'To Promote the Progress of Science': Is It Time to Adopt a Research Use Exemption in U.S. Patent Law?

Joe L. Fore, Jr.

Senior Honors Thesis
Terry Stanford Institute of Public Policy
Duke University
Durham, North Carolina

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Executive Summary

Over the past twenty-five years, the U.S. biotechnology industry has been one of the most prosperous and innovative segments of our economy. One of the key developments which has allowed this growth has been the ability of research institutions, both public and private, to rely on the patent system to protect their lucrative intellectual property. Accordingly, the number of patents granted for biotechnological inventions has skyrocketed, particularly on DNA sequences, proteins, instruments and other inventions which are known as "research tools", products which can be used as inputs in further biomedical research. Because of this patent protection, acquiring the rights to use these materials can be potentially time-consuming and expensive.

This has led many observers, especially those in the academic community, to fear that research tool patents could stifle university biotechnology research, as many researchers would not have the time or financial resources to obtain the licenses to use these patented inventions. Historically, researchers in university or other nonprofit settings were not greatly concerned about obtaining the necessary licenses or paying royalties because it was generally assumed that their work was covered under a common law "research use exemption". Since their work was not motivated by a commercial purpose, it was widely believed (and reflected by court opinion) that these researchers and their institutions were exempt from patent infringement suits. However, in the 2002 case of *Madey v. Duke*, the court found that, indeed, universities and their scientists could be sued for infringement for unauthorized use of patented research tools, even if their work contained no hint of commercial enterprise.

This legal decision has caused many in the academic community to argue for a statutory research use exemption, which would protect academic research and allow scientists unfettered access to patented research tools. Many have pushed for a broad statute, which would exempt a wide range of activities, including research performed *with* the patented invention, which, in theory, should increase university innovative output. However, this type of exemption could severely impact the profits of biotechnology companies that produce these inventions, which could limit their ability to continue to produce new and better research tools. To examine the consequences of this type of exemption, a two-pronged quantitative analysis was performed, analyzing the potential effects of a research *with* exemption on: 1) universities and 2) research tool companies.

The cost-benefit analysis for universities showed that it appears likely that university innovation would increase as a result of the policy, primarily due to reduced spending on licensing fees and a freeing up of previously undoable lines of research that would likely accompany the implementation of the law. The other portion of the quantitative analysis examined the stock performance of a group of biotechnology companies who should have been negatively impacted by a Supreme Court decision that essentially created a de facto research use exemption. However, the analysis was inconclusive and unable to show that this de facto exemption had a statistically significant effect on the companies' market valuation.

In addition to this quantitative analysis, the consensus from most observers in the academic community is that the fears about the negative effects of biotechnology patents have largely gone unrealized. Most researchers are not being impeded by patent and

licensing hurdles, and even in the wake of the *Madey* decision, it appears that most firms are still willing to tolerate infringement on the part of universities to maintain friendly relationships with the academic community. Therefore, a broad research *with* exemption, while marginally beneficial, might be ultimately unnecessary.

Based on this reality and on international precedents, this paper concludes that it is more appropriate for Congress to enact a more limited exemption, which would permit research *on* a patented invention for the purposes of testing the claims of the patent, finding novel uses for the invention, or to find improvements or substitutions for the product. The paper also finds that while many of the concerns about research tool patents have not yet materialized, it is essential that the federal government and academic institutions continue to monitor the effects of biotechnology patents to ensure that they are not impeding biomedical research in the noncommercial community. Ultimately, it appears that the limited research *on* exemption crafted in this paper would benefit the United States; an assessment of the political situation in Congress, however, suggests that action in this area is unlikely for the foreseeable future.

Introduction

This paper explores the possibility of creating a statutory research use exemption in United States patent code. Calls for such legislation have come primarily in response to the great increase in patenting in the biotechnology, computing, and telecommunications sectors, particularly on inventions that function as inputs for further research. Such patenting, many observers claim, could ultimately stifle downstream innovation, as academic and nonprofit researchers would not be able to access these vital technologies for use in their work. Some in the academic field have claimed that a research use exemption is needed to mitigate these concerns, by shielding some researchers from patent infringement suits. Without fear of a lawsuit, scientists, particularly those in the academic community, would have unfettered access to these patented inventions. This project explores the source of the problem, the legislative options facing Congress, and the potential impact of codifying a research use exemption.

The structure of the paper is as follows. Section 1 puts the current situation into historical context by explaining changes in the biotechnology sector over the past twenty-five years and the expansion of biotech patenting. It also discusses the increased importance of patenting in universities and the spread of the university technology transfer model, which has made academic institutions key players in biotechnological innovation. Finally, Section 1 examines the changing nature of the relationship between academia and industry, a link that will be essential to examining the need for and consequences of a research use exemption.

Section 2 explores the history of the common law research use exemption in U.S. law. First articulated in the 19th century, the common law research exemption became

part of judicial dicta and survived until 2002, when two crucial court cases, *Madey v. Duke* and *Merck v. Integra*, altered the way the exemption was treated by the courts. Section 2 provides valuable insight into the history of the common law exemption, which can then inform the decisions made in crafting legislative alternatives.

The scope of the problem is specified in Section 3, which explores the current climate of academic research. Since arguments for a research exemption typically rest on the assumption that nonprofit research is being impaired, this section analyzes how much university research is being affected by patent and licensing issues, especially in light of the 2002 *Madey* decision.

Section 4 defines the options facing Congress and develops a model for a reasonable statutory research use exemption that addresses the scope of the problem as laid out in Sections 1-3. The section begins with a theoretical examination of exemption proposals and criteria for evaluating the merits of a statute. Next, the section explores several specific examples of exemptions which are already in place in U.S. and foreign patent codes and serve as models for potential legislative action. Finally, the section develops specific elements that could be incorporated into the legislation, based on U.S. and international precedents and recommendations from federal groups, foreign governments, and observers in the legal community.

Based on sections 1-4, Section 5 performs a stakeholder analysis to determine the effects of a research use exemption. Specifically, the section performs a quantitative analysis to estimate the effects of the legislation on innovative output. The analysis is divided into two sections to examine the consequences for the two biggest stakeholders: 1) universities; and 2) research tool companies. The section also contains a political

analysis, which explores the likelihood of Congress's willingness to actually take up and adopt such a measure. Based on these analyses, Section 6 offers a set of findings and recommendations for legislative action.

Section 1

The U.S. biotechnology industry over the past 25 years

The past twenty-five years have seen the explosion of patenting and commercial activity in genomics and biotechnology. While, clearly, technological progress has driven much of the growth in the sector, these increases can also be attributed to legal changes that encouraged the patenting of genomics-based discoveries and changes in the patenting behaviors of universities and other nonprofit entities.

Changes in the legal framework

The first change was the rise of the biotechnology industry, which began in the mid to late 1970s. Suddenly, the promise of large profits and the corresponding influx of capital persuaded companies (and to a lesser extent, universities) to find ways to quickly commercialize their research. This typically meant seeking patent protection for their potentially lucrative discoveries. Several changes in the U.S. legal system supported an increased propensity to patent. The first was the 1980 Supreme Court decision in the case of *Diamond v. Chakrabarty*, which held that genetically modified organisms could be patented (Murray, 2006). The Court found that even living things, if substantially altered by humans, could meet the criteria for an invention, which included "anything under the sun that is made by man"[1]. Thus, DNA-based patents (such as therapeutic forms of naturally occurring proteins or modified organisms for the production of medicines) were now acceptable as "inventions".

[1] *Diamond v. Chakrabarty*, 447 U.S. 303, at 309

A second change focused on the way in which cases involving patents were adjudicated in federal courts. In 1982, the Court of Appeals for the Federal Circuit (CAFC) was established, unifying patent dispute cases under a single, federal jurisdiction (Mowery, Nelson et al., 2001). In cases where one party sought to have another party's patent invalidated or revoked, the CAFC soon gained a reputation for generally siding with patent holders, establishing a presumption in their favor, a reversal of prior federal appeals court precedent. Rai points out that the Court has taken an "expansive approach to patent eligibility while relaxing the stringency of standards for patent protection, such as utility and nonobviousness" (Rai and Eisenberg, 2003). These changes in the judiciary meant that inventors were now more likely to be granted patents on naturally occurring DNA products and that those patents were more likely to be upheld, if challenged in federal court.

University technology transfer

Changes in U.S. patent law and policy did not just encourage commercial enterprises to commercialize their inventions. Congress also sought to increase innovation by creating incentives for patenting and licensing discoveries made in universities and other federally-funded institutions. The concern among many lawmakers and others in the research community was that most discoveries with potential social benefit were going undeveloped or ignored because no one would invest in commercializing the results of such research (Eisenberg, 1996). The reason was simple: discoveries (and any patents filed on them) made using federal funds generally reverted to the federal government. Without ownership of the intellectual property rights, most companies would not invest the capital needed to bring the products to market. The fear

that many important inventions were being ignored was legitimate; in the early 1980s, only 5 percent of patents owned by the U.S. government were actively being used (Schacht, 2000).

Congress sought to increase innovation by granting ownership of the patents to those institutions which made discoveries using federal dollars. With the potentially lucrative patent rights, these institutions would be in a position to commercialize their discoveries or license them to corporate partners. The first of these laws was the Stevenson-Wydler Technology Innovation Act, which encouraged government research laboratories to actively patent and attempt to commercialize their findings and made "technology transfer an integral part of the research and development responsibilities" (Eisenberg, 1996). Some federal agencies had already made licensing a priority; this policy made tech transfer an important aim across the board (Eisenberg, 1996). The second of these policy changes was the Bayh-Dole Act, which gave universities and other federally-funded research institutions ownership over patents filed on their inventions. This was particularly important to research universities, where most discoveries came in the form of "basic research", far upstream of commercial products. Colyvas points out that, generally, "university research results of potential use in industry were embryonic inventions requiring a lot of follow on work in industry…it often facilitated technology transfer, and sometimes was necessary for it, if the university took out a patent on the invention" (Colyvas, Crow et al., 2002).

The Bayh-Dole Act had the intended effect of increasing university patenting, a trend which continues today. Universities were granted just 583 patents in 1985. By 1998, that number had jumped to 3,151 (Cohen, Walsh et al., 2002). In the fiscal year

2004, members of the Association of University Technology Managers (AUTM) reported filing for more than 11,000 patents.[2] This increased patent activity was also above and beyond increases in patenting in general, as measured by U.S. patents issued each year. Rai points out that university patenting increased by a factor of ten between 1979 and 1997, while the number of U.S. patents granted overall doubled (Rai and Eisenberg, 2003).

In order to capitalize on their patents, universities began to form their own technology transfer divisions. While some institutions, such as Stanford, had previously had offices which specialized in patenting and licensing matters, the creation of dedicated tech transfer units became standard for most major research institutions. In 1980, there were only 25 universities that had such offices; just a decade later, there were 200 (Cohen and Walsh, 2000). The trend continued to grow throughout the 1990s, and even spread to include technology managers abroad. By 2006, AUTM had more than 3600 members, representing 350 universities and other nonprofit research centers in 45 countries.[3] These university tech transfer offices greatly increased the efficiency of the patenting process and the overall output of patents and licenses. From 1975 to 1990, the ratio of patents to R&D investment increased from 57 granted patents per billion dollars of R&D to 96 patents per billion dollars of research investment (Mowery, Nelson et al., 2001).

These gains reflected the increased savvy of technology transfer offices, which became more skilled in soliciting invention disclosures from researchers and more successful in capitalizing on the commercial potential of their patents. These trends continued throughout the 1990s. In 1991, just over one-fourth of invention disclosures

[2] www.autm.org/about
[3] http://www.autm.net/about/

resulted in a new patent application (26 percent); by 2002, half of all invention disclosures led to the filing of a patent application (NAS, 2004). Between 1991 and 2000, licensing surveys conducted by AUTM showed an 84 percent increase in invention disclosures, a 238 percent increase in new patent applications, a 161 percent increase in the number of licensing agreements, and a 520 percent increase in the amount of royalties collected from patents (Thursby and Thursby, 2003).

As technology transfer has become an integral part of the research university, it has fostered an increasing amount of collaboration between academic institutions and commercial firms and blurred the traditional lines between "basic" and "applied" research. The National Research Council (NRC) claimed that "the growing propensity of universities to enter into collaborative R&D arrangements with business and government laboratories has been a major trend in the R&D environment over the past two decades" (NRC, 2005). As federal funding in many areas of research has decreased, nongovernmental sources, including commercial entities, have filled the funding gaps. Mowery reports that "in 1970, federal funds accounted for 70.5 percent of university performed research and industrial support 2.6 percent; by 1997, federal funds accounted for 59.6 percent of totally university research and industry's contribution had increased to 7.1 percent" (Mowery, Nelson et al., 2001). In absolute terms, between the late 1960s and 2002, overall industry support for academic research and development increased by 900 percent (NAE, 2003).

DNA patents: a potential disaster?

The increases in university patenting have been skewed heavily in the direction of DNA based patents. While overall university patenting has increased, their gains in the

field of genomics have been particularly impressive, with academic institutions accounting for a larger share of these patents than in other areas (Sampat, 2004). In 2003, universities were responsible for more than 15 percent of the genomics patents issued, whereas they were awarded just 6 percent of total patents issued in that year (Sampat, 2004). Universities and other noncommercial centers have emerged as leaders in genomic research and their gains are reflected in the high proportion of patents in therapeutics, proteins, genes, sequences and other genetically based inventions owned by universities. A recent survey of DNA patents conducted by Pressman, et al. (the most thorough analysis of this segment of patents) found that 13 of the top 30 entities with the most number of DNA based patents were nonprofit academic institutions (Pressman, Burgess et al., 2006). The study also found that overall, nearly one fourth of all DNA patents (22 percent) were controlled by nonprofit institutions, leading the authors to comment that research universities and other academic centers are "major players in the patenting and licensing of DNA based inventions" (Pressman, Burgess et al., 2006).

The main problem with these DNA patents is, as Professor Arti Rai points out, that they "do not cover commercial end products, but rather fundamental research discoveries and research tools" (Rai and Eisenberg, 2003). A "research tool" can simply be defined as any "product or method whose purpose is use in the conduct of research" (Newman, 2003). This class of tools can include instruments (like microscopes or lasers), processes (like DNA sequencing techniques or the polymerase chain reaction), or materials (such as DNA segments, nucleotides, proteins, or molecules). These have become increasingly prevalent in university patenting. For instance, in Columbia

University's patent portfolio, one of the most lucrative in U.S. academia, more than half are research tools (Rai and Eisenberg, 2003).

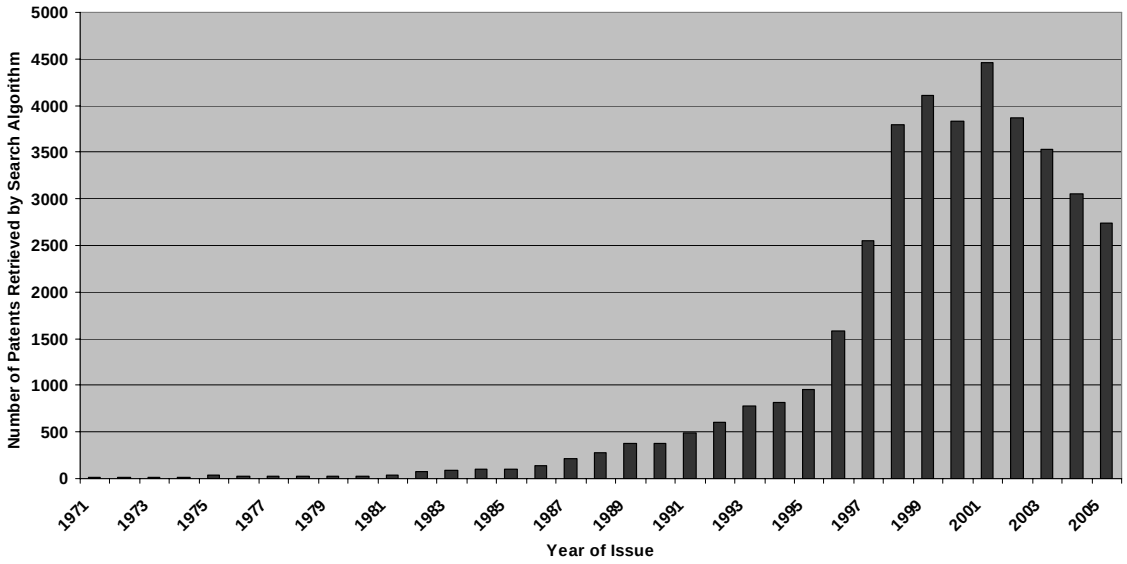


Figure 1. DNA Patents Issued 1971 to 2005. DNA patent counts determined by search of the DNA Patent Database (http://dnapatents.georgetown.edu), which contains patents with one or more claims based on DNA or RNA. *Source:* (Pressman, Burgess et al., 2006).

Biological research tools represent a unique and troublesome class of patents. These tools have become more commonplace in molecular biology and genomic research, and are often required to undertake even basic, noncommercial research. Restricting or limiting use can hamper downstream research, which can stifle further genomic discoveries. Some commentators have claimed that the increases on patented research tools is creating a "patent thicket, a dense web of overlapping intellectual property rights that a company [or university] must hack its way through…With cumulative innovation and multiple blocking patents, stronger patent rights can have the perverse effect of stifling, not encouraging innovation" (Shapiro, 2001). Josh Sarnoff, a

professor of law at American University, claims that restricted access to research tools may take four forms: "1) a refusal to license; 2) increased or insurmountable costs; 3) increased time in licensing negotiations and less time in the lab; and 4) onerous licensing offers that discourage licensing" (Sarnoff, 2002). We will consider the first three of these potential concerns in turn.

Refusal to license

All patents provide the patent owner with the right to restrict use of his or her patent. Rochelle Dreyfuss, from New York University argues that the "problem with research tools is that the patentee now has a right to say 'no', not say, 'give me two dollars', has a right to say 'no, you can't do that research'" (NAS, 2004). Hoffmann points out that the right to exclude (the cornerstone of the patent system) normally does not interfere, but has the potential to have dire consequences in genomic research: "Proponents of the patent system assume that most patent holders will act rationally to maximize the economic utility of their inventions by freely granting licenses. Although this has been true in most industries, it may not always be the case in biotechnology, where innovations 'stand on the shoulders' of previous inventions. Patent holders are not obligated to license their technologies to competing researchers: they may refuse to grant licenses or hold out against the tantalizing possibility of extraordinary future profits" (Hoffman, 2004). Research may be forestalled due to a simple inability to obtain licenses or materials from patent owners.

