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Cover Page Footnote

The author wishes to thank his wife, Kimberly, for her loyal support throughout law school, and Professor Gretchen Bender for bringing her enthusiasm, charisma, inspiration, and encouragement to the University of Dayton and for her direction in the composition of this article.

THE GLOBAL EXPORTATION OF THE U.S. BAYH-DOLE ACT

Thomas J. Siepmann Ph.D.[*]

I. INTRODUCTION

A global experimental analysis of the effect of exportation of the Bayh-Dole Act ("BDA")[1] reveals the Act's success. The BDA allows government funded agencies, such as universities, to retain intellectual property rights to inventions derived from the fruits of government-funded research.[2] Much of the debate surrounding the enactment and effect of the Bayh-Dole Act centers on the potential pitfalls the BDA created as compared to its positive impact on research and the U.S. economy.[3] An international analysis of the exportation of the BDA to other countries shows that many countries are seeking to imitate the Act because they desire the positive effects the BDA has had on the United States. This article aims to step back from the usual U.S.-centered analysis to better understand the impact of the Act on the U.S. in comparison to other countries that do not have similar legislation.

As a scientist, I found it helpful to analyze the BDA as a national experiment in patent law. This article attempts to analyze the effect the BDA has had on the U.S. as a scientist would analyze the outcome of an experiment. Imagine a country, such as the U.S., placed into a test tube (a

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[1] *Patent and Trademark Amendments Act of 1980*, Pub. L. No. 96-517, 94 Stat. 3015-28 (codified at 35 U.S.C.A §§ 200-212 (2001)).

[2] 35 U.S.C. §§ 200-212.

[3] For recent publications on the debate, *see* Diane M. Sidebottom, *Updating the Bayh-Dole Act: Keeping the Federal Government on the Cutting Edge*, 30 Pub. Cont. L. J. 225 (Winter 2001) (contending that the BDA actually increases the evils it was meant to address rather than remove the evils); Peter S. Arno & Michael H. Davis, *Why Don't we Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed Upon Patents Deriving in Whole or in Part From Federally Funded Research*, 75 Tul. L. Rev. 631 (2001) (citing abuses of the BDA and the negative costs it inflicts); Rebecca S. Eisenberg, *Public Research And Private Development: Patents And Technology Transfer In Government-Sponsored Research*, 82 Va. L. Rev. 1663 (1996) (stating many oppositions to the theoretical premise of the BDA itself); Mark G. Bloom, *University Licensing: Past, Present and Into the New Millennium*, in *2002 Licensing Update* § 7.06 (Gregory J. Battersby & Charles W. Grimes eds., Aspen Law & Business, 2002) (contending that the BDA is largely responsible for creating the competitive edge the US now enjoys in the intellectual property market).

really big test tube) as the test subject, and an experimental variable, such as the BDA, delivered to the test tube. Then imagine watching through the test tube glass to see what changes take place. What instruments would one use to measure these changes? What physical properties of the test subject would be measured or measurable? The goal of this discussion is to pull together observed changes taking place inside the test tube upon addition of this variable and, hopefully, to come to some clear conclusions regarding its effect. In addition, a purpose is to make predictions about what effect such legislation may have elsewhere in the world, on other test subjects, such as Germany, the United Kingdom (U.K.), or Italy.

The BDA was enacted to address a specific intellectual property problem. Problems have existed in the multi-billion dollar national public research arena[4] since the U.S. government began funding basic research. Though some discoveries made by U.S. government laboratories were patented, the opportunity to exploit intellectual property gains from government funded research was largely ignored by private industry before the BDA was enacted.[5] The parties involved - the U.S. government, universities[6] and private industry - expressed a long-felt need to make new discoveries generated in government funded research projects more accessible. The legislators' hypothesis[7] could be summarized as follows: passage of the BDA will accelerate technology growth in the U.S. and allow the government to capitalize on research discoveries through commercial exploitation. The center of many scholarly and political debates is the question: has the BDA actually fixed what was thought to be "broken"?[8]

The scientific method espouses to provide objective answers to problems through logically-designed experiments.[9] In the 13th century,

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[4] The magnitude of the U.S. research budget is billions of dollars. Total research expenditures by 66 U.S. universities, hospitals, and non-profit research institutes were $15.7 billion. The U.S. spent $18.1 billion in Fiscal Year 2000 on research. Assn. of U. Tech. Managers, *AUTM Licensing Survey: FY 2000: A Survey Summary of Technology Licensing (and Related Performance for U.S. and Canadian Academic and Nonprofit Institutions and Patent Management Firms)*, 6 (Lori Pressman ed., 10th Anniversary ed., Assn. of U. Tech. Managers, Inc. 2002) (available at http://www.provendis.info/home/downs/AUTMFY2000Survey.pdf) [hereinafter *AUTM FY 2000 Survey*].

[5] Bloom, *supra* n. 3, at 209.

[6] The term "university" is meant to connote all institutions of higher education including non-profit institutions that regularly perform basic science research.

[7] In scientific lingo, a "hypothesis" is a premise the researcher hopes to be true. Scientists are trained to be objective observers and thus, though they may be emotionally invested (and in some circumstances financially invested) in a particular outcome, their task is to design an experiment that either proves or disproves the hypothesis in such a way that leaves no question or doubt to their peers, who may be equally emotionally and financially invested in the exact opposite hypothesis.

[8] *See* Eisenberg, *supra* n. 3, at 1663-71.

[9] There are many ways to define the scientific method. One definition includes the following steps: "1) observe some aspect of the universe, 2) invent a tentative description, called a hypothesis, that is

Roger Bacon championed Aristotle's method of logical induction. Later, in the 17th century this method was further expanded and developed by such scientific forefathers as Francis Bacon.[10] The method, as originally developed, involved a repetitious cycle of observation, hypothesis and experimentation with independent verification. The essential elements of the scientific method, used in various forms in laboratories throughout the world, consist generally of: observation; hypothesis; design of a test (logically predict results and perform experiment); formulate a conclusion based on the data; and, finally, develop a new hypothesis (it is a seemingly never-ending process). Scientific papers published in peer-reviewed scientific journals[11] generally mirror this process. Scientific publications usually contain an introduction revealing everything currently known to be true about the subject, a materials and methods section describing in detail the conditions under which experiments were performed, a results section providing detailed data given by the experiments, and a conclusion that attempts to filter this data through current state-of-the-art knowledge of the field.

Here, the scientific method is applied in an attempt to provide a new view of the problem legislators faced at the time the BDA was enacted and new insight into its effects both on a national and global scale. Thus, this article deviates from the normal law review format as follows. The Introduction contains the experimental conditions. This section is somewhat more detailed due to the complex nature of the subject: describing the status of a country's public research system. While individual reports contain this information for each country, to date there is apparently no comprehensive review published in a single article. Thus, the Introduction consists of a brief description of the experimental sample (the U.S. economy just prior to enactment – the object of observation) into which the BDA (the experimental variable) is introduced. Every good experiment needs control samples, preferably in triplicate.[12] The samples

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consistent with what you have observed, 3) use the hypothesis to make predictions, 4) test those predictions by experiments or further observations and modify the hypothesis in the light of your results, 5) repeat steps 3 and 4 until there are no discrepancies between theory and experiment and/or observation." Jose Wudka, *The Scientific Method*, http://phyun5.ucr.edu/~wudka/Physics7/Notes_www/node6.html# SECTION02121000000000000000 (accessed April 6, 2003).

[10] Wikipedia the Free Encyclopedia, *Scientific Method*, http://en.wikipedia.org/wiki/Scientific_method (accessed February 9, 2004).

[11] For instance, Journal of Biological Chemistry, Journal of Molecular Biology, Journal of the American Chemical Society, etc.

[12] In science there are positive and negative controls which must be run in every experiment to allow for subtraction of background and to ensure the experiment is actually working as designed. A negative control sample, in scientific lingo, refers to a sample run in parallel with the experimental sample, under identical conditions in all respects except the control is devoid of the experimental variable. For instance, if one were measuring the conversion of a molecule by an enzyme from substrate to product, the negative control sample would not contain any enzyme (to measure the background rate of

are countries, each country with its own legal framework, representing a unique sample. The introduction describes these controls. The negative control samples (also countries) include all other developed countries around the world that do not have similar legislation, but otherwise have political, economic, social, and industrial conditions similar to or on par with the U.S. For the purposes of this article, the current conditions in several European countries, to a first approximation, constitute good negative control samples. The positive control sample is a theoretical country in which the public research system has no problems translating discoveries into innovations that immediately benefit the public.

Section II describes enactment of the BDA, its goals and objectives, its language, and its basic operation. Section III discusses both quantitative and qualitative outcomes about the positive and negative effects enactment that the BDA has yielded. Section IV summarizes these observations into a single, coherent conclusion by considering the controls and comparing them to the U.S. experiment. The BDA continues to have a significant and valuable effect on the U.S. economy. Without the BDA, the U.S. would not be the world leader in biotechnology, nor in any other area of technology, that it is today.

II. BACKGROUND

A. *Description of the U.S. System & Control Systems*

Scientific publications usually include an introduction describing all relevant generally accepted knowledge published within their specific field of study. This introduction includes a brief description of the system and the current knowledge commonly believed to be true or proven regarding pertinent aspects of the public research system. In this study, the U.S. represents the experimental sample. To describe this sample, various interactions are summarized, including: the genesis of government funded research and its spread to universities, the interaction between universities and private industry, and the interaction between government laboratories and private industry. Though the parties may interact for varying reasons and purposes, the motivational force at the heart of these interactions is acquisition of money and patents. A full description of the U.S. system requires a brief review of the foundations of the U.S. patent system and the condition of the U.S. system just prior to BDA enactment.

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conversion without enzyme present). With this control, the scientist can more accurately determine how much of the conversion is directly attributable to the experimental variable, the enzyme, and not some other unknown variable. There are also positive controls – controls in which the event being measured is pushed to its maximum, *e.g.* in our hypothetical, a system in which the molecule is completely converted through addition of excess enzyme to the sample. This allows the scientist to affirm that the method of detection is working properly.

