PROPOSED PATENT REFORM LEGISLATION: LIMITATIONS OF EMPIRICAL DATA USED TO INFORM THE PUBLIC POLICY DEBATE

A REPORT
PREPARED FOR THE BIOTECHNOLOGY INDUSTRY ORGANIZATION

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January 30, 2008

EXECUTIVE SUMMARY

Certain groups are calling for serious overhaul of the nation's patent system. They are using three reports produced by the Federal Trade Commission, the National Academy of Sciences and the National Research Council to justify their call for overhaul. The study begins by providing background material and analyzing these reports that supporters of patent overhaul have cited to justify their efforts. They are:

- The Federal Trade Commission's (FTC) report, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*
- The National Academy of Sciences' (NAS) Committee on Intellectual Property Rights in the Knowledge-Based Economy, *A Patent System for the 21st Century*
- The National Research Council Committee (NRC) on Intellectual Property Rights in Genomic and Protein Research and Innovation. *Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation, and Public Health*, (hereafter called NRC).

By examining and critiquing the reports, the study determines that:

- The recommendations that the reports make are based more on conjecture, anecdote, and individual publicized cases, rather than upon empirical evidence.
- The primary empirical evidence offered in the reports demonstrates that patents are *not* hampering innovation and successful commercialization.

The study finds that there is evidence in the three reports that the current system is working well. Specifically, the primary empirical evidence offered by the FTC, NAS and NRC reports are two surveys concerning the biotechnology industry, which has been perceived to be the industry most likely to suffer from an anti-commons (that is, over-patenting leading to less innovation). However, both surveys demonstrate that an anti-commons is being avoided in the industry. Moreover, the evidence presented in the reports indicates that to the extent industry participants are experiencing alleged "patent thickets" or other issues associated with poor quality patents, they are finding solutions or ways around these problems. Further, the concerns raised by the NAS report regarding increasing patent litigation due to patent quality issues are undermined by the fact, that at the time of the report the litigation rate was just over 1 percent

The study then discusses three recent court decisions. The *Madey* decision blurred the boundaries between universities and their missions and industry. But, despite the worry voiced by the reports discussed above, the only evidence that the consequences of *Madey* might contribute to an anti-commons through increased litigation activities is an informal poll showing that some universities have received more notification letters warning of infringement. Further, due to the *eBay* decision, there is now less certainty as to whether injunctive relief will be granted when patents are infringed. This should effectively ease the concerns of some of the FTC panelists that findings of infringement too often lead to automatic injunctive relief. Finally, the *KSR* decision has, in essence, agreed with one of

the major recommendations for patent reform made by the FTC, the NAS, and the NRC -- the obviousness standard should be strengthened.

The study concludes that there is a lack of evidence that justifies overhauling the patent system in a way that could potentially disrupt the incentives of industries that rely on patents to innovate. Indeed, the surveys mentioned above suggest that there is no basis to believe that the proliferation of patents is hindering research. Moreover, the courts, particularly the Supreme Court, have taken the lead in initiating reforms to the patent system and the industries that are affected by it.

CAN PATENT REFORM LEGISLATION BE JUSTIFIED?

INTRODUCTION /PATENT REFORM LEGISLATION

The **Patent Reform Act of 2007** (S.1145, H.R.1908) was introduced in April 2007 and included major patent overhaul measures. If enacted, this legislation may have a significant impact on the U.S. patent system. Among the controversial provisions are: limitation of damages to the economic value of the improvement associated with the patent; reform of the doctrine of "inequitable conduct"; the imposition of new requirements on patent applicants; and the initiation of post-grant opposition proceedings.[1]

The patent system supplies many industries the incentives needed to innovate. So before new measures are adopted, it is important that there is compelling empirical evidence justifying the need for reform. In this report, we examine the empirical basis upon which the proposed legislative overhaul is based. For reasons set out below, we conclude that the empirical data which is being used to justify the need for overhaul either has serious methodological limitations or is non-existent. Furthermore, and ironically, the limited studies which do exist, at least in the biotechnology industry, have not found that the patent system imposes serious impediments to innovation and successful commercialization. As it stands, it cannot be said, with any degree of certainty, that there is or is not a problem with patent quality, patent thickets, litigation abuses, or any other potential impediments to innovation and successful commercialization. We are simply lacking methodologically sound empirical evidence that could justify making major changes to the current patent system.

This report begins by providing background material on the three major reports upon which overhaul proponents have relied. We then examine the empirical studies relied upon by the reports to make their recommendations and comment upon the validity of this data. Finally, we look at recent judicial decisions which may have completely changed the landscape and bring into question whether the limited data, which do exist, are still applicable. The effect of these recent decisions has not been adequately evaluated or assessed. Thus, we recommend other empirical studies are needed to inform public policy as to whether patent overhaul is necessary.

