellectual property licenses have already successfully incorporated a viral aspect,[349] most prominently the GNU General Public License ("GPL").[350] Note that instances may arise where there may be disagreements as to whether a subsequent innovation is a derivative of the earlier exclusively licensed work or not. Such disagreements have already occurred in the software industry. There are also legitimate concerns that viral or infectious terms in an exclusive license may serve as a disincentive to license, or more importantly may constitute patent misuse.[351] Finally, licensees who have an exclusive license with a viral clause may find other commercial entities unwilling to collaborate or to even license their patents for a product that is derived from a virally licensed academic innovation.

E. Anticommons Concerns and Experimental Use Doctrine

This regime would also limit the potential anti-commons effects thought to be associated with aggressive patenting and

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[349] *See* Sapna Kumar, *Enforcing The GNU GPL*, 2006 U. ILL. J.L. TECH. & POL'Y 1, 9 (2006); Andrés Guadamuz González, *Viral Contracts or Unenforceable Documents? Contractual Validity of Copyleft Licenses*, 26 EUR. INTELL. PROP. REV. 331 (2004), *available at* http://opensource.mit.edu/papers/guadamuz.pdf. Note, it is unclear whether the viral component of a GPL license would actually stand up in an American or even European court—all cases on point have been settled out of court. Additionally, there are solid arguments questioning the ability of such a license to withstand the requirements of contract law—particularly issues such as privity.

[350] *See* GNU General Public License Version 3, http://www.gnu.org/copyleft/gpl.html (last visited Jan. 29, 2009).

[351] *See* 35 U.S.C. § 271(d) (2006).

> No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having done one or more of the following: . . . (5) conditioned the license of any rights to the patent or the sale of the patented product on the acquisition of a license to rights in another patent or purchase of a separate product, unless, in view of the circumstances, the patent owner has market power in the relevant market for the patent or patented product on which the license or sale is conditioned.

Id.; *see also* Robin Feldman, *The Open Source Biotechnology Movement: Is it Patent Misuse?*, 6 MINN. J.L. SCI. & TECH. 118, 118 (2004) (concluding that the patent misuse doctrine should not apply to so-called open-source biotechnology).

restrictive licensing,[352] predominantly by changing the nature of the technology transfer office from an inhibitory gatekeeper to a facilitator of technology transfer.[353]

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[352] *See* Michael Heller & Rebecca Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 699 (1998).

> The anticommons refers to a situation wherein "a resource is prone to under use . . . when multiple owners each have a right to exclude others from a scarce resource and no one has an effective privilege of use. . . . Transaction costs, strategic behaviors, and cognitive biases of participants" exacerbates the issue . . . . Once an anticommons emerges, collecting rights into usable private property is often brutal and slow.

Id.; *see also* Eyal Press & Jennifer Washburn, *The Kept University*, ATL. MON., Mar. 2000, at 39.

> [T]he National Institutes of Health issued a report to NIH director, Harold Varmus, warning that changes in the way universities guard their intellectual property are endangering the free exchange of basic research tools—such as gene sequences and reagents—that are crucial to all research. The NIH found that the terms universities impose on their research tools, through their technology-licensing offices, 'present just about every type of clause that universities cite as problematic in the [contracts] . . . they receive from industry.

Press & Washburn, *supra*. Note that technology transfer offices themselves are often found to be too aggressive in exercising their intellectual property rights. *See* Siegel et al., *supra* note 279.

[353] *See Hearing on Nanotechnology Before the Subcomm. on Science, Technology and Space of the S. Comm. on Commerce, Science and Transportation*, 107th Cong. (2002) (testimony of R. Stanley Williams, HP Fellow, Hewlett-Packard Laboratories, Hewlett-Packard Company), http://www.hp.com/hpinfo/abouthp/government/testimony-nanotechnology.pdf.

> American Universities have become extremely aggressive in their attempts to raise funding from large corporations. Severe disagreements have arisen because of conflicting interpretations of the Bayh-Dole act. Large US-based corporations have become so disheartened and disgusted with the situation they are now working with foreign universities, especially the elite institutions in France, Russia and China, which are more than willing to offer extremely favorable intellectual property terms.

Id.; *see also* NAT'L INSTS. OF HEALTH, REPORT OF THE NATIONAL INSTITUTES OF HEALTH (NIH) WORKING GROUP ON RESEARCH TOOLS (June 4, 1998), *available at* http://www.nih.gov/news/researchtools/index.htm.