A detailed description of the control samples (foreign countries) follows the description of the U.S. sample. This later section is further divided into controls that give property rights to the universities, and those that do not. These individual sections are broken down by country. Of course, every country in the world cannot be analyzed since data is available for only a few of the countries within the global system. As in most experiments, to simplify the outcomes and conclusions, only a part or subset of the total system is examined. The countries analyzed generally compare in development to the U.S.

1. The Experimental Sample: The U.S. Condition Prior to the BDA

Knowledge was, and still is, considered a source of power to the underclass; a means to achieving a way of life better than that given to them. Since the Venetian patent system was established in the 15th century, economically developed societies placed a high value on pursuit of knowledge and the fruits of those efforts.[13] Throughout early science, only private, wealthy citizens had the time and the resources to pursue science and philosophy. During this time in history, Kings and Queens granted patents, or monopolies, to noblemen of their choosing to enforce throughout their land in whatever manner they sought fit (which often caused much consternation among governing bodies).[14] However, in the 13th century, public and private universities and colleges were established in such places as Paris, Oxford, Cambridge, Bologna, Padua, and Montpellier.[15] These institutions were capable of teaching many students and funded their own research. At these higher educational institutions, non-aristocratic, middle, and lower class citizens could pursue whatever field of interest caught their

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[13] There is debate surrounding the emergence of the very first patent system and in which country it arose. A majority of historians subscribe to the view that the Venetian Act of 1474 was the first patent legislation enacted in the world. This Act stemmed from the guild system, circa 1300, which allowed policing of various crafts and industries within Venice. The alternative view, the "Tyrolean View," expressed by Professor Erich Kaufer, is that modern patent systems can be traced to Germanic roots in which patents to Waserkünste, or water mines, were enforced by the "Constitutiones Juris Metallici" enacted by King Wenceslaus II in 1300. Both views point to the same year for the inception of a patent ideology. Erich Kaufer, *The Economics of the Patent System*, in *Fundamentals of Pure and Applied Economics* 1, 4 (J. Lesourne and H. Sonnenschein eds., Routledge 2001).

[14] Adam Mossoff, *Rethinking the Development of Patents: an Intellectual History, 1550-1800*, 52 Hastings L. J. 1255, 1259-66 (August 2001); *see* Kaufer, *supra* n. 13, at 6.

[15] The reader may consider Plato's "Academy," established in 399 B.C., as the first university. Though physiology, anatomy, mechanics, and astronomy were studied as early as 500 B.C., it is not until the early 13th century that the studies began to form into the modern defined fields of chemistry, physics, medicine, biology, etc. The inductive/deductive (Francis Bacon v. René Descartes, respectively) method debate occurred in the early 17th century. In the middle of that century, scientific societies such as the Royal Society of London and the Paris Academy of Sciences were formed. Questions about ownership of scientific inventions did not really arise until late in the 19th century, when science-based technology began to become useful in industry (industrial revolution). Erich Kaufer, *The Incentives to Innovate Under Alternative Property Rights Assignments with Special Reference to the Patent System*, in *The New Institutional Economics* 233, 237 (Eirik G. Furubotn & Rudolf Richter eds., Texas A&M University Press 1991).

attention, so long as they displayed enough intellectual acumen to gain the confidence of university administrators and fellow colleagues.

The division between academia and industry is long and deep. Historically, any potential industrial applications of scientific discoveries made within academia were deemed public knowledge and, therefore, not protected by patents.[16] An invisible wall seemed to exist between industry and academia, preventing their interaction throughout most of early scientific development. One scholar remarked that "[i]f modern science is seen as having been born around 1600 A.D., then 'for an amazingly long time advances in science and progress in the practical arts ran parallel, with few interconnecting ties.'"[17] This dichotomy of an independent academic development, alongside a private industry that benefited from this development, presents special problems. The evolution of an industrial society increasingly benefited financially from innovations and discoveries made at the universities. Universities, however, gained no tangible or financial benefits other than perhaps increased enrollment or better quality teachers if the publications were well regarded and respected by scientific peers. Unfortunately, in some cases, scientific discoveries were left unused and unapplied.[18]

U.S. funding of private industry projects had its genesis during World War II. Efforts to win the war led the U.S. government to the realization that private industry had to be tapped to provide the necessary resources. After the war, U.S. leadership announced a different kind of war - a war against disease. The U.S. government realized that it also lacked the capacity to complete the research required to win this war alone. Thus began the era of government funded research within institutions of higher education and other non-profit organizations.[19] A brief chronological overview of this development follows.

In 1950, for the first time in U.S. history, Congress created and funded a government agency for the sole purpose of conducting scientific

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[16] Research efforts and discoveries of scientists are regularly published in scientific journals with world-wide circulation for all to read as part of the "publish-or-perish" paradigm tacitly enforced in most universities. Though protected by U.S. copyright laws, these publications are and have been for centuries, a rich, crucial source of intellectual work culled for scientific techniques and ideas to be practiced and explored in a laboratory setting. Public disclosure of these ideas and techniques precludes patent protection under U.S. patent law, 35 U.S.C. § 102(b), which states that no intellectual property disclosed to the public 12 months prior to application for patent is patentable. 35 U.S.C. § 102(b) (2004).

[17] Kaufer, *supra* n. 15, at 237 (citing J. Conant, *Science and Common Sense*, pinpoint reference, (New Haven, 1951)).

[18] Ted Agres, *Euros for Discoveries? European Scientists Follow Their US Counterparts to the Market*, http://www.the-scientist.com/yr2002/apr/prof1_020429.html (accessed April 29, 2002).

[19] Bloom, *supra* n. 3, at 209.

research.[20] At that time, there were no statutory provisions outlining the disposition of property rights to innovations created in government funded research laboratories. Some agencies experimented with Institutional Patent Agreements ("IPA"s) but they were "fraught with restrictive provisions that . . . [made it] unworkable . . . for transferring technology to the private sector."[21] Prior to the passage of the BDA, IPA's were the only contracts available to private industry groups seeking access to inventions arising from government funding.[22] Every government agency and university had their own unique rules regarding ownership of the property rights to these inventions. Often these rules varied from agency to agency and from university to university, presenting private industry with a confusing and inconsistent landscape of rules and regulations.[23]

Some private companies, apparently motivated by the deep pockets of government funding, were nonetheless willing to navigate the labyrinth of rules and regulations.[24] Additionally, several universities, such as the University of California, Iowa State, and the University of Wisconsin-Madison, patented inventions for profit before the BDA was enacted.[25] This activity represented only a small fraction of the total utilization theoretically possible. At that time, the federal government accumulated over 30,000 patents, only 5% of which were actually licensed. An even smaller fraction of patents were commercially exploited.[26] Harbridge House produced a study in 1968 concluding that contractor-held inventions were 10.7 times more likely to be utilized commercially than government inventions.[27] As Mark Bloom, Manager of Licensing and patent attorney at the Cleveland Clinic Foundation, succinctly states, the feeling was that "what is available to everyone is of interest to no one."[28]

In 1963, President Kennedy issued a memorandum that essentially re-affirmed "that the rights to publicly funded, health-related inventions should remain in the government."[29] In 1965 and 1971, Science Advisors to the President recommended the varied and inconsistent policies be consolidated into a more uniform policy, enabling efficient use of

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[20] *Id*.
[21] *Id.* at 213.
[22] *Id*.
[23] *Id*. at 209; Arno & Davis, *supra* n. 3, at 656 (citing Sen. Subcomm. on Sci., Tech., & Space of the S. Comm. on Commerce, Sci., & Transp., *Patent Policy: Hearings on S.1215*, 96th Cong. 216, 220 (1979).
[24] Sidebottom, *supra* n. 3, at 234.
[25] Bloom, *supra* n. 3, at 209.
[26] *Id*.
[27] *Id*. at 211 (citing Harbridge House, Inc., *Government Patent Policy Study for the FCST Committee on Government Patent Policy*, Vol. II, Parts II and III (May 15, 1968).
[28] Bloom, *supra* n. 3, at 211.
[29] *See* Arno & Davis, *supra* n. 3, at 642 (citing Memorandum for the Heads of Executive Departments and Agencies) (Government Patent Policy); *see also* 3 C.F.R. § 861 (1963).

intellectual property stemming from government funded research.[30] Scholars who closely examined the legislative history behind the BDA concluded "the legislative history is replete with claims that granting title, as opposed to a mere license, to federal contractors would speed and enhance technological progress."[31]

The BDA was not built in a day or even in a year. There was at least one middle step between chaos and uniformity in the public research system. A predecessor to the BDA, "[t]he Stevenson-Wydler Act made technology transfer a mission of government-owned, contractor-operated laboratories."[32] This Act required all federal government funded laboratories to establish a technology transfer office to aid private industry in the translation of research outcomes to commercially viable uses.[33] This Act, however, was largely considered ineffective and was later amended by more robust legislation.[34]

Following passage of the BDA, several additional pieces of legislation expanded upon the same theme. For instance, the Federal Technology Transfer Act ("FTTA"), which was an amendment to the "failed" Stevenson-Wydler Act, stated that continued support of federal funding of basic science research was critical.[35] It contended that the government should not compete with the private market in exploitation of inventions created through government funding. Further, the FTTA encouraged enactment of legislation providing incentives to motivate the translation of these innovations to private industry.[36] More significantly, the FTTA expanded the original coverage of the BDA to include businesses of all sizes.[37] The FTTA created the ability of government funded laboratories to enter into wholly new arrangements called Cooperative Research and Development Agreements ("CRADA"). CRADAs allow government funded research administrators to enter into licensing agreements or assign rights to patents arising from the contracted work to any contracting party. Administrators of these research programs, through