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[1] Patent Reform Act of 2007 (H.R. 1908 and S.1145). Passed by the House on 9/7/2007. Among the Acts major provisions are:

- First-to-file rights;
- Provisions to facilitate filing a patent application without inventor cooperation;
- Limitation of damages to the economic value of the improvement;
- Limitations on when damages may be trebled for willfulness;
- Post-grant opposition proceedings;
- Venue limitations;
- Authority to the PTO to create additional regulations.

BACKGROUND

The Constitutionally-mandated purpose of the U.S. patent system is to stimulate and promote the advancement of science and the useful arts by giving patentees the time-limited right to exclude others from the unauthorized making, use, or sale of the patented invention. Patents represent an exchange with society. In return for finite exclusionary rights, the invention is disclosed for future inventors to use.

But issues associated with patent reform have ignited the imagination of the public, academics, and Congress. The public is regularly told that the patent system is dead or broken;[2] it is in the hands of "trolls;"[3] it supports the proliferation of patents, which reduces innovation;[4] it results in high costs, which are passed on to the eventual consumer,[5] etc. There is a huge body of academic literature on the subject of patent reform, and members of Congress are proposing changes that would have a dramatic effect on the patent environment.[6] But what legitimizes calls for patent reform? What data exists to show that reform is necessary?

There are three reports from prestigious institutions that supporters of patent system overhaul have cited to justify their efforts. They are the Federal Trade Commission's report, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, (hereafter called FTC); [7] the National Academy of Sciences' Committee on Intellectual Property Rights in the Knowledge-Based Economy, *A Patent System for the 21st Century*, (hereafter called NAS); [8] and the National Research Council Committee on Intellectual Property Rights in Genomic and Protein Research and Innovation. *Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation, and Public Health*, (hereafter called NRC). [9]

The three reports have different goals, but common to the three reports are concerns associated with an anti-commons or patent thicket and the associated issues and potential problems associated with poor patent quality. An anti-commons (an expression coined by

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[2] Bill McDermontt, *The Patent System is Broken*, post.gazette.com, July 27, 2007 Available http://www.post-gazette.com/pg/07208/804719-109.stm

[3] William M. Bulkeley, *Aggressive Patent Litigants Pose Growing Threat to Big Business*, Wall St. J., Sept. 14, 2005, at A1.

[4] Adam B. Jeffe And Josh Lerner. Innovation And Its Discontents: How Our Broken Patent System Is Endangering Innovation And Progress, And What To Do About It. Princeton University Press, Princeton N.J. (2004) at 2.

[5] M. Heller and R.S. Eisenberg. *Can Patents Deter Innovation? The Anticommons in Biomedical Research.* 280 Science (1998): 698-701.

[6] Supra note 1.

[7] Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, (FTC 2003) online at http://www.ftc.gov/os/2003/10/innovationrpt.pdf

[8] Committee on Intellectual Property Rights in the Knowledge-Based Economy, *A Patent System for the 21st Century*, (National Academy of Sciences 2004) online at http://lab.nap.edu/nap-cgi/discover.cgi?term=a%20patent%20system&restric=NAP

[9] National Research Council. Committee on Intellectual Property Rights in Genomic and Protein Research and Innovation. *Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation, and Public Health*. (Washington D.C. National Academies Press 2006) online at http://fermat.nap.edu/catalog/11487.html?onpi_newsdoc11172005

Heller and Eisenberg) raises the concern as to whether or not the multitude of patents that have been granted actually inhibits rather than facilitates the transfer of technology.[10] An anti-commons occurs when multiple owners hold the right to exclude each other from a scarce resource, so that no one holds an effective right of entry, and under-use of the resource results.[11] An example may be the problem of royalty stacking, where an inventor must obtain multiple licenses to commercialize a product. Carl Shapiro has discussed similar concerns using the term "patent thickets." He contends that technologies that depend on the agreement of multiple parties can be held up by any one of them, making commercialization difficult.[12]

Moreover, it has been theorized [13] [14] that litigation and the risk of litigation adversely affect the ability to innovate and commercialize. Patent litigation and strategies followed by firms to protect them from the risk of litigation (e.g., defensive patenting by enlarging a firm's portfolio of patents to influence settlement terms or foregoing otherwise valuable research because of the risk of litigation[15]) generate costs which may divert resources away from innovative activities or may make subsequent commercialization no longer feasible or more costly than it need be.