Insurmountable licensing fees

Assuming researchers can obtain access to the intellectual property rights, there is also the potential problem of excessive licensing fees. Research involving patented

genomic tools often requires multiple inputs. Often, each separate input (a protein, sequence, technique, etc) is covered by a different patent, held by a different owner. If each of these requires a separate licensing fee, a researcher would have to pay multiple rights holders to run a single experiment, which can increase the cost of doing research. Such "royalty stacking" could be render entire fields of research prohibitively expensive. "Transaction costs mount quickly", Rai comments, "when the basic research discoveries necessary for subsequent work are owned not by one entity, but by a number of different entities" (Rai and Eisenberg, 2003).

Delays resulting from licensing negotiations

As nonprofit institutions become more patent savvy, projects may be delayed until universities are able to obtain the proper intellectual property rights. Particularly with projects involving multiple patented tools, "it becomes more difficult for researchers working on complex projects to amass the necessary authorizations from upstream patent holders" (Weschler, 2004). However, often IP issues are an afterthought for researchers and are not considered until projects have been substantially planned or are already underway, leading to the situation where "unanticipated need to negotiate licenses before initiating or while in the midst of research projects may forestall or seriously disrupt ongoing research" (Keyes, 2002).

While technology transfer and the boom in DNA-based patents have led to explosive growth in the biotechnology and genomics sectors, they have brought with them the danger of potentially deterring subsequent research. Section 3 of this paper examines the extent to which these possible hindrances are actually playing out in the research community.

The next part of this section explores another key development in the biomedical research community over the past two decades: the increasingly commercial role played by universities and their changing interactions with industrial partners.

University/industrial relations: an "uneasy" partnership?

As universities are becoming major players in the world of DNA patenting and licensing, the traditional lines that once clearly separated "basic", "noncommercial", or "academic" work and "applied", "commercial", or "industrial" research have become blurred to the point that such labels are almost completely useless. Whereas universities and academic institutions were once primarily purchasers or licensees of technology, today they are just as likely to own the patent rights to lucrative research tools and to earn money from royalties. This shift has had implications for the interactions between universities and corporate entities. Mowery, et al. illustrate that "[i]n some fields, such as research materials or tools, university and industrial researchers now are competitors as much or more so than collaborators, and industry researchers are often required to obtain licenses to use patented university research results. Facing such demands from universities, industrial research managers see no reason why they should not make similar demands on universities" (Mowery, Nelson et al., 2004).

And yet, it is still very much in industry's interest to cooperate with the academic community, to whom companies turn for employees and consultants, as well as research findings and business partners (Sandelin, 2006). Therefore, companies are also wary not to force universities into licenses which they may see as onerous or overly burdensome. This balance between securing profits from valuable licenses and maintaining good relations with universities has resulted in what one author has deemed an "uneasy"

partnership (Cohen, Florida et al., 1998). This somewhat precarious situation is summed up by Cristina Weschler: "Due to the unique working relationship that exists between universities and industry, one characterized as much by cooperation and interdependence as by competition, it is often in companies' interests to come to a working arrangement…" (Weschler, 2004).

These arrangements, or "working solutions" as they have been called by Wes Cohen, John Walsh and Ashish Arora, have been cited as a crucial factor in maintaining the functional relationships between industrial and academic entities (Walsh, Arora et al., 2003). One of these informal solutions involves the successful negotiation of licenses at reduced rates, a move which Weschler refers to as a "subtle form of price discrimination" (Weschler, 2004). Companies are aware that tight grant budgets often make it infeasible to pay high licensing fees, especially when the projects in question constitute noncommercial or basic research, with little chance of profitability. Other types of "working solutions" include "inventing around patents, going offshore…court challenges, and using the technology without a license (i.e. infringement)" (Walsh, Arora et al., 2003).

Infringement as a "working solution"

It is this last method, infringement of patents by academic researchers, which has caused the most uneasiness among observers in both the nonprofit and commercial sectors. The surveys of Walsh and Cohen have found infringement by university researchers (as well as corporate R&D personnel) to be a widespread, convenient way of avoiding the patent thicket problem. After all, concerns over stalled licensing negotiations and burdensome royalties can be avoided entirely if the researcher simply

forgoes the licensing process and uses the tool or material without formal permission. What is even more confounding is that biotechnology companies have traditionally tolerated such behavior, ignoring rampant infringement by the academic community. This "rational forbearance" has become the norm in university/industry relations (Cai, 2004). Why? There are several reasons, including a lack of financial incentives and a willingness to stay on good terms with universities. A university technology transfer interviewed by Walsh and Cohen summed up the reasons for condoning infringing behavior: "Asserting against a university doesn't make sense. First, there are no damages. You cannot get injunctive relief and/or damages. What have you gained? You've just made people mad. Also, these firms are consumers of technology, as well. No one will talk to you if you sue. We all scratch each others' backs. You will become an instant pariah if you sue a university" (Walsh, Arora et al., 2003).

The lack of financial damages is a powerful disincentive to initiate an expensive lawsuit. In suits against a university, "[m]onetary rewards could be reduced to zero for the same reasons that monetary relief is traditionally low in some situations: the relevant user groups—in this case, noncommercial research institutions—lack resources to pay for the inputs they need. Moreover, the economic value of the use—in this case, basic research—is highly speculative, and courts do not generally award speculative damages" (Dinwoodie and Dreyfuss, 2004). Another strong motivator is the desire for firms to maintain good relations with academic institutions. Jon Sandelin, who works in Stanford's tech transfer office, points out that companies are "very sensitive about their position with the university and they want to be seen as a good friend of the university…because they look to the university, in many cases, to outsource some of their

R&D, and, of course, for hiring employees, and in building consulting relationships with faculty" (Sandelin, 2006). Allowing infringement of a company's patent is also a shrewd way for firms to reap the benefits of academic research work. If a university researcher infringed a research tool patent and made a potentially lucrative discovery, the company which owned the patent rights on the tool could swoop in and cherry pick downstream profits. This attitude was present in the surveys of Walsh and Cohen, who reported that "several respondents noted that they actually welcomed universities using their patented technologies because if the university discovers a new use, the patent holder is best positioned to exploit the innovation" (Walsh, Arora et al., 2003).

These motives all provide strong incentives for companies to tolerate some level of infringement of their patents by the university community. Even when companies have discovered specific cases of unauthorized use, they may send letters or name the culprits, but they have generally stopped short of bringing suit against individual researchers or their institutions. One example occurred in 1995, in the case of Hoffmann La Roche v. Promega, a suit over the polymerase chain reaction (PCR), a nearly ubiquitous genomic research tool. As part of its case, pharmaceutical giant (and owner of the PCR patent) Roche supplied the court with the names of more than 200 researchers (including scientists from Harvard, M.I.T., the National Cancer Institute, and Stanford Medical School) who, they claimed, had been infringing their patents by using the PCR technique without licenses. However, the company refused to take any action against the researchers, choosing instead to go after the commercial entity which had enabled the infringement and supplied the unauthorized materials (Fore, Wiechers et al., 2006).

Thus, infringement suits against universities are rare; one author claimed she could find just two instances of such a suit, one in 1996 and another in 2002 (Weschler, 2004).

The reluctance of companies to sue scientists and universities has given them cause to avoid taking licenses and paying royalties in many instances. Until 2002, academic researchers thought they might have another trump card that they could play if threatened by a lawsuit. Because most of their work was noncommercial in nature and was used primarily for basic research purposes, many felt that their work was covered by a "research use exemption", based in U.S. common law, which shielded them from claims of infringement.

Section 2

The common law research use exemption

Origins of the common law exemption

The basis for a research use exemption is not grounded in statute. Rather, it can be traced back to a dictum first articulated by Supreme Court Justice Joseph Story in the 1813 case of *Whittemore v. Cutter* [4], where he established the argument that some uses of patented inventions should not be labeled as infringement. In his opinion, Justice Story wrote that "it could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its desired effects." Thus, in laying the foundation for an experimental use exemption, Justice Story defined two conditions under which otherwise infringing activities would be excused: 1) if the invention in question was used purely for "philosophical" research, or 2) if the accused infringer was attempting to verify the claims of the patent.

Later that same year, Justice Story added another condition to the experimental use exemption litmus test. In the case of *Sawin v. Guild*[5], he claimed that "[T]he making of a patented machine to be an offense…must be the making with an intent to use for profit..." The idea that infringement should be tied to monetary gain was echoed by William Robinson in *The Law of Patents for Useful Inventions*, in a treatise entitled "No Act an Infringement unless it Affects the Pecuniary Interests of the Owner of the Patented

[4] 29 F. Cas. 1120 (C.C.D.Mass.1813) (No. 17,600)
[5] 21 F. Cas. 554 (C.C.D.Mass1813) (No. 12,391)

Invention" (Karp, 1991). Up until the 1980s, U.S. courts generally continued to uphold this notion that infringement was contingent upon commercial interest (Karp, 1991). Absent any financial damage to the patent holder, the doctrine of *de minimis non curate lex* [the law is not concerned with trifles] was cited and courts were reluctant to award damages or grant injunctions against researchers or institutions whose work did not threaten the profitability of the patents they were accused of infringing (Karp, 1991). However, courts were far less willing to entertain the experimental use defense when the "research" activities contained even a hint of commercial enterprise.

In 1980, judicial precedent had already carved a narrowly-defined, common law exemption which seemed to shield most academic researchers, so long as their work avoided commercial incentives. However, in that year, the passage of the Bayh-Dole Act, which encouraged universities to patent and commercialize discoveries, further blurred the line between "academic" and "industrial" research. Important research discoveries and the promise of valuable intellectual property rights were now inextricably linked (Lee, 2004). In addition to the passage of Bayh-Dole, the continued growth of the nascent biotechnology industry precipitated an increase in the assertion of intellectual property rights by courts, resulting in an even further narrowing of the informal experimental use exemption (Lee, 2004).

This new attitude was reflected in the 1984 case of *Roche Products, Inc. v. Bolar Pharmaceuticals Co.*[6] Bolar, a generic drug manufacturer, had obtained and manufactured patented drug chemicals in order to do research needed to secure FDA approval of a generic version of Roche's drug Dalmane. However, the Court of Appeals found Bolar's research constituted infringement because "Bolar's intended

[6] 733 F.2d 858 (Fed. Cir. 1984)

'experimental' use [was] solely for business reasons and not for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry."

As a result of this case, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly referred to as the "Hatch-Waxman Act"), which allowed drug companies to perform research on patented materials (including drugs and medical devices) in order to obtain clinical data required for government approval (Thomas, 2004). Specifically, the Hatch-Waxman Act amended 35 U.S.C. § 271, by adding that infringement would be exempted when patented inventions were used "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs…"[7] However, this narrow exemption was limited to the arena of pharmaceuticals, and did not address the broader question of the use of patented research tools.

Madey v. Duke

In 2002, the ability for researchers to claim protection under a research use exemption was further restricted in a case involving Duke University.[8] The case centered on John Madey, a physics professor, who operated a lab at Duke containing laser technology for which he held patents. After his resignation, Duke continued to operate the equipment for research and educational purposes. When Madey sued for patent infringement, Duke claimed that since its use of the patented items was for basic research and was not commercially motivated, they were exempt from patent infringement under the experimental use defense. A North Carolina District Court found

[7] 35 U.S.C. § 271(e)(1)
[8] 307 F.3d 1351 (Fed. Cir. 2002)

this argument sufficiently compelling to dismiss the infringement charges.[9] However, upon appeal, the U.S. Court of Appeals determined that the District Court's interpretation of the experimental use exemption was "overly broad", and that the defense was not applicable in this circumstance.[10] The Federal Court found that even though Duke's activity was not commercially motivated, the use of the patented materials "unmistakably further[ed] the institution's legitimate business objectives, including educating and enlightening students and faculty participating in these projects." The important distinction made by the Court here was that the absence of economic incentive was no longer the key determinant in applying the experimental use doctrine:

> *regardless of whether a particular institution or entity is engaged in an endeavor for commercial gain*, so long as the act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly defined experimental use defense. Moreover, the profit or non-profit status of the user is not determinative. [emphasis added]

This new precedent seemed to suggest that even scientists involved in basic research, far from industrial use, could still be held liable for infringement.

Merck KGAA v. Integra

A more recent case also appears to have affected the scope of the research use exemption, this time concerning primarily the "Hatch-Waxman" exemption, 35 U.S.C. § 271 (e) (1). In the late 1980s, Merck KGAA (Merck) began sponsoring research at Scripps Research Institute to study angiogenesis (the formation of blood vessels) within tumors, using a class of proteins known as "RGD peptides" (Scalia, 2005). These peptides had previously been discovered and patented by the biotech company Integra

[9] 266 F. Supp. 2d 420 (M.D.N.C., 2001)
[10] 307 F. 3d 1351

Lifesciences (Integra), who sued Merck for infringing the patents. Merck claimed that it was exempt from patent infringement, because the research it sponsored was related to drug development and should therefore come under the protection of the Hatch-Waxman exemption, since the research produced data that would ultimately be required for submission to the FDA.

However, both the District Court and the Federal Circuit Court of Appeals found Merck's argument unconvincing, finding that "the Scripps work sponsored by [Merck] was not clinical testing to supply information to the FDA, but only general biomedical research to identify new pharmaceutical compounds." In other words, the Merck research was too basic, too far upstream to be considered "reasonably related" to drug discovery. Notably, though, Judge Pauline Newman in the Court of Appeals, issued a vehement dissenting opinion, arguing that Merck/Scripps' activities should be immune under the traditional formulation of the common law exemption because their work involved "research into the science and technology disclosed in [the] patents" (Newman, 2003). In her dissent, Judge Newman claimed that the Merck/Scripps research was covered by the whole spectrum of exemptions, with the § 271 (e) (1) exemption picking up where the common law exemption ended: "…the territory that the Scripps/Merck research traversed, from laboratory experimentation to development of data for submission to the FDA, was either exempt exploratory research, or was immunized by § 271 (e) (1)" (Newman, 2003).

In 2004, the case was taken up by the U.S. Supreme Court, which found that the two lower courts had applied a construction of the § 271 (e) (1) exemption that was improperly narrow. The Court held that Merck/Scripps' research, even though not

directly intended to produce drug data for submission to the FDA, was covered by the "safe harbor" exemption because it was foundational research required in the drug discovery pipeline, perhaps broadening the Hatch Waxman exemption to cover many types of basic biomedical research. However, the Court was measured in its words and was very careful not to construe the ruling too broadly, especially into the area of research tools. In a footnote, the Court explicitly stated that "[w]e…need not—and do not—express a view about whether, or to what extent, § 271 (e) (1) exempts from infringement the use of "research tools" in the development of information for the regulatory process" (Scalia, 2005).

In the wake of the *Madey* and *Merck* cases, many have argued that the common law exemption is, at best, extremely ambiguous, and, at worst, completely useless to academic researchers. Therefore, calls for a codified research use exemption have received renewed interest. However, before examining the various legislative proposals, it is necessary to examine the current research climate, in order to determine the appropriate scope of any patent reform legislation.

Section 3

The current climate of university research

To avoid unintended consequences and the unnecessary weakening of patent rights, the reach of any exemption proposal should extend just far enough to address the scope of the underlying problems of patented research tools. Therefore, it is necessary to examine the current climate of academic research to see if conditions warrant action, and, if so, which proposals are best suited to reduce hindrances to innovation. This examination will proceed by first considering whether or not the general concerns over patented research tools have become manifest, as many commentators have feared. Secondly, we will examine the specifics of research in the post-*Madey* environment, to determine if firms have changed behaviors and if there is an increased risk of suits being brought against universities for infringement.

Are biotech patents hindering research?

The aforementioned potential obstacles to academic research resulting from intellectual property rights on research inputs (anticommons effect, patent thickets, and royalty stacking) have been cited as problematic for more than a decade. Have these patent issues stifled academic or basic research? There is some evidence that patent rights on genomic discoveries does hinder downstream use of the product or process, particularly in the area of DNA sequences that are used as research tools.

One way of tracking the effects of patenting on downstream use is by using the number of times an article describing a technology is cited by subsequent research articles as a proxy for how broadly the technology is available to the research

community. The more times an article is cited, theoretically, the more easily it is obtainable by scientists. One quantitative citation analysis by Bhaven Sampat found that articles describing patented genomic discoveries received approximately 8 percent fewer citations than similar articles, the subject of which were unpatented materials (Sampat, 2004). However, this effect was due almost entirely to declines in citations on patented DNA sequences used as research tools. Sequence based patented discoveries experienced a 14 percent decline in citations versus unpatented sequences, while for nonsequence genomic tools, patenting caused no decline in subsequent citations (Sampat, 2004). Another quantitative citation analysis by Murray and Stern discovered that citations on biotechnology articles in *Nature Biotechnology* declined 9 to 17 percent after a patent was granted on the discovery in question, leading the authors to conclude that "there is robust evidence for a quantitatively modest, but statistically significant anticommons effect" (Murray and Stern, 2005).

So, if there is some evidence that patents may interfere with downstream academic use, is that having an effect on the research community? Anecdotally, there seems to be evidence that patents can affect how research is conducted. Sue Patow, an officer in the University of Minnesota's technology licensing office claims that IP concerns have become so severe that "universities are reticent to share information" for fear of violating licensing agreements or undermining lucrative patent rights (Patow, 2006). A 2005 survey conducted by Steven Hansen of the American Association for the Advancement of Science (AAAS) community found that "[i]n the case of university based bioscience researchers, 35 percent who acquired patented technologies reported difficulties affecting their research" (Hansen, Brewster et al., 2005). Of those scientists

who reported difficulties, more than half (58%) had their research delayed, while more than one quarter (28%) had to abandon the research project entirely (Hansen, Brewster et al., 2005).

