Patents and Technological Innovation: Issues and Opportunities

Margo Bagley*

*University of Virginia School of Law, mbagley@virginia.edu
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Abstract

This book chapter, designed for use in the TI:GER (Technological Innovation Generating Economic Results) program, discusses some of the current issues raised by the use of patents in technology commercialization. After introducing how patent laws operate in the global marketplace the chapter provides an overview of the U.S. patent system, describing aspects of the process by which patents are obtained and enforced. The focus of the chapter then turns to some of the benefits and costs to academia of the impact of the Bayh-Dole Act, which allows universities to capture returns from federally-funded research. The chapter identifies some of the challenges created by the expanding scope of subject matter eligible for patent protection and concludes with a discussion of some of the issues and opportunities associated with the strategic licensing and enforcement of patents that may impact invention and innovation in the academy and beyond.
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Introduction

In June 2006, Research in Motion, Inc., maker of the Blackberry® handheld device, agreed to pay NTP, Inc. $612.5 million to settle a patent infringement suit that threatened to shut down its Blackberry® service. In 2004, Microsoft Corp. was ordered to pay Eolas Technologies $521 million in patent infringement damages. After the U.S. Court of Appeals for the Federal Circuit’s (“CAFC”) decision in 2000 that Eli Lilly’s patent on Prozac was invalid, shareholders dumped $36 billion in Lilly stock, roughly a third of the pharmaceutical giant’s market capitalization. In the NTP and Eolas cases the patent holder had not commercialized the patented technology. Nevertheless, the innovative use of the technology in each case exposed the respective defendant to significant financial liability. These are just a few examples of the power of patent protection to create issues and opportunities for inventors, innovators, and the consuming public.

In the university context patents can have considerable significance. As licensor of the patent on which Eolas sued, the University of California is set to receive 25% of the $521 million judgment against Microsoft. In fiscal year 2004 alone, approximately 154 U.S. universities reaped over $1 billion in net patent licensing income, and executed 3928 new licenses, largely as a result of university-industry technology transfer initiatives (Stevens, 2005). Moreover, in 2005, Emory University announced its $525 million sale of intellectual property, considered to be the largest such sale in the history of American higher education (Press Release, 2005).
Such statistics are made possible by patents on university-generated research which allow for the creation of revenue for university coffers, stimulate economic growth in surrounding municipalities, and provide beneficial products to consumers around the world. For example, the Wisconsin Alumni Research Foundation (“WARF”), which handles technology transfer for the University of Wisconsin-Madison, has contributed approximately $750 million to fund basic research at the university over the past 80 years (Gulbrandsen, 2005).

Not surprisingly, the power potential of patents causes them to be both very popular and very controversial in the university context and beyond. Recent studies of the patent system by the National Academy of Science and the Federal Trade Commission, and even testimony by the head of the United States Patent & Trademark Office (“USPTO”) in congressional hearings, highlight strengths and flaws in a system that some say is in crisis (Merrill, Levin, & Myers, 2004; Federal Trade Commission, 2003; Dudas, 2005). This chapter provides a brief overview of the global and U.S. patent systems and considers some of the current issues relating to the promise and peril of patents, with a particular focus on their use in the commercialization of university-generated research.

The Global Patent System

Patent law historically has been territorial in nature, with sovereign states granting patents and providing means for patentees to enforce their rights only within their borders. Treaties pertaining to patents have generally taken one of two forms: procedural or substantive. Procedural treaties generally make it easier for applicant’s to obtain patent protection in other countries by, for example, limiting protectionist actions by member countries. Substantive
treaties generally require member countries to provide minimum levels and types of protection for patent holders thus increasing the value of patents internationally.

The two most important procedural treaties are the Paris Convention for the Protection of Industrial Property and the Patent Cooperation Treaty, both administered by the World Intellectual Property Organization ("WIPO"), a United Nations agency. The Paris Convention, first signed in 1886, is the oldest intellectual property treaty and provides the key benefits of national treatment and a right of priority. "National Treatment" means that if a member has a patent system, it must provide patent rights to foreign applicants on the same terms as it provides them to domestic applicants. The right of priority gives an applicant in a first member country the right to file a patent application in other member countries within one year of her initial filing date and have those later filings treated as if they were filed on the date of the first application, essentially giving applicants more time to determine where they would like to seek patent protection. The Patent Cooperation Treaty extends the Paris Convention right of priority out to 30 months, giving applicants even more time to evaluate the commercial potential and likely markets for the invention and to generate capital that can be used to pay the often expensive costs of prosecuting patent applications in multiple countries.

The most significant substantive intellectual property treaty is the Agreement on Trade Related Aspects of Intellectual Property ("the TRIPs agreement"), an annex to the World Trade Organization ("WTO") agreement negotiated during the Uruguay Round of the General Agreement on Tariffs and Trade ("GATT") in 1994. The patent provisions of the TRIPS agreement raised the level and scope of protection for patents in many countries by requiring member countries to provide a minimum 20 year patent term from filing, patent protection for
inventions in all areas of technology (with limited exceptions), and a variety of remedies and enforcement protections for patent owners.

The TRIPS agreement is controversial, in part because 75% of the member countries of the WTO are developing or least developed countries, most of which do not have highly developed R&D infrastructures. As a result, many patents in such countries are obtained by foreigners, increasing prices for domestic consumers and resulting in a flow of money out of the country to those foreign patent holders. Even more troubling, many of the developing country members are plagued by a variety of public health challenges such as HIV/AIDS, and a high incidence of chronic diseases such as diabetes. Among other things, the TRIPS agreements’ limitations on the ability of countries to engage in compulsory licensing—authorizing third parties to practice the invention and pay a royalty without the consent of the patent holder—raised fears that countries might not be able to provide their citizens with affordable drugs. While a recent amendment to the TRIPS agreement was designed to address this concern, a variety of criticisms of the agreement remain.