Questionable patents or patents of poor quality are those patents which have been granted that might be deemed invalid if challenged either by litigation or reexamination because they fail to meet the statutory requirements of novelty, non-obviousness, or utility, or because they contain claims that are unclear, not enabled across their full scope, or suffer from an insufficient technical description.[16] For instance, a claim might be worded so as to make its boundaries indefinite, perhaps allowing the patentee to stretch the terminology to cover a large number of technologies, including even later-arising technologies that the inventor could not have envisioned at the time of disclosure.[17] In other words, a questionable patent is a patent that may have been improperly granted by the Patent and Trademark Office (USPTO) and that, more likely than not, would be declared invalid upon legal review by a court.

The issue of questionable patents imposes costs on firms that can be seen as unnecessary or illegitimate. For instance, even though a questionable patent would likely be found invalid if challenged, it may be that a firm prefers to pay a licensing fee that is lower than

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[10] Supra note 5 at 698.
[11] Id.
[12] C. Shapiro. *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting*. In A. Jeffe, J. Lerner and S. Stern, eds. Innovation Policy and the Economy. (March 2001). Available at SSRN: http://ssrn.com/abstract=273550
[13] J.R. Allison, M.A. Lemley, K.A. Moore, R.D. Trunkey. *Valuable Patents*. Georgetown L J, 435-477. (2004).
[14] G. Parchomovsky R.P. Wagner. *Patent Portfolios*. University of Pennsylvania Law Review 154 U. Pa L.Rev. 1 (Nov 2005).
[15] Atif I. Azher. *Anti-trust Regulators and the Biopharmaceutical Industry: Compulsory Licensing Schemes Ignoring Gene Therapy Patients' Needs*. 25 U. Pa. J. Int'l Econ. L. 383 (2004)
[16] Christopher M. Holman. *Biotechnology's Prescription for Patent Reform*, 5 J. Marshall Rev Intell Prop L 317, 319 (Spring 2006).
[17] Jeffrey D. Sullivan and David Loretto. *Symbol Technologies v. Lemelson: Prosecution Laches, and the Unmet Challenge of Junking "Junk Patents,"* 86 J Pat & Trademark Off Soc'y 748, 757 (September 2004).

the risk-adjusted cost of litigation.[18] It may be that the firm chooses to design around a patent, or a firm may decide that it is in its interest to cease the allegedly infringing activity altogether.[19] The issuance of questionable patents may result in higher costs in the process of innovation and successful commercialization.

The focus of the three reports on issues associated with an anti-commons or patent thicket and poor quality patents means that some of the recommendations they made for patent reform are similar. But more importantly, *despite evidence to the contrary*, each report concluded that there are serious and systemic problems with the patent system. Thus, this conclusion coming from prestigious organizations is used by those who wish to overhaul the patent system to justify overhauling the patent system. Below we discuss the reports.

THREE REPORTS

To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy

The Federal Trade Commission and the Department of Justice, over the course of 2002, interviewed more than 300 representatives and academics which are referred to as "panelists" from the biotechnology industry, the pharmaceutical industry, the computer hardware industry, (including semiconductors) and the software and internet industries, in an effort to understand whether or not the patent system, and the framework of laws and regulation governing competition, promote innovation.[20] These panelists included business representatives from large and small firms and the independent inventor community; leading patent and antitrust organizations; leading antitrust and patent practitioners; and leading scholars in economics and antitrust and patent law.[21] Given the differences between the industries, for instance, in the way innovation occurs, the costs associated with innovation, entry costs, the length of time needed to bring a product to market, it is not surprising that panelists disagreed as to whether or not the patent system was relevant to or was accommodating their industries by promoting innovation and successful commercialization. For instance, representatives from both the pharmaceutical and biotechnology industries agreed that the patent system was essential to create incentives for innovation. Representatives from the computer hardware industry and the software and internet industries were less certain that the patent system promoted or provided incentives for innovation. For instance, one panelist in the software and internet industries said, "Compared to the effect of competition in this industry, the current patent system has relatively little effect on the motivation to innovate." [22]

Panelists also disagreed with the nature and degree to which the patent system might be hindering innovation specifically in regard to the issues of an anti-commons or patent

[18] David G. Barker. *Troll or no Troll? Policing Patent Usage with an Open Post-Grant Review*, Duke L. & Tech. Rev. 9, 10. (2005)
[19] Ted Apple. *The Coming US Patent Opposition*, 23(2) Nat Biotechnology., 245, 245 (2005).
[20] Supra note 7 at 3.
[21] Id at 3-4.
[22] Supra note 7 Chapter 3 at 49.

thicket and the issue of questionable or poor quality patents. We summarize the FTC findings from the four industries below in regard to whether or not an anti-commons or patent thickets is emerging in each industry as well as panelists' concerns about poor quality patents.