However, surveys and interviews conducted by John Walsh, Wes Cohen, and Ashish Arora contend that patents on research tools are having, at most, a very modest effect on university research and are not posing a significant threat to innovation. While over a third of respondents acknowledged that concerns over patented research tools caused delays and increased the cost of projects, the authors found that "almost none…reported commercially or scientifically promising projects being stopped because of issues of access to IP rights to research tools" (Walsh, Arora et al., 2003). Out of 55 respondents who cited delays due to patent concerns, only one could identify a specific project being abandoned because of a failure to obtain patent rights (Walsh, Arora et al., 2003). A 2005 follow up study found that "even modifications or delays are rare, each affecting around 1% of our sample" (Walsh, Cho et al., 2005). Furthermore, in cases where there are delays, "the vast majority of agreements [over licenses or materials] are settled in under one month" (Walsh, Cho et al., 2005). The authors conclude that the anticommons effect "has not been especially problematic" (Walsh, Arora et al., 2003).

But what about royalty stacking and increased costs of licenses? Has this prevented academic researchers from pursuing worthwhile projects? Again, the studies of Walsh, Cohen, and Arora suggest not. The survey and interviews found that although licenses and royalty fees (sometimes to multiple owners) had increased the cost of research, researchers thought such increases were "within reason largely because of the productivity gains conferred by the licensed research tools were thought to be worth the

price" (Walsh, Arora et al., 2003). Also, the added cost of licensing fees was found to be small in most cases. Twenty-two of twenty-three researchers responding to a question about licensing fees responded that there was *no* fee requested by the patent holder for their use of the technology; the other respondent claimed the fee was in the range of $1 to $1,000. (Walsh, Cho et al., 2005). These responses led the authors to conclude that "royalty stacking does not represent a significant threat to ongoing R&D projects" (Walsh, Arora et al., 2003).

As a result of the two studies, the authors have determined that most of the concerns over the effects of patented research tools on basic research have not become reality. The authors acknowledge that while "the patent landscape has indeed become more complex, with more patents on upstream discoveries…few of the frictions that had been anticipated had materialized" (Walsh, Cho et al., 2005). These findings have been echoed by researchers in other countries. A 2006 report by the Organization for Economic Cooperation and Development (OECD) claimed that "these findings [of the Walsh/Cohen surveys] are in keeping with the results of an earlier, smaller, German study. The work of Straus suggests that 'patents on research tools have not had a discernible effect on the cost or pace of research in Germany'" (Dent, Jensen et al., 2006). An earlier work by the OECD had also concluded that "a large gaps exists between the concerns of the public [over complex IP arrangements] and the actual problems identified by experts and documented by survey" (OECD, 2002).

Still, Walsh/Cohen and others acknowledge that even though concerns about research tool patents may be unfounded at this point, there is the potential for them to hinder research in the future. Walsh and Cohen concluded that although they found little

evidence that multiple patents are hindering access, "conditions may indeed be conducive to a tragedy of the anticommons" (Walsh, Arora et al., 2003). The authors also warned that "our interviews and prior cases suggest that…ongoing scrutiny is warranted" (Walsh, Arora et al., 2003). Furthermore, "although stopped and stillborn projects are not especially evident, many of the working solutions to the IP complexity can impose social costs…[T]he use of substitute research tools, inventing around or going offshore—although all privately rational strategies—constitute a social waste" (Walsh, Arora et al., 2003). In 2003, the President's Council of Advisors on Science and Technology (PCAST) also warned of the potential for patents to begin hindering downstream innovation and recommended further monitoring to ensure "access to these [research] tools for further research and exploration" (PCAST, 2003). Thus, while it appears that patents on research tools represent, at worst, a moderate threat academic research, the potential does exist that future conditions could exacerbate this situation and seriously affect academic research, and even current "working solutions" may not be the socially optimal solution to these issues.

***Madey v. Duke* and university tech transfer**

The second question to ask regarding the current research climate concerns the fallout from the *Madey v. Duke* decision in 2002. The court's finding, which essentially eliminated universities' ability to escape infringement claims by using the common law research use exemption, could alter firm behavior and allow companies to begin asserting patents against universities, undermining the traditional "rational forbearance" that has defined the academic/industrial relationship for two decades. Not only could companies continue to file suits against other firms, but "patentees may be emboldened by the

decision…to extend their aggressive patent enforcement to noncommercial 'pure research' as well" (Keyes, 2002).

The biggest threat, however, is not just that individual institutions could face legal battles and costly damages. The decision itself, and the lack of a common law exemption on which to rely, could have profound effects on technology licensing offices and university behavior. Josh Sarnoff, in an amicus curiae submission to the Court of Appeals for the Federal Circuit, argued that "[a]s recognition and understanding of the Madey decision continues to expand…the willingness of scientists and their institutions to ignore patents will continue to deteriorate" (Sarnoff, 2005). Universities would no longer be able to turn a blind eye toward scientists who did not take licenses and would be especially unwilling to "countenance unauthorized use, knowing there is a risk of treble damages for willful infringement" (Dreyfuss, 2003). Caught in legal limbo, where they are unsure if their activities could be protected under any type of an exemption, some fear that universities "will be forced to bear substantial administrative and financial costs to cover patent searches, infringement opinions, licensing agreements…" (Keyes, 2002). This kind of work regarding intellectual property is standard operating procedure in industrial settings, but could pose a major problem for nonprofit, academic institutions, because "[w]hile corporations have legal departments geared towards answering potential legal quagmires, universities do not have the infrastructure to render routine opinion work to researchers" (Barash, 1997).

In addition to the financial burden which would be placed on universities to more strictly monitor patent rights, the time and energy devoted to such an enterprise would considerably overtax tech transfer staff. Joyce Brinton, of Harvard University, claims

that if universities were required to work out licenses for each use of patented materials, "it would be a disaster for the research community and the academic world…it would be a terrible problem. We would be spending all of our time negotiating licenses, it would be an enormous impediment to research. It's not merely negotiating in terms of regarding how much are you going to pay…that's the least of the problem" (Brinton, 2006). Sue Patow, from the University of Minnesota, echoing this claim, pointed out that while costs may be an issue, another major problem is "the bureaucracy of getting all the agreement agreed upon" (Patow, 2006). For these reasons, the National Research Council warned that if firm behavior shifted as a result of the Madey decision, or universities became wary of relying on the tenuous common law exemption, "[t]he administrative burden on investigators and their institutions and the financial cost of efforts to ensure observance of patent rights could be considerable" (NRC, 2004).

But have these threats materialized? We will answer this question by examining two different subquestions: 1) Are firms more likely to assert patent rights against universities since the *Madey* decision?; and 2) Have universities become more vigilant in preventing illicit use by their researchers and have those changes in university behavior affected research?

***Firm behavior post*-Madey v. Duke**

Immediately following the *Madey* decision, there was some concern that universities were getting an increasing number of letters from companies, stating that particular researchers were violating patent rights by using materials without a license ("notification letters"). This behavior could have signaled that companies were, indeed, emboldened by the decision and felt more justified in demanding universities take

licenses. The National Research Council (NRC) reported that "[a]n informal poll of research institutions…revealed that a number of institutions were receiving more notification letters…in the aftermath of the decision" (NRC, 2004). An increase in notifications was reported by the AAAS, which had collected information from 66 research institutions (NRC, 2006). A presentation to the National Academies concluded that "[t]he percentage of participating institutions receiving notifications has already increased" (NAS, 2005).

However, in the four years since the *Madey* decision, the fears that companies would no longer tolerate infringement seem to be dying down. It appears observers believe that increases in letters are negligible, certainly not the wave of assertions which some had expected following the verdict. Steve Heinig, of the American Association of Medical Colleges (AAMC), claims that there "hasn't been a big blip as far as we can tell as far as activity of institutions receiving letters…I don't think there's terribly much concern at this time that there are more companies, or that any one company is more apt to assert a patent right" (Heinig, 2006). Joyce Brinton agrees with this assessment: "You know, there might have been a few more after the court case, but not enough to make any real difference…The marginal increase in numbers of inquiries is so minor so as to be almost not worth thinking about…" (Brinton, 2006).

The surveys of Walsh, et al. also demonstrated a small increase in the number of assertion letters: "Five percent of our academic respondents have been made aware of such notification. This is not much different from the 3 percent of our respondents who report having received such notification five years ago, prior to the *Madey v. Duke* decision. It is interesting to note that these numbers remain quite small" (Walsh, Cho et

al., 2005). Even when universities receive letters, the effects on research are typically minimal. The National Academies presentation which noted an increase in letters also pointed out that for 77 percent of the cases in which a letter was received, the project was not affected at all. Five percent of the letters resulted in a delay, and five percent required changing the project. Only two percent of the projects were abandoned as a result of a notification (NAS, 2005). This minimal increase in assertions, and their lack of effect on research projects has led some to conclude that "[d]espite the dire predictions regarding Madey's implications, it appears that university research thus far has survived largely unscathed. Many university researchers continue to use patented materials without permission and are not being sued, or even questioned, by the relevant patent holders (Weschler, 2004).

***University tech transfer post*-Madey v. Duke**

Despite the apparent lack of an industry-wide response, have universities changed their behavior in response to the loss of the common law exemption? It appears that for researchers, many of whom continue to use patented materials without licenses, the Madey decision has made little impact on their concerns over IP rights. Walsh, et al. reported in 2005 that the decision had "only a modest effect on the sensitivity of academic bench scientists to the use of others' intellectual property, since only 2% of our academic respondents have started looking for patents since that decision" (Walsh, Cho et al., 2005). Joyce Brinton points out a similar lack of urgency from scientists at Harvard: "[C]ertainly there has not been a rush from researchers to come to the [technology transfer] office to say, 'Oh dear, I'm worried about my project because I may have need for technology that is patented by somebody else'" (Brinton, 2006).

However, while scientists appear to be no more concerned with patents than before Madey, the institutions themselves do seem to be more observant. The 2005 Walsh study found that "institution level concern [over infringement] appears to be growing" (Walsh, Cho et al., 2005). The 2005 survey revealed that 22 percent of researchers had been contacted by their institution to watch out for patents in their research, a 7 percent increase from the number who reported such notification before the Madey decision (Walsh, Cho et al., 2005). Sue Patow points out that the University of Minnesota has stepped up efforts to warn researchers of respecting IP rights: "[W]e're making sure our scientists understand who owns the IP, where it lies, as well as whose IP they're going to be using to do their research…They were very cavalier in the past about, 'Well, I'm just going to use this because I'm just doing internal research', and we're saying, 'That doesn't hold anymore'" (Patow, 2006).

Patow also points out that companies have somewhat altered their behavior in terms of licensing agreements. The companies, she claims, have sensed an opportunity to force universities to take licenses, and that "the agreements that come from these companies are incredibly onerous…I see a lot more of it since *Madey v. Duke*" (Patow, 2006). These terms can be so burdensome that they force universities to alter their willingness to agree to licenses, which may be impeding research: "I have to be honest, there are some [licensing agreements] that we're walking away from, and we're basically saying to our researchers, 'We're not going to sign this agreement, it's not fair, you're going to have to find another source'" (Patow, 2006). However, Jon Sandelin, at Stanford, insists that he hasn't witnessed any great shifts in the academic industrial relations since *Madey*: "I haven't personally seen any significant changes in our

relationships, and our dealings, how we approach dealings, how we basically handle ourselves because of these issues" (Sandelin, 2006). He claims that this stability is due to the fact that "companies and universities aren't competitors, they're motivated in the same direction, and that is to take some technology created in the university and move it forward into commercial markets, and that creates profits for the company and royalties for the universities and everybody wins" (Sandelin, 2006). Thus, it appears that while the number of assertions may be little changed, there may already be some shifts in firm behavior, with a correspondent change in university attitudes toward patent rights.

Future potential consequences of *Madey*

However, while the worst fears of full-fledged litigation increases have to this point been avoided, there is still the danger that aggressive behavior by firms could alter the delicate situation facing nonprofit research institutions. Joyce Brinton emphasizes that the success of the current steady state "depends upon whether there's a real increase in that enforcement mentality [by companies] and that's possible" (Brinton, 2006). Such a change could occur quickly. One respondent to a study by the Australian Council of Intellectual Property (ACIP) pointed out that "it would only take a small number of significant infringement suits against researchers…to see a significant degree of 'shyness' develop in the research community" (Dent, Jensen et al., 2006). The National Research Council claimed that just "a few cases of successful patent assertions could have a powerful demonstration effect [on universities]" (NRC, 2006).

This potential danger and the precarious standing of the current situation seem to be the primary driving force behind exemption proposals. Since there have been no major suits brought against universities in the wake of *Madey*, all concerned parties are

unsure how the newly defined exemption will be applied. Instead of settling the research exemption question, the Court's ruling "may heighten any problems raised by uncertainty over the reach of the experimental use defense" (FTC, 2003). Josh Sarnoff also advocates for a clarification of the exemption through statute, despite the relatively small effects on the research community thus far: "[Y]ou see a low level of science experiments that are delayed or rejected, but an increasing number and the question is: 'should you be concerned about that?' And I think you should be very concerned because any system which depends on, for its ability to continue to do the science on ignoring the law as its currently stated in Duke is a bad system" (Sarnoff, 2006).

Steve Heinig, who has been an active member in discussions about the AAMC's position on the research use exemption, claims that while "there's a lot of conformity that [the chances of companies suing universities] is not a very great danger at this time…I think that there's also an agreement generally that this could be a worry, and then the difference in opinion is active to become to head off or to remediate a situation that hasn't arisen yet" (Heinig, 2006). Steve Merrill, who staffed the NRC committee that recommended a form of research exemption, shares the sentiment with Heinig, explaining that while the committee thought lawsuits against university were still unlikely, "they thought it was possible, and to the extent that there were public policy measures that could intervene and prevent it and didn't have other downside effects, then they ought to be considered and maybe adopted" (Merrill, 2006).

Section 4

Crafting a codified research use exemption

The need for legislative action

Certainly, the unclear status of the current common law exemption is a source of uneasiness and confusion among researchers and their institutions, both academic and industrial. While the informal approach and "working solutions" adopted by universities and businesses have performed well to this point, the "social costs associated with this de facto exemption can be quite substantial" (Weschler, 2004). Therefore, many have championed the idea that a statutory research exemption in U.S. patent law "undoubtedly would protect experimental research more efficiently and with more certainty than this non-legal working arrangement" (Weschler, 2004). Additionally, a properly written codified exemption could help clear up the ambiguities which have arisen from judicial opinions on the matter.

Some critics have advised that federal courts (even the Supreme Court) are not the appropriate arenas in which to settle the issue of the proper scope of the research use exemption. They contend that since a strong patent code is so important to our nation's innovative capacity, legislators are in better position than justices to decide the appropriate form of any exemption. Some believe the task is simply too great for the courts to undertake, that judges "should not engage in the kind of nuanced policy balancing necessary to craft a meaningful experimental use defense" (Mueller, 2004).

In an amicus brief to the Federal Circuit in the *Madey v. Duke* case, Solicitor General of the United States Theodore Olson insisted that "any substantial altering of the balance between the goals of the patent laws and the demands of academic research calls for judgments that are legislative, not judicial, in nature" (Olson, 2002). Olson also went on to point out the potential absurdity of relying on Justice Story's original precedent, given the changes in research practices over the past two centuries: "Indeed, it seems improbable that a 190 year old judge-made defense with little rooting in any statutory text could anticipate the challenges of the modern academic and research environment and adequately accommodate the competing policy concerns raised by the parties in this case" (Olson, 2002). Not only have courts be unable to adequately define the exemption but most federal courts have been reluctant to even confront the issue. Most court decisions (with the exception of the *Madey* and *Merck* cases) have employed sufficient judicial restraint so as to avoid directly defining the research use exemption. In light of this refusal to even take up the issue, it appears that congressional action may be the only way to solidify the exact nature of the experimental use exemption (Mueller, 2004).

Defining the statutory exemption: the options

Should Congress find compelling reason to attempt to codify such an exemption, what would be the factors which it would have to take into consideration? Obviously, given the concerns of the academic community, the exemption should protect researchers and universities engaged in basic research activities for the purpose of promoting innovation. However, another challenge would also be to maintain the benefits of the monopolies granted by patent system which, themselves, are the cornerstone of U.S. innovative policy. As the OECD points out, "a first rate patent policy provides investors

with an incentive to invest, while not limiting any knowledge spillovers that will have only a small effect on this incentive to invest" (Dent, Jensen et al., 2006). Balancing these simultaneous factors would not be an easy challenge. Therefore, the first step in designing a codified exemption would be determining the scope of the exemption, how broad should such an exception be?

The consequence of drafting an exemption that is too broad could be disastrous for U.S. innovation and, indeed, antithetical to the goals of the patent system. Firstly, an overly broad exemption could "dissuade inventors from using the patent law to protect their ideas, thus reducing the level of public disclosure of new inventions" (Karp, 1991). The cornerstone of the patent bargain is that in exchange for a temporary monopoly over the use of their invention, patent owners must fully disclose their invention to the world, which prevents hording of ideas and encourages further innovation. Knowledge of a broad exemption "would encourage inventors to resort to state trade secret protection or perhaps no legal protections at all" (Karp, 1991). Such a result would undermine the entire U.S. patent system and could, ironically, stifle innovation much more severely than would happen in the absence of any exemption.

Secondly, and perhaps more importantly, an overly broad exemption would rob patent holders of licensing and royalty income and prevent them from recouping R&D money which they had invested in creating their invention. Especially in the world of research tools, where basic research constitutes a large percentage of the market share, a broad exemption would have the effect of "effectively eviscerating the value of patents on research tools" (Eisenberg, 1997). This loss of profitability would make it harder for smaller companies, whose business model is selling research tools, to attract investment

capital, which would reduce their ability to produce further products (Freeburg, 2005). Paradoxically, since universities and other smaller entities are more likely to have their patents stolen or imitated by larger firms, they could actually suffer more from a broad exemption: "A broad exception would be especially harmful to small firms, research centers, and universities that invent important advances, but do not have the resources to develop the advance into a commercial product" (Michel, 1992). Overall, the loss of profitability could "eliminate incentives for private firms to develop and disseminate new research tools, which could, on balance, do more harm than good to the research enterprise" (Eisenberg, 1997). The gains in output from universities and other research institutions would potentially have to be very great to make up for the decreases in innovation from biotech companies who would lose their incentive to invent.