In addition to these broad international treaties, there are also several regional treaties that allow an applicant to file one application with a central office and obtain patent protection in multiple countries. The most significant regional treaty is the Convention on the Grant of European Patents (“EPC”), signed in 1973 by a group of countries seeking to create a uniform European patent system. The EPC established the European Patent Office (“EPO”) and contains substantive and procedural requirements for obtaining a European patent, valid in all member countries with only a single application. However, the European patent that results is in actuality a bundle of national patents that still must be enforced in each country where infringement is taking place.
Having to enforce patents in multiple jurisdictions creates considerable uncertainty for patentees since the decisions of a court in one country are not binding on a court in another country. Thus the same patent could be found valid and infringed in one country and invalid and not infringed in a neighboring country. As a result, many patentees would prefer a global patent that could be obtained by filing a single application in one patent office, would cover all countries, and could be asserted in a single court proceeding against infringing activity in multiple countries. While there have been and will continue to be efforts to harmonize patent law, such as the ongoing negotiations at the World Intellectual Property Organization on the Substantive Patent Law Treaty, the many obstacles to such a system are too numerous to consider here. Suffice it to say that such a system, if it can be achieved at all, is likely a very long way off in the future.

**Patent Law Basics**

The substantial power a patent can allow its owner to wield has caused patents to be considered the “gold standard of intellectual property protection” (Schotchmer, 2004). Patents give their owners the right to exclude others from making, using, selling, offering to sell, or importing the patented invention for a term of about twenty years (35 United States Code §§ 271(a), 154). The U.S. patent statute provides for both injunctive relief, at the discretion of the court, and money damages for patent infringement. In addition, damages may be trebled for willful infringement (35 United States Code § 284).

Patent rights can be extremely lucrative and provide significant incentives both for inventors to create innovations that can be patented and for investors to fund research that may result in a patent. For example, WARF holds broad patents covering embryonic stem cells and
methods for producing them. While the validity of those patents is currently being challenged, if the claims survive intact, it is estimated that WARF could reap royalties of $200 million/year just from research performed under California’s Proposition 71 alone (Gallagher, 2005).

U.S. patent law actually provides for three different types of patents: utility patents, for useful, novel, and non-obvious machines, compositions of matter, articles of manufacture, and processes, design patents covering novel and non-obvious ornamental designs for articles of manufacture, and plant patents, covering new and distinct asexually reproducible (i.e., non-seed reproduction such as by budding or grafting) plants (35 United States Code §§ 101, 156, 161). Utility patents are the most common, with the USPTO having issued over 7 million of them, compared to ~500 thousand design patents and ~16 thousand plant patents. As such, the word “patent” in the remainder of this chapter will refer to utility patents unless otherwise noted.

More generally, the word “patent” is used to denote to both the public document in which an invention is disclosed and the bundle of intangible rights granted by the federal government to an inventor in exchange for the disclosure of his or her invention to the public. This federal system of invention promotion and disclosure has been in place since the 1790 Patent Act, created by the first Congress pursuant to Article I, § 8, cl. 8 of the U.S. Constitution which authorizes Congress “to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.”

Although the exclusionary power of patents is anticompetitive, patents co-exist quite peaceably with the antitrust laws. In fact, guidelines promulgated by the U.S. Department of Justice (DOJ/FTC Guidelines, 1995), which polices antitrust violations, articulate some of the perceived benefits of patents and other types of intellectual property:
The intellectual property laws and the antitrust laws share the common purpose of promoting innovation and enhancing consumer welfare. The intellectual property laws provide incentives for innovation and its dissemination and commercialization by establishing enforceable property rights for the creators of new and useful products, more efficient processes, and original works of expression. In the absence of intellectual property rights, imitators could more rapidly exploit the efforts of innovators and investors without compensation. Rapid imitation would reduce the commercial value of innovation and erode incentives to invest, ultimately to the detriment of consumers.

Patents are important for encouraging both invention, the creation of new processes and objects, and innovation, which is involved in the process of commercializing inventions and introducing them to the marketplace. They provide incentives for parties to undertake expensive and risky research. Patents induce upfront funding of projects with the expectation that monopoly profits can be generated over the longer-term. They also encourage the disclosure of information that others can build upon in developing even more innovations. Patent licensing income can be an important component of a company’s bottom line: reported revenue from patent licensing topped $100 billion in 1998 (Rivette & Kline, 2000). It is no surprise that more and more applicants are filing patent applications on their discoveries than ever before.

To obtain a patent on an invention, an inventor must prepare and file an application disclosing and claiming the invention in the USPTO and participate in the prosecution of the application. Prosecution is the process by which the USPTO determines whether a patent should issue on an invention. While an inventor can choose to prepare, file and prosecute the
application *pro se*, many inventors choose to hire a patent attorney or patent agent to handle the process.

Both patent attorneys and patent agents have science or engineering backgrounds and are registered to represent clients before the USPTO, the difference between the two is that patent attorneys are also lawyers. While the patent application must be filed in the inventor’s name, for university and corporate researchers, the inventors generally will have assigned the ownership rights to their inventions to their employer as a condition of employment, and the employer will prosecute the application and enforce any resulting patent.

In the U.S. patents may only be granted for claims directed to new and useful processes, machines, articles of manufacture, and compositions of matter. These four subject matter categories are not mutually exclusive; an invention can be classifiable in more than one category. Likewise, an inventor need not specify which category his/her invention is properly classified in as long as it can be encompassed within one of the four.

Abstract ideas, natural phenomena, and laws of nature historically have been considered ineligible for patent protection. However, over the past twenty-five plus years these categories have been construed narrowly in the face of an unprecedented judicial expansion in the scope of patent eligible subject matter which has been deemed, by the United States Supreme Court, to include “anything under the sun that is made by man” (Diamond v. Chakrabarty, 447 U.S. 303, 313 (1980)). Thus, living organisms such as bacteria, transgenic animals, and plants, some of which could be considered natural phenomena, as well as computer software and business methods, some of which could be considered abstract ideas, now are all eligible for U.S. patent protection. 4
In addition to being of the right type, an invention must be novel and non-obvious to be patentable. To determine whether the requirements of novelty and non-obviousness are met, the claimed invention must be compared with the prior art. Prior art is defined in the U.S. patent statute and can be described as the body of information against which a claimed invention is compared in the determination of whether it is new and non-obvious. While applicants are not required to conduct a search of the prior art before filing a patent application, they do have a duty, throughout the pendency of the application, to inform the USPTO of information of which they are aware that may be material to the patentability of the invention. Failure to comply with this duty can result in the unenforceability of later patents issuing from an application in which inequitable conduct (i.e. violation of the duty) took place.

In the U.S., patent-defeating prior art can include printed publications from anywhere in the world, public knowledge or use of the invention in the U.S. before the applicant’s date of invention, or public use or sale in the U.S. more than one year before the patent application filing date. Thus an inventor can lose the right to obtain a potentially lucrative patent on an invention by publicly disclosing her invention, such as through presentation or publication, before filing a patent application.