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[30] *See* Bloom, *supra* n. 3, at 211-12 (citing 28 Fed. Reg. 200 (October 12, 1963); *see also* 66 Fed. Reg. 166 (August 26, 1971).
[31] *See* Arno & Davis, *supra* n. 3, at 693 n. 11 (citing H.R. Subcomm. on Sci., Research & Tech. of the House Comm. on Sci. & Tech., *Government Patent Policy*, 96th Cong. 4-5 (1979); *see also* Sen. Rpt. No. 96-480, 27-30, at 16 (1979).
[32] *See* Arno & Davis, *supra* n. 3, at 643 (discussing 15 U.S.C.A. §§ 3701-3717 (West 1998)).
[33] *Id.*
[34] *Id.* "Translation" refers to the process of transfer of potentially commercially useful scientific discoveries made within the academic environment to the public, either through utilization by private industry or release into the public domain.
[35] *Id.*
[36] Bloom, *supra* n. 3, at 222 (*see generally* Federal Technology Transfer Act, Pub. L. No. 99-502, 100 Stat. 1785 (1986)).
[37] Tamsen Valoir, *Government Funded Inventions: The Bayh-Dole Act and the Hopkins v. CellPro March-in Rights Controversy*, 8 Tex. Intell. Prop. L.J. 211, 214 (2000).

the FTTA, are required to share royalties with researchers directly involved in creation of the subject matter behind the patent.[38] The BDA was amended only in minor aspects, including an expansion applying the BDA provisions to all contractors, regardless of their size or status.[39]

Meanwhile, as a backdrop to these legislative efforts, historically significant changes were occurring within the judicial branch. A groundbreaking case, *Diamond v. Chakrabarty*, was decided by the U.S. Supreme Court in 1980.[40] In this case, the Supreme Court held that current U.S. patent laws, founded on Article I of the U.S. Constitution, did not preclude the patenting of living organisms.[41] The organisms in question were bacteria engineered with specific enzymes able to digest oil byproducts.[42] The patent had method claims of making and using the bacteria, but also contained a claim encompassing the newly created bacterial strain.[43] The Supreme Court essentially held that the invention was consistent with the plain meaning of the description of "patentable material" provided by 35 U.S.C. § 101.[44] Additionally, the Court held that it was the legislature's role, not the judiciary's role, to determine the limits and bounds of what was patentable.[45] Contrary to the Supreme Court's prediction, this decision contributed to the creation of the strongest biotechnology industry in the world: the U.S. biotechnology empire.[46] Moreover, in 1982, the Court of Appeals for the Federal Circuit was created specifically to handle patent and other intellectual property concerns.[47] Many scholars feel this altered the tides in the public's perception that patents were "evil" because they granted monopolies to private industry.[48]

2. The Control Samples: European Country Conditions as Negative Controls

Descriptions of the negative control samples (foreign countries) are

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[38] Arno & Davis, *supra* n. 3, at 644 (discussing 15 U.S.C.A. §§ 3701-3714 (West 1998)).
[39] *See* Sidebottom, *supra* n. 3, at 228 (*citing* Ronald Reagan, *Government Patent Policy, 1983 Pub. Papers 1, 248*).
[40] 447 U.S. 303 (1980).
[41] *Id.* at 318.
[42] *Id.* at 305.
[43] *Id.*
[44] *Id.* at 318.
[45] *Id.*
[46] 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*, http://www.sipa.columbia.edu/RESEARCH/Paper/99-7.pdf (accessed Nov. 12, 2004). The authors state that "[a]n earlier version of this paper was presented at the conference on 'The U.S. and Japanese Research Systems,' Kennedy School of Government, Harvard University, September 10-12, 1998." *Id.*
[47] *Id.*
[48] Valoir, *supra* n. 37, at 212.

provided to better contrast the status of the negative control with that of the U.S. experimental sample after introduction of the BDA. These countries are considered negative control samples because, to a first approximation, these countries are similarly developed and, until very recently, lacked any legislation resembling the BDA. These countries had access to the same technology, experienced similar standards of living, were governed by similar political systems, and actively and substantially funded government research projects (although not to the same extent as the U.S.). Additionally, to a first approximation, the subject matter protected by patent, copyright, and trademark in the U.S. is also protected in Europe (with some exceptions).

There are some substantive differences, however, between the U.S. experimental sample and the negative control samples. Many European academic researchers are only hesitantly, if at all, interested in the exploitation of their research in the private sector.[49] Due to the limited number of positions in most European nations' academic institutions and the extremely competitive nature of their system, many European researchers rightly fear any potential negative fallout stemming from failed inventions or discoveries that can potentially harm the public.[50] While this is also true in the U.S., such fallouts appear to be more tolerated since in the U.S. there are many more universities and laboratories conducting research and in need of scientific expertise.[51] Additionally, in contrast to most European Union ("EU") countries, the U.S. has no price control measures in place to control the amount of money private industry can charge on prescription drugs (regardless of whether drug development occurred collaboratively with government entities).[52] Logically, it is anticipated that markets lacking price control lead to more profits than those in which prices are tightly regulated and tied directly to cost. Therefore, the potential for better-than-average profit may stimulate additional investment from the private sector. Also, while the U.K. has had much success in their public research system without a BDA-like set of laws, their laws did clearly allocate ownership rights to such inventions.[53] In the U.S., however, prior to enactment of the BDA, it was entirely unclear who owned the rights to inventions funded by public monies.[54] The clarification provided by the U.K. system allowed for a more efficient exploitation of inventions than

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[49] Agres, *supra* n. 18, at ¶15.
[50] *Id.*
[51] *See infra* n. 196 and accompanying text.
[52] Arno & Davis, *supra* n. 3, at 633.
[53] Royal Society: The National Academies Policy Advisory Group, *Intellectual Property & the Academic Community*, 36 (available at http://www.royalsoc.ac.uk/displaypagedoc.asp?id=5772) (last updated March 1995).
[54] Eisenberg, *supra*, n. 3, at 1671.

that which may have occurred without it.[55]

Other considerations include the high cost in many countries of prosecuting patents and the weak intellectual property laws that govern them. Many European governments and leaders continue to express the dire need for a community-wide, perhaps even world-wide, patent system to help decrease costs of prosecution.[56] The combination of weak intellectual property laws and expensive patent prosecution can be fatal to a country's intellectual property regime, as is the case in Spain.[57] The EU condenses all these problems into the following list of concerns[58]:

> Poor EU performance could be explained by the culture of many EU research institutions. Problems cited included:
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> - a continued over-reliance on a 'linear' approach to innovation, which assumed that investment in the supply side would automatically result in marketable innovations downstream;
> - measuring academic success on the basis of research papers or academic citations, with intellectual property creation, for example, often not given parity of esteem as a research publication;
> - peer review (and lack of external examination), which may tend to prevent academic networks opening up to external scrutiny; and
> - academics being given insufficient time, or promotion incentives to engage in commercial activities.

The EU is vocal and specific in calling for reform of the research systems within its member nations and cites a litany of problems from "poor knowledge transfer mechanisms from the science base to industry," to "significant barriers" within the academic culture itself that prevent commercialization.[59] The EU also cites an overall lack of clarity among many member nations as to who actually owns intellectual property

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[55] Royal Society, *supra* n. 53, at 40.
[56] The European Union, Economic Policy Committee, Working Group on Research and Development, *Report on Research and Development*, EPC/ECFIN/01/777-EN, 32 (January 22, 2002).
[57] The European Union, Economic Policy Committee, Working Group on Research and Development, *Report on Research and Development*, *Final Annex A: Detailed Reports of Visits to Member States and US/Canada and Examples of Good Practic*e, EPC/ECFIN/01/777-EN, A21 (January 22, 2002).
[58] The European Union, Economic Policy Committee, Working Group on Research and Development, *Report on Research and Development*, EPC/ECFIN/01/777-EN, 34 (January 22, 2002).
[59] *Id.* at 36.

stemming from government funded research.[60] If legal scholars cannot interpret the laws surrounding intellectual property in this context, it is unlikely that scientists can either. The EU specifically recommends that "increased use of procurement for public research could facilitate contracting within and between public and private sectors," and that establishment of "national procurement programmes" (sic) could lead to community-wide benefits of increased economic potential stemming from a robust research industry.[61]

The variety of country responses to the problems in existence today creates a confusing morass of indefinite rights. This current European condition is similar in many respects to the condition of the U.S. prior to enactment of the BDA (*circa* 1970-1980). The summary below serves to describe the current condition of the negative control group.

a. Negative Control Samples: Countries that Grant Intellectual Property Rights to the Universities

A review of the current conditions of a few countries in Europe serves to better describe the negative control sample group. Several countries appear to be following in the footsteps of the U.S. by enacting very similar legislation, such as the United Kingdom ("UK"), Germany, and Denmark.[62] The UK has long been revered as a research powerhouse in Europe and continues to improve on its already impressive track record for translation of academic research to industrial use. Germany recently passed new legislation that generally effectuates BDA provisions.[63] Belgium has research institutes blazing new paths in licensing and is establishing cooperative agreements and partnerships between industry and academia.[64] Other countries are implementing similar plans but with different variations including funding of private/public organizations to oversee the translation of academic research into industry.[65] The remainder of this section is devoted to a more detailed analysis of the current conditions of these countries.

i. The United Kingdom

According to the UK Patent Act of 1977, which is similar to the

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[60] *Id*.
[61] *Id*. at 46.
[62] Agres, *supra* n. 18, at ¶ 11.
[63] 2002 BGBI.I, S. 414.
[64] Agres, *supra* n. 18, at ¶ 4; Belgian Bioindustries Association, *Industrial and Scientific Affairs*, http://www.bba-bio.be/common/bba_industrial.asp (accessed April 16, 2003); Erik Nooteboom, *Commission of the European Communities, Statement of the Commission, Presidency Conference on Growth, Prosperity and Patents*, http://www.innovationskraft.dk/en/eu/conf/doc/28_nooteboom2.doc (accessed April 16, 2003).
[65] Agres, *supra* n. 18, at ¶ 11.