Thus, it appears that any codified exemption should not represent a legislative free-for-all, as a broad exemption could be worse than no action at all. The question then becomes: how to craft a narrow exemption that will sufficiently protect and promote basic, university research, while ensuring an appropriate level of incentive for inventors to innovate and rely on the patent system. Steve Heinig points out that the trouble is "that we don't know exactly how to write a statutory exemption, it's very problematic to actually sit down and write out what we think would be exempted and what wouldn't be" (Heinig, 2006). Clearly, the devil is in the details. This paper will focus on creating an exemption based on two different distinctions: 1) commercial vs. noncommercial intent, and 2) research *on* an invention vs. research *with* an invention.

Commercial vs. noncommercial

Many observers have considered that the primary consideration in deciding which types of behavior would be exempted focus on the entity performing the research and whether or not there is commercial intent in the infringing behavior. Over the past century, the judicially-crafted common law exemption has rarely been applied to situations where the infringement was performed in conjunction with a business or commercial application.[11] The main theory was that "allowing an experimental use exception in a commercial setting allows subsequent inventors to free ride on the original inventor's work…This free riding can make it impossible for the original inventor to appropriate returns on early R&D investment" (Michel, 1992). Thus, some contend that any statutory research exemption should focus solely on noncommercial entities, whose work is conducted in the "public interest, broadly defined" (Sewell, 2005). Exempting their behavior is particularly important because, unlike industrial, commercial firms, academic institutions "do not always have the resources—or even the expectation of resources—to pay licensing fees for the technologies they need" (Dreyfuss, 2003).

Supporters of limiting an exemption to nonprofit institutions also point out that exempting their infringing behavior will also have little impact on the commercial entities which control the patents, because the university research is less likely than a for profit firm to use the patent to develop a product which would compete with the original invention (Strandburg, 2004). Of course, there is considerable difficulty in determining what constitutes nonprofit, basic, or academic work. Some have advocated a minimum threshold of federal funding (such as 50 percent) in order to qualify (Michel, 1992).

[11] The exception to this general rule of noncommercial status to invoke an exemption is, of course, the Hatch-Waxman exemption, which was intended to apply specifically to commercial entities. The key distinction is that the Hatch-Waxman exemption was meant to apply to a different context, the creation of generic drugs.

Others insist that any work done in a "noncommercial" setting should be exempted, if a substitute for the tool or reagent is not available (Hoffman, 2004).

The commercial/nonprofit dichotomy is particularly confusing in the biotechnology sector, given the intricacies of the academic/industrial interaction and the degree to which many universities have gone from "research collaborators to commercial competitors" in the biotech industry (Mowery, Nelson et al., 2004). Given that universities are major players in the acquisition of genomic patents and often reap huge profits from licensing fees, "a division of exempted and nonexempted research activities based on commercial implications would not make sense in today's research environment either" (Cai, 2004). Arti Rai contends that "[t]he key problem with any research exemption is that, given the commingling or research and commercial activity even in nonprofit institutions such as universities, delineating the activities to which the exemption should apply is likely to prove very difficult" (Rai, 2002).

Aside from being a difficult line to draw, the commercial/noncommercial distinction also may not be a fair one to make. After all, universities are engaged in drug discovery and other lucrative areas and do control valuable patent portfolios. Therefore, "[i]t might seem ironic, considering the number of patents secured by universities…and the revenue that such universities secure from the exploitation of such patents that implicit in such surprise and concern is an assumption that 'basic research' undertaken by universities should be treated differently from the same sort of research when undertaken in industry" (Cook, 2004). Some supporters contend that, "while it is certainly true that universities can be treated like commercial actors, doing so ignores crucial differences and could, ultimately, kill the traditional role that universities play in teaching, training,

and creating the spillover benefits that are ultimately reaped by the private enterprise" (Dreyfuss, 2004). However, U.S. Solicitor General Theodore Olson also notes the irony of the argument, claiming that "[t]here is nothing in the current patent laws to suggest that modern universities—many of which have themselves taken *advantage* of patent protection and entered into licensing arrangements—are somehow outside the class of potential infringers because of an asserted noncommercial status" (Olson, 2002). There is also the fear that if the exemption applied only to nonprofit research, a corporation could simply move its research operation onto university soil and reap the benefits of the exemption (Michel, 1992).

Paradoxically, an exemption targeted at noncommercial entities could also hurt universities, especially those who control lucrative patents, the majority of which are research tools that are licensed to other universities. Harvard's Joyce Brinton recognizes the danger of singling out universities for an exemption: "God forbid that anybody would propose this kind of legislation that is that research with [patented materials] is fine for nonprofits, but is not fine for anybody else. I don't think that the university community needs that kind of situation where they're being treated so differently, especially if at the same time they're licensing their patents for revenue" (Brinton, 2006).

Thus, since the commercial/noncommercial distinction appears to be problematic, perhaps it is appropriate to extend the exemption to activities conducted in a commercial setting, and possibly even those with a commercial intent. Given today's research climate and the extent to which universities are engaged in commercial enterprise, "[p]rofit motive should no longer be held antithetical to the experimental use doctrine,"

and any codified exemption should "consider the commercial realities of the twenty first century research and development process" (Mueller, 2001).

However, Josh Sarnoff points out that this is not necessarily a new idea. Even in the historical construction of the common law exemption, the fact that research was conducted by a business did not preclude the use from being exempted: "this type of activity [research which fell under the common law exemption] develops innovation and it shouldn't be restricted by patent law, period…if it was legitimate research, even though legitimate research helps a business, that was just fine" (Sarnoff, 2006). Clearly, social benefits from experimental use of patented inventions and profit are not mutually exclusive and the present of commercial potential does not taint the user from enjoying the protection of the exemption. Ducor echoes this sentiment, asserting that although the post-*Madey* research exemption "systematically exclude[s] from exemption all experimentation occurring in commercial settings...valuable follow-on research can and does occur in such contexts, and there is no policy justification for not exempting them" (Ducor, 1999). Rai concludes that "if we are going to have a research exemption to reduce deadweight loss, that exemption should apply to all research" (Rai, 2002).

Therefore, it appears that attempting to define an exemption based on commercial status is an extremely problematic way of crafting the scope of a statutory exemption. In today's confusing research climate, where the lines between traditional "basic" and "applied" research have become hopelessly blurred, and any attempt to establish any meaningful definitions for "nonprofit" and "commercial" research would be a futile effort. The OECD warned which warned that "[u]nclear definitions of exemptions could

have a chilling effect on the progress of basic science" (OECD, 2002). This is hardly the policy goal we are after.

***Research* with *vs. research* on**

Since using the commercial/noncommercial axis as the basis for a codified exemption may be difficult, perhaps even impossible, in today's research climate, many observers have concluded that the better alternative would be to base an exemption on the nature of the use, regardless of the profit motive of the user. The use of this criterion, assumes two basic ways in which patented inventions can be used in research. The first type of use (which we shall call experimentation *with* the invention) involves using the invention in the course of research in its prescribed way in order to achieve some goal or complete a project. For example, research *with* a microscope would involve using the microscope to examine cancer cells to explore how they grow in response to a certain anticancer drug. Most research using "research tools" falls into this category. The second type of use (which we shall call experimentation *on* the invention) involves research which is designed to study the invention itself. For instance, research *on* the microscope might involve taking it apart to examine how the lenses were arranged, or adjusting the mirrors to try to increase its resolution.

One champion of this strategy was Judge Pauline Newman in the *Merck v. Integra* case, where she advocated using these criteria in determining whether certain behaviors should fall under the experimental use doctrine. Judge Newman claimed that the "prohibition of all research into patented subject matter is as impractical as it is incorrect", noting the "fundamental distinction between research *into* the science and technology disclosed in patents, and the use in research *of* patented products or methods,

the so-called 'research tools'" (Newman, 2003). Accordingly, the Newman approach ignores profit motive as a criterion: "…an ultimate goal or hope of profit from successful research should not eliminate the exemption. The better rule is to recognize the exemption for research conducted to understand or improve upon or modify the patented subject matter, whatever the ultimate goal" (Newman, 2003).

Many other commentators have been persuaded to use this as the main criterion for establishing a research use exemption. "The experimenting *on* versus experimenting *with* dichotomy offered by dissenting Judge Newman in Integra has been widely accepted by commentators as an important, if not entirely determinative, factor in assessing experimental use" (Mueller, 2004). The idea of comparing research *with* to research *on* has also been cited as a key way to apply the experimental use exemption to research tools. Ducor claims that "applying the experimental use exemption to research tool patents is neither impossible nor unfair, provided one keeps in mind the policy goals underlying the patent system and makes the right distinction between research *on* an invention and research *with* an invention" (Ducor, 1999). In order to balance these needs, we must to return to our overall policy goal, summarized beautifully by Katherine Strandburg: "The purpose of an experimental use exemption should be to protect the patentee's ability to recoup her research and development investment while preventing her from using her exclusive rights to exercise unwarranted control over subsequent innovation" (Strandburg, 2004).

Supporters of a research *with* form of exemption claim that it addresses the most pressing issues surrounding patented research tools. Indeed, most research tool patents cover products that are generally used in a manner which would fall under the research

with criterion. For instance, patented gene products, sequences, techniques, and machines are all primarily used in the course of genomic research to develop other products, such as therapeutics or diagnostics. Rarely are the inventions themselves the subject of the research. Therefore, if the goal is to ensure adequate access to these inventions and preventing university researchers from having to pay burdensome licensing fees, then a codified exemption would ideally cover this type of research.

However, there are substantial downsides to exempting this kind of use of patented inventions. First, there is contention over whether allowing this kind of exemption would even be fair, considering that researchers would simply be using a product for its intended use and that exempting such use could undermine companies whose entire business models rely on their ability to sell these tools. Strandburg makes this point, drawing an analogy to other products these researchers use: "[t]here are many patented research tools…that are widely available on the market from parties whose business consists in selling such items. There is no immediately obvious reason that nonprofit research laboratories should avoid paying…for such inventions, just as they do for patented copy machines, computers, and staplers" (Strandburg, 2004). An Australian biotech company made a similar analogy, pointing out that "[r]esearch organizations do not get their computers free, they do not get software from Microsoft free, nor do they get their chemical lab supplies, staff, space, equipment and utilities free of charge. Why should they be empowered to utilize intellectual property free of charge without consideration or benefit for the inventor?" (ALRC, 2004).

Proponents of a research *with* exemption claim that the increased research and innovation which is enabled through money saved on licenses and expanded access to

patented tools more than makes up for the lost profits of a few research tools manufacturers. However, these arguments fail to take into account that any research *with* exemption would not only hurt research tool revenues in the short run, but would create disincentives for those same companies to develop new and better research tools. Universities fund most of their research through grants, and so loss of research tool revenues would be less catastrophic, but companies that sell research tools generally cannot fund their R&D without patent royalties. Without the promise of recouping their R&D investments, research tools manufacturers (many of whom are universities themselves), may be unwilling to even attempt to develop new research tools.

Considering that the new era of genomic research has been made possible in large part thanks to the introduction of research tools, the consequences of such an exemption could be devastating in the long run. All of these leads Ducor to conclude that "experimenting *with* a patented invention amounts to using it according to the purpose for which it was first designed, and for which the patentee was granted a monopoly…that such activities might lead to innovation in fields other than that of the patented invention, patentable or not, does not change the analysis" (Ducor, 1999).

On the other hand, allowing an exemption for experimentation *on* an invention may be in line with the basic aims of patent law: to encourage inventors to share their knowledge with others and foster increased innovation. In fact, many commentators believe that research *on* an invention (in order to test its properties or to verify the patent claims) is simply an extension of the disclosure required of the inventor (Dreyfuss, Rai et al., 2005). Since a patent application requires the inventor to fully disclose how the invention works (in verbal description and schematics), some claim that it would be

illogical to forbid other inventors from making or using the invention to examine if it works as advertised. This type of research is also very close to Justice Story's original formulation of the experimental use exemption, permitting researchers to "ascertain the verity and exactness of the [patent's] specification".[12] Proponents of exempting research *on* a patented invention claim that allowing other inventors to build and test the invention serves as a check on the patent system, helping to ensure inventions live up to their claims and weed out patents that have been granted erroneously.

However, the greatest argument in favor of exempting research *on* an invention comes from the fact that new inventions are rarely truly novel ideas; most represent additions to or improvements on previous inventions. To prevent scientists from tinkering with patented inventions would hinder their ability to make new discoveries. While granting patent protection to an idea is essential in promoting innovation for the initial inventions in a certain field, "[i]n order to *further* promote innovation, the patent system has to limit the monopoly of patent owners so as not to hinder subsequent research and improvements on existing technology. Innovation stems from the free availability of existing technologies, including patented ones" (Ducor, 1999). Downstream innovation based on experimentation *on* a patented invention could take many forms, including the discovery of a previously unknown use for the invention or of an improvement to the invention (Mueller, 2004).

But there is conflict over exactly what types of research *on* activities should be exempted. Uses aimed at discovering properties of the invention, or to test its claims, or even attempting to find a novel use for the product are consistent with the original common law exemption and promote the goals of the patent system. Furthermore, they

[12] *Sawin v. Guild*, at 555

do not pose a commercial threat to the inventor, since "invention is used for a different purpose from that for which it was originally designed. Such use represents only a minimal loss of revenue for the patentee, as his or her main market resides in other, non-experimental uses" (Ducor, 1999).

However, the question of experimentation to improve upon the invention or "design-around" attempts (the making of substitutes for an invention) are more contentious. Should it be permissible to allow researchers unfettered access to an invention, only to piggy-back on the original inventor's hard work and design a product which will replace it? Some say that is the essence of the patent system; since the end goal is to build a better mouse trap, it doesn't matter whose profitability is undermined, so long as innovation advances. If the second inventor's product is superior to that of the first, then he/she should receive the monetary award that comes from building a more useful product. Strandburg supports this notion, claiming that "the patent system anticipates that competitors will use the patent disclosure to make improvements or design-arounds…" (Strandburg, 2004). Furthermore, because this promotes the inherent goals of the patent system, "there is no reason to confine this type of experimental use to noncommercial applications" (Strandburg, 2004).

However, there is not a consensus that these types of possibly commercial behavior should be exempted. Opponents claim that while some of the more benign research *on* uses may be permissible, "it is unjustified and inconsistent with patent law to assume that these uses include experimental activity…in a commercial attempt to develop either a noninfringing alternative (design around) or an improvement upon an existing patent (Karp, 1991). Since we have already determined that the

commercial/noncommercial dichotomy is too difficult of a line to draw, any exemption which permitted research *on* a patented invention would have to address the question of which behaviors would be allowed, especially with regard to improvements or the creation of design-arounds.

Past U.S. exemptions and proposals

Previous attempts at codifying a research use exemption have often been met with resistance, and no such generic exemptions have been adopted. However, these prior proposals can inform the current debate and offer a potential template for the form and scope of a legislation option.

H.R. 5598, The Patent Competitiveness and Technological Innovation Act of 1990

Title IV of H.R. 5598 contained an exemption which, according to the Judiciary Committee report, would create "an incentive for research and experimentation activities that is the life blood of U.S. competitiveness in the world marketplace" (Kastenmeier, 1990). Section 402 of the bill sought to add the following exemption to 35 U.S.C. § 271:

> It shall not be an act of infringement to make or use a patented invention solely for research or experimentation purposes unless the patented invention has a primary purpose of research or experimentation. If the patented invention has a primary purpose of research or experimentation, it shall not be an act of infringement to manufacture or use such invention to study, evaluate, or characterize such invention or to create a product outside the scope of the patent covering such invention.

The bill was in the spirit of a research *on* exemption; infringing activity would not be permitted if the "patented invention has a primary purpose of research or experimentation" (Kastenmeier, 1990). The committee report on H.R. 5598 listed six activities that would be exempted under the statute:

1. testing an invention to determine its sufficiency or to compare it to prior art;
2. tests to determine how the patented invention works;
3. experimentation on a patented invention for the purpose of improving on it or developing a further patentable invention;
4. experimentation for the purpose of "designing around" a patented invention;
5. testing to determine whether the invention meets the tester's purposes in anticipation of requesting a license; and
6. academic instructional experimentation with the invention. (Kastenmeier, 1990)

The impetus for the research exemption originally came from a patent reform proposal in the previous Congress regarding transgenic animal patents, which contained a research use exemption. During the hearings on that legislation, the committee found support (including at least one representative from the Association of University Technology Managers) for the idea that a research exemption should extend to all patents, and not confined to the realm of transgenic animals (Kastenmeier, 1990). Another argument advanced by Rep. Robert Kastenmeier in support of the bill was that the statute would clear up ambiguity about the scope of the common law research exemption: "Confusion in the general patent law is contrary to sound public policy. Unnecessary litigation occurs, excessive threats are leveled, transaction costs are raised, and experimentation and research are chilled" (Kastenmeier, 1990).

However, not all parties agreed on the need for a codified exemption. Some observers pointed out that the current status of the common law exemption was sufficient and that the bill "fixes a problem that does not exist" (Barash, 1997). Rep. Carlos Moorhead, in an addendum to the committee report, pointed out the robustness of the common law exemption: "This long standing legal principle [the common law exemption] is sound and is a recognized feature of the patent system. I am not aware of

any reason to believe that there is a need for Congress to codify this doctrine." He went on to question the belief that the codified exemption was needed to protect university research: "I fail to understand what universities are being protected from. There has never been a case, to my knowledge, where a university has been sued for patent infringement for carrying on research on a patented invention" (Kastenmeier, 1990).[13] Others felt that the exemption, as defined in the bill, overstepped judicial construction of the research use doctrine and constituted a broadening of the common law experimental use exemption, instead of a mere codification (Michel, 1992). Despite the objections of some members of the Judiciary Committee, the research exemption survived the committee markup and was included in the final version of H.R. 5598, which passed out of the committee on October 26, 1990 with bipartisan support. However, the bill never came before the full House for consideration.

H.R. 3967, the Genomic Research and Diagnostic Accessibility Act of 2002

A similar research exemption appeared during the 107th Congress as part of H.R. 3967:

> USE OF GENETIC SEQUENCE INFORMATION- It shall not be an act of infringement for any individual or entity to use any patent for or patented use of genetic sequence information for purposes of research. This paragraph shall not apply to any individual or entity that is directly engaged in the commercial manufacture, commercial sale, or commercial offer for sale of a drug, medical device, process, or other product using such patent for or patented use of genetic sequence information.[14]

Here, Congress recognized the use of genomic sequences as a type research tool and sought to ensure their availability to the research community. In presenting the bill to the

[13] This objection, of course, was raised before the *Madey v. Duke* decision, and, therefore, is less relevant to the current debate.
[14] H.R. 3967. Section 2.