The definition of a “printed publication” is very broad, and has been interpreted by courts to include microfilm, microfiche, internet postings, videotapes, and, most recently, slides affixed to poster boards, as long as they are publicly accessible. That latest expansion of the phrase was enunciated in the Court of Appeals for the Federal Circuit’s 2004 In Re Klopfenstein decision. For the first time, the court held that university researchers who presented study results at a scientific conference more than two years before filing a patent application covering the advance were barred from patenting the disclosed invention even though no copies of any enabling
document were distributed (In Re Klopfenstein, 380 F.3d 1345, 1352 (Fed. Cir. 2004)). The rejection was based on the fact that slides disclosing the later-claimed invention were displayed on posters at the conference for two and a half days without any notice that note-taking was prohibited. Thus researchers who engage in early public data-sharing of their results may jeopardize their ability to later patent findings if they do not track and control the timing, nature, and circumstances of their disclosures.

In most countries, an inventor creates prior art that will prevent her from later obtaining a patent on her invention if she discloses the invention to the public before filing a patent application. In the U.S., inventors have a one-year grace period in which they can disclose the invention to the public and still retain the right to obtain a patent on the invention. The grace period is an important policy tool that recognizes an inventor’s need to assess the commercial potential of an invention or engage in public academic discourse before making the decision to seek patent protection.

However, there are at least two problems with the current grace period for academic researchers. First, the lack of a one-year grace period in major foreign patent systems virtually eliminates the benefit of the U.S. grace period for inventors whose discoveries will require patent protection abroad to fulfill their commercial potential (Bagley, 2006). Second, even a one year grace period often is not long enough to accommodate the needs of many researchers due to the realities of academic research and technology transfer office (“TTO”) practices. It is not uncommon for more than a year to transpire before academic research progresses to the point where its commercial potential can be assessed effectively. University inventions tend to be at a very early stage when they are first disclosed to TTO personnel who generally have limited resources and data for making decisions about which inventions to attempt to patent (Thursby,
This situation is complicated by the propensity of TTOs to use provisional patent applications to save money while securing a priority filing date for university-generated inventions.

Introduced into U.S. law in 1995, provisional applications offer applicants a lower filing fee and an additional 12 months beyond the one year grace period in which to determine whether to file a regular non-provisional application for a patent. Provisional applications also protect an applicant’s right to file in other countries as long as the provisional application is filed before the invention is disclosed to the public. The provisional application is not examined by the USPTO, and will simply lapse after 12 months and have no further effect unless a regular non-provisional application is filed by that time.

Provisional applications are attractive to TTOs precisely because of the embryonic nature of most university inventions. Funding and staffing are perpetual problems for most university TTOs and provisional applications provide benefits in both areas. For a university, the filing fee for a provisional application in 2006 was $75.00 versus $500.00 for a non-provisional (regular) utility application. Moreover, since the provisional application will not be examined, TTOs may chose to spend less time and money on the drafting of the provisional application based on an understanding that in a year’s time, many will lapse because the covered technology will not justify (at the time the decision must be made) the cost of filing a further non-provisional application.

Evidence of the disproportionately higher use of provisional applications by university TTO’s can be seen in the Association of University Technology Managers (“AUTM”) annual survey. According to the survey, in fiscal year 2004, of the 8286 new U.S. utility applications filed by U.S. universities, hospitals and research institutes, 75% were provisional applications.
Conversely, the USPTO reports that provisional application filings for fiscal year 2004 only accounted for ~30% of total utility application filings across all applicants (USPTO Performance & Accountability Report, 2004).

U.S. law requires that patent applications filed in the USPTO must include an adequate written description of the invention that would enable a person of ordinary skill in the art to which the invention pertains to make and use the invention, and must disclose the best mode known to the inventor of practicing the invention (35 U.S.C §112). The application must also include claims that particularly point out and distinctly claim what the inventor considers to be her invention. The claims are the metes and bounds of the invention and define the inventor’s ultimate right to exclude once the patent issues.

If two inventors file applications in the USPTO claiming the same invention, the Office will generally initiate an interference proceeding to determine which of the applicants is the first inventor and thus is entitled to a patent on the claimed invention. Interferences are unique to U.S. patent law, since the patent systems of other countries award patents based on which applicant was the first to file an application claiming the invention in the relevant patent office, not on which applicant was the first to make the invention. Interference proceedings are priority contests in which claimants can put forward proofs to establish that they are the first inventor of the disputed subject matter and are entitled to the patent or that for some other reason the other party is not entitled to a patent. Patent reform legislation currently under consideration by Congress would change the U.S. patent system from first to invent to first inventor to file, eliminating interferences and bringing the U.S. system closer to that of other countries. Even if the U.S. moves to a first inventor to file regime, the first to invent rules will still have relevance in litigation involving any of the millions of patents issued under that system.
The terms “patented invention” and “claimed invention,” though commonly used, are somewhat misleading in that they suggest that each patent contains only one invention. While a patent may disclose one broad inventive concept, it will include as many inventions as it has claims because each claim defines an invention and the written disclosure, enablement, and best mode requirements must be met for each claim. In addition, the subject matter of each claim must be useful, novel (new), non-obvious to a person of ordinary skill in the art, and classifiable as a process, machine, article of manufacture, or composition of matter (35 United States Code §§ 101-103).

Once an application is filed in the USPTO it is examined for compliance with formal (e.g., proper fee, oath that applicant believes she is the true inventor) and substantive (e.g., novelty, non-obviousness) requirements. Prior to 2000, patent applications were maintained in secrecy by the USPTO until they were either abandoned or issued as patents. However, since 2000, the USPTO has been publishing patent applications 18 months after their earliest filing date in order to facilitate early disclosure of inventive information to the public. Applicant’s can still avoid having their applications published if they notify the USPTO that they will not file for patent protection on the same invention in a foreign country (35 United States Code §122).