U.S., academic researchers in the UK are technically employees of the university at which they work.[66] Therefore, patent rights stemming from research results within that employment relationship belong to the university. As the Royal Society described the situation in its review of the current UK patent system, "[v]arious royalty sharing schemes now operate in universities: a common pattern is for all or a very high proportion of initial returns to go to the inventor(s); with larger proportions thereafter going to the institution, sometimes with a further tranche for the department concerned."[67] Most universities apparently have agreements with students - since students are not technically considered employees - that stipulate ownership of property rights to be held by the university with a share of the royalties going to the student. The Royal Society in general agrees with this approach for the optimal use and exploitation of discoveries while preventing them from being "taken off surreptitiously to the private sector."[68]

An analysis of the revenues gained from this legislative backdrop reveals very positive impacts for the UK. In 2001, the Medical Research Council ("MRC") realized £9.6 million due to licensing of its inventions.[69] In 2002, it was predicted that this would increase from £10 to £12 million.[70] Along with the usual exploitation of intellectual property, the MRC generated 16 new start-up companies, established a venture capital fund, and has over 330 licensing agreements on their books.[71] In addition, the UK Patent Office, in a collaborative project with the Association of University Research and Industry Links, is working to make university technology more accessible to the European community by creating a web site that will contain a database of patents held and available for license to industry.[72] The EU noted this change along with the UK's increase in establishment of research and technology organizations and "[g]overnment support for building links between universities and industry," but felt the country still needed improvement due to non-uniformity among universities and their handling of intellectual property rights.[73] Thus, the situation in the UK mirrors that in the U.S. to a degree, resulting in some favorable outcomes for the UK economy, in contrast with different conditions found in other countries.

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[66] Royal Society, *supra* n. 53, at 36.
[67] *Id*. at 37.
[68] *Id*.
[69] Agres, *supra* n. 18, at ¶ 7.
[70] *Id*.
[71] *Id*.
[72] Department of Trade and Industry United Kingdom, *The Patent Office Quinquennial Review*, *Conclusions and Recommendations*, http://www.dti.gov.uk/patent_office/conclusions.pdf (accessed April 16, 2003).
[73] The European Union, Economic Policy Committee, *supra* n. 57, at A24.

ii. Germany

In Germany, enactment on January 18, 2002, of an amendment to the German Employed Inventor's Act revoked the long-standing privilege for employees of universities, such that a university now can lay claim to inventions created by its employees with government funding on its campus.[74] Prior to the amendment, many believed this privilege stifled commercialization of inventions made in academic institutions.[75] The amendment stipulates that employees must receive 30% of the profits stemming from the commercialization of their discovery.[76] The new provisions of section 42 of this Act, in summary, hold that: 1) inventors are allowed to publish their inventions so long as they give their employing institution a two month notice prior to publication; 2) inventors may retain a non-exclusive right to use their invention in their capacity as employee; and 3) the rights to the invention may be retained by the university for exploitation.[77]

The Max Planck Institute reported licensing revenues in 2003 of DM 32 million.[78] Bernhard Hertel, managing director of the Max Planck Society's ("MPS") technology transfer division, says that, "[t]here is an increasing demand from young scientists who want to start their own companies, not only at MPS but elsewhere in Germany."[79] Germany also maintains a program called "EXIST" that promotes "networks between universities, capital providers, and service companies to facilitate university spinouts."[80] The EU notes that despite these efforts, there is under-utilization of technology and lack of cohesive technology transfer policies.[81] The EU, however, was encouraged by Germany's recent efforts in 2001 including an "action scheme to promote technology transfer."[82] Germany is establishing "regional patent and commercialization agencies which help groups of universities and non-university research institutes . . .

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[74] *Id*. at A12. The privilege law is named as such because it allowed university researchers the privilege of taking possession of patent rights to their inventions. *Id*.
[75] *Id.*
[76] Kuhnen & Wacker, *The so-called "university professor privilege" has been amended ahead of the total revision of the German Employed Inventor's Act*, http://www.patentfirm.de/news/feb_02_04_e.htm (accessed April 16, 2003).
[77] Rough translation provided by Cornelius A. Bobbert, attorney with Kuhnen & Wacker, Munich, Germany. Personal communication (original on file with author).
[78] Agres, *supra* n. 18, at ¶ 8.
[79] *Id*.
[80] The European Union, Economic Policy Committee, *supra* n. 57, at A11.
[81] *Id*. This is evidenced by the reluctance of "SME"s to patent discoveries and the effect of the "professor privilege" which has led to undercommercialization and that public institutions for research are unprepared to exploit technology. Lack of cohesive technology transfer policy is evidenced by the recent amendments made to their patent laws, aimed at fixing such problems.
[82] *Id.* at A12.

to exploit R&D results."[83]

iii. Denmark

In 1999, Denmark enacted an amendment to its patent laws simplifying many unresolved, murky issues regarding ownership of property rights to inventions made in university settings.[84] Furthermore, these changes encourage "all parties to generate and exploit scientific inventions by dividing the revenue from IPR (intellectual property) contracts between the inventing researchers and the institutions."[85] The EU, however, still sees areas that need improvement, including communication.[86] The EU further reports that "58 million DKK (approx. 8 million euros) over a four year period has been granted for the implementation of the new legislation," and the government is working on establishing networks between institutions to aid in utilization of patent information.[87]

iv. Belgium

Belgium has two research institutions vigorously seeking and implementing research translation opportunities for its discoveries. The Flanders Interuniversity Institute for Biotechnology ("VIB") and the Belgian Bioindustries Association ("BBA") both strive to increase their country's utilization of these resources. The VIB handles technology transfer issues for "nine university departments and five associated laboratories."[88] In 2001, the VIB submitted 29 patent requests and increased their "active patent families" by 20% to a total of 94.[89] The BBA is focused on "[e]stablishing contacts between public research institutes and Belgian bioindustries in order to strengthen and diversify activities of the members as well as to stimulate collaborations."[90] Belgium also has a program called Formation and Impetus in the field of Scientific and Technological Research ("FIRST") that fosters professional collaborations between academic institutions and industry aiding researchers in establishing new spin-offs and allowing scientists to take industry sabbaticals for 3-6 months.[91]

Speaking at a recent conference, Belgium's Erik Noteboom,

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[83] *Id.* at A11-A12. "R&D" means research and development.
[84] *Id.* at A6.
[85] *Id.*
[86] *Id*.
[87] *Id*.
[88] Agres, *supra* n. 18, at ¶ 4.
[89] Flanders Interuniversity Institute for Biotechnology, http://www.vib.be/ (accessed April 16, 2003).
[90] Belgian Bioindustries Association, *Industrial and Scientific Affairs*, http://www.bba-bio.be/common/bba_industrial.asp (accessed April 16, 2003).
[91] The European Union, Economic Policy Committee, *supra* n. 57, at A32.

Principal Administrator, Commission of the European Communities, Brussels, said:

> [t]he Commission's Directorate-General for Research is engaged in several activities intended to address the IPR-related needs of the European research community. These include identifying, promoting and disseminating best practices for the use of IPR in the research & innovation process. This covers not only issues in specific scientific or technical sectors such as bioinformatics, but also generic issues, like Internet-based collaborations, and the need to clarify the rules applying to the ownership and management of IPRs arising from publicly funded R&D and university-industry collaborations.[92]

The changes taking place in Belgium in the last two years were highlighted in an interview with Stein Larsen, acting head of the Secretariat at the Danish Council for Research Policy. Specifically, the Secretariat said, "[t]he new law on intellectual property rights in public research has changed the former situation where the individual researcher owned the IPR. Now it's up to institutions to take advantage of the IPR, to commercialise it and make profit sharing arrangements with the individual researchers."[93] The Secretariat expresses enthusiasm for the new changes, but also cautions reading too much into it too quickly. He predicts there will be continued debate surrounding the potential problems caused by the new laws.[94]

In sum, the countries within this section, though attempting to enact legislation similar in effect to the BDA, either made these moves very recently, or the moves were not of the same magnitude as the BDA experiment in the U.S. These countries can be considered an intermediate data point between experimental conditions containing the variable at full strength (introduction of the BDA) and no variable at all (no BDA provisions). This data point, however, probably lies much closer to the negative control than to the full strength experimental condition.

b. Negative Control Samples: Countries that Do Not Grant Intellectual Property Rights to Universities

Several countries either do not notice the changes in the U.S.

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[92] Erik Nooteboom, *Commission of the European Communities, Statement of the Commission, Presidency Conference on Growth, Prosperity and Patents*, http://www.innovationskraft.dk/en/eu/conf/doc/28_nooteboom2.doc (accessed April 16, 2003).
[93] Euroabstracts, *Research Driving the Economy*, ftp://ftp.cordis.lu/pub/euroabstracts/docs/archive6-02.pdf (December 2002).
[94] *Id.*

intellectual property laws and their effects, or have explicitly chosen not to follow.[95] Some countries decidedly turned the other way by granting individual researchers even stronger rights to their inventions.[96] Some of these countries are just now beginning to heed the message of the EU regarding how the EU feels they should handle their technology.[97] Others, with long-standing problems throughout their research systems, such as Italy, are simply being left behind in the race to profit from translation of government-funded intellectual property.[98] The current conditions of some of the countries are described in more detail below.[99] It is apparent that Europe is in a state of flux, wherein even some of these negative control countries are today working hard to try to implement BDA-like legislation and activities.[100]

i. Sweden

Since 1949, Swedish intellectual property laws stipulated that researchers retain all rights to their inventions.[101] The Swedish government, however, motivates researchers to commercialize their inventions.[102] Sweden founded Technology Link Foundations with the goals of commercialization of university research, "lowering knowledge search costs for firms and stimulating co-operation between SMEs in joint projects."[103] Sweden allows universities to invest in "University Holding Companies" and form "Patent & Exploitation Offices" in the hopes that investment in such programs will spur translation of university research into the private sector simply by making it easier with readily-identifiable resources.[104] The Parliamentary Committee on Research floated a proposal that allowed universities to take charge and participate in inventions obtained through government funded research.[105] This was met, however, with vivid criticism within the Swedish populace, indicating that enactment of Bayh-Dole like legislation in Sweden remains a long shot, at best.[106] Today, "Sweden has the highest level of research and development expenditure per capita in the EU."[107] Its spending on R&D exceeds Japan's