House, Representative Lynn Rivers of Michigan stated that the amendment would "protect from patent infringement scientists doing basic, fundamental, non-commercial research."[15] However, after being presented to the House in March of 2002, the bill was referred to the Subcommittee on Courts, the Internet, and Intellectual Property, and no further action was taken.[16]

Research exemption as fair use?

Another possible template for a codified exemption can be found in a different area of intellectual property: copyrights. Some observers have pointed out that the best way to frame a research exemption would be to adhere to the "fair use" doctrine, a well defined feature of copyright law that "provides that certain unlicensed but socially beneficial uses of copyrighted works such as reproduction for purposes of scholarly research, teaching, criticism, and reporting are not infringement" (Mueller, 2004). In deciding whether activities fall under the fair use exemption, courts apply a four way test, which takes into account: 1) the nature of the use (including commercial intent), 2) the properties of the protected work itself, 3) the amount of the work which was reproduced, and 4) the financial impact of the use on the rights holder (Grossman, 1990).

In the 1985 case of *Harper & Row Publishers, Inc. v. Nation Enterprises*, the court upheld the notion that fair use of copyrighted materials was consistent with the aims of patent law and that preventing some use of these works would stifle further artistic progress: "The author's consent to a reasonable use of his copyrighted works ha[d] always been implied by the courts as a necessary incident of the constitutional policy of

[15] Congressional Record, March 14, 2002. "Introduction of the 'Genomic Research and Diagnostic Accessibility Act of 2002' H.R. 3967 and the 'Genomic Science Technology and Innovation Act of 2002' H.R. 3966" p. E-353.
[16] H.R. 3967. Bill Summary and Status. http://thomas.loc.gov/cgi-bin/bdquery/z?d107:HR03967:@@@X

promoting the progress of science and the useful arts, since a prohibition of such use would inhibit subsequent writers from attempting to improve upon prior works and thus…frustrate the very ends sought to be obtained" (Grossman, 1990).

Therefore, because of the successful application in the field of copyrights, some feel that a fair use approach to a research exemption would create the desired effect without the worry of unintended consequences. But what would such an exemption look like? There are currently two examples of research exemptions based on copyright law. The *Semiconductor Chip Protection Act of 1984* amended title 17 U.S.C. § 906 (a) (1) and covers copyrights on the particular arrangement of elements on a computer chip called the "mask work"[17]. The amendment claims that is "not an infringement of the exclusive rights of the owner of a mask work for…a person to reproduce the mask work solely for the purpose of teaching, analyzing, or evaluating the concepts or techniques embodied in the mask work". In a similar exemption, the *Vessel Hull Design Protection Act*, researchers and boat-builders are permitted to construct copyrighted hull designs "solely for the purpose of teaching, analyzing, or evaluating the appearance, concepts, or techniques embodied in the design…"[18]

International Precedents

While current and proposed amendments offer insight into the possible structuring of a research exemption, statutes enacted by other nations can also serve as models. Member countries of the World Trade Organization (WTO) are bound by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to grant robust patent

[17] "Mask work" refers to "a two or three-dimensional layout of an integrated circuit (IC), i.e. the arrangement on a chip of semiconductor devices such as transistors and passive electronic components such as resistors and interconnections." http://en.wikipedia.org/wiki/Mask_work.
[18] 17 U.S.C. § 1309 (g)

protection. However, Article 26 of the document allows member countries to "provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties" (WTO, 1994). While the wording of the phrase is left extremely vague, when the phrase has been the subject of disputes, some countries have claimed that the statute implies acceptable "experimental" uses include design around attempts, improvements, and academic instruction (ACIP, 2005).

Most international statutory exemptions take a form similar to the Hatch-Waxman Act, allowing for experimental uses for the acquisition of clinical data in making generic drugs. One example is Canada's "Patent Amendment Act, 1992", which allows use of patented inventions "solely for uses reasonably related to the development and submission of information required under any law of Canada…"[19] However, some countries do, in fact, have more broadly defined exemptions, which cover a range of activities. The most broadly articulated exemptions in this category come from Europe, where most statutory regulations have followed the research *on* model. Article 31 of the European Community Patent Convention of 1975 provided a research exemption for "acts done privately and for noncommercial purposes" and "acts done for experimental purposes relating to the subject matter of the invention" (Cook, 2004). Although the Community Patent Convention was never officially adopted, most European Union countries have incorporated nearly identical language into their patent laws, applying the same two part test in defining the scope of the exemption. For example, the United Kingdom's "Patent Act 1977" contains an exemption which shields users from

[19] R.S.C. 1985, c. 2, s. 4. (Supp. 1992)

infringement claims if the activity: 1) is "done privately and for purposes which are not commercial"[20]; and 2) is "done for experimental purposes relating to the subject-mater of the invention."[21] Figure 4.1 shows several examples of current statutory exemptions in the U.S., United Kingdom, and Canada.

Figure 4.1: Examples of current research use exemptions

Name	Statute	Country	What is exempted
Hatch-Waxman Act	35 U.S.C. § 271(e)(1)	U.S.	Uses related to the submission of data needed for drug approval
Semiconductor Chip Protection Act of 1984	17 U.S.C. § 906(a)(1)	U.S.	Reproduction "solely for the purpose of teaching, analyzing, or evaluating" the mask work
Vessel Hull Design Protection Act	17 U.S.C. § 1309(g)	U.S.	Reproduction "solely for the purpose of teaching, analyzing, or evaluating" the hull design
Patent Amendment Act, 1992	R.S.C. 1985, c.2, s.4. (Supp. 1992)	Canada	Uses related to the submission of data needed for drug approval
Patent Act 1977	1977 Chapter 37 § 60(5)(a)	U.K.	Purposes that are "not commercial" and those "relating to the subject-matter of the invention"

Other nations outside of Europe have also adopted statutory research use exemptions. Israeli law exempts acts that are "not on a commercial scale and [are] not commercial in nature" and also those whose objective is to "improve the invention or to develop another invention" (Derzko, 2003). On the other hand, Japanese law lacks the requirements on commercial intent as articulated in the European exemptions, claiming simply that "the effects of this patent right shall not extend to the working of the patent right for the purposes of experiments and research" (Cook, 2004).

The unique case of Australia

In examining international attitudes toward experimental use exemptions, perhaps no other country's experience is as valuable to the United States as Australia's. This is

[20] Patents Act 1977. 1977 Chapter 37 § 60 (5) (a)
[21] Patents Act 1977. 1977 Chapter 37 § 60 (5) (b)

because, like the U.S., Australia also has no codified research exemption its patent law. However, the Australian government is in the process of seriously considering options, and two separate reports have been filed on the subject, one by the Australian Advisory Council on Intellectual Property (ACIP), the other by the Australian Law Reform Commission (ALRC).

Both ultimately suggested the adoption of a form of a limited codified research use exemption, while cautioning that exempting too broad of a range of activities could undermine the effectiveness of the patent system. Citing the current narrowing of the common law exemption in the United States, the ACIP concluded that "the current US approach is best avoided, as this reduces allowable experimental activity to a narrow set of circumstances that does not appear to be in accord with the fundamental principles of the patent system" (ACIP, 2005). The ALRC laid out a set of justifications for the recommended that a codified exemption should only be adopted if the statute, among other things, "…promotes attainment of new knowledge about patented inventions; promoted the development of new and improved technologies…removes a burden on researchers…and involves minimal interference with the patent holder's economic interests" (ALRC, 2004).

Specifically, the ALRC recommended a research *on* exemption, suggesting that the country amend the law to exempt "the use of a patented invention to study or experiment on the subject matter of the invention; for example to investigate its properties or improve upon it" (ALRC, 2004). Because the nature of "commercial" use has become such a murky issue, the commission also stressed that "[t]he legislation

should make it clear that the existence of a commercial purpose or intention does not affect the availability of the defence [*sic*]" (ALRC, 2004).

The ACIP echoed the majority of these sentiments, including the claim that the commercial/noncommercial distinction has become too difficult to form the basis for a research exemption (ACIP, 2005). Accordingly, the council recommended an exemption for "acts done for experimental purposes relating to the subject matter of the invention that do not unreasonably conflict with the normal exploitation of the patent" (ACIP, 2005). Acts which fall under the exemption include "determining how the invention works; determining the scope of the invention; determining the validity of the claims; seeking an improvement to the invention" (ACIP, 2005). The commission recognized that their exemption would inevitably create some ambiguities that could only be completely removed through case law (ACIP, 2005). However, the report also outlined several benefits of the proposal, including the notion that "the limits to patent rights are clarified, thus reducing uncertainty and resulting inefficiencies and underperformance in the research industry" (ACIP, 2005). However, the council also pointed out the advantage of adopting a law similar to the EU exemptions, pointing out that the proposed amendment would bring Australia "substantially in harmony with European provisions" (ACIP, 2005).

This argument about harmonization is also particularly relevant to the American situation. Through international agreements like TRIPS, there has been a strong movement toward unifying intellectual property laws across different countries, reducing barriers to technology transfer and removing unnecessary transaction costs associated with different laws in different regions of the world. Many observers feel that

implementing a research exemption in countries which do not have the provision would also be a beneficial step toward harmonization with other countries which currently have such a statute (Dent, Jensen et al., 2006). In the current situation, where there is little uniformity between exemptions in different regions, Cook claims that "[d]isparities in the scope of experimental use defenses can, in the long run, be expected to result in the shift of research from jurisdictions with a narrow such defense to those with a more permissive such law" (Cook, 2004). In this vein, some American commentators have suggested that if the U.S. fails to adopt a research use exemption (particularly in light of the narrowed, post-*Madey* experimental use defense) it could lead to increased outsourcing of research and a corresponding decrease in U.S. innovative output (Mueller, 2004).

Specific Legislative Options

Should Congress attempt to codify a statutory research exemption, legislators could rely on the recommendations of a number of groups, agencies, and commissions, both inside and outside the government, in addition to past legislative attempts and numerous international examples. While some of the following options vary significantly in scope, they almost universally share the characteristic of being in the category of research *on* exemptions.

AIPLA

One legislative option was presented by the American Intellectual Property Law Association (AIPLA) at a 2004 meeting of the group's Board of Directors. Relying on the model articulated by Judge Newman in the *Merck v. Integra* case, the organization ratified a resolution stating that it supported a statutory research use exemption, aimed at allowing research *on* a patented invention (NAS, 2004). Specifically, AIPLA endorsed

congressional action which would exempt activities performed to: 1) test the validity of the patent; 2) study the "features, properties, inherent characteristics or advantages" of the invention; 3) investigate new methods of making or using the invention; 4) invent alternatives (design-around) (Caltrider and Davis, 2004).

While the first two prongs of the recommended exemption met with little resistance, the last two suggestions worried some constituencies, who were concerned that the exemption would significantly erode the rights of patent holders. The Association of University Technology Managers (AUTM) adopted a resolution opposing AIPLA's recommended exemption. Mark Crowell, AUTM's President, explained in a letter to Michael Kirk, Executive Director of the AIPLA, that "AUTM is quite concerned that the AIPLA proposal…substantially broadens the common law exception to the detriment of patent holders, many of whom are U.S. universities and nonprofit research institutions who own patents in research and experimentation tools" (Crowell, 2005). Citing a lack of compelling evidence that university research was being hindered by fears of patent infringement, Crowell stated that "AUTM does not support an effort to seek an express research exemption at this time" (Crowell, 2005).

AAU/AAMC

Another recommendation for legislative action comes from a union of research/academic organizations led by the American Association of Universities (AAU) and the American Association of Medical Colleges (AAMC) and others. In responding to proposed bill H.R. 2795, the Patent Reform Act of 2005, AAU and AAMC, among others, recommended that the House Judiciary Committee "give careful consideration…to inclusion of an experimental research exemption in any patent reform

bill that goes forward" (AAU, ACE et al., 2005). Although a research exemption had not been included in the text of the bill, the academic institutions advised the inclusion of a "narrowly crafted exemption" which would "at a minimum allow research…to determine whether it functions as claimed, to better understand its operation under various conditions, to discover something unknown about it, or, under appropriate circumstances, to improve upon it" (AAU, ACE et al., 2005). However, at present, the recommendation has not been heeded and the Patent Reform Act of 2005 (H.R. 2795) does not contain any provisions for a research exemption.

Recommendations from the U.S. government

It is not, however, simply lobbying interests or concerned constituencies that have recommended specific legislative change in the United States. Multiple government entities and agencies have weighed in on the research exemption question, with most favoring a limited, research *on* exemption.

In 2003, the Federal Trade Commission issued its report "To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy" on the role of the U.S. patent system in ensuring scientific and technological progress. While the report embraced the notion of a limited research exemption, it admitted that the idea of exempting activities aimed at improving the invention or designing around it was a potentially highly contentious issue. The report debated the merits of exempting such behavior, claiming that it "poses the most difficult problem, because it affects the division of profits between initial and competing follow on innovators, both of which need adequate incentives, if their independent contributions are to be sustained" (FTC, 2003). Furthermore, the FTC warned against broadening the scope of such a statute to

include research *with* a patented invention, specifically in the case of research tools: "Extending an experimental use defense to infringement arising through use of tools to develop unrelated products appears problematic. Inventors of tools used by researchers need an income stream from those who use their inventions" (FTC, 2003).

The National Institutes of Health (NIH) has also commented on the research use question, through its Working Group on Research Tools, a group convened to combat the potential research slowdowns associated with the patenting of biomedical research tools. In 1998, the group advised that any serious examination of policies designed to alleviate the problems of patented research tools should include investigating proposals for a statutory "experimental use exemption" (NIH, 1998). The group cited the typical foreign model of the research *with/on* dichotomy, claiming it was a "sensible distinction" (NIH, 1998). The group also cautioned against an excessively broad exemption, which "could eliminate incentives for private firms to develop and disseminate new research tools, which could, on balance, do more harm than good to the research enterprise" (NIH, 1998).

Perhaps the most vocal proponent of a codified research exemption is the National Research Council, which has recommended such legislative action in two separate reports. In the 2004 report, *A Patent System for the 21st Century*, an NRC committee recommended that Congress should pass legislation to "shield some research uses of patented inventions from liability for infringement", although the group admitted that "reaching agreement on how this should be done will take time" (NRC, 2004). In laying out the arguments for and against the research exemption, the committee recognized the difficulty in formulating the exact scope of the policy, but ultimately concluded that "the

lack of a problem free formulation does not mean that Congress should not consider the options and try to craft a second best solution" (NRC, 2004).

A 2006 NRC report entitled *Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation, and Public Health* echoed the earlier call for a research exemption, this time offering a more thoroughly-crafted recommendation. This time, the committee advised Congress to adopt a research *on* exemption, using nearly identical language to the AIPLA proposal: "Congress should consider exempting research…if done to discern or discover: a) the validity of the patent and cope of afforded protection; b) the features, properties, or inherent characteristics or advantages of the invention; c) novel methods or making or using the patented invention, or; d) novel alternatives, improvements, or substitutes" (NRC, 2006). However, while the recommendation was meant to curb some of the fears of the academic community with regard to patent infringement, the committee still stopped short of recommending an exemption that would allow for unlicensed use of patent research tools.

Joyce Brinton, a member of the committee, notes that "there was consensus on the committee that having a research *on* exemption clearly annunciated would alleviate a problem, but not the problem that *Madey v. Duke* points toward" (Brinton, 2006). The recommendation of the research *on* exemption, Brinton explains, while not as directly applicable to concerns of nonprofit researchers, was still seen as a positive reform in the eyes of the committee, particularly in terms of harmonization with other countries: "Obviously, it's not the kind of thing in general that a university would be pursued about…but it was one that people felt safe in being able to make a recommendation

about, and that would be very similar to the patent laws of other countries" (Brinton, 2006).

Stephen Merrill, who staffed the NRC committee and edited the report, claims that the recommendation was "mainly proposed as a sort of prophylactic measure rather than to solve an immediate problem" (Merrill, 2006). As far as not recommending a research *with* exemption, Merrill explained that the committee felt "that it would not be supported by the patent bar, and secondly, that it would raise questions about the viability of firms engaged in developing and marketing research tools, whose business plans might be undermined" (Merrill, 2006). Merrill also noted that the introduction of a research *with* exemption would, far from harmonizing U.S. patent law with other countries, overshoot the foreign precedents for an exemption: "We would be bucking a lot of interests [with a research *with* exemption], including the interest in having a more uniform international catalog" (Merrill, 2006).

Analysis

So, after examining the legislative options for a codified exemption, which would be most appropriate for Congress to consider? To begin, it appears that the commercial/noncommercial distinction is far too difficult to apply, given the current climate of academic research and the commingling of "basic" and "applied" experimental activities. Therefore, any exemption proposal should not consider noncommercial status of the researcher or organization as a criterion necessary to be protected. Universities have become prime players in the area of genomic discoveries, the acquisition DNA patents, and the development of profitable research tools. To treat them differently

would be ideologically inconsistent with the aims of increasing the overall output of innovation. If that is the goal, then all research entities, whether nonprofit or commercial in nature, should be eligible for the exemption.

Since the commercial/nonprofit nature of the organization is not the defining criterion for defining a research exemption, it appears that the nature of the use is the only other logical distinction that can be made. Specifically, the line can be drawn between research performed *on* the patented invention, and research performed *with* the patented invention. Most uses falling under the heading of research *on* appear to be an appropriate extension of the enabling disclosure requirement, as they are simply intended to verify the claims of the patent or to examine the invention first hand. These uses clearly fall under the scope of Justice Story's original formulation of the common law research use exemption, would not affect the inventor's financial stake in the invention, and would generally be met with little or no resistance.

However, two other uses are more controversial: experiments aimed at finding novel uses or finding alternatives to the invention (design-around research). These two options are most problematic because they have the possibility of undermining the profitability of the invention, which could erode patent rights and make inventors hesitant to invest R&D capital or to patent their discoveries. However, there are two main arguments that appear to trump this fear. Firstly, in the case of novel uses, if a researcher discovers a new use for a patented invention, the inventor is in the prime position to capitalize on these new uses because they own the patent, regardless of the use. For example, if a university scientist reveals that a particular drug, created to treat diabetes, also cures a certain type of cancer it is the pharmaceutical company, not the researcher or

the university, which will make money off of the new discovery because they own the underlying patent. Moreover, a license to use the original invention would be required to sell a service or product embodying the improvement, so the original inventor would benefit, even though deprived of revenue during the research phase of the follow-on invention.