> Many scientists and institutions involved in biomedical research are frustrated by growing difficulties and delays in negotiating the terms of access to research tools . . . . Over and over again, firms complained to us that universities "wear the mortarboard" when they seek access to tools developed by others, yet they impose the same

Succinctly, anticommons theorists fear that the transaction costs resulting from a system that over-incentivizes patenting and allows the control of scarce resources to be balkanized, i.e., too many individuals exerting the right to exclude others from those resources, will lead to the underutilization of patented innovations.[354]

One particular anticommons-related issue has been the concern over the evisceration of the experimental use doctrine, formerly thought to generally exempt academic researchers from patent infringement if their research was not commercial in nature. In *Madey v. Duke*,[355] the Federal Circuit ruled that Duke University could not claim that their infringement of Professor Madey's patents was defensible under an experimental use doctrine.[356] This ruling essentially threw out any notion that academic institutions had any legal right to avoid paying licensing fees on patents, opening up the door to additional prosecution of academic researchers who infringe on someone else's intellectual property. Universities, generally known to be risk averse, have responded to this decision by making it more difficult for researchers to use potentially proprietary tools and inventions.

Heller and Eisenberg predict that "[a]n anticommons in biomedical research may be more likely to endure than in other areas of intellectual property because of the high transaction costs of bargaining, heterogeneous interests among owners, and cognitive biases of researchers."[357]

In this proposed system, the flat relatively cheap license, divorced from the inventor's control and with minimal transaction

> sorts of restrictions when they enter into agreements to give firms access to their own tools.

Id.

354 Michael Heller, *The Tragedy of the Anticommons*, 111 HARV. L. REV. 621, 676–77 (1998).

355 Madey v. Duke Univ., 307 F.3d 1351 (Fed. Cir. 2002) ("[R]egardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense.").

356 *Id.* at 1362.

357 Heller & Eisenberg, *supra* note 352, at 701.

costs, will allow even academic institutions to simply and easily pay the license fee for use of patented innovation and not have to worry about the threat of a lawsuit. Such a system could also incorporate lower licensing rates for research institutions.

F. Streamlining the System

Under the current Bayh-Dole system there are typical logjams in the technology transfer process that take up the valuable research time of academic scientists. A non-exhaustive list would include invention disclosures, complex negotiations, and the drafting of patents and licensing contracts. To distinguish itself from the current crop of Bayh-Dole-like systems, it is integral that this proposed process guiding the patent from bench to license be as streamlined and as straightforward as possible.

Practically speaking, the centralized technology transfer office and/or its potential subsidiaries, can easily be overwhelmed without a simple uncomplicated procedure to process the potentially thousands of patent applications and licenses. A backlog at these offices would hurt innovation by preventing scientists from publicizing their data for fear of losing their patent and grants and, additionally, by serving as a disincentive for scientists to transfer their technology at all, recreating the effects of the Bayh-Dole system that this process was designed to avoid.

With a streamlined process of commodifying innovation through the centralized agency, researchers can worry less about restrictions placed on publicizing their data, particularly in those regions that do not benefit from the publication safe harbors.[358] Under the current Bayh-Dole system researchers often need to clear their talks, presentations, and papers with the technology transfer office so as to not disclose any IP. Such a disclosure often destroys the ability to patent an innovation. The U.S. requires that patents be filed within one year of the public disclosure of the invention, and many foreign IP rights are immediately lost upon public disclosure of IP prior to having a patent on file.[359] Under

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[358] *See* 35 U.S.C. § 102(b) (2006); *see also* John A. Tessensohn & Shusaku Yamamoto, *Japan's Novelty Grace Period Solves the Dilemma of 'Publish and Perish'*, 25 NATURE BIOTECH. 55, 57 (2007).

[359] 35 U.S.C. § 102(b) (2006).

this proposed system patenting done by a dedicated team of centralized professionals could lead to much quicker filing and less hindrances on discussing current research.

Notwithstanding the desire to centralize the technology transfer process, it is here that a local technology transfer office would remain most useful. Without the need to create the next big multimillion-dollar license deal, and with researchers proactively choosing to commodify their research, one could imagine a productive symbiotic relationship between technology transfer professionals and scientists, even on a local level. And, to deal with those scientists who want to forgo the grant incentives and market their discovery on their own, local technology transfer officers should look to relatively cheap local university resources—i.e., law and business professors—to work with the scientist to effectively market the discovery to keep costs down.

The system can be further streamlined, through the use of a web portal that could allow for easy uploads of new innovations by the researcher, and easily searched by industry with access to the potentially vast number of patents that will be available through the centralized office. Corporations could even have the option to have the latest innovations in their field emailed to them as they come into the centralized office, thus keeping industry up-to-date on the latest academic innovations. IP licensing portals covering small swaths of the IP universe are already in existence. The possibility of creating a multi-tool database warehousing the bulk of the inventions coming out of the entire university system would seem to be very useful.[360]

G. Long Term Implementation

To avoid unrealistic expectations, developing nations should recognize and accommodate the relatively long time scales—

[360] *See, e.g.*, The iBridge Network, http://www.ibridgenetwork.org/iBridgeNetwork (last visited Jan. 30, 2009) ("[A] program of the non-profit Kauffman Innovation Network, Inc., provides the transparency and access to university developed innovations that will lead to further advances and next-generation products. The Network aggregates research materials, technologies, and discoveries in an online, easy-to-search forum—the iBridge Web Site."); *see also* IP Supermarket, http://ipsupermarket.com; UTEK Knowledge Express, http://www.knowledgeexpress.com.