The patent statute provides that an applicant is entitled to a patent unless the USPTO (through its examiners) can establish that she is not. Consequently, the burden is on the examiner, in the first instance, to show that a claimed invention fails to meet one or more statutory requirements. Once compliance with all requirements is established, a patent will issue from the USPTO. If compliance is not established, the applicant will have the opportunity to abandon the application or appeal the examiner’s rejection(s) to the Board of Patent Appeals and
Interferences and from there to the Court of Appeals for the Federal Circuit and ultimately to the United States Supreme Court. 7

While this process may seem fairly straightforward, it rarely is. Patent examiners routinely reject the claims initially filed in an application based on combinations of prior art references, usually patents or other published documents that, in the examiner’s view, disclose the claimed invention. The cycle of examiner rejections and applicant responses to rejections can go on for years and can easily consume tens of thousands or even hundreds of thousands of dollars before an examiner concludes a patent should issue on a claimed invention or the applicant either appeals or gives up and abandons the application. 8

After a patent issues, a patentee must pay escalating maintenance fees to the USPTO at four, seven, and eleven year intervals to keep the patent in force. An issued patent can also be the subject of a request for reexamination filed by the patentee or a third party. Anyone can file a request for the USPTO to reexamine a patent based on patents or printed publications that raise a substantial new question regarding the patentability of one or more patent claims. Filing the request does not guarantee that a patent will be reexamined; only if the USPTO determines that a substantial new question of patentability in fact has been presented will such a proceeding be initiated.

Once a patent issues, its owner can use it to exclude others from making, using, selling, offering to sell, or importing the patented invention for the term of the patent. Moreover, the patent has a presumption of validity, which means that clear and convincing evidence will be required to invalidate it. This standard has been criticized because of the perception that many patents issuing from the USPTO are of low quality and do not deserve the presumption. Critics trace patent quality problems to a variety of sources including a lowering of the non-obviousness
requirement for patentability and insufficient examination resources in the USPTO (Jaffe & Lerner, 2003). Examples of patents cited as emblematic of the problem include ones for a method of swinging on a swing, a crustless peanut butter and jelly sandwich, and an options pricing method well known to industry experts.9

In addition, as patentees have garnered large financial awards from enforcing their patents, interest in obtaining patents has increased. This confluence of factors has created a near-crisis situation at the USPTO where the backlog of applications awaiting examination exceeds 400,000 and is still climbing. In testimony before Congress in 2005, USPTO Director, Jon Dudas noted the following (Dudas, 2005):

Patent applications in the U.S. have more than doubled since 1992. . . .

[T]he USPTO issued more patents last year alone (173,000) than it did during the first 40 years of its existence. While the sheer volume of applications is staggering, the technical complexity of patent applications is escalating rapidly. In 1905, more than 1/3 of U.S. patent filings were bicycle related. Today, the USPTO routinely examines patent applications in areas such as nanotechnology, bioinformatics, and combinatorial chemistry—art areas that did not even exist one hundred years ago. Some patent applications are received on CD-ROMs, containing literally the equivalent of millions of pages of data on paper.

In 1982, Congress created the Court of Appeals for the Federal Circuit (“CAFC”) to hear appeals in all patent cases and bring uniformity to patent law.10 The CAFC is widely seen as having increased the lure of patents by strengthening and broadening patentee rights, upholding large damages awards, and lowering the standards for obtaining and enforcing patents. The result has been likened to “convert[ing] the weapon that a patent represents from something like
a handgun or a pocket knife into a bazooka, and then . . . handing out the bazookas to pretty much anyone who asked for one, despite the legal tests of novelty and non-obviousness.” As a result, it is now arguably “easier to get patents, easier to enforce patents against others, easier to get large financial awards from such enforcement, and harder for those accused of infringing patents to challenge the patent’s validity” (Jaffe & Lerner, 2003).

Not surprisingly, there also has been an increase in patent infringement litigation, and the cost of defending against such a suit, even if the patent is believed to be invalid, can be prohibitive. In 2001, the median cost of defending against a large ($25 million) patent infringement suit was $3 million (American Intellectual Property Law Association, 2001). While reexamination by the USPTO is a lower cost option available to third parties seeking to challenge a patent, the U.S. reexamination system is widely seen as deficient and inferior to, for example, an opposition system such as that used by the European Patent Office.

Several commentators have proposed the adoption of a post-grant opposition system in the U.S. to improve patent quality and lower the costs and uncertainty of the present system (Graham & Harhoff, 2006; Levin & Levin, 2002). Such a proceeding would allow challengers to oppose a granted patent on a more level playing field than in reexamination and at a lower cost than district court litigation. A patent reform bill under consideration by Congress at the time of this writing includes a post-grant opposition provision, but it remains to be seen whether such a system ultimately will be introduced in this country.

**Patents and Technology Transfer: The Bayh-Dole Act**

As noted earlier, universities obtain, license, and enforce patents on university-generated research and, as a result, are moving products from the lab bench to the marketplace. For
example, the website of the Association of University Technology Managers ("AUTM") contains a 25+ page listing of "product stories" describing successful university-generated products and programs.

However, these achievements have not come without a cost to academia. Historically, universities have existed for the purpose of promoting inquiry and advancing the sum of human knowledge. To further these goals, university researchers would publish and present their scientific findings as soon as possible in accordance with communal norms promoting the prompt and open sharing of data. But today, many academic researchers are being encouraged by TTO and industry sponsors to delay publishing and presenting their work until after filing a patent application and sometimes even longer than that (Knedlik, 2004; Maclanahan, 2004; Heisler, 2005). In addition, the growth in patent-related litigation involving universities and the much hyped "tragedy of the anticommons" in the patenting of basic research tools are both costs attributable, at least in part, to technology transfer initiatives. While not amenable to precise quantification, the stifling of discourse and the erosion in the norms of sharing and colloquy historically associated with the scholarly enterprise, are costs that must be balanced against the technology transfer gains.

Both the impressive numbers and the negative side effects are usually traced to the Bayh-Dole Act of 1980. When Congress passed the Bayh-Dole Act, it gave universities presumptive title to inventions produced with federal funds, as long as they complied with specific requirements. By allowing patent title to initially vest in universities, the Bayh-Dole Act paved the way for more interaction between universities and companies which could now obtain exclusive licenses to such patents and commercialize academic research that previously might have lain dormant and unused.
In a prepared statement before a congressional subcommittee, Dr. Phyllis Gardner, Associate Professor of Medicine at Stanford University, succinctly outlined the pre-Bayh-Dole problem:

Prior to Bayh-Dole, federal agencies would rarely relinquish ownership of federally funded inventions to academic and private institutions, even when private sector scientists and engineers actually contributed to the inventions. Valuable technology was left languishing on the shelves of research institutions. For example, in the 1960s, the U.S. government asserted that it owned rights to 5-fluorouracil (an important anti-cancer drug) even though it had provided merely a fraction of the funding that went into discovery. As a result, market entry of this critical product was unnecessarily delayed and industry distanced itself from federally funded university research.