The Pharmaceutical Industry

Panelists from the pharmaceutical industry did not seem concerned about the possibility of a patent thicket or anti-commons occurring in the industry. One panelist noted that patent thickets in the pharmaceutical industry are generally not problematic because pharmaceutical products are based on a low number of patents.[23]

The issue of questionable patents seemed to be of concern to panelists in reference to incrementally modified drugs. One panelist argued "…that the PTO issues too many questionable patents which creates a gridlock of patent litigation in the district court system and thereby delays generic entry."[24] In support of this statement, the FTC offered its "Generic Drug Study"[25] which found that over time, "…for blockbuster products, brand name companies are suing for infringement on more patents and those suits take longer on average than suits involving a single patent."[26]

It should be noted that the Generic Drug Study was initiated to investigate whether or not two provisions of The Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act were being abused. These two provisions governed generic drug approval prior to patent expiration (the 180 day exclusivity and the 30-month stay provisions). Since that time, however, the Food and Drug Administration has changed its rule to prevent brand name companies from obtaining additional 30 month stays.[27] Therefore, the data contained in the Generic Drug Study may no longer be relevant.

The Biotechnology Industry

Some, but not all, panelists believed that the biotechnology industry can be threatened by a patent thicket or anti-commons – especially in regard to research tools. "A research tool is a technology that is used by pharmaceutical and biotechnology companies to find, refine, or otherwise design and identify a potential product or properties of a potential drug product." [28]

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[23] Id at.5.
[24] Id at 9.
[25] Federal Trace Commission, Generic Drug Study: Prior to Patent Expiration (2002) at www.ftc.gov/os/2002/07/genericdrugstudy/pdf
[26] Id at 47-48 and supra note 7 Chapter 3 at 9.
[27] See Applications for FDA Approval to Market a New Drug; Patent Listing Requirements and Application of 30-Month Stays on Approval of abbreviated New Drug Applications Certifying That a Patent Claiming a Drug is Invalid or Will Not be Infringed, 68 Fed Reg. 36,675. (2003).
[28] Supra note 7 Chapter 3 at 18.

But, the FTC report also contains the findings of Walsh et al.[29] which other panelists echoed (hereafter called the "first Walsh study"). The first Walsh study found that industry participants use a number of mechanisms to avoid the risk of an anti-commons or patent thicket.[30] Mechanisms include relying on a research exemption, obtaining a license, or inventing around patents. Moreover, the authors suggest that new USPTO guidelines governing utility (in January 2001, the USPTO adopted new utility guidelines to clarify patentability standards for emerging technologies, such as gene-related technologies, where uses for new materials that have not been fully characterized are not readily apparent),[31] [32] active intervention from the National Institutes of Health (NIH) (the NIH has a number of initiatives aimed at promoting greater access to research tools),[33] and overall shifts in the courts' attitudes[34] [35] toward research tool patents also have lessened the risk of a patent thicket or anti-commons. Moreover, as cited in the FTC report, the first Walsh study also observes the "…very high technological opportunities in the biotechnology industry, which enables firms to redirect their research efforts to areas less encumbered by patent claims to avoid possible infringement issues."[36] The first Walsh study warned, however, that the Federal Circuit case, *Madey v. Duke University*[37] which emphasized the narrow scope of the research exemption available to universities, might make these findings inapplicable. (The case is discussed below.)

In response to concerns voiced about royalty-stacking hindering innovation or making the final product more expensive than it need be, one panelist said, "…licensors tend to be 'fairly sensitive' to the implications of royalty-stacking for product commercialization." "If the licensor…is about to propose a royalty that is going to kill the product, [the licensor] is not going to make any money. And, most of the players in this field are sophisticated enough to understand that."[38]

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[29] John P. Walsh, Ashish Arora & Wesley Cohen. *Effects of Research Tool Patents and Licensing on Biomedical Innovation, in Patents in the Knowledge-Based Economy* (Wesley M. Cohen & Stephen Merrill eds).285-340 (2003) Available at http://books.nap.edu/book/0309086361/html/285.htm1#pagetop

[30] Supra note 7 Chapter 3 at 24-25.

[31] United States Patent and Trademark Office Utility Examination Guidelines, 66 Fed. Reg 1092 (2001)

[32] J. Barton, Intellectual Property Rights. *Reforming the Patent System*. Science 287:1933-1934 (2000).

[33] See http://ott.od.nih.gov/policy/policies_and_guidelines.html for NIH policy on research tools

[34] Walsh et al report that their respondents are particularly concerned about with the *University of California v. Eli Lilly & Co.* in which California tried to argue that its patent on insulin which was based on it work on rats meant that Lily was infringing because it covered Lilly's human-based bioengineered insulin production process. The CAFC ruled that the claim was not valid because California did not possess the claimed invention at the time of filing.