Secondly, the best response to the concern over design-arounds appears to be that it is exactly the type of activity the patent system is supposed to incentivize. If the aim of patent law is to increase innovative output, then the U.S. Patent and Trademark Office (USPTO) should be primarily concerned with the net number of inventions, not where they are coming from. If research *on* a patented invention leads to a better mousetrap, so be it. That is the aim of the free market, within the context of the patent system.

Finally, the argument for harmonization, while not entirely determinative, is a compelling reason for legislative action. Particularly in the area of intellectual property law, where there has been so much push by the United States and WTO for uniformity across international boundaries, it seems inconsistent that the U.S. would not want to bring its policies in line with those of many of our major trading partners in Europe and Japan.

While implementing a research *on* exemption seems like a beneficial policy from the perspective of exempting certain types of innovative research, it would not address the main problem facing academic researchers, the potentially detrimental case of patented research tools. The research *on* activities are not typically the ones about which a researcher would be sued, since they don't threaten the profitability of the patent. The biggest problem of research tools is associated with the research *with* activities. In order

to clear up the problem posed by *Madey v. Duke*, then, the ideal solution would be the proposal of a research *with* exemption, which would alleviate the pressure on academic researchers and technology transfer managers. Without the fear of lawsuits, researchers (particularly those working on tight grant budgets) could save money on licenses and royalties and ensure access to the required tools. However, the danger in that kind of proposal is that it would eviscerate the value of almost all research tool patents. Without the promise of recouping their initial R&D investments, research tool producing companies and universities may be hesitant to invest in new tools, which could, in the long run, reduce U.S. innovative output. Even those entities which continued to develop new tools might be reluctant to rely on the patent system for protection, and might instead turn to trade secrecy or other methods of "hording" their ideas.

However, if it could be implemented without significantly undermining the profitability of research tools, the research *with* exemption would likely be a superior alternative to the research *on* exemption. The problem is that there has been very little quantitative examination of the effects of a research exemption of either variety. Would the proposal discourage companies from developing new tools? As the OECD points out, "The ideal conditions under which research exemptions should exist revolve around the impact of patenting on investment incentives. Unfortunately, there are no empirical studies which analyze this issue specifically" (Dent, Jensen et al., 2006). Would a research *with* exemption render research tool patents worthless? Would the exemption proposal, on balance, increase the innovative output in the United States? Bob Cook-Deegan claims that in arguments over various exemption proposals, "[t]here is often

more rhetoric than data" (Malakoff, 2004). The next section of this paper will attempt to provide just such data.

Section 5

Stakeholder analysis of a research use exemption

This section will explore the potential stakeholder and limited quantitative analysis of the likely effects of implementing a research use exemption. Assuming that research *on* exemptions would be unlikely to severely impact the pecuniary interests of the patent owner, I will limit my analysis to the outcomes of a research *with* style exemption. The analysis will be broken into three sections: first, examining the effects of an exemption on universities; secondly, the effects of an exemption on research tool companies; and, finally, a political analysis, indicating Congress' likelihood of action on the subject.

For this analysis, I will assume that the exemption would include only noncommercial research (however, a for-profit goal of the sponsoring institution would not prevent claims to the exemption), but would shield the use of all biomedical research tools. However, since the main source of data is the annual licensing survey from the Association of University Technology Managers, I will concentrate primarily on university research. While the survey only includes 164 university respondents, these represent the largest academic research institutions in terms of investment and innovation, so it is likely that these data reflect the lion's share of university innovation and research investment.

A. Effects of an exemption on university innovation

Building the model: costs and benefits

Of course the main benefit of the research exemption outlined above would be to ensure unfettered access to research tools for scientists conducting basic research. This should, theoretically, allow researchers to undertake more projects and produce knowledge and results that can then bubble up to industrial firms, who can use this knowledge to create products, for instance, pharmaceuticals, building on that foundational research. Knowledge flow is particularly valuable to the pharmaceutical industry, which relies on publicly supported research to a greater extent than almost any other commercial industry. One study conducted by Wes Cohen found that 58 percent of pharmaceutical respondents cited "public research as a source for new ideas", the highest proportion of any industry surveyed, leading the author to conclude that in the drug industry, noncommercial research has a "substantial impact on industrial R&D" (Cohen, Walsh et al., 2002). Another survey by Edwin Mansfield found that 31 percent of the new pharmaceutical and medical products introduced between 1986 and 1995 "could not have been developed (without substantial delay) in the absence of recent academic research", which was the highest rate for any industry surveyed (Mansfield, 1995). Thus, we can see that increased levels of output from academic researchers could substantially increase innovative output from pharmaceutical companies, who would have more knowledge inputs for their research projects.

However, it does not appear that a research exemption would throw open the floodgates of basic research. Firstly, a research exemption would only increase basic research outputs to the extent that it would enable projects which are currently being delayed or abandoned due to patent concerns. Therefore, the impact of a research exemption depends greatly on the amount of research currently being hampered. As

suggested by the studies of Walsh, et al. the number of such projects could be very small, perhaps just one or two percent of all university research (see page 31). Even if one considers the higher numbers from the Hansen AAAS survey, it appears that only around 10 percent of researchers have been forced to delay or abandon projects due to patent restrictions (see page 30).

Secondly, the "linear model" of knowledge flow has become outdated and no longer reflects the reality of the research enterprise, particularly in the biomedical community. Whereas universities and nonprofit institutions were the traditional source of basic research, companies and other non-university actors have become major players. Between 1980 and 1998, the percentage of U.S. basic scientific research conducted by industrial enterprises more than doubled from 13.7 to 28.4, and Scherer claims that "[i]ncreases in biological research probably played a substantial role in this heightened industry attention to basic research" (Scherer, 2002). In 2000, more than half (57 percent) of all basic research was carried out in a setting other than universities (Sarnoff, 2002). Given this increase in the basic research focus of companies, they may be less dependent on university research outputs and more than able to pick up any slack created by sagging university knowledge outputs.

Another fundamental change that has occurred is the extent to which universities are collaborating with commercial firms in research projects. The percentage of academic R&D supported by industry more than doubled in the two decades from 1970 to 1990 (Cohen, Florida et al., 1998), and in recent years, total industry support for university research has topped $3 billion annually, around 8 percent of total research expenditures (NAS, 2004). For fiscal year 2004, the AUTM licensing survey reported

research expenditures from industrial sources were just over $2.5 billion, approximately 6.8 percent of total research expenditures (AUTM, 2005). And just as knowledge inputs are essential to pharmaceutical input, patent rights are essential to attracting this kind of cooperative work between the academic and the industrial world. One biotechnology representative, testifying before the FTC, claimed that "patents are the key asset for us. They enable us to have access to capital markets and to continue our innovation and development" (FTC, 2003).

A research *with* exemption could undermine the robustness of certain classes of biomedical patents. And without the assurance of intellectual property protection, companies may be reluctant to enter into joint research with universities. Joyce Brinton cites the potential that, in the absence of strong patent rights, "there would be valuable research tools that would not be developed because you can't get somebody to make the investment because they have no proprietary position in the marketplace" (Brinton, 2006). It is hard to predict exactly how much research would be affected by a reduction in patent protection, but one study by Scherer found that, in their survey sample, 38 percent of patents jointly held by a university and another entity involved a private company as the partner (Scherer, 2002). Michelle Cai goes so far as to suggest that this loss of corporate sponsorship could cause universities to be "worse off if the experimental use defense is broadly applied to nonprofit academic research," because, "[m]any of the universities' own patents could lose exclusivity with respect to other academic researchers and their perceived value in the eyes of investors may therefore be reduced" (Cai, 2004).

Another area where a research exemption would impact universities would be in terms of licensing revenue. As previously mentioned, universities have become leaders in the development and commercialization of genomic research tools and other DNA based products. And many of these have become very lucrative income sources for some research universities. Big winners include the Cohen-Boyer patents on recombinant DNA and the Axel patents for cotransformation, both of which have earned hundreds of millions of dollars for Stanford and Columbia University, respectively. Income generated from royalties is typically split between the technology transfer office, inventors, and the inventors' departments (NRC, 2006). John Sandelin, of Stanford, explains that among academic departments, these licensing and royalty revenues are very useful because "they can be used for anything, whereas a lot of the monies they get in from research sponsorship or other forms have restrictions on what they can be used for" (Sandelin, 2006). These funds have also become important for setting research priorities for upcoming years. Sandelin points out that some departments "will ask for estimates of what we [the technology transfer office] think the department or the school income will be. So, in some sense, they are planning ahead on what they are likely to spend it on" (Sandelin, 2006). Colyvas notes that "enhancing university revenues, which was not a central argument for the policies articulated in Bayh Dole, now clearly is an important objective of universities in their patenting and licensing policies" (Colyvas, Crow et al., 2002). Since many valuable university patents cover biological research tools, a broad research exemption could rob these enterprising institutions of millions of dollars in licensing revenues.

An exemption might not reduce university income as much as it may seem. First of all, licensing revenues are not the cash cow they might appear at first glance. While there are a handful of universities who manage to make large profits from their licenses, most of these come from a handful of inventions. A survey by Thursby and Thursby showed that "on average, 76 percent of the license revenue reported by universities is attributable to their top five inventions" (Thursby and Thursby, 1995). A 2006 study by Pressman, et al. found that only 2 percent of university DNA based patents had been licensed more than nine times (Pressman, Burgess et al., 2006). So, we can see that the number of blockbuster patents for universities is tiny.

Even the number of universities generating these licensing revenues is relatively small. An analysis of data from the 2000 AUTM licensing survey showed that while average licensing income was around $8 million per university, this number was skewed by a small number of big earners, as more than half had revenues of less than $824,000 (Thursby and Thursby, 2003). Furthermore, these licensing revenues are dwarfed by the amount spent by the universities on research. A 2003 NAE report found that "royalties from university patents represented only about 2 percent of R&D expenditures" (NAE, 2003). For the 2004 fiscal year, gross licensing income generated by universities participating in the AUTM survey was $1.09 billion, just under 3 percent of the $37 billion spent by those same universities on research (AUTM, 2005). Statistics like those above lead some to conclude that "[u]niversity based technology transfer is not a good way to make money," based, in part, on the example of MIT, a first class research institution whose research expenses top $350 million per year, but whose gross licensing

income was $8 million, with just $3 million of those dollars reaching the departments and university directly (NRC, 1997).

Cost-benefit analysis

This section attempts to quantify some of these issues into a cost-benefit analysis. The benefits of an exemption for universities include:

- the amount of research newly enabled by the exemption (i.e. the amount of innovation currently being stifled by restricted access to inputs, onerous licensing agreements, and other patent-related concerns) [$R_{enabled}$];
- money saved because it would not have to be paid to universities and other patent holders in the form of royalties [L_{univ}, L_{ind}].

The costs of the proposed policy would include:

- Lost licensing revenue paid from universities who use the technology to universities who own the patents [L_{univ}], and;
- Lost industrial sponsorship for research projects [R_{lost}].

So, the equation would appear as follows: $\mathbf{f(CBA)= R_{gain} + L_{univ} + L_{ind} - L_{univ} - R_{loss}}$. Universities would experience a net increase in innovation whenever f(CBA)> 0.

Figure 5.1: Costs and benefits for universities under the research *with* exemption

Costs	Benefits
• Lost industrial-sponsored research activities	• Enablement of research that is currently being stifled
• Lost licensing revenues from nonprofit users	• Money saved from being spent on licensing fees and royalties

In order to provide a meaningful equation, all figures must be expressed in terms of an innovative output measured against the current level. Which innovative output should be used to measure? Patents granted? Research R&D? New inventions? This analysis will use "invention disclosures" as a measure of innovative output. While this does not correlate precisely with the amount of innovation going on in a university, it gives some measure of how many projects are producing potentially patentable outcomes, which are viewed by the scientific community as being novel and having some innovative significance. For many of these disclosures, technology transfer offices may ultimately decide not to file a patent application. However, whereas granted or filed patents have a significant lag time, invention disclosures correlate better with the work which was actually performed in a given fiscal year. Relying on patents issued or applications filed would offer a proxy on how much innovative activity went on one or two years prior, because of delays associated with the processing and examination of a patent application.

Since some of the variables in the equation represent dollar amounts, it is also necessary to convert these into a number of invention disclosures filed. In order to do this, it is necessary to establish a constant multiplier that links a patent application with a fixed research investment dollar amount. To provide this number, I used aggregate data from the FY 2004 AUTM licensing survey. In FY 2004, the total respondent U.S. universities received 15,002 invention disclosures from researchers, while total research expenditures for the year were $37.162 billion for the same group of universities. Dividing total research expenditures by patent applications shows an average of $2.48 million spent on research per patent application. Using this factor (2.48/patent

application), we can convert the dollar totals into invention disclosures to estimate the innovative output in an environment with a permissive research exemption.

There may be some reservations about the method by which this number was chosen. After all, its impact on the final analysis could be very large. The AUTM data does not take into account whether the sponsored research activity was in the field of genomics or biotechnology. Accordingly, it could be argued that the funding required to file a patent application in the biomedical sector is much higher than $2.48 million, given the expense associated with genomics/health related research. However, since these areas are also the source of many more patent applications, perhaps they are a more efficient source of patent application generation, requiring less than the $2.48 million of investment for an invention disclosure. Therefore, given the uncertainty and apparent lack of better alternatives, I will rely on this factor for my analysis.

Therefore, adding in our investment/innovation ratio, the equation becomes: $f(CBA)= R_{gain} + (L_{univ}/2.48) + (L_{ind}/2.48) – (L_{univ}/2.48) – (R_{loss}/2.48)$. However, we can simplify the equation to reflect the fact that the royalties paid by universities to other universities are a transfer, a zero-sum shift in resources, which does not affect the net outcome of the equation.[22] Thus, these terms can be eliminated, leaving us with simply: $f(CBA)= R_{gain} + (L_{ind}/2.48) – (R_{loss}/2.48)$.

The next task in the analysis is to insert numerical values for those terms which we know. Since R_{gain} represents the percentage of research which is currently being stifled, it is a fraction of the total number of patent applications. Therefore, R_{gain} can be

[22] With the exception of a few major inventions, such as the Cohen-Boyer or Axel patents, most of the royalties earned by universities from other universities are extremely small, as many institutions do not require licensing agreements for use of their products by other universities, and many others do not charge a fee. So, these terms can be viewed as a net transfer or a negligible amount, and, either way, can be eliminated.

represented as **15,002*x***, where *x* is the percentage of research projects currently being abandoned or prevented due to patent considerations. L_{ind} represents the licenses and royalties paid to companies that universities would not pay, given the research exemption. While it may not be a quite realistic assumption, this analysis will assume that in the event of a robust "research with" exemption, universities would have to pay no licensing fees to companies for the use of their research tools. Therefore, L_{ind} actually equals the percentage of total expenditures spent by universities on licenses. Given the $37.16 billion spend on research in FY 2004, this quantity could be represented as **37,162*y***, where *y* is the average percentage of total research expenditures devoted to paying for licenses and royalties. Finally, the variable R_{loss} represents the amount of industrial sponsorship that would be lost if companies, absent the guarantee of robust patent protection, decide not support university research. Total research support from industrial sources, according to the FY 2004 survey, were $2.55 billion. Therefore, R_{loss} could be represented as **2554*z***, where *z* is the percentage of industry-sponsored research that would be abandoned in the wake of a research *with* exemption.

Using the conversions discussed above, our equation is reduced to:

f(CBA) = 15,002*x* + (37,162*y*/2.48) – (2554*z* /2.48), and simplifies to:

f(CBA) = 15,002*x* + 14,984.68*y* – 1029.84*z*.

While we are left with three variables, we can set some parameters. Obviously, since they are all proportions, *x*, *y*, and *z* must all be between 0 and 1. However, we can go even farther, to see what values of *x* and *y* would result in a beneficial outcome. Setting *x* = 0, and z = 1, we can see that the upper limit on *y* is 1029.84/14,984.68 or .069 (6.9 percent). Similarly, setting *y* = 0 and *z* = 1, we find that the upper bound on x is

1029.84/15,002, also 6.9 percent. Therefore, if either *x* or *y* exceeds 6.9 percent, the net benefit will be positive, and the outcome of the policy will be favorable. The most difficult portion of the analysis comes from assigning values to the three remaining unknowns.

The assigning of the *z* value amounts to little more than speculation, since it is a hypothetical conjecture about how firms would respond to a reduction in patent protection. This is particularly difficult given the lack of empirical data on the importance of patenting on R&D investment. The National Research Council (NRC) has commented on the lack of "systematic empirical analysis of the impact of patents on innovation," and recognized that "the narrower question of whether patenting stimulates research and development investment has only recently begun to be studied" (NRC, 2003). While patents certainly appear to be a important incentive in biotechnology and pharmaceutical research (Scherer, 2002), it is unlikely that a significant number of companies would immediately stop their corporate sponsorship of university research initiatives.

As previously mentioned, there are also a number of other factors which the corporate/university interaction besides just profit, and it appears unlikely that companies would sever these ties simply because of a reduction in patent rights, especially if they would still be able to enforce their tool patents against other corporations. Additionally, because of contracts and funding obligations, most collaborations could not be terminated overnight. Therefore, especially in the short term, *z* might be very close to 0. For the purposes of this analysis, I will assign *z* a value of .1, which acknowledges that some fraction of companies may seek to end their sponsorship of university research, but the

bulk will remain. With one variable filled in, the equation is now: **f (CBA) = 15,002*x* + 14,984.68*y* ─ 103.0 .**

This new equation allows us to create a new set of parameters for *x* and *y*. This time, setting *x* equal to zero, we see that the equation will result in a new benefit if *y* is greater than .0069, or .69%. Similarly, setting *y* equal to zero, we see that *x* value above .0068, or .69% will produce a net benefit. So, how big are *x* and *y* likely to be? Are they big enough to produce a net benefit for universities?

There are conflicting estimate for the value of *x*, the amount of research currently being abandoned or halted due to patent and licensing considerations. The work of Walsh and Cohen represents the low end of the estimate, while Hansen's AAAS survey could be seen as an upper-limit estimate. One thing is certain, even the lower estimates of *x* appear to be larger than the .6% threshold, indicating that our analysis will certainly show a net benefit for university innovative output. Therefore, I will use both as bookends to gauge the range of the innovative increase which could be expected for universities.