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[95] *See e.g.* France and Italy's summaries, *infra* pts. II (A)(2)(b)(ii) and (iii).
[96] *Id.*
[97] *See infra* pt. II(A)(2)(b)(i), Sweden.
[98] *See infra* pt. II(A)(2)(b)(ii) and (iii), France and Italy, respectively.
[99] *See infra* pts. II(A)(2)(i) – (iii).
[100] *See infra*, pt. II(A)(2)(b)(i), Sweden.
[101] Agres, *supra* n. 18, at ¶ 12.
[102] *Id.*
[103] The European Union, Economic Policy Committee, *supra* n. 57, at A33.
[104] *Id.*
[105] European Commission, *European Trend Chart on Innovation*, *October 2001 – September 2002*, http://trendchart.cordis.lu/Reports/Documents/Sweden_CR_September_2002.pdf, 34 (accessed April 16, 2003).
[106] *Id.*
[107] Economic and Social Committee, Section for Economic and Monetary Union, *Opinion of the*

and approaches U.S. levels.[108] A full 85% of this research is carried out by private companies.[109]

ii. France

In France, it is largely unclear who owns intellectual property rights to inventions created in state funded research institutions. The EU report characterizes France's universities as "relatively weak in hard sciences" and "poorly organized to address the complex issues of patent rights."[110] There are a few bright spots highlighted by the EU, such as state-subsidized incubators and "technology research and innovation networks" designed to connect university researchers with private industry for specific niches of scientific investigation.[111] The European Commission flatly concludes that "there are no specific measures that encourage large public facilities to benchmark their activities in technology transfer and partnership with enterprises."[112]

iii. Italy

Italy defiantly and steadfastly continues its refusal to follow the crowd. In 2001, Italy specifically enacted legislation to award ownership of university research property rights to researchers.[113] The European Commission's Trend Chart for Italy is devoid of statements regarding technology transfer or stimulation of commercialization of university research innovations. The report, however, outlines in detail many administrative and cultural problems with Italy's research system, suggesting these issues cause Italy to lag far behind in its development of industry.[114]

B. *Materials & Methods: Introducing the Bayh-Dole Act into the U.S. Sample*

The purpose of this section is to describe the variable (the BDA) added to the test tube. To gain insight into the laws of nature and the

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Economic and Social Committee on "Sweden: Economic Situation and Implementation of the Structural Reforms Envisaged by the Cardiff Process and the Council Recommendation on Economic Policy, Commission of the European Communities, Preparatory Acts O.J. (C 048) 147, 153 (November 29, 2001).

[108] *Id*.

[109] *Id*.

[110] The European Union, Economic Policy Committee, *supra* n. 57, at A9.

[111] *Id*.

[112] European Commission, *European Trend Chart on Innovation*, *Theme-specific Country Report: France*, http://trendchart.cordis.lu/Reports/Documents/France_CR_March_2002.pdf, 19 (accessed April 17, 2003).

[113] Agres, *supra* n. 18, at ¶ 12.

[114] European Commission, *European Trend Chart on Innovation*, *Theme-Specific Country Report: ITALY*, http://trendchart.cordis.lu/Reports/Documents/Italy_CR_March_2002.pdf (accessed April 16, 2003).

universe, scientists conduct experiments which yield empirical observations from which conclusions about the world around us may be drawn. These experiments involve several integral steps. First, the conditions under which the experiment is performed must be carefully observed and recorded.[115] Second, the variable used to perturb the system must be well defined. Third, the effect of the introduction of this variable into the system must be empirically measured to a degree that allows the observer to draw conclusions about its effect.[116]

The enactment of the BDA promised new sources of substantial funding and new efficiencies of translation of scientific research into useful application for the benefit of the public good.[117] The legislative history surrounding the enactment of the BDA is covered in great detail in other scholarly publications.[118] The goals of the BDA are many and varied. Specifically, the "Policy and Objective" introductory section of the Act states the following goals:

> It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and to minimize the costs of administering policies in this area.[119]

These lofty aims were effectuated by provisions enumerated in

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[115] *See supra* pt. I.
[116] *See infra* pt. III.
[117] *See* 35 U.S.C. §§ 201-212.
[118] *See* Arno & Davis, *supra* n. 3, at 640-56; Eisenberg, *supra* n. 3, at 1674-95; and *see generally* John M. Golden, *Biotechnology, Technology Policy, And Patentability: Natural Products And Invention In The American System*, 50 Emory L. J. 101 (2001).
[119] 35 U.S.C. § 200.

sections 201-212 of U.S.C., Chapter 18, Title 35.[120] The Act encompasses four basic ideals regarding government funded patentable inventions: 1) in government funded research under contract with a private individual (or contractor), the private individual may retain legal title to the invention, but the government is allowed "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 . . . "[121]; 2) contractors must notify the government of the existence of any invention made (disclosure requirement); 3) contracting entities retaining title to inventions must first try to manufacture the product in the U.S. and if unable to do so, must be able to show they at least tried; and 4) the government retains "march-in" rights that allow it to force the contractor to grant a license to another entity if certain conditions are met.[122] The government can exercise march-in rights only under certain, limited conditions, as follows:

> the Government must determine that (1) the contractor is not taking effective steps to achieve practical application of the invention within a reasonable time, (2) the contractor is not reasonably satisfying national health and safety needs, (3) the contractor is not reasonably satisfying regulatory requirements for public use, or (4) the contractor has not received the required permission from the Government under the U.S. industry preference clause before licensing.[123]

In simpler terms, the BDA granted universities the ability to enter into contractual arrangements to perform research in collaboration with private industry and to license the patented inventions discovered through these collaborations and other federally funded research programs. Through this Act, government institutions have the authority to collect royalties from those with whom they enter into licensing agreements.[124] The BDA, however, does not explicitly define a minimum or reasonable royalty rate.[125]

Researchers working for contractors must disclose potential inventions to the contractor's legal counsel. Once this internal disclosure is made, the contractor must disclose the information to the U.S. government entity from whom it obtained the benefits of government funded

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[120] *Id*.
[121] 35 U.S.C. § 202(c)(4).
[122] Sidebottom, *supra* n. 3, at 228-30.
[123] *Id.* at 230; *see* 35 U.S.C. § 203(1)(a)-(b), 203(c)–(d).
[124] Valoir, *supra* n. 37, at 240.
[125] *Id*.

research.[126] Within two years of disclosure, the contractor must decide if they wish to retain title to the potential invention. If the contracting party wishes to keep the rights to the invention, it must file, within one year, a patent application that includes a legend indicating the government funding source of the invention.[127]

Income from royalties and licensing, after expenses are deducted, is dispersed to the government researchers who provided the basic scientific knowledge behind the invention and to the employing university to support the research and educational mission of the institution.[128] Though universities may use this income to support graduate students with stipends, to fund initial set-up expenses of new faculty, and to launch new research projects, BDA provisions do not apply directly to research performed by individuals in government laboratories funded through "scholarship[s], fellowship[s], training grant[s], or other funding agreement made by a Federal agency primarily to an awardee for educational purposes."[129]

There is debate whether this Act represents a "normal" approach to solving problems within the U.S. legislative history, or whether it is a radical departure - an untested and abnormal extension of law for its time. Some scholars feel this Act represented a "sea change" in the approach of government towards the handling of intellectual property derived from research funded by the U.S. government.[130] Others feel the BDA represented merely a predictable continuation of progress towards utilization of the resources belonging to the public.[131] Indeed, it is difficult to characterize this legislation as a radical departure from previous government legislation because the government allowed these parties to license intellectual property between themselves for many years prior to the BDA. Opponents of this view base their contention on a more extended view of the history of patents and legal theory behind patent laws.[132]

C. *Results: Quantitative & Qualitative Data*

The observations collected to date include not only empirical, quantitative data, but also qualitative factors arising from implementation of the BDA. Objective, accurate quantitative data is the gold standard most often used in science.[133] Many studies by necessity, however, must be

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[126] Arno & Davis, *supra* n. 3, at 647 (discussing 35 U.S.C. § 202(c)(1)-(2), 37 C.F.R. § 401.14(c)(1)-(2) (2000)).
[127] *Id*. at 647-48 (discussing 37 C.F.R. § 401.14(c)(3)).
[128] *See generally* AUTM FY 2000 Survey, *supra* n. 4.
[129] 35 U.S.C. § 212.
[130] Eisenberg, *supra* n. 3, at 1663; Arno and Davis, *supra* n. 3, at 646.
[131] *See supra* pt. I.
[132] *See generally* Eisenberg, *supra* n. 3.

concluded entirely on qualitative analysis of experiments (*e.g.* a subtle increase in intensity of a faint signal, an increase of an unknown amount in the size of a protein or strand of DNA, or the appearance of a detectable signal where there previously was none). Where an event cannot be accurately observed quantitatively, thus requiring the reliance on qualitative data, conclusions often cannot be clear cut. Conclusions based on qualitative data speak in generalities and trends and often aid in the proposal of new experiments aimed at more precisely determining the outcome.

To fully describe the U.S. sample, observations must be made from as many angles and perspectives as possible. In this case, observations include, for instance, the viewpoint from research scientists inside and outside academia and government, socio-political viewpoints, historical viewpoints, and legal viewpoints. Observations are divided into "positive" effects and "negative" effects on the U.S. system. Normally, scientific data is not split into these preconceived notions of "good" and "bad" because the data must speak for itself. However, qualitative and quantitative outcomes are divided in this way for organizational purposes.

In this experiment, the quantitative data is represented by statistics concerning licensing and other economic numbers. Even these statistics may be considered somewhat qualitative due to their level of accuracy. Despite this, the quantitative data is summarized as a positive factor due to the overall perceived positive outcomes reported. Qualitatively, there is a fertile field of legal, scientific and political scholarly comment on both the positive and negative facets of enactment of the BDA. Some of these factors are also summarized.