(Gardner, 2003). The impetus for Bayh-Dole was the belief that a wealth of basic, useful research developed in U.S. universities was languishing in those ivory towers as it took, on average, 15-20 years for basic research disclosed in publications to result in marketed products (Mowery, Nelson, Sampat, & Ziedonis, 2004). This delay was attributed to reluctance by private industry to invest in commercializing federally funded research because they could not obtain exclusive rights to it. Such reluctance created a “death valley” between publicly funded research and its commercialization by the private sector. The Bayh-Dole Act provided a type of “bridge” over this valley by allowing universities to take title to inventions developed with federal funds and grant exclusive licenses to entities willing to commercialize such technology.

While not without critics, Bayh-Dole is widely viewed as a success; in fact, many foreign countries are implementing changes to their laws to mirror its policies.
But appearances can be deceiving. The Act brought to universities the lure of new money, a potential influx of new capital from licensing revenue derived from transferred technology. But in order to capitalize on the opportunity, universities had to comply with the myriad rules mandated by Bayh-Dole, such as seeking patents on inventions and licensees to commercialize the inventions. With increasing frequency, universities began establishing TTOs to perform these functions. In 1980, 25 institutions of higher learning were involved in technology transfer; by 1992, that number had climbed to 200. The number of patents issued during that period also jumped--from an average of 250 a year to 1,500 (Mowery, Nelson, Sampat & Ziedonis, 2004). Research by Rogers, Ying, and Hartman, 2005, suggested a likely impetus for the rapid and widespread adoption of the TTO model by many universities across the country:

The diffusion of technology transfer offices may have been influenced by the so-called "big winner" technologies that have occurred at some universities. Examples are the $160 million that Michigan State University has earned over the life of two cancer-related patents . . . , the $37 million that the University of Florida has earned from the sports drink Gatorade, the $27 million that Iowa State University has been paid for the fax algorithm, and the $143 million earned by Stanford University for the recombinant DNA gene-splicing patent . . . . A "big winner" can dominate the total license income at a research university; for example, $18 million of Michigan State University's $18.3 million license income in FY 1997 came from the two cancer-related drugs.

But very few universities setting up TTOs have seen these types of blockbuster successes. In 2000, about half of the total licensing income generated by all universities was earned by the
top five grossing institutions. Creating a patenting culture in a university requires a substantial, long-term investment of resources with no guarantee of success. On average, it takes from 5 to 10 years before a TTO breaks even, and poor management of the office can result in researchers having negative experiences with the technology transfer process that can create ill will and hinder the development of productive relationships.

Bayh-Dole and other enabling legislation are evidence of a Congressional desire to facilitate technology transfer between universities and industry by using patent policy, with the ultimate goal of benefiting the public. But luring academics into this brave new world of patents and royalties has created some unintended side effects. For example, university research often progresses in stages and the traditional model of scholarly discourse involves the presentation and publication of research conclusions and insights at those various stages.

Moreover, the Bayh-Dole Act mandates that universities share royalties from patented inventions with researchers. This requirement has created a pathway for some faculty to become millionaires, thus eroding, to some extent, the pull of the publication incentive structure. Also, many researchers receive study funding from industry sources and such sponsored research agreements often specify a term of secrecy for results generated under the agreement. Yet the rigid patent novelty rules directly conflict with this model by requiring an inventor to file a patent application either before or within 12 months of exposing the invention to the public (depending on the country) to avoid losing the right to obtain a patent. These rules constrain researcher behavior in ways that are not conducive to academic discourse.

The unforgiving nature of patent novelty rules also encourages a culture in which the dissemination of even very early stage research, sometimes no more than a proof of concept, is delayed while a provisional patent application is prepared by the university TTO. As a result,
secrecy is on the rise among academic researchers, particularly in the life sciences, with many university scientists choosing to limit and/or delay disclosures of their work in order to participate in the patent/technology transfer arena (Grushcow, 2004; Walsh & Hong, 2003).

For example, in 1966, 50% of surveyed experimental biologists felt safe in sharing information on current research with others; only 26% felt that way by 1998 (Walsh & Hong, 2003). In a recent study of geneticists, 35% perceived academic scientists as somewhat or much less willing to share information and data than a decade ago, 58% reported adverse data withholding effects on their own research, and 56% reported adverse data withholding effects on the education of students and post-doctoral researchers (Campbell et. al., 2002). Not all of these results are due to patents. Difficulties in obtaining research materials requested in material transfer agreements (MTAs) is perhaps an even larger problem for researchers and is likely influenced more by competitive pressure and the burden of complying with the request than patent concerns (Walsh, Cho & Cohen, 2005).

Whether benefits associated with patenting or obtaining sponsored research funds are causing many researchers to shift from a focus on basic to applied research is unclear. Nevertheless, it appears that the incentives of the patent system can affect the publication norms and practices of some academics. Consider the following fact-based scenario:

Peter, a 23 year old PhD student in Chemistry at Big X University, discovers some interesting properties of a class of compounds he is experimenting with and decides to publish an article disclosing some of his early findings. Based on counsel from the Big X University TTO, Peter waits until a provisional patent application covering his results is on file with the USPTO before publishing his article. Peter’s research continues to proceed but not as quickly
as he had hoped, and, 12 months after the filing of the provisional application, he still has
several technical hurdles to clear, and commercial applications of his work are still years away.

Forced to make a prediction of the commercial potential of Peter’s work, the TTO
chooses not to file a non-provisional application at the end of 12 months and the provisional
application becomes abandoned. Peter makes more progress over the next several months but is
then counseled by his advisor to significantly change the direction of his research. This is
because the publication of the article covering his early findings is now prior art to any future
patent application he might file on his new, related discoveries, which probably would not be
considered to be different enough from the earlier public disclosure to overcome an obviousness
rejection. Despite Peter’s great interest in the area, he follows the instruction and changes his
research focus.

Peter’s predicament is troubling for a variety of reasons. First, Peter’s delay in
publishing his results until after the filing of a provisional application is part of a growing trend
of secrecy among university researchers in scientific disciplines (life sciences in particular) that
runs counter to traditional academic and scientific community norms of open discourse and
knowledge sharing. By delaying publication of his research until after the filing of the
provisional patent application, Peter potentially has retarded the expansion of knowledge in his
area by limiting the pool of information available for others to build upon.