For the lower bound, I will use Walsh's estimate of approximately one percent. Hansen's numbers suggest more researchers have had to abandon or change projects due to patent considerations, that around ten percent of university bioscience researchers have experienced difficulties in conducting their research (Hansen, Brewster et al., 2005). Inputting Walsh's one percent estimate into the equation, we are left with f (lower) = 150.02 + 14,984.68*y* ─ 103.0, which simplifies to **f (lower) = 47.02 + 14,984.68*y***. Conversely, inserting Hansen's estimate of *x* = .1 yields: f(upper) = 1500.2 + 14,984.68*y* ─ 103.0, simplifying to **f (upper) = 1397.2 + 14,984.68*y***.

The final piece of the analysis, then, is to determine an approximate value of *y*, the percent of total research expenditures currently devoted to paying licensing fees and royalties. Generating a precise estimate for *y* across all university research would be a very difficult prospect and could be the subject of an entire study of its own. However, in this case, I will again find a lower and upper limit for *y* in order to determine the possible range of the benefit. On one hand, Wes Cohen claims that the number is likely to be extremely low. Based on his surveys with researchers, he believes the amount spent on licensing fees is "basically zero, with few exceptions."[23]

In order to establish the upper limit for *y*, I tried to examine research institutions who, by the nature of their work, devote a high percentage of their budgets to paying licensing and royalty costs. One set of institutions which have these high royalty costs are DNA sequencing labs, which use large amounts of patented reagents to perform genome sequencing. Since the cost of each reagent includes a markup to cover royalties, the calculation involves two parts. The first is to find out the percentage of the institution's budget which funds reagents. Once this number is known, it could be multiplied by the percentage of the price of the product which goes to covering royalties. Multiplying these two numbers together should produce an estimate of the total institution budget which goes to just paying licensing costs.

I contacted the Baylor Human Genome Sequencing Center, and a representative from that institution responded with an estimate that approximately 33 percent of total costs are devoted to supplies/reagents.[24] From here, it is difficult to obtain the second number, because the center likely utilizes many different licensed products, such as DNA

[23] Email correspondence with Wes Cohen. August 22, 2006.
[24] Email correspondence with Michelle Rives. October 20, 2006.

sequencing machines and fluorescent dyes for sequencing, all of which have a different royalty percentage. It might be impossible to figure a precise estimate for the royalty percentages because they are bundled in the price, and many of the terms are not publicly available. Still, based on estimates for the royalty rates of PCR and other genomic research tools a reasonable guess for licensing fees on a typical reagent or machine is probably in the range of 5-15 percent (NRC, 1997). Therefore, with a moderate level of confidence, it seems likely that the highest percentage which universities could be paying would be approximately 33% x 15% = **4.95%**.

Inserting the estimates of $y = 0$ and $y = .0495$ into the lower and upper limit equations, respectively, we are left with: **f (lower) = 47.02** and **f (upper) = 2138.94.** These two disparate estimates represent the range of the possible increase in invention disclosures we might expect, given the model of the research exemption outlined above. This would represent an increase in innovative output of between .31 and 14.3 percent. While this is a broad range, it seems safe to assume that the gains would be toward the smaller end of the spectrum. The estimates in the upper limit calculation, particularly those based on the expenditures from sequencing centers, seem much higher than would be expected from the majority universities, at large. Accordingly, the actual increase would likely be well below the ten percent level, and would, perhaps, be much closer to the estimate of .31 percent, which would, nonetheless, indicate a net benefit for universities. **Therefore, based on this analysis, it appears that universities would experience a net, though likely modest, increase in innovative output as a result of a research *with* exemption.**

B. Effects of exemption on research tool companies

Of course, the money saved by universities and other nonprofit institutions would likely come out of the pockets of patent holders, especially biotechnology and research tool companies. And without revenues or the promise of robust intellectual protection, the development of new research tools might slow, which could devastate innovation in the long term, especially in the pharmaceutical sector. One witness, testifying before the Federal Trade Commission, pointed out that "patent protection will be critical in encouraging investment in the next generation of research tools, which might reduce the costs and time required for clinical trial phases" (FTC, 2003). However, a counterargument could be that universities have become better capable of developing and commercializing their discoveries (including genomic research tools) entirely in-house, without having to rely on industrial production. Universities have no doubt become better at bringing products to market, but there is some evidence that private companies may be more efficient at developing genomic research tools, particularly in the area of DNA sequencing methods (Scherer, 2002).

While impossible to pinpoint the effect of reduced patent protection on innovation in this sector, it seems apparent that a research *with* exemption has the potential to severely impact the profits of research tools companies, who rely on licensing revenues and sales of their products to fuel further R&D. Would a research *with* exemption completely devalue these patents and drastically reduce the revenues of research tools companies?

Luckily, we have been presented with just such a test case. In the wake of *Merck v. Integra*, many commentators have predicted that the broadening of the "safe harbor"

exemption (as evidenced by the Supreme Court's decision) would have just the effect of devaluing research tool patents. Judge Rader, of the Court of Appeals for the Federal Circuit wrote that "expansion of § 271 (e) (1) to include the Scripps-Merck activities would effectively vitiate the exclusive rights of patentees owning biotechnology tool patents." In a brief filed on behalf of the Wisconsin Alumni Research Foundation and other academic research institutions, Rolf Stadheim warned: "Should the safe harbor of section 271 (e) (1) be expanded to include general pharmaceutical research, it is inconceivable that such research patents will have any value left" (Stadheim, 2005).

Given these predictions, and the outcome of the Supreme Court's decision, therefore, we can examine the effects of research tools companies in the wake of a legal shift which some claimed would "nullify the commercial value" of their key asset, their intellectual property (Stadheim, 2005). Therefore, this analysis of companies will examine research tool companies whose patent portfolios include products similar to Integra's RGD peptides, and track their stock prices, R&D expenditures, and revenues to see what effects this de facto, court-induced research *with* exemption has had.

This analysis, therefore, attempted to locate research tool companies who were most likely to be affected by the ruling and examine their performance over the past year 16 months to see if they were, indeed, harmed by this de facto research *with* exemption.

Methodology

The first step in conducting the financial analysis was to locate companies whose business models rely heavily on their ability to license small molecules that are similar to the peptides described in the *Merck* case and are used in drug discovery. Based on the Supreme Court's ruling, such products would likely fall under the safe harbor exemption,

potentially impacting the ability of these companies to collect licensing revenues on their products. A list of potential companies was generated by using the Delphion patent database to search for companies who held patents with similar classifications as the patents disputed in the *Merck* case, as well as companies who held patents which cited the peptide patents (USPTO patents: 4,988,621; 4,792,525; 5,695,997; 4,879,237). Ultimately, this search produced a list of approximately twenty companies who held numerous patents of small molecules that were similar to Integra's peptides. These companies were then examined, selecting for only U.S., publicly traded companies. (The decision to only select domestic, public companies was made in order to facilitate the gathering of financial data and stock prices.) Then, once that was completed, each company's website and annual reports were read to find the companies whose business models most heavily relied on their ability to license the small molecules on which they owned patents for drug discovery. Ultimately, this yielded a list of six companies that would serve as the "experimental" group: **Sangamo Biosciences, Inc., Medarex, Inc., Lexicon Genetics Incorporated, ArQule, Inc., Sirna Therapeutics, and ARIAD Pharmaceuticals.**

The next step in the analysis was to find a group of research tool groups that sold products that were not related to peptides or drug discovery. These would serve as one control group, ensuring that trends observed in the experimental group were not merely a reflection of broader trends in the research tool sector as a whole. In order to locate the control group of research tool companies, I started with Hoover's online financial database of companies listed as "Biotechnology Research Equipment". Foreign companies or private companies would have required laborious efforts to obtain financial

records and convert data into U.S. dollars. Moreover, their markets might not be U.S.-based. Once this list was selected, it produced 22 companies as candidates for the control group. From this group, I then chose 10 companies that would serve as the control. The list of 22 companies was arranged alphabetically from 1 to 22, and then 10 numbers were selected randomly using an online random number generator.[25] This produced a final list of ten research tool companies to serve as the control: **Alpha Innotech Corporation, Applied Biosystems Group, Bio-Rad Laboratories, Inc., Illumina, Inc., Immunicon Corporation, Incyte Corporation, Invitrogen Corporation, Nanogen, Inc., SEQUENOM, Inc., and Tripos, Inc.**

In order to gauge the effects of the Supreme Court's ruling on the experimental research tool companies, the decision was made to use stock price as an indicator of the companies' ability to continue to generate profit. There are several caveats to using this approach. Firstly, the use of stock price does not directly measure performance, such as revenue. However, it does offer insight into what observers in the sector feel the companies are worth. Theoretically, if the experimental companies were no longer able to generate licensing revenue due to the ruling, this should have been reflected in a drop in the stock price, as analysts and investors evaluated the effects of the de facto exemption.

Secondly, a company's stock price could be influenced by many factors other than simply the inability to license these small molecules. Trouble with board members or executives, talks of takeovers or mergers, FDA approvals or denials, patent awards or rejections, these are just a few of the things which could affect individual company's stock price. Additionally, although every effort was made to choose companies most

[25] www.random.org

heavily dependant on small molecule licensing revenues, the companies no doubt have other revenue streams, which, in some cases, might be able to overcome the loss of income from their patented drug discovery research tools. In the end, however, stock price analysis was viewed as the only viable financial data that could be analyzed for statistical purposes. Since the Supreme Court's decision, only five fiscal quarters have passed. Therefore, if the analysis looked at revenue or R&D investment to gauge the effects of the ruling, it would only be able to use five data points, too few to make any statistically significant inferences from the data.

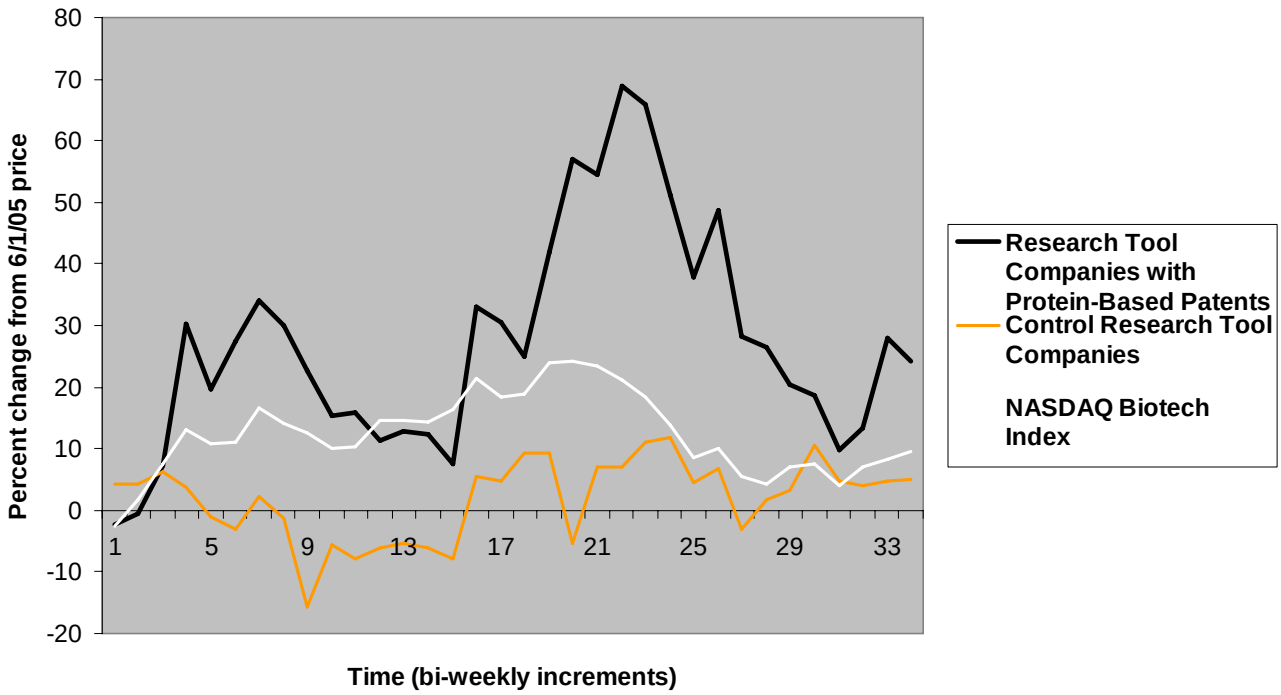
In order to collect historical stock price data, my analysis used historical stock prices obtained online from the Big Charts Marketwatch database.[26] Stock prices were collected for each company in the list in bi-weekly increments on Wednesdays, beginning with June 1, 2005 (just before the Supreme Court's opinion in *Merck v. Integra* was released) and ending with September 20, 2006. In order to control for market fluctuations in the entire biotechnology sector (not just research tools), historical prices for the NASDAQ Biotechnology Index [NBI] (which consists of over 120 biotech companies) were also gathered. All prices were normalized to account for stock splits. Once all of the stock prices were collected and entered into a Microsoft Excel spreadsheet, the percent change from the June 1, 2005 price was calculated for each company for each week. Then, the percentage changes were averaged for the experimental and control research tool groups, and plotted along with the percentage change in the NBI.

Results

[26] http://bigcharts.marketwatch.com/historical/

Figure 5.1 shows the results of the first plot, examining the percent change in stock price from the June 1, 2005 price. The x-axis represents time in two week increments (i.e. time number "2" represents four weeks because it is comprised of two, two-week periods). The y-axis represents the percent change from the 6/1/05 price, for the experimental and control research tool groups, the percent change reflects the average change of all companies in the group, while the NASDAQ line is just the percent change in the NBI.

Figure 5.1: Stock prices 6/1/05 through 9/20/06

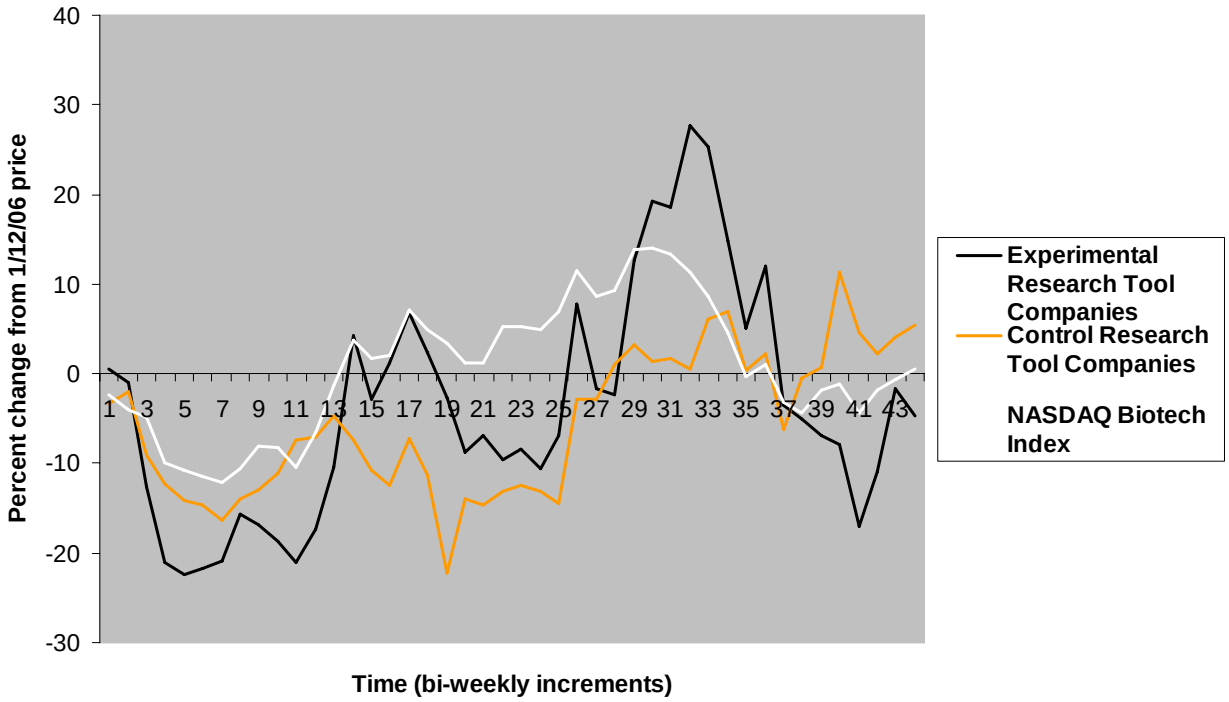


Originally, the theory advanced by some observers was that this ruling would have serious consequences for companies like the experimental group, who would lose a key revenue source. However, if this was the case, it certainly does not appear to have affected the stock price after the ruling. As is evident in the graph, the research tool

companies with patents most similar to those involved in the Merck case have actually outperformed both the NASDAQ Biotechnology Index and the control research tool companies for almost the entire past fifteen months. This appears to suggest that the ruling and the de facto exemption has had little negative impact on these companies, or, if it did affect their licensing of small, protein based molecules, they were able to compensate for the loss in revenue through sales in other business units.

However, there is another possibility with regards to an impact on the stock price: perhaps the market anticipated the Court's decision and the correction in the stock price actually occurred prior to the release of the opinion in June 2005. In order to analyze this possibility, stock prices were gathered for all companies and the NBI going back to the beginning of 2005, starting with January 12 of that year. Again, these prices were recorded and averaged for each group and the percentage changes from January 12, 2005 were plotted along with the NBI. Figure 5.2 shows the changes in stock price from January 12, 2005 to September 20, 2006.