[35] Ian M. Cockburn, Samuel Kortum, Scott Stern. *Are All Patent Examiners Equal? Examiners, Patent Characteristics and Litigation Outcomes* in Patents in the Knowledge-Based Economy 19 (Wesley M. Cohen & Stephen Merrill eds.) 19-53 2003) Available at http://books.nap.edu/book/0309086361/html/285.htm1#pagetop in which Cockburn et. al. find that the CAFC went from upholding the plaintiff in about 60 percent of cases to finding for the plaintiff in only about 40% of cases in recent years.

[36] Supra note 7 Chapter 3 at 25.

[37] *Madey v. Duke University*, 307 F. 3d 1351, 1362(Fed Cir. 2002), *cert denied*, 123 S. Ct. 2639 (2003)

[38] Supra note 7 Chapter 3 at 25.

Industry panelists voiced concerns about poor patent quality hindering innovation, but there was disagreement about whether or not patent quality was any different in other fields. One panelist noted that biotechnology patents may be of higher quality because of "the concentration of the Patent Office on guidelines and resources in the biotech field in the last ten years."[39]

The Computer Hardware Industries, including Semi-Conductors

Panelists had different views on the patent system and the incentives it supplies to innovate, depending on the type of company they represented. They viewed competition and trade secrecy as drivers of innovation for integrated design and manufacturing firms, but for specialized design firms, panelists emphasized patents as important for innovation.[40]

In regard to a patent thicket or anti-commons, "none of the panelists disputed the existence of densely overlapping patent rights in the computer hardware industries." [41] (A patent thicket might emerge if differing industry participants hold overlapping patent rights, because it might be difficult to distinguish who owns what which may hinder innovation and successful commercialization.) Three reasons for a potential patent thicket were identified and discussed. The first is the nature of innovation in these industries which is cumulative. The second is the rise of defensive patenting, and the third is the ease of obtaining patents from the USPTO.

The technology associated with the computer hardware industries is complex, rapidly changing, and characterized by incremental innovation. Thus, overlapping patents occur. Moreover, as pointed out by Bronwyn Hall and Rosemarie Ziedonis in a study on the domestic semiconductor industry,[42] referenced by the FTC report, strengthening patent rights in the United States spurred "patent portfolio races" among capital intensive firms, which we believe is an entirely expected result of strengthening intellectual property rights. Firms engaged in defensive patenting to avoid their research and product development being "held up," by either litigation or a preliminary injunction, which could cost a firm millions of dollars;[43] to ensure favorable terms when licensing agreements were needed; and to reduce the risk of being found guilty of infringement.[44]

Another problem that troubled the panelists and that could contribute to a patent thicket or anti-commons is the rise of the "Non-Practicing Entities." Non-practicing entities are organizations that can employ a hold-up strategy without fear of retaliation because although they can patent or buy patents they do not engage in making or selling products associated with their patents.[45] Professor Ziedonis observed that one third of the lawsuits

[39] Supra note 7 Chapter 3 at 21.
[40] Supra note 7 Chapter 3 at 30.
[41] Supra note 7 Chapter 3 at 34.
[42] Bronwyn H. Hall and Rosemarie H. Ziedonis. *The Patent Paradox Revisited: An Empirical Study of Patenting in the US Semiconductor Industry*. RAND Journal of Economics, (32)1 101-128 (Spring 2001)
[43] Supra note 7 Chapter 3 at 38.
[44] Supra note 7 Chapter 3 at 35.
[45] Supra note 7 Chapter 3 at 38.

filed by a group of 136 companies involved patents not invented by the company.[46] (Because this remark seemed to indicate the presence of "trolls" in the semi-conductor industry, we researched the basis of her remark. The remark stems from a report on patent litigation in the semi-conductor industry[47] in which Professor Ziedonis compared the characteristics of "manufacturing" firms and "design" firms that are involved in litigation from January 1, 1973 through June 30, 2001.[48] "Manufacturing" firms are those firms that design and manufacture their products, and "design" firms are those which specialize in chip design but contract with third parties to manufacture their products. [49] In 30 percent of identified cases, legal title to a litigated patent had been reassigned from the original inventor or assignee to one of the litigating parties – typically to the plaintiff in an infringement suit. Ziedonis notes that these patents are acquired, as for instance through the acquisition of one company by another or bought from outside inventors. She offers no evidence on the possibility of trolls in the semi-conductor industry except to observe, "There also was an apparent rise in infringement suits brought by specialized "patent licensing" companies."[50] No number or rate is given in the report.)

Although all panelists agreed that the existence of overlapping patent rights among industry participants could and did present problems associated with a patent thicket, panelists also agreed that cross-licensing, patent pools, and the licensing requirements of standard setting organizations have helped to mitigate the potential harm to innovation caused by patent thickets.[51]

The Software and Internet Industries

Perhaps, the most divergent views on the role of patents in promoting innovation were offered in this industry, as panelists repeatedly mentioned that competition was the main catalyst of innovation and that other available protections were available to the industry, namely, copyrights and open source software. However, panelists were divided on the merits of applying two intellectual property regimes to an industry.