Second, by failing to file a non-provisional application before the provisional application
lapsed, the Big X University TTO inadvertently may have led Peter to believe he had protection
that he really did not have and he may be 1) more secretive in the future regarding his research
results or 2) more hesitant to participate in the patent process. These are both detrimental
effects but for different reasons. Greater secrecy on the part of university researchers further
stifles discourse and delays third parties in building on information, an important concern in light of the cumulative nature of most scientific advances. Hesitation by university researchers to participate in the patent process, while not facially a negative result, is harmful if patents are important to the commercialization of university-generated research, which quite a bit of data suggest they are.

This problem could be mitigated through better TTO education of and communication with, academic inventors regarding the patent application timeline and the percentage of provisional applications that are normally converted to non-provisionals at that university. Such communication could help the inventor make a more informed decision about, for example, whether to engage in prior-art generating presentation or publication activities on the strength of a provisional application filing. But the information would not change the fact that 12 months simply may be an insufficient period of time in which to assess the commercial potential and technical difficulty of a discovery.

A proposal for addressing this issue made by the author elsewhere would involve injecting more flexibility into the patent system by creating an opt-in extended grace period which would provide more time for academic researchers to publish and present early stage research before having to file a patent application. Such an extension, coupled with early application publication (i.e. publication of designated applications immediately after filing, instead of after an 18 month delay), would allow researchers to engage in traditional academic discourse while retaining the ability to obtain proprietary rights necessary for commercialization of their inventions. Importantly, it would also provide early disclosure of discoveries for other scientists to build upon. However, it would not address other concerns related to the patenting of upstream research in the university context such as those discussed below.
Research Tool Patenting and Experimental Use

The same year that Congress put technology transfer on the university map with the Bayh-Dole Act, the United States Supreme Court gave it a further boost with its decision in Diamond v. Chakrabarty, 447 U.S. 303, 313 (1980). This case expanded the scope of patent-eligible subject matter to include living organisms, there genetically engineered bacteria, thus jump-starting the fledgling biotechnology industry and further fueling National Institutes of Health (NIH) funding of university research in the life sciences.

The importance of the combined impacts of the *Chakrabarty* decision and the Bayh-Dole Act on the increase in technology transfer-related patenting is significant. As one commentator notes “at roughly the same time universities were permitted to claim intellectual property rights to the fruits of federally funded research as a matter of course, the universe of potentially patentable research results expanded and the potential value of intellectual property increased” (Newberg & Dunn, 2002). For example, the relaxation of patent subject matter standards meant that universities, often engaged in upstream, early-stage research, could patent embryonic discoveries that, prior to the *Chakrabarty* decision, likely would not have been eligible for patent protection.

However, it also meant that many types of research tools—methods or products used in the process of scientific experimentation—employed by scientists in their work might now be the subject of patents. As noted earlier, the substantial increase in the overall level of patenting in the U.S. is problematic for the USPTO and the expansion in patent-eligible subject matter is a significant factor in the increase. But the increase in patenting along with what is perceived to be
a low inventiveness requirement for patentability creates an opportunity for “patent thickets,” many overlapping patents covering an area, to form in certain technical disciplines.

While the actual presence of significant patent thickets in biotechnology research has not been confirmed empirically and is the subject of much debate, commentators have identified several challenges that such thickets could create for university research. For example, research may be hindered if access to needed tools is too costly because of patent license fees, too complex to obtain because of the need to negotiate with multiple patent holders, or is simply denied altogether (Merrill et. al. 2004). This is a particular concern in relation to material transfer agreements, where onerous terms in the agreements—such as reach-through claims to products developed with the material, limitations on disclosure, and more—can end or delay negotiations and thus hinder research.

Another challenge created by the increased patenting of upstream research inputs relates to increased patent-infringement liability exposure for researchers if they use patented tools without obtaining permission. One of the complicating factors in the increase in patenting of upstream research tools is the lack of a clear experimental use exemption for patented inventions. Unlike the laws of many other countries that allow scientists to experiment on or with an invention for the purpose of research, U.S. law does not contain a broad statutory exemption for such activities. According to the CAFC:

On its face, 35 USC 271(a) prohibits any of “making, using or selling.” Any one act of the three is enough to create liability. A mere “use” which doesn’t result in a sale is still actionable: Thus, the patentee does not need to have any evidence of damage or lost sales to bring an infringement action.
(Roche v. Bolar, 733 F.2d 858, 861 (Fed. Cir. 1984). In fact, in a 2001 case, which dealt with the unauthorized use of a patented invention by researchers at Duke University, the CAFC held that regardless of whether the allegedly infringing act was performed for commercial gain “so long as the act is in furtherance of the alleged infringer’s legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry” the act was infringing (Madey v. Duke Univ., 307 F.3d 1351 (Fed. Cir. 2002), *cert. denied*, 123 S. Ct. 2639 (2003)).

Various commentators have proposed the creation of a limited experimental use exemption for researchers (Strandburg, 2004; Meuller, 2004). However, the current situation is that university researchers engaged in the “business” of teaching students and conducting research are not automatically entitled to an experimental use exemption to patent infringement. While the likelihood of an academic researcher being sued for patent infringement may be quite low, the uncertainty created by lack of a clear exemption may chill some research activities.

Much has been written on problems associated with the Bayh-Dole Act in relation to over-zealous patenting, litigation, and licensing practices of some university TTOs and the potential for access issues for upstream research tools, increased secrecy among university scientists, and more. To address these perceived problems, several commentators have called for reformation of the Act, as well as other changes to the patent system such as heightening the subject matter and utility standards and creating a statutory experimental use exemption to patent infringement (Eisenberg, 1996; Mowery et. al., 2004, Rai & Eisenberg, 2003; Leaf, 2005). These meritorious proposals could, if implemented, have the effect of improving some aspects of the current patenting regime. However, it should be noted that there is not a consensus that there even is a problem; other commentators question these same contentions and argue that no, or at most minimal, changes are required (Kieff & Parades, 2006; Epstein & Kulik, 2004).
Despite these countervailing views, change seems likely to come from one or more of the three main bodies engaged in patent matters: Congress, the USPTO, and the U.S. Supreme Court. The U.S. Congress recently has considered a variety of patent reform bills and more are expected to be introduced. The USPTO also has proposed dramatic changes to patent prosecution to deal with its backlog and quality issues. The U.S. Supreme Court in times past was seen as detached from patent matters but has, since 2005 at least, evidenced a renewed appetite for patent appeals and is now poised to make further significant changes to patent law jurisprudence with its decisions.