Figure 5.2: Stock Prices 1/12/05-9/20/06

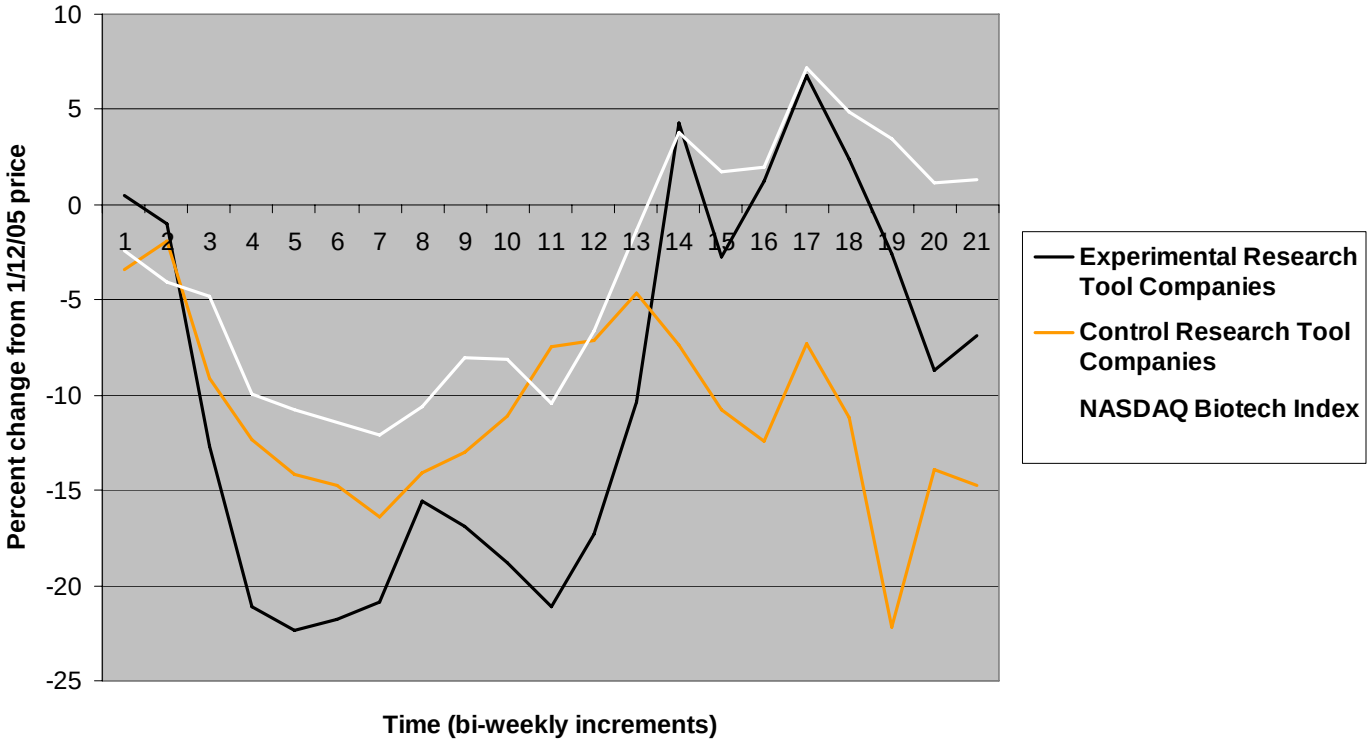


A look at this graph reveals a slightly more nuanced view of the potential effects of the Supreme Court's decision. Time period twelve marks the point at which the decision was released, and it is clear that prior to this time period, the experimental group had underperformed with respect to the control research tool group and the NBI. Specifically, the experimental group shows a downturn between time period eight and eleven, during a period when both the NBI and other research tool companies experienced a net increase in stock price. It is interesting to note that time period seven on the horizontal axis corresponds to the point at which the Merck case was argued

before the Supreme Court. It seems safe to assume that if there were going to be a correction in the stock price prior to the release of the decision, it might occur within this range, after the case was argued, but before the opinion had been formally released. Anxious investors might have reacted negatively to the oral arguments or simply become worried about the possibility of the cases outcome just prior to the release of the opinion.

To more closely analyze this segment , we can zoom in on the time period in question. Figure 5.3 shows the changes in stock price from five months prior to the release of the decision to six months after.

Figure 5.3: Stock prices five months before and after Supreme Court decision



Again, time period seven corresponds to the date the case was heard, while time period twelve approximates the date on which the opinion was released. It is clear that within

this timeframe, the experimental groups did, indeed, decrease more than either control group. However, the analysis required some quantitative description of how much more the experimental groups decreased and whether this change was statistically significant.

To see if these variations are statistically significant, a one- and two-sample t-tests were performed. This was based on input from research assistants at the Statistical Consulting Center at Duke's Institute of Statistics and Decision Sciences, which suggested that this statistical test would be appropriate for comparing the stock price data over a time series. The goal of performing these tests was to determine whether or not the declines in the experimental group were significantly different from the normal fluctuations experienced by the control groups.

Four separate tests were run, utilizing two different time periods. The first test compared the changes in price of the experimental group to the change in the NBI between January 12, 2005 and June 15, 2005. The t-test confirmed that the changes in the two groups were significant at the 1% level ($t = -3.991$ with 5 degrees of freedom). Test two compared the experimental group with the control research tool group over the same time period. In this case, quantitative analysis showed that the change in the experimental group, as compared to the control group of research tools, was not statistically significant ($t= .298$ with 5 degrees of freedom, $.40>p>.25$).

The other two tests compared the experimental with the control groups between January 12, 2005 and May 18, 2005 (time period nine). This second date was chosen because it was between the oral arguments and the Supreme Court's decision, and, therefore, should have provided a good opportunity to gauge any potential effects of investors selling off in anticipation of the ruling. The first test for this time period

compared the experimental group to the NBI. Again, results were significant, allowing me to reject the null hypothesis at the .5% level ($t = -4.586$ with 5 degrees of freedom). However, when it came to comparing the experimental group with the control research tool group, the results were not statistically significant. The two-sample t-test revealed that we could not reject the null hypothesis at the traditional 5% level ($t= .40$ with 5 degrees of freedom, $.40 > p > .25$). Therefore, based on the analysis, it appears that the experimental research tool companies did undergo a decrease prior to the release of the Merck decision that was significantly different from normal fluctuations experienced by the overall biotechnology sector. However, since the results were not significantly different from the control research tool group, it is possible that the decreases in the companies with Integra-like patents were simply a reflection of declines in the wider research tool industry of the biotechnology sector.

Based on these statistical analyses of stock price, it appears that the de facto research use exemption handed down by the Supreme Court in *Merck v. Integra* may, indeed, have given investors the impression that the decision would threaten firms' ability to generate revenue in the post. Admittedly, however, the declines in stock price occurred before the decision was released, and I must remind the reader that since the decision was released, the stock prices of the experimental research tool companies have outperformed other research tool companies, as well as the NASDAQ Biotech Index as a whole.

Additionally, the fact that these companies have increased instead of the predicted decrease could be due to a number of factors, most notably the fact that the Supreme Court's decision may not have had the assumed of effect of establishing a research

exemption at all. Since the Court's opinion with regard to the scope of a research use exemption is simply dicta and not law (indeed, the court intentionally sidestepped the issue of the exemption for research tools entirely), it is possible that companies have not changed their behavior at all in the wake of the decision. The more reliable method for gauging the impact of the decision would be to analyze the revenues of the experimental research tool companies. However, as mentioned previously, it is likely too soon to observe trends in revenues and to be able to analyze them with any statistical significance. Ultimately, I must conclude that the results of the stock price analysis are inconclusive. Therefore, it is difficult to extrapolate and predict, based on this analysis, the quantitative effect that a research *with* exemption would have on research tool companies.

C. Political Analysis

Of course, all the talk of a research exemption is contingent on the willingness of Congress to take up patent reform legislation and the ability of a majority to pass a proposal. At this point, the prospects seem dim. There are two principle reasons. Firstly, is the unlikelihood of patent reform to receive considerable attention from Congress. Traditionally, patent reform has been viewed as a low priority, and without a sufficient compelling reason for immediate reform, patent legislation has tended to fall by the wayside. One need only look at the failed 1991 Kastenmeier patent reform bill. Despite passing out of the House Judiciary committee with broad, bi-partisan support, the bill ultimately failed to even come before the full House of Representatives for a vote. A similar fate appears to have befallen H.R. 2795, the Patent Reform Act of 2005. Introduced in June 2005, the bill was sent to the Subcommittee on Courts, the Internet,

and Intellectual Property and was the subject of two separate hearings. However, since that time, no further action has been taken. The House Judiciary committee of the 109th Congress, embroiled in legislation concerning illegal immigration, border security, constitutional amendments, federal court jurisdictions, NSA wiretapping investigations, and other urgent matters, appears to have bumped patent reform to the back of the line.

The second reason for pessimism toward a statutory research exemption is the small chance that an exemption would be placed in any patent legislation, even if were able to gain congressional support. Congressional patent reform proposals have included what many members consider to be essential reforms, which are mostly non-controversial. Given the contentious debate over research exemption proposals, some staffers and observers see any research exemption as a deal killer. Steve Heinig of the AAMC points out that "the feedback we're getting from the Hill is that in order to get patent legislation to pass, which everyone agrees is important, they're going to have to strip the bill [H.R. 2795] down to some very essential reforms, and this [the research use exemption] may not make the cut as an essential reform" (Heinig, 2006).

There are two main reasons that the research exemption would prove controversial. The first reason is the absence of evidence that university and academic research is truly being stifled in the absence of a statutory exemption. As discussed previously, the fears that many had regarding a "chilling" effect on scientific research have simply not materialized. The NRC concluded that "[r]ealistically, the likelihood that Congress will pass research-exception legislation in the absence of compelling circumstances is small" (NRC, 2004). Steve Merrill claims that a major push for congressional action would require a significant shift in firm behavior: "I think there

would have to be some serious attempts to stop infringement, either by threats of lawsuits or with some frequency that universities found potentially threatening" (Merrill, 2006).

Secondly, the realities of political lobbying appear to be working against the push for a statutory research exemption. On one hand, the influential groups whose influence would probably be necessary to push an exemption proposal (such as the AIPLA) have not aggressively pursued the issue as part of their lobbying efforts (Merrill, 2006). Furthermore, the university community (including AUTM, and other interested organizations) have not been able to reach a consensus on the form, or even the need for an exemption. On the other hand, the commercial interests who would be most negatively impacted by a statutory exemption, namely research tool companies and pharmaceutical firms, appear united in their opposition to reform. According to Weschler, the absence of a cohesive coalition lobbying for the exemption, coupled with the "immense political power possessed by large pharmaceutical companies makes it unlikely that a statutory change will be made in the near future" (Weschler, 2004).

Section 6

Findings and Recommendations

Findings

1. **Patenting of biotechnological research tools does not appear to be negatively impacting academic research.**

Based on both the literature performed in this area and my interviews with members of the academic and tech transfer community, it seems that most of the fears about the negative impacts of research tool patents are largely unfounded at this point. The work of Cohen and Walsh suggest that bench scientists are still not particular mindful of patents, nor are they experiencing significant delays in their research due to concerns over patent considerations, even in the wake of the *Madey* decision. Even if one accepts the data collected by Stephen Hansen and AAAS, the numbers appear to be rather low compared to the entire research enterprise. Additionally, the interviews with members of the university technology transfer community and observers at NRC and AAMC suggest that there is not a great deal of concern that biotech patents are stifling research currently. The overwhelming sentiment seems to be that a problem certainly could arise at some point, but that the current situation is tenable for the foreseeable future.

2. **Firm behavior does not appear to have shifted substantially in the wake of *Madey v. Duke.***

Similarly, there appears to be little evidence that companies have changed their behavior or are more likely to pursue litigation against universities in the wake of the

Madey decision. The interviews with representatives from universities suggest that firms have an interest in maintaining friendly relations with universities and that industry norms would discourage filing suits against academic institutions or researchers. Quite simply, even if companies have the legal ability to sue universities for infringement, it does not appear as if they have the desire. Again, while most observers agree that the potential exists for industrial norms to change, most seem to believe that the relationship between the university and industry is dynamic, and will be able to adapt to most challenges with extralegal, mutually beneficial solutions.

3. **A research *with* exemption would likely cause a net increase in university innovative output, although the effects on research tool companies are less clear.**

Based on the quantitative cost-benefit analysis in this paper, it appears that universities would likely benefit from a research *with* exemption in terms of innovative output. While it is true that universities would experience some loss of industry-supported research, the loss of these research dollars would be offset by the savings on licensing fees and royalties for their use of patented inventions and the opening up of previously unavailable lines of research. Given this scenario, it seems that universities would be in a position to increase their invention disclosures somewhere in the range of .3 to 14.3 percent, although likely trending toward the lower end of the estimate. The impact on research tool companies is much less certain. The results of the stock price analysis (which was, by its design an imperfect gauge of the effects of an exemption), were inconclusive and were unable to directly link a change in stock price to legal changes which should have mimicked a research *with* exemption.

4. **The likelihood that Congress will implement any research use exemption is very small, unless there is a dramatic shift in the academic research climate.**

Given the current political climate in Washington, it appears that patent legislation is simply not enough of a priority to be addressed by Congress in the near future. Additionally, any patent legislation which *does* reach the floor is likely to not include a research exemption, which is viewed as too controversial, especially when there are good, relatively innocuous changes to the patent code which are more pressing. Most of this can simply be traced to the lack of cohesion among the various constituencies, even among those who support an exemption, in principle: AIPLA, AAU, AAMC, NIH, individual universities, and legal scholars. Ultimately, however, it is probably the lack of urgency which makes a research use exemption politically unfeasible. If firms were to suddenly shift their behavior, or biotechnology patents suddenly began holding up valuable research, then congressional action might appear more likely. However, absent these changes in the status quo, the odds of Congress even considering, let alone passing, such legislation, appears slim.

Recommendations

1. **Congress should adopt a research *on* exemption. Specifically, the exemption should cover:**
    a. **Both commercial and non-commercial activities;**
    b. **Uses designed to test the claims of the patent disclosure;**
    c. **Research aimed to "design-around" the invention, and;**
    d. **Research designed to discover novel uses for the invention.**

There are a number of benefits to adopting this type of a legislative option. The statute itself would help clear up the ambiguity surrounding the status of the common law research exemption and would provide more direction to university tech transfer offices

and companies about which types of behavior could be carried out without fear of infringement suits. And while there may not be a huge danger of U.S. companies moving offshore to find more accommodating research exemptions, this statute would bring American patent law into harmony with most of our major trading partners with respect to an exemption. The specific provisions of the statute also offer advantages to researchers in both sectors.

The lack of distinction between commercial and noncommercial is key. As mentioned in Section 4, attempting to exempt only noncommercial work would be inconsistent with the aims of the patent system and would require extremely difficult and delicate line-drawing. Exempting activities aimed at verifying the patent claims is a non-controversial provision and is just an expansion of the enabling disclosure requirement. Parts C and D, as mentioned previously in Section 4, would likely be met with some apprehension. However, these provisions are consistent with the exemptions found in Europe and with the overall aims of the patent system, which is to spur a net increase in innovative activity.

In terms of why a research *on* exemption is preferable to a research *with* exemption, there are several advantages in the approach outlined above. The first is that it does not pose a significant threat to companies who own patents. Most uses which would fall under the scope of the exemption would not have commercial purposes which threaten the commercial viability of their inventions. However, perhaps most important is the fact that this is the most politically feasible option facing Congress, given its relatively non-controversial nature. A similar option has already been recommended twice by the National Research Council. Admittedly, the research exemption suggested

above does little or nothing to address the main concerns of the academic community in the wake of the *Madey* decision, but the legislation could also serve as a stepping stone for further congressional action, should it become necessary. With this form of an exemption in place, it would likely be easier for Congress to expand on it if the research climate changes dramatically, perhaps expanding to include research *with* the patented invention.

2. **Organizations such as the AAMC, AAU, NRC and NIH should continue to monitor the climate of biotechnology research and the impacts of patenting and firm behavior.**

While there appears to be little evidence that biotechnology patents are stifling research in the way once feared, it is clear that the development of significant problems is still a possibility. Additionally, while this report found that firm behavior has not changed significantly since the *Madey* case, the potential certainly exists for a shift in behavior to occur, perhaps suddenly. Organizations from the federal government and academic research community should continue to monitor the situation to ensure that these problems are not negatively impacting biomedical research. The committees formed by the National Research Council and the AAAS are an excellent way to keep tabs on the research climate, especially insofar as they directly survey bench researchers to get the ground-level view of the effects of patenting on scientific.

3. **Congress should investigate the possible impact of a research *with* exemption.**

Ultimately, even an exemption such as the one I have proposed is unlikely in the absence of a major shift in firm behavior or a dramatic increase in the impact that patents are having on academic research. Based on the current climate of research in the United States, however, both of these seem rather unlikely for the time being. Still, Congress

must be prepared to act in the event that universities do face increased pressure and be willing to adopt the necessary measures to protect the research that is at the backbone of our national scientific enterprise. To this end, Congress should charge the NRC, Office of Management and Budget (OMB), or other entity with exploring the potential economic impact of a research *with* exemption. As bad as it would be to have no exemption prepared, the effects of a poorly-constructed policy could be even more detrimental to our national innovative output, by impacting the companies, which invest more heavily in biomedical R&D. Arti Rai beautifully sums up this argument with a word of warning about the impropriety of hasty and overly broad changes: "Given that overall private investment in biomedical R&D today exceeds public funding, the strong belief of private sector investors that patents are essential to their profit expectations urges caution in changing the underlying legal rules that support these investments" (Rai and Eisenberg, 2003).

Ultimately, it is Congress' responsibility to live up to its constitutional duty by "promot[ing] progress of science". In order to do this, legislators must carefully weigh the balance between legal structures which offer exclusive proprietary rights and those which permit the open dissemination of knowledge and materials. A limited research use exemption, as I have proposed above, seems like an appropriate step, which is consistent with the aims of our patent system. However, before implementing more drastic changes to patent code, Congress must be sure to survey the research climate and maintain sufficient respect for the patent rights which has, in part, allowed the U.S. to lead the way throughout the biotechnology revolution.

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List of abbreviations and acronyms

AAAS- American Association for the Advancement of Science

AAMC- American Association of Medical Colleges

AAU- American Association of Universities

ACIP- Australian Council on Intellectual Property

AIPLA- American Intellectual Property Law Association

ALRC- Australian Legal Research Council

AUTM- Association of University Technology Managers

MIT- Massachusetts Institute of Technology

NBI- NASDAQ Biotechnology Index

NIH- National Institutes of Health

NRC- National Research Council

OECD- Organization for Economic Cooperation and Development

PCAST- President's Council of Advisors on Science and Technology

PCR- Polymerase chain reaction

R&D- Research and development

TRIPS- Trade-Related Aspects of Intellectual Property Rights

USPTO- United States Patent and Trademark Office

WTO- World Trade Organization

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