1. Positive Effects of the BDA

The heavy weight of impressive statistics show great benefits for the U.S. system after introduction of the BDA. The Association of University Technology Managers reports that at the end of fiscal year 1999, over 21,000 licensing agreements were created.[134] In addition, 2,922 new business ventures were generated and 12,324 patent invention disclosures.[135] These new activities at universities generated a reported $862 million in royalties for teaching hospitals and universities in fiscal year 1999 alone.[136] It is estimated that these financial benefits yield an influx to the U.S. economy of $40.9 billion per year.[137] Furthermore, it is

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[134] AUTM FY 2000 Survey, *supra* n. 4, at 1.
[135] *Id*.
[136] *Id*.
[137] Assn. of U. Tech. Managers, *AUTM Licensing Survey: FY 1999: A Survey Summary of Technology Licensing (and Related Performance for U.S. and Canadian Academic and Nonprofit Institutions and Patent Management Firms)*, 1 (Assn. of U. Tech. Managers, Inc. 2000) (available at

estimated that the Act supports over 270,000 jobs.[138] Patent issuance to U.S. universities has increased over 10-fold since introduction of the BDA.[139] In 2000 alone, universities collected a staggering $1.26 billion in adjusted gross income through translating government funded research into the private market.[140]

The Public Health Services branch of the U.S. government is responsible for funding scientific research through the National Institutes of Health ("NIH"). In 2003, the NIH spent over $27 billion for research.[141] The U.S. Congressional Joint Economic Committee estimates that if this investment yields medical advances that give rise to at least a 10% increase in longevity, U.S. citizens will realize a $240 billion return on their tax payer investment.[142] When examining a specific sector of technology experiencing rapid acceleration of growth, such as genetic engineering, the U.S. Department of Health and Human Services, the University of California, and the private company Genentech were the top three patentees between 1977 and 1997.[143] In a report to Congress in 2001, the NIH made the following remarks which shed light on the overall effect this has had on the U.S.:

> Current practices in technology transfer have yielded a dramatic return to the taxpayer through the discovery of new technologies that extend life and improve the quality of life and through the development of products that, without the successful public-private relationship, might not be available. The transfer of federally funded technology has also resulted in financial returns from licensing activity, and such funds are used to buttress the biomedical research enterprise that has made the U.S. the world leader in this field.[144]

This report mentions several qualitative factors such as benefits to research, introduction into the market of life-saving technology, and other benefits to

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http://www.provendis.info/home/downs/AUTMFY1999Survey.pdf).

[138] AUTM FY 2000 Survey, *supra* n. 4, at 7.

[139] Agres, *supra* n. 18, at ¶ 9.

[140] AUTM FY 2000 Survey, *supra* n. 4, at 1.

[141] Data taken from the National Institutes of Health website, http://www.nih.gov/about/ (last visited February 23, 2005).

[142] Dan Vergano, *Money Alters Scientific Formula; Profiting From Research is Here to Stay, but Ethics Questions Still Linger*, USA Today D5 (May 13, 2002).

[143] European Commission, *Report from the Commission to the European Parliament and Council – An Assessment of the Implications for Basic Genetic Engineering Research of Failure to Publish, or Late Publication of, Papers on Subjects Which Could be Patentable as Required Under Article 16(b) of Directive 98/44/EC on the Legal Protection of Biotechnological Inventions*, Commission of the European Communities, Preparatory Acts (January 14, 2002) (available at http://www.stepc.gr/~katharak/ BIOTECH_PAT_EUROPE_REP_EUR_PARL.pdf).

[144] AUTM FY 2000 Survey, *supra* n. 4, at third introductory page.

the general public.

Prior to the BDA, university researchers who investigated technologies wholly owned by private industry faced two hard decisions. The investigator either had to pay monopoly fees to the private industry to obtain the rights to use the material under investigation (but if large quantities were needed, the cost could exceed the funds available for research), or pursue the research in some other related but different field. Today, under the BDA, private industries can partner with the university laboratory to fund a joint project, allowing investigation and continued discovery through basic research using the protected technology.

The AUTM FY 2000 survey lists several unique and novel inventions brought to market and made available to the public through use of BDA provisions.[145] This provides only a mere sampling of the myriad of potentially life-saving and life-extending technologies that have made it to market through the BDA provisions. In fiscal year 2000 alone, 347 new products were introduced into the market.[146] It is difficult, considering the history of under-utilization of public funded research, to make the blanket statement that these discoveries would have yielded marketable and useful "industrial arts" despite the passage of the BDA. Legal scholars comment on the need for the patent system to incentivise the innovation process. The following famous passage from Kaempffert's writings is illustrative of this concept:

> To be sure, inventors long for wealth. So do poets. But the patent laws are no more responsible for great inventions than are copyright laws for great poems. Watt was no more impelled by the desire to make money when he invented the separate condenser than Milton was impelled to earn the equivalent of twenty-five dollars by writing Paradise lost.[147]

In this case, the investigator, Watt, certainly discovered the condenser innovation.[148] But, he also expended eleven years, and *sixty* man years of labor, to perfect his product - an operational steam engine.[149] It is doubtful that Watt would have proceeded with this project without the promise of a patent because, in order to raise capital for such ventures, investors want some assurance that there is a possibility for recouping the

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[145] *Id*. at 1.
[146] *Id*.
[147] Kaufer, *supra* n. 15, at 241 (citing W. Kaempffert, *Invention and Society*, p. 19 (Chicago, 1930)).
[148] *Id*.
[149] *Id.*

investment. Patents afford this assurance.[150]

Universities are academically enriched through interaction with the private industry. Scientific studies that may not have otherwise been performed are now possible. Investigators are enriched through increased interactions between fellow scientists, stimulating discussion, and thought. The old adage still holds true today: two brains are better than one.[151] Prior to the BDA, communication was basically only one-way; research results were on uni-dimensional trajectories where they were all abandoned to the public domain. Now, there can be a cross-pollination in which results are shared. This cross-talk can potentially spawn new projects. The universities' reputations also benefit when their scientists are courted throughout the world for their expertise. Students at the universities benefit by having the opportunity to gain superior training and potential advanced placement in industry through contacts and establishment of a reputation within specific projects. Industries benefit in many ways from these interactions as well. "[S]uch partnerships can offer: (1) access to advanced academic research, expertise, and prestige; and (2) opportunities for recruiting highly-qualified students."[152]

The AUTM study reveals many positive impacts on the U.S. economy, including the creation of hundreds of thousands of new, high-technology jobs.[153] There are billions of dollars in revenue gained from these interactions.[154] Proponents of the BDA claim these moneys represent tax payer dollars being recouped and recycled to provide even more research results.[155] The public, after all, benefits from these innovations in many ways, including extended life and increased quality of life.[156] This in turn relieves the strain on the U.S. healthcare system, saving more tax payer money.[157]

Within the biomedical field, there are other positive factors, including time saving measures to industry and a stronger focus on research targeted at curing disease. Pharmaceutical products developed through collaborative studies with universities are perceived to be higher in quality than those not developed through these collaborations.[158] The autonomy

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[150] *Id.*
[151] Kaufer, *supra* n. 13, at 22.
[152] Joshua A. Newberg and Richard L. Dunn, *Keeping Secrets In The Campus Lab: Law, Values And Rules Of Engagement For Industry-University R&D Partnerships*, 39 Am. Bus. L.J. 187, 197 (2002).
[153] AUTM FY 2000 Survey, *supra* n. 4, at second introductory page.
[154] *Id*. at 1.
[155] *Id*. at third introductory page (citing the National Institutes of Health, *A Plan to Assure Protection of Taxpayers Interest* (August, 2001)).
[156] *Id*. at third introductory page.
[157] *Id*.
[158] *Id*.

the public university setting provides its investigators and the participation of fellow colleagues on government review boards involved in approving such products correlate to a greater trust in the data behind the products seeking approval.[159] Autonomous peer review of such products provides objective safety measures assuring only safe and effective products make it to the public.[160]

During the recession years of the 1980's, the NIH began to place an increased focus on allotting research dollars to those projects targeted to curing specific diseases. The emphasis became more pronounced in later years when the NIH was concerned with effectuating its mission of winning the war against disease.[161] The war against cancer became a major focus of millions of dollars in funding. Any scientist wishing to perform basic science[162] research needed to in some way or manner link their studies to a system involved in an important disease to ensure funding approval. This is still true today. Private industry, whose major motivation is profit, helps scientists to apply their research more directly to curing specific diseases by developing specific products.

The AUTM FY 2000 survey also highlights the steady acceleration of universities that take financial interests in start-up companies. These start-up companies are usually based on more risky, "forward-looking ideas" that would otherwise find it hard to establish funding.[163] In 2000 alone there were 372 start-up companies reported in which universities held equity.[164] This represents a significant increase from the prior year, and the trend is expected to continue. One report states "the amount of the licensee's stock for early-stage life science companies is generally in the range of 1% to 10% of the stock outstanding at the time of the license grant" in these start-up companies.[165] Investment in these start-up companies, while appearing to be risky, can substantially benefit the public because these "forward-looking" projects often yield large leaps in technological innovation.[166]

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[159] *Id*. at fifth introductory page.
[160] *Id*. at 17.
[161] H.R. Sci. Comm., *National Science Policy Study, Part V: The Irreplaceable Federal Role in Funding Basic Scientific Research*, 105th Cong. 42 (April 22, 1998). Rep. Lynn Rivers (MI) states that there has been "a continuous and real erosion for funding for basic research in this country over the last 10 or 15 years" (indicating that the U.S. is not funding basic research "to the degree that we used to"). *Id*.
[162] In scientist lingo, "basic science" research is that research which, on its face, does not seem aimed at any particular practical application, such as the study of rings coffee mugs leave behind on counter tops or whether running in rain versus walking keeps you drier, *etc*.
[163] AUTM FY 2000 Survey, *supra* n. 4, at 14.
[164] *Id.* at 15.
[165] Knox Bell, *Win/Win Licensing: University to Biotechnology Company*, 22 Biotechnology L. Rep. 9, 14 (Feb. 2003).
[166] AUTM FY 2000 Survey, *supra* n. 4, at 14.