**Patent Licensing and Enforcement**

Patent owners often choose licensing as a vehicle to extract value from their patents. The influential book “Rembrandts in the Attic” by Rivette and Kline, 2000 encouraged companies to analyze their patent portfolios for hidden value in the form of patents that could be licensed to increase revenue or provide a competitive advantage. IBM’s aggressive efforts in this area are legendary: the company, which for many years has obtained more U.S. patents than any other company in the world, boosted its annual patent licensing revenue 3,300%--from $30 million in 1990 to nearly $1 billion in 2000 (Rivette & Kline, 2000). In another approach to extracting value from patents, Rivette and Kline cite Dell Computers, which obtained numerous patents relating to its system for selling, distributing, and providing support for computers, used its patent portfolio as collateral in a $16 billion cross-licensing deal with IBM.

The Monsanto Company (“Monsanto”) has developed a particularly creative way to extract maximum value from its patents on genetically modified seeds. The company uses two main types of license agreements to confer rights in relation to its intellectual property. First, it
licenses seed producers to make and sell seed containing its proprietary traits. Seed companies pay royalties to Monsanto in accordance with these licenses. Second, it licenses growers, to plant transgenic seeds covered by its patents, but only for planting a commercial crop in a single season, and prohibits growers from saving any seed from that single crop for replanting or supplying to third parties in the future (Monsanto v. McFarling, Fed. Cir. 2002). These two agreements, together, allow Monsanto to capture maximum value from its intellectual property investment and maintain control of its technology. Without the agreement with the grower, Monsanto would only be capturing value from one user of the technology, the seed producer, who would then be free to capture additional value from the grower.

Thinking about patents strategically early in the development process can also provide a competitive advantage for a company. When Gillette, Inc. (“Gillette”) set out to design its Sensor® shaver, it included on the R&D team patent attorneys who conducted a full patent analysis of various designs for the shaver examining the strengths and weaknesses of the patent position of each design (Rivette & Kline, 2000). The company ultimately chose to go forward with the design that competitors would have the most difficulty designing around from a patent standpoint, and identified, and sought patents on, 22 different inventions related to various aspects (e.g., handle, springs, container, blade angles) of the product.

But such strategic approaches to patents can create significant problems not only for competitors, but also for users and even for innovation in a technology area. For example, farmers have been saving seed for millennia, and Monsanto’s aggressive enforcement of its licensing strategy (suing 90 farmers over several years) has caused many farmers to file for bankruptcy (Kimbrell & Mendelson, 2005). In the semiconductor industry, companies routinely cross-license each others patent portfolios because otherwise, very little innovation could take
place as a single product may be covered by a plethora of patents owned by different entities (Jaffe & Lerner, 2003). However, because the terms of the cross-license agreements are a function of the size and quality of each company’s patent portfolio, there is an incentive to accumulate as many patents as possible, even if the patents are covering only marginal advances. This not only creates waste and adds to the backlog at the USPTO, it also can create problems for small innovators that lack a large patent portfolio for negotiations and thus may be unable to maneuver through this “patent thicket” without incurring patent infringement liability. Moreover, a large patent portfolio may be of little benefit to a company facing an infringement suit by a small, non-practicing entity that lacks any interest in cross-licensing and is in no danger of being counter-sued for infringement.

As noted earlier, the cost of defending against a patent infringement suit can be considerable, and until recently, patent owners could routinely obtain an injunction to shut down a business if they won a patent infringement suit in addition to collecting significant damages. These facts combined with the expansion of the scope of patent subject matter and the seemingly lower standards for obtaining and enforcing patents has resulted in an increase in assertions of patent infringement by patent owners who do not themselves practice the invention covered by their patent and may in fact have obtained the patent, by purchase or otherwise, for the sole purpose of extracting rents.

This phenomenon, denominated “patent trolling” by some, has created a considerable amount of controversy, especially since there is a perception that many of the patents asserted relate to business methods and thus may be more likely to be of suspect quality because of the USPTO’s lack of familiarity with the subject matter and prior art in the area. A recent U.S. Supreme Court decision eliminating the CAFC’s rule that injunctions should routinely issue if
patent infringement is found, is widely seen as a positive step in addressing the “troll” problem because the threat of an injunction is a huge stick that patent owners can use to achieve a settlement (eBay v. MercExchange, 126 S. Ct. 1837 (2006)). While not without critics, the decision now allows courts to consider, among other things, whether money damages would be sufficient to compensate the patent owner for infringement when deciding whether an injunction should issue.

It is worth noting that while aggressive patent licensing efforts are widespread, open source models are gaining traction as well. For example, in 2005 IBM, announced the creation of a commons initiative in which it pledged not to assert 500 patents if the technologies covered by the patents are used in projects falling under an open source initiative license. Moreover, several open source initiatives are underway in the biotechnology area, such as the Public Project in Genomics (P3G) consortium which promotes collaboration between researchers using population genomic databases (Joly, 2006; Boettinger & Burk, 2004; Rai, 2005). Having a variety of approaches to protecting and disseminating the fruits of intellectual endeavor available to researchers should be a boon to innovation in the academy and beyond.

**Conclusions**

Patents are important as incentives for discovery, innovation, investment, disclosure, and more. An important question under consideration in many quarters is whether the patent incentive is necessary or desirable for a variety of inventions for which protection is sought or whether there are areas of technology and endeavor, such as upstream research tools, genes, and business/financial/tax methods, for which the patent system should be off limits. This chapter has also highlighted a variety of other issues associated with the procurement, use, and
enforcement of patents that will continue to be analyzed and addressed in the coming years. So much is in flux in the patent system today that aspects of this chapter will surely be obsolete as soon as it is published. Yet one thing is certain: the U.S. will continue to have a patent system that can provide meaningful opportunities and obstacles for researchers for many years to come.

References


In Re Klopfenstein, 380 f.3d 1345, 1352 (Fed. Cir. 2004).


Monsanto v. McFarling, 302 F.3d 1291, 1293 (Fed. Cir. 2002).


Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law

For a more in-depth discussion of patent eligibility standards in the U.S., see Margo A. Bagley, _Patently Unconstitutional: Geographical Limitations on Prior Art in a Small World_, 87 MINN. L. REV. 679 (2003).