Innovation in the software and internet industries is incremental. "Although some panelists stated that software and business method patents foster innovation, many disagreed, asserting that such patents are often questionable and are actually stifling innovation by increasing entry barriers and creating pervasive uncertainty." [52] Some panelists felt that software patents should not be issued at all. Others felt that patents should not be granted for more than five years. Another panelist pointed out that since

[46] Supra note 7 Chapter 3 at 39.
[47] Rosemarie Ham Ziedonis, *Patent Litigation in the U.S. Semiconductor Industry*. (Wesley M. Cohen & Stephen Merrill eds).180-212 (2003) Available at http://books.nap.edu/book/0309086361/html/285.htm1#pagetop
[48] Id at 182.
[49] Id at 183.
[50] Id at 185.
[51] Supra note 7 Chapter 3 at 43.
[52] Supra note 7 Chapter 3 at 44.

the industry innovates incrementally, and technological change is rapid, entire product life cycles sometimes pass before a patent is issued. [53]

A number of panelists agreed about the existence of a patent thicket in the software industry.[54] Panelists noted that a product could contain dozens, if not hundreds, of patents covering individual components of a product. Moreover, the increase of patenting in the industry has accelerated defensive patenting which in turn contributes to a patent thicket. Defensive patenting is occurring in the industry for the same reasons it is occurring in other industries, namely, to maintain détente with rivals, to obtain portfolio cross licenses, and to raise a patent infringement counter claim should a firm sue for infringement.[55]

Panelists seemed uncertain as to whether or not open source software could serve as an antidote to the anti-commons they perceive in the industry. Open source software is software that is distributed with its source code so that users may modify it.[56] As scholars have pointed out, there are advantages and disadvantages to using open source software. On one hand, the proprietary nature of software may generate income. On the other hand, open source software may have cost advantages.[57]

To summarize, panelists across industries disagreed about the nature and degree to which the patent system might be hindering innovation and successful commercialization specifically with regard to the issues of an anti-commons or patent thicket and questionable or poor quality patents. Moreover, as the evidence indicates, in the biotechnology industry and the computer hardware industries, to the degree to which industry participants are experiencing patent thickets and facing issues associated with poor quality patents, they are finding solutions or ways around these problems. Similarly, other industries are finding solutions or at least potential solutions to these problems.

A Patent System for the 21st Century

In 2004, the NAS released its report on the patent system, "*A Patent System for the 21st Century"* which undertook to critique the patent system against seven desirable criteria.[58]

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[53] Supra note 7 Chapter 3 at 45.
[54] Supra note 7 Chapter 3 at 52.
[55] Id.
[56] Supra note 7 Chapter 3 at 47
[57] Supra note 7 Chapter 3 at 48.
[58] These seven criteria are:

1. The patent system should accommodate new technologies
2. The patent system should reward only those inventions that meet the statutory tests of novelty and utility, that would not at the time they were made be obvious to people skilled in the respective technologies, and that are adequately described.
3. The patent system should serve its second function of disseminating technical information.
4. Administrative and judicial decisions entailed in the patent system should be timely, and the costs associated with them should be reasonable and proportionate.

Two criteria were directly concerned with issues associated with poor quality patents and an anti-commons or patent thicket. They are:

- The patent system should reward only those inventions that meet the statutory tests of novelty and utility, that would not at the time they were made be obvious to people skilled in the respective technologies, and that are adequately described; and
- Access to patented technologies is important in research and in the development of cumulative technologies where one advance builds upon one or several previous advances.

The report recognized that, at least theoretically, scholars agree how important it is for the patent system to appropriately reward inventors.[59] But, it also noted other scholarly arguments that purport to show how doubts about the validity of patents are likely to encourage more litigation, raising the transaction costs of the system and discouraging investment.[60] It pointed to other scholars who suggest that questionable patents may cause investment in research to decline or be abandoned.[61] The NAS report offers examples of some poor quality patents such as a patent for cutting or styling hair using scissors or combs in both hands.[62] These concerns are similar to the concerns raised in the FTC report.