2. Negative Effects of the BDA

Scholars criticize the BDA for several reasons: potential compromise of ethical standards in application of the scientific method and administrative implementation of the Act itself, the potential for financial and personal interests to conflict with use of sound research techniques, and potential delays in publishing (because competitors need to keep their inventions secret to maintain the competitive edge.)[167] Scholars also criticize the negative impact of motivating scientists to perform more applied research instead of basic theoretical research, and the vulnerability caused by the potential dependence of academia on industry.[168]

Other scholars posit that the BDA is really not making any money at all. Lawyer fees in 2000 alone were $142 million.[169] From 1985-1994, the NIH collected $76 million in royalties.[170] While this may appear to be a large sum, when compared to the rest of NIH's budget, it represents "less than 1% of NIH's intramural funding during this time period."[171] Careful analysis of the $1.26 billion figure provided by AUTM, in concert with accompanying relevant data, reveals that the universities really are not making large profits above operating costs.[172]

Some critics feel that, if the U.S. thinks it needs legislation like the BDA, then there is a basic misunderstanding of our entire intellectual property rights system. In the past, the motivation for innovation came from "the system of property rights which evolved in mutual dependence with the process of economic development and change."[173] Thus, if the government needs to provide new specific incentives to innovate, there must be a sort-of "evolutionary deficit."[174] Defining this deficit should be

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[167] Peter J. Harrington, *Faculty Conflicts Of Interest In An Age of Academic Entrepreneurialism: An Analysis of the Problem, The Law and Selected University Policies*, 27 J.C. & U.L., 779, 787-88 (2001).
[168] *Id*.
[169] AUTM FY 2000 Survey, *supra* n. 4, at 9.
[170] *Id*.
[171] Arno & Davis, *supra* n. 3, at 640 (citing National Institutes of Health, *Technology Transfer Activities FY1993- FY1999* (http://ott.od.nih.gov/newpages/webstats99.pdf) (accessed Nov. 18, 2004)).
[172] Eisenberg, *supra* n. 3, at 1713. Professor Eisenberg's calculations are reproduced here for clarification: "For FY 1994, AUTM United States university members reported collecting $265,932,578 in gross royalties received, paying $20,747,204 in royalties to other institutions, and expending $53,345,200 in legal fees, of which $25,600,573 were reimbursed. Id. at 28 attachment F. Subtracting royalties paid from royalties collected, and further subtracting unreimbursed legal fees, yields a net royalty figure of approximately $217 million, before subtracting internal operating costs. No data are provided on these internal costs, but AUTM reports that the U.S. university respondents employed 595.67 full-time professional equivalents and 440.41 staff support full-time equivalents. Id. at 19 attachment D. Dividing the net royalty figure calculated above by an aggregate staff of 1036 full-time equivalents (over half of which are professionals) yields net revenues of approximately $209,459.50 per staff member nationwide, before subtracting such costs as salaries, benefits, office space, and the like." *Id*.
[173] Kaufer, *supra* n. 15, at 233.
[174] *Id*.

the main focal point of remedying the problem. Perhaps the BDA is merely acting as a "band-aid" by only treating the symptoms of the problem rather than the deep-rooted cause itself.

Additionally, there is intense concern about U.S. citizens being "billed twice" as they must pay through taxes for government funded research, and then pay again for increased costs in prescription drugs due to licensing fees passed on to the consumer through the industries engaged in research projects with universities.[175] Some argue wholesale transfer of rights to the private sector without proper or adequate policing results in very little royalty returns and increased costs to consumers who must now pay monopoly prices for the goods derived from these agreements.[176] The "taxpayers must pay twice" fear is rationalized as follows: once private industry obtains the rights to the intellectual property developed with taxpayer funds, private industry companies owning the rights will charge higher prices for the commercial goods stemming from these rights in order to pay the royalty fees imposed by the BDA.[177] These companies may charge even more because they now own a monopoly. The taxpayer must pay not only for the development of the basic research, but also for the commercialization, royalties, and monopolistic advantages provided by the system. The lack of oversight is argued to produce other negative qualitative factors. Only a very small percentage of BDA patents contain the required BDA statement regarding Government funding.[178]

Joshua Kalkstein, Senior Corporate Counsel-Research for Pfizer, Inc., suggests that universities should lean more towards non-exclusive licensing.[179] He also counsels that universities have the ability to enter into both exclusive and non-exclusive licenses simultaneously. The problem with exclusive licenses is the licensees are viewed as hording inventions without letting other respectable researchers utilize the technology in other ways. This exclusivity can be a limiting problem; keeping the government from maximizing the use of the technology it has. Kalkstein goes on to say, "It is deplorable that some types of research tools, previously easily

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[175] Eisenberg, *supra* n. 3, at 1666.
[176] Arno & Davis, *supra* n. 3, at 640-41.
[177] Eisenberg, *supra* n. 3, at 1667.
[178] *Id*. at 648-49 (citing: H.R. Subcomm. on Regulation, Bus. Opportunities, & Tech. of the House Comm. on Small Bus., *Underreporting Federal Involvement in New Technologies Developed at Scripps Research Institute, Hearings of H.R.XX* 103d Cong. 104 (1994)). *See* 35 U.S.C. 202(c)(6), requiring contractors who receive government funding for research and who file a patent applications on behalf of the United States to include within the specification of the application a statement specifying that funding for the invention was received from the U.S. Government. 35 U,S.C. § 202(c)(6) (2004); *See also* The Manual of Patent Examining Procedure, § 310.
[179] Joshua A. Kalkstein, *Who Should Be Licensed Under the Bayh-Dole Act?*, 431 P.L.I., Patents, Copyrights, Trademarks, and Literary Property Course Handbook Series 287, 290 (March 1996).

available to all, are now the subject of restrictive licensing practices."[180] The AUTM survey reports that 90% of licenses executed in 2000 were exclusive.[181]

Because the information is sometimes considered proprietary, an increase in patenting and protection of these innovations may lead to more barriers for scientists who wish to collaborate.[182] Professor Eisenberg remarks that such withholding of information "threatens to impoverish the public domain of research science that has long been an important resource for researchers in both the public and private sectors."[183]

Some feel the increased dependence of academia on industry ties and private funding can make the academic system, as a whole, more vulnerable to manipulation. Around 1924, one of the earliest criticisms of such arrangements between private and public parties was expressed. It was then feared that these arrangements would motivate researchers to "work only on those ideas that appeared to have commercial potential."[184] Academic institutions pride themselves on their autonomy from politics and favoritism. They are held up as bastions of objectivity. Scientific research projects are directed by professors who hold tenure. Tenure affords professors the protection to say and publish what they want and to choose to perform research in the area of study they wish without fear of retribution from administration, who may be motivated by other factors.

Apparently, this system is turned on its head by allowing the very same investigators to now collaborate with private industry, whose motivations are singular and non-objective. These interactions have the propensity to be manipulated both at the scientific level and the administrative level. A 1985 study showed "faculty who received industrial support were much more likely than other biotechnology faculty to report that their research had resulted in trade secrets and that commercial considerations had influenced their choice of research projects."[185]

Peter J. Harrington, Associate General Counsel for UMass Memorial Health Care, describes conflicts of interest as "situations in which financial or other personal considerations may compromise, or have the appearance of compromising, an investigator's professional judgment in conducting or reporting research."[186] Harrington further summarizes the

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[180] *Id*.
[181] AUTM FY 2000 Survey, *supra* n. 4, at 10.
[182] Harrington, *supra* n. 168, at 775, 779.
[183] Eisenberg, *supra* n. 3, at 1667.
[184] Bloom, *supra* n. 3, at 208.
[185] Harrington, *supra* n. 168, at 782 (discussing David Blumenthal, et al., *Relationships Between Academic Institutions and Industry in the Life Sciences*, 334 New Eng. J. Med. 368 (1996)).
[186] *Id*. at 787.

potential conflicts of interest into three general categories: (1) potential for private industry collaborator to manipulate the academic scientist's objective choice of "technical approach" (types of experiments chosen to complete the project); (2) potential for proprietary concerns to effect the academic scientist's natural need for free and open discussion of the data, not only with the rest of the scientific community, but also with their own students and other laboratory personnel; and (3) potential for the industrial sponsor to further influence the academic scientist's "choice of, or approach to, future research."[187] Additionally, conflicts of interest arise when university scientists stand to gain financially from the research project depending on the outcome of the experiments.[188]

Other conflicts include conflicts of personal time management of the academic researcher. Professors are in involved in a myriad of duties including teaching, tutoring graduate students, overseeing as many as a dozen research projects, committee commitments, and responsibilities of obtaining funding. Adding the extra dimension of overseeing privately-funded research to all these responsibilities may be too burdensome for some, requiring them to neglect one or more of their other duties to the university system.[189] The potential loss of objectivity so carefully guarded by the academic institution is the ultimate sacrifice arising from potential conflict of interest issues.[190] This loss in perceived objectivity may cause the general public to discontinue its belief in the results of academic research and cause reluctance to follow advice arising from research results. Additionally, there is fear that collaborations between private and public parties will result in delayed publishing of scientific research results or even withholding of these results entirely.

Finally, there are those that proclaim the many rules and regulations stipulated by the BDA and its attending regulatory statutes are too burdensome for private industry and actually effectuate the opposite of its intention. These regulations, while well-defined, are set in stone and non-negotiable.[191] Contracts derived from the BDA provisions require time for execution and layers of government administrative approval to process.

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[187] *Id.* at 788.
[188] *Id.* at 776.
[189] *Id*.
[190] *Id.* at 779.
[191] Sidebottom, *supra* n. 3, at 233, 234 (discussing Debra Van Opstal, *Integrating Civilian and Military Technologies: An Industry Survey, An Interim Report from the CSIS Integrating Commercial and Military Technologies for National Strength Project*, in *Center For Strategic & International Studies* 12 (Dec. 1993)).

III. DISCUSSION

Determination of the effect of the BDA on the U.S. requires a balancing of the goods it hoped to accomplish against the evils it may cause. This experiment is not designed well enough to yield a clear cut, yes or no, conclusion. Thus, the conclusion must be based on something less than quantitative and, instead, will depend on the weight each individual person places on various aspects of the factors involved. Moreover, the power and dominance of the U.S. in certain technology markets brought about through the contributions of the BDA is associated with many benefits that can be difficult to assess.