potentially up to 20 years— involved in realizing positive returns resulting from the implementation of any technology transfer regime.[361]

But there should be positive returns. "[I]t is widely accepted that the process is of economic benefit. The many countries that are investing resources in technology transfer development confirm that there is widespread confidence that the investment is worthwhile and generates a positive return."[362] Universities, agencies and countries should set up adequate benchmarks to accurately monitor the situation and adapt it when necessary. Without clear and feasible benchmarks, "[u]nrealistic expectations of the benefits from technology transfer in smaller countries and institutions can damage the innovation process and lead to withdrawal of support—at the time when success may be just around the corner."[363]

CONCLUSION

Bayh-Dole is still seen by many in the United States Congress as a paradigmatic piece of legislation designed to bridge the divide between the constitutional call to "promote the progress of science and useful arts" and the methodology prescribed by the constitution: "by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries"[364] In Bayh-Dole, Congress saw an approach that could fund universities (a large producer of progress in science), help them create from their science some useful arts through promoting patenting and commercialization, and, through using its power as a funding source, cabin the exclusive rights provided by the Constitution, those same rights that promote science but also may hamper it—principally through carving out government

361 A.D. Heher, *Return on Investment in Innovation: Implications for Institutions and National Agencies*, 31 J. TECH. TRANSFER 403, 403 (2006).
362 *Id.* at 409.
363 *Id.* at 412–13.
364 U.S. CONST. art. I, § 8, cl. 8.

march-in rights and the like.[365] Given that Bayh-Dole has not noticeably increased funding to universities from industry, cannot take much of the credit for the patenting culture in universities, and hasn't effectively cabined the exclusive rights of patents, Congress, and countries interested in mimicking the Bayh-Dole legislation, must come to terms with the only real spawn of Bayh-Dole—the problematic technology transfer office.

"[E]arning licensing income from academic research is neither a lucrative nor a reliable financial investment."[366] Unfortunately, it seems that many technology transfer offices act as if their goal is to make money for the university. To this end, technology transfer offices have numerous policies and regulations, many required to comply with the regulatory requirements imposed by Bayh-Dole, that attempt to structure and fit scientific discovery into a patent-oriented process. This drive clashes head on with most scientists' desire to not be regulated and just continue to do their research, and, if and when desired, patent, but at their own pace.[367]

Granted, Bayh-Dole gave scientists the opportunity to patent their discoveries and innovation, and it probably has helped promote innovation without devastatingly harming research. Unfortunately, the present actions of technology transfer offices is threatening to ruin any positive effects of Bayh-Dole and hamper innovation.[368]

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365 *See, e.g.*, John H. Raubitschek & Norman J. Latker, *Reasonable Pricing—A New Twist For March-In Rights Under The Bayh-Dole Act*, 22 SANTA CLARA COMPUTER & HIGH TECH. L.J. 149, 150 (2005). The government has never, in the history of Bayh-Dole, exercised its march-in-rights and might never do so.

366 Sobolski et al., *supra* note 198, at 3138.

367 Freedom and the dearth of regulations are integral parts of what makes American basic science research so successful. *See, e.g.*, BUSH, *supra* note 75, at 19. ("It is chiefly in these institutions that scientists may work in an atmosphere which is relatively free from the adverse pressure of convention, prejudice, or commercial necessity . . . . All of these factors are of great importance in the development of new knowledge, since much of new knowledge is certain to arouse opposition because of its tendency to challenge current beliefs or practice.").

368 *See* Grose, *supra* note 15, at 18–19 ("Joe O'Brien, [a Hewlett Packard employee] recall[s] an era that ended some 20 years ago . . . when corporate-sponsored research contracts with university labs were casually reached over a cup of coffee with the faculty member who would lead the investigation . . . '[one] could have a collegial dialogue with faculty,' and deals were quickly agreed upon. . . .").

Developing nations ought to look beyond importing Bayh-Dole-like legislation. It will, more often than not, not be the panacea for transforming their economies into innovation powerhouses. This Article has attempted to show the minimal effect that Bayh-Dole had on the American technology transfer phenomenon and to highlight the particular characteristics of the American university that allowed for the American successes.

This Article, in addition to providing suggestions for gathering better and more useful data on the nature of the American technology transfer system, promotes a radically different type of system that should alleviate many of the negative issues associated with the American system.

In 1995 the newly elected Republican Congress threatened to significantly cut back on funding for granting agencies. Responding to this threat, a number of Fortune 500 companies took out an ad in the Washington Post stating that "large and small companies in America, established and entrepreneurial, all depend on two products of our research universities: new technologies and well educated scientists and engineers."[369] The proposed system in this Article would help fund and commercialize new technologies and, through direct grants to the researchers themselves and not to the bureaucracies of the universities, help fund the education of new scientists and engineers.

[369] A Moment of Truth for America: An Open Letter to Congress from the Executives of Some of America's Leading Technology Companies (May 1995), *available at* http://www.cs.washington.edu/homes/lazowska/cra/ceo.letter.html.