In regard to the USPTO which has come under sharp attack in recent years for issuing poor quality patents, the NAS notes "…the claim that quality has deteriorated in a broad and systematic way has not been empirically tested."[63] Nevertheless, it claims, "…a nontrivial number of errors in judgment are inevitable in a system whose output by 3,000 individual examiners is 167,000 patents annually."[64]

The report points to three seemingly direct measures of quality. They are: 1) the ratio of invalid to valid patent determinations in infringement lawsuits; 2) the error rate in USPTO quality assurance reviews of allowed patent applications; and 3) the rate of claim cancellation or amendment or outright patent revocation in re-examination proceedings in the USPTO.[65] Studies using these measures give mixed results with some studies suggesting that validity is being upheld more than invalidity and other studies indicating

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5. Access to patented technologies is important in research and in the development of cumulative technologies where one advance builds upon one or several previous advances.
6. Greater integration of or reciprocity among the three major patent systems would reduce public and private transaction costs.
7. There should be a level field, with intellectual property rights holders who are similarly situated enjoying the same benefits while be subjected to the same obligations.

[59] Supra note 8 at 46.
[60] Id.
[61] Id.
[62] Supra note 8 at 47
[63] Supra note 8 at 48.
[64] Supra note 8 at 48.
[65] Id.

the reverse,[66] and the error rate of the USPTO is currently on a downward trend at around 4 percent.[67] But, as pointed out by the report there are serious deficiencies with each measure. There are selection bias effects associated with litigation. For instance, parties will rationally avoid futile litigation over patents that are very strong, patently invalid, or commercially worthless. Generally, only patents in the middle, those whose validity can be rationally disputed with a reasonable expectation of success, will be found in litigation. More importantly, however, the numbers of patents associated with any of these procedures is very small. At the time of the report, the litigation rate was just over 1 percent; only 2-3 percent of a year's patents are reviewed by the USPTO; and re-examined patents represent about 0.3 percent of the total number of patents.[68]

But, despite the lack of evidence showing a systematic decrease in the quality of patents issued – and some evidence showing that the quality of patents has not declined but is actually improving, the NAS believes that the USPTO is issuing more poor quality patents. The NAS cites four reasons to justify this belief. First, the NAS points to studies which show that that the number of examiners per 1000 applications is down about 20 percent over the past few years[69] and the NAS notes the complexity of patents is increasing.[70] In regard to the productivity of examiners, the NAS reports that, at the time of writing, even though examiners have access to scientific and technical databases capable of automated search for prior art, automated filing and processing of applications is only now being implemented. Second, the NAS believes that the patent approval rate is significantly higher in the United States relative to other industrialized countries,[71] even though the available studies show differing rates of patent approval. For instance, Quillen and Webster estimate that the approval rate is between 85 percent and 97 percent, while Clark's analysis puts the approval rate at closer to 75 percent.[72] (The USPTO reported that in 2006 its approval rate was 54%.[73] More recent studies put the approval rate at about 67%.)[74] The NAS admits that the inability to follow individual applications and application families from original filing to final disposition of all members may mean that arriving on a precise approval rate may be elusive.[75] Third, although the USPTO has implemented changes in policy regarding the treatment of genomic[76] and business method patents,[77] partly in response to criticisms associated with the quality of patents it

[66] Id.
[67] Id.
[68] Supra note 8 at 49.
[69] Supra note 8 at 51.
[70] Id.
[71] Supra note 8 at 52.
[72] Supra note 8 at 53.
[73] http://www.uspto.gov/web/offices/com/speeches/06-73.htm
[74] Mark Lemley and Bhaven N. Sampet. *Is the Patent Office a Rubber Stamp?* Standford Public Law and Legal Theory Working Paper Series. July 2007 available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=999098#PaperDownload
[75] Supra note 8 at 54.
[76] In 2001 the USPTO introduced new utility guidelines declaring that the claimed invention must be "specific, substantial, and credible." See supra note 26.
[77] The "Business Methods Patent Initiative" was introduced in 2000. The initiative consisted of four stps:1) improved technical training of Class 705 examiners, 2) revised examination guidelines, 3) mandatory

issues, the NAS claims to be unable to assess the impact of these changes.[78] Fourth, the NAS believes that there may have been some dilution in the application of the non-obvious standard as a result of court decisions and their incorporation in the examination guidance compiled in the USPTO's Manual of Patent Examining Procedure.[79]

Specifically, the NAS believes that the guidance for determining obviousness, as set forth in the three cases known as the "Graham trilogy," [80] can lead to conceptual confusion depending on how it is applied. (The U.S. Court of Appeals for the Federal Circuit has supplemented this guidance with the "teaching-suggestion-motivation" (TSM) test. This test was designed to eliminate hindsight bias in the determination of obviousness. Critics argue that applying the TSM test effectively lowers the bar that Congress set for patentability when it codified the pre-existing law of non-obviousness because the Patent Office and litigants essentially have to prove that an invention is not non-obvious, as opposed to proving that it is obvious.) But, the recent *KSR International Co. v. Teleflex Inc. et al.* decision as discussed below, is expected to significantly lower the burden for patent examiners and litigants to establish the obviousness of a claimed invention.