Quantitative conclusions from a comparison of the negative control samples with the experimental sample (U.S.) are somewhat more clear cut. The numbers reveal a stark contrast in research economies. The two largest licensing/royalty income powerhouses in U.S. academia are Columbia University and the University of California. These two institutions alone brought in $400 million in royalties and licensing deals in 2000, according to the Association of University Technology Managers Licensing Survey.[192] The average U.S. academic institution brought in about $4 million in the same year.[193] In contrast, no European academic institution brought in more than $2 million.[194] Compared with over 12,000 patent disclosures in 1999 for U.S. universities, European counterparts will patent approximately six or seven inventions per year per institution.[195]

Yet, direct comparisons between negative European sample countries and the U.S. are hard to make due to the differences in funding between the two regions. For instance, the European Union has approximately 3300 universities, whereas the U.S. has over 4000.[196] In the U.S., 550 of these universities issue doctorates, 125 are "research universities, and 50 "account for the lion's share of American academic research capacity, public funding in support of university research and the country's Nobel prizes for science."[197] The U.S. investment in higher education amounts to roughly 2.3% of its GDP, whereas the European Union only spends 1.1%.[198] The EU chalks this up to lack of private funding (0.2% in EU, 1.2% in USA).[199] Half of the European citizens who attend school in the U.S. stay for several years, but many of them do not

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[192] AUTM FY 2000 Survey, *supra* n. 4, at 12.
[193] *Id*.
[194] *Id*.
[195] Agres, *supra* n. 18, at ¶ 13.
[196] European Union Prep. Acts, *Communication from the Commission – The Role of the Universities in the Europe of Knowledge* § 3.2[9] (Ellis 2003) (available on Westlaw).
[197] *Id*.
[198] *Id*.
[199] *Id*. at § 5.1 [23].

return.[200] "[T]he budget for the National Institutes of Health (NIH) in 2001 is 50 times the amount the EU is planning in its Framework Programme for biomedical research for the next 5 years."[201]

On average, though several countries seem to be well on their way to optimizing the use of their research innovation rewards, these countries' new legislation and approaches still have "complicated and limited the transfer of technology and transnational cooperation."[202] Europe may not be able to fix these problems very quickly. Some countries are enacting BDA-like legislation, but the legislation is too diverse, sporadic, and imprecise to allow for the full effect observed in the U.S.[203] Furthermore, "European universities generally have less to offer and lower financial resources than their equivalents in the other developed countries, particularly the USA."[204] The infrastructure needed to capitalize on research results from universities and other government institutions does not appear to be at the required level of competency needed to make investing worthwhile.[205] Europe is finally beginning to realize that, "[t]hrowing knowledge over university walls and hoping for the best is not now perceived as sufficient to encourage the application of that knowledge for economic and social benefit."[206] The European Commission states, "[f]rom a competitiveness perspective it is vital that knowledge flows from universities into business and society."[207] AUTM reports that international membership is increasing at a pace faster than any other membership segment.[208]

There are scholars who downplay the overall effect the BDA has had on the U.S. These scholars contend federally funded research can be harvested without the enactment of the new legislation.[209] Further, these scholars propose that the enormous financial gains are due to increases in government funding of basic biomedical research starting in the 1960's, a shift to a more favorable disposition towards patent rights in the judicial system, legislative action to strengthen intellectual property rights, and

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[200] *Id*.
[201] Brian Ager, *Industrial Concerns with Respect to European Pharmaceutical Policy*, *European Federation of Pharmaceutical Industries and Associations*, http://www.efpia.org/5_conf/AgerEuropfiles.pdf (accessed April 23, 2003).
[202] European Union Prep. Acts, *supra* n. 199, at § 5.1.3 [27].
[203] *See generally* European Union Prep. Acts, *supra* n. 199.
[204] *Id*. at § 2 [2].
[205] A.F., *Education - Commission Launches Debate On Future Of Universities* (European Report 2003).
[206] Commission On Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy*, http://www.iprcommission.org/papers/pdfs/final_report/Ch6final.pdf, 123 (accessed April 17, 2003).
[207] European Union Prep. Acts, *supra* n. 199, at § 3.3 [14].
[208] AUTM FY 2000 Survey, *supra* n. 4, at first introductory page.
[209] *See* Vergano, *supra* n. 143.

government efforts to push for favorable intellectual protection overseas.[210]

As the debate simmers, with proponents and opponents staunchly entrenched in their own beliefs and fears about whether or not the BDA approach is good for the U.S., the rest of the world is apparently taking notice. Why? Because financially, there is so much at stake. Almost as a mirror to the public debate about the evils and benefits of the Act, European countries and others are enacting or have already enacted legislation that either parallels, or contradicts the BDA. Kerry Capell, in a recent article in Business Week, aptly summarizes some of the worst fears of some European countries by placing in stark contrast the following facts: (1) Novartis, a large pharmaceutical company in Switzerland, announced that it is building a new research and development center in Cambridge, MA to the tune of $250 million; and (2) a day later the European Commission released "a damning report on the state of the European drug industry."[211] In widely cited and well-known - but still frightening - statistics, it is maintained that European investment in overseas R&D catapulted from 27% in 1990 to 41% in 1999.[212] Capell states nobody is really surprised by the European Commission's conclusions.[213] She cites senior vice-president of Cambridge Pharma Consultancy, Barrie James, as saying, "[y]ou can almost hear the sucking sound as all the money goes across the pond . . . ."[214] Investments in pharmaceuticals, in particular, doubled parallel investments in Europe (*e.g.* investments during the 1990's increased by five fold in the U.S., but only half that rate in Europe).[215]

Qualitatively, however, there appear to be some very crucial negative factors to resolve. Concern about publishing, though, may not be as troubling as it first appears. Private industry also has a motivation to publish early and publish often. Private companies do this to provide "market signaling" strategies which help to attract top level scientists, alert competitors regarding the areas the company is going into, and to gain respect from competitors and peers. In Europe, a recent study showed "only a small fraction of researchers and organizations [who] actually experience a considerable delay in publication of research results that are the subject of a patent application . . . ."[216] Investigators at universities

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[210] Mowery, Nelson, Sampat & Ziedonis, *supra* n. 46, at 3. The authors subject three U.S. universities that reported the highest licensing and royalty income in the 1990's to strict empirical analysis to determine what effect, if any, the BDA had on the universities' research programs.
[211] Kerry Capell, *How Europe Could Cure Its Ailing Drugmakers*, Bus. Wk. 58 (May 27, 2002).
[212] Kerry Capell & Pharmaceutical Research and Manufacturers of America, *Pharmaceutical Industry Profile 2002*, Biomedical Mkt. Newsl. 51 (July 31, 2002).
[213] Capell, *supra*, n. 215.
[214] Capell, *supra* n. 215, at 1.
[215] Brian Ager, *Industrial Concerns with Respect to European Pharmaceutical Policy* 3 (available at http://www.efpia.org/5_conf/agerspeech.pdf) (last accessed February 23, 2005).
[216] European Commission, *supra* n. 144, at 4.

publish their results in peer-reviewed journals. There already exists a built-in publication delay in the current research system. Furthermore, academic investigators must regularly make decisions regarding which research to place in peer-reviewed manuscripts and when to submit these manuscripts for publication. Delays in publication may be caused by any number of reasons, not the least of which is the desire to withhold research results for the purpose of trumping other academic competitors by publishing the most groundbreaking results first. A recent review reports that "there have been very few documented cases of important collaborative research results being held in secret to the detriment of the academy or the public-at-large."[217]

The potential manipulation of the academic research community is a frightening prospect. However, "although industry support of university research has been increasing rapidly in recent years, it still amounts to just seven percent of all university R&D expenditures."[218] Furthermore, academic scientists already have financial incentives in place that give them potentially conflicting motivations in the laboratory. In order to be successful, investigators require funding. Funding is most often obtained through grants from the government or non-profit organizations. The best way to assure continued funding for research projects and continued employment is to show successful results in the laboratory. These financial incentives have been in place since the government began funding research in 1950.[219]

The taxpayer penalty on royalties is also a significant negative detractor from proponents of the BDA. It may help to consider, however, who pays this extra "tax." For instance, if a new drug is developed to fight a specific disease through collaboration between government and private industry, the people buying these new drugs are those that most directly benefit from the research. Therefore, although the tax on the public may appear burdensome, it is a very specific and targeted tax.

IV. CONCLUSION

At a minimum, the translation of academic, publicly funded research into commercial applications is a very important issue to our U.S. economy. The survey of countries included in this report is representative

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[217] Newberg & Dunn, *supra* n. 153, at 215 (citing David Blumenthal et al., *Withholding Research Results in Academic Life Science: Evidence From a National Survey of Faculty*, 277 JAMA 1224, 1227 (1997), which concludes on the basis of a national survey of 2167 life science academics: "our findings suggest that data withholding is not widespread").
[218] Newberg & Dunn, *supra* n. 153, at 215.
[219] Eisenberg, *supra* n. 3, at 1671-72.

of issues being debated and actions being taken by countries across the globe. There is no doubt that in the near future, every country will be forced to reconsider their intellectual property laws and how they either hinder or enable competition with the U.S. market. Foreign nations see this type of legislation as the extra incentive their country needs to better compete with their neighbors and the U.S. in the global economy.[220] If nations like Germany, the UK, and Denmark continue to lag behind in commercialization of research innovations, they must consider whether altering the patent rights regime between researcher and institution was not the path to take.

Could so many countries seeking to follow the U.S., and so many people debating this national experiment, be so incorrect about the apparent positive effects the BDA has had on the U.S. research economy? In weighing the potential benefits to a country's economy - both in terms of jobs and property - against the potential negative side-effects, the consensus is very clear: most countries are choosing to follow in the Bayh-Dole Act's footsteps, importing the Bayh-Dole Act for its perceived positive impact on the economy.

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[220] Thors Astrid, *Written Question P-0959/02 by Astrid Thors (ELDR) to the Commission. Researchers' right to inventions*, 2002 O.J. C 229, 0165-0166 (2002) (recommending adoption of measures to clarify "the rules on the right to inventions made at universities").