The impact on state and local economies can be quite important. The Wisconsin Alumni Foundation also boasts that “[t]o date, more than 30 companies based on WARF technology have spun out of the university, with all but one of them based in Wisconsin.” _Guide Offers Aid to Campus Entrepreneurs_ (Apr. 14, 2004)

Some issues include differences in views on the proper subject matter of patents, the language of the patent document and proceedings, the location and jurisdiction of such a patent office and court, compulsory licensing provisions and traditional knowledge protection, sovereignty issues, and much, much more.

A much earlier decision, _Parke-Davis & Co. v. H.K. Mulford & Co._, 196 F. 496 (1926), in combination with _Chakrabarty_, set the stage for the patenting of genes, DNA, and other naturally occurring biological material isolated from, and in a purified state relative to its natural condition. While abstract ideas, natural phenomena, and products of nature are still nominally excluded from patent eligibility, the allowance of patents covering isolated genes and purified DNA narrows the scope of “natural phenomena” that is in the public domain and not eligible for patent protection. For a more in-depth discussion of patent eligibility standards in the U.S., see Margo A. Bagley, _Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law_, 45 WILLIAM & MARY L. REV. 469 (2003).

See Thursby, Jensen & Thursby, 2001: “Products and processes based on early stage technologies are often years away from commercialization . . . it is difficult to specify royalty income based on sales . . . for very early stage technologies since the nature of the final product is often unknown”.

For example, an applicant can seek to show that an opponent derived the invention from someone else and is thus not a true inventor, or that the subject matter is unpatentable and that no one is entitled to a patent on it. _See_ 37 CFR 641.121. Interferences are not limited to two parties, nor to pending applications. As long as at least one pending application is involved and the same subject matter is being claimed, there can be multiple applications or even patents involved in the interference. If only patents are involved in a priority dispute, the dispute is beyond the jurisdiction of the USPTO and must be resolved in federal district court. _See_ 35 USC § 291.


Average application pendencies in the USPTO vary based on technology.

Jaffe & Lerner 2003. at 34. For arguments that some of the claims of the crustless sandwich patent may indeed be valid see http://www.patentfizz.com/fizzdisplay.php?patno=6004596.

This is a bit of an overstatement. The CAFC has jurisdiction over appeals of cases in which the plaintiff’s complaint contained a claim “arising under” the Patent Act.

While the funding agency could make the decision to allow licensing, such decisions were rare and were made on a case by case basis resulting in significant uncertainty regarding the likelihood of a favorable result. It was well understood, of course, that commercialization was well beyond the mission, resources, and expertise of university researchers and should be handled by the private sector.


See, e.g., AUTM Licensing Survey: FY 2003 Survey Summary, Association of University Technology Managers, _at_ http://www.autm.net/surveys/dsp.surveyDetail.cfm?pid=16 (visited Oct. 9, 2005) (citing announcements by the United Kingdom, Canada, Germany and Japan of investment programs and/or statutory changes to enhance the commercialization of research from academic institutions as foreign countries “continue to strive to emulate U.S. success in harnessing the intellectual output of its academic institutions.”); _Patent Law Reform: Hearings Before the Subcomm. on Courts, the Internet, and Intellectual Property of the House Judiciary Committee_ (June 9, 2005) (statement of Carl Gulbrandsen, Managing Director, WARF) (noting that “at WARF, we receive numerous visitors each year from around the world. Invariably our foreign visitors ask about Bayh-Dole and express the wish that their own countries would adopt such forward-thinking legislation.”).


See Owen-Smith & Powell, 2001: “faculty decide to patent because of their beliefs about the positive personal and professional outcomes of establishing IP protection. . . . the decision to disclose a new finding . . . depends upon . . .

http://law.bepress.com/ualwps/ualaw_publiclaw/art65
conceptions of the patent benefits, framed by the costs of interacting with licensing professionals and technology transfer offices.”

16 Congress’ most recent effort in this area, the Collaborative Research and Technology Enhancement Act of 2004 ("the CREATE Act"), is designed to encourage research collaborations between academic institutions and private enterprises by making it easier for the partners to obtain patents on inventions created by joint inventors from both organizations.

17 For example, under Emory University’s Intellectual Property Policy, inventors receive 100% of net royalties up to $25,000, 33% of net revenue up to $4 million, and 25% of net revenue over $4 million. Consequently, Emory’s $540 million Emtriva sale made the three faculty inventors millionaires. The policy is available at http://www.emory.edu/PROVOST/policy_bylaws/IP_policy.pdf.

18 As reported by Thursby & Thursby, 2001: “Half of the firms in our industry survey noted that they include delay of publication clauses in at least 90% of their university contracts . . . . The average delay is nearly four months, and some firms require as much as a year’s delay.”

19 This is not to suggest that increasing secrecy is solely, or even predominantly, the result of the patent novelty rules. There are a variety of contributing factors, such as the widespread inclusion of secrecy clauses in industry sponsorship agreements, and the increasingly competitive nature of academic research in general. Nevertheless, the potential of the patent novelty rules to encourage this kind of behavior cannot be ignored.

20 See Thursby & Thursby, 2001: “[m]uch of the concern of those who question [Bayh Dole’s] impact comes from fears that financial returns to licensing would divert faculty from basic to applied research. . . . we cannot reject the notion that faculty research has shifted.”

21 Based on an actual event. Names and identifying features have been changed.

22 See Owen-Smith & Powell, 2001: “The failure to pursue smaller scale ‘bread and butter’ disclosures limits future chances for commercial success by encouraging faculty to bypass the TTO or avoid commercial activities altogether.”

23 Bayh-Dole’s perceived successes have made it quite popular with members of Congress, universities and other interest groups, and more than minimal changes to the current Act seem unlikely in the near term. For example, patent reform legislation currently pending before Congress does not include meaningful changes to Bayh-Dole. Moreover, the CREATE Act of 2004 provided the ideal opportunity for Congress to address issues with the Bayh-Dole Act since the legislation specifically related to enhancing the Act’s technology transfer mandate, yet none of the abovementioned commentator reforms were included in that legislation. Instead, the Bayh-Dole Act was uniformly praised in congressional remarks. See, e.g., The Cooperative Research and Technology Enhancement Act of 2004, S. 2192, 108th Cong. (enacted) (Statements of Senators Spector and Leahy, and Representative Berman).