The NAS specifically states, "Neither USPTO resources in relation to its workload, nor patent approval rates, nor changes in the treatment of genomic and business method inventions and the non-obviousness standard are, separately, conclusive evidence that patent quality is too low or declining. However, taken together they lead the committee to conclude that there are reasons to be concerned about both the courts' interpretations of the substantive patent standards, particularly non-obviousness, and the USPTO's application of the standards in examination."

With regard to questions of access (an anti-commons or patent thicket) the NAS noted that there was only one area – biotechnology research and development, primarily when applied to human health – where it was repeatedly suggested that there might be a significant problem of access to patented technology. [81] In order to understand whether or not access to research tools was being prevented by an excess of patents, the NAS commissioned Walsh et. al.[82] to undertake the survey discussed above. (This is the first Walsh study, which was used in the FTC report.) And, as we discussed above, the first Walsh study found that there did not appear to be an anti-commons or patent thicket but rather industry actors were finding "working solutions" to any potential anti-commons or patent thicket.

Concerns were also expressed about university researchers' use in clinical research of diagnostic tests involving patented technologies. The NAS discussed the findings of

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search of specified sources of prior art and 4) a new "second review of all allowed applications to ensure compliance with the search guidelines and the appropriateness of allowed claims. See supra note 8 at 56.

[78] Supra note 8 at 56

[79] Supra note 8 at 59

[80] *Graham v. John Deere Co*.; *Calmar, Inc. v. Cook Chemical Co*., 383 U.S. 1(1966); and *United States v. Adams*, 383 U.S. 39 (1960)

[81] Supra note 8 at 71.

[82] Supra note 8 at 25

Merz, Cho and their colleagues[83] on the impact on clinical laboratories of royalty rates on patented tests, infringement claims, and refusal to license some tests at all. Merz et al found that 25 percent of laboratory physicians reported abandoning a clinical test because of patents and royalty rates ranging from 9 percent for polymerase chain reaction to 75 percent for the human chorionic gonadotropin patent. However, as the NAS acknowledges, clinical laboratories charge their patients or their insurers, thus earning revenue that distinguishes the provision of clinical services from non-commercial research. Moreover, no evidence was found indicating that patients lacked access to these tests.[84]

Similar to the FTC report discussed above, the NAS report does not offer empirical evidence supporting assertions that a patent thicket is inhibiting innovation and successful commercialization or that patent quality is decreasing. Indeed, as the NAS points out, at the time of the report, the litigation rate was just over 1 percent; only 2-3 percent of a year's patents are reviewed by the USPTO; and re-examined patents represent about 0.3 percent of the total number of patents[85] Further, the first Walsh report which the NAS commissioned does not support these assertions. Moreover, the NAS report offers conflicting evidence concerning patent approval rates, and a disbelief that the USPTO could be correct about its allowance rate. This does not constitute solid empirical evidence.

Reaping the Benefits of Genomic and Proteomic Research

The report published by the National Research Council (NRC) was more limited in scope than the two early reports discussed in that it only focused on the trends in the patenting of genomic and protein related inventions. It did, however, express similar concerns as those discussed above as to the effects of patenting on innovation and successful commercialization. To address these issues to the widest extent possible within the constraint of limited resources, the NRC consulted the existing research literature and received testimony from scholars in the field. In addition, it engaged in three original research efforts:

1. a search for issued patents and published patent applications in selected biotechnology categories;
2. a small survey of university licensing of selected categories of patents;
3. a survey of biomedical research scientists to ascertain their experience with intellectual property and its effects on research.[86]

We discuss the NRC's findings below.

[83] J. Merz, F.D.G. Kriss, D.D.G. Leonard, and M.K. Cho. *Diagnostic Testing Fails the Test*." 577-579 Nature 415 (Feb 2002). See also supra note 8 at 73.
[84] Id.
[85] Supra note 8 at 49.
[86] Supra note 9 at 100

A Search for Issued Patents and Published Patent Application in Selected Biotechnology Categories

NRC staff consulted with USPTO supervising examiners to develop search algorithms for each category identified. The identified categories are: gene and gene regulation, haplotype/SNPs, gene expression profiling, protein structure, protein-protein interactions, modified animals, software, algorithms, databases, EGF pathway, $CTLA^4$ pathway, NF-kB pathway. These searches were run on the patent claims field to obtain the number of U.S. patents and assignees, assignee countries, inventor countries, applications years, and ultimate assignees over the period from January 1, 1995 to February 1, 2005. Similar searches were run on the extensive genomic and genetic database maintained by Georgetown University Staff with support from the National Institutes of Health.[87] The results corresponded very closely but not exactly.[88]

Researchers found that the numbers of issued patents declined in most categories beginning in 2000-2001. The only case that this was not apparent is with protein structures, where the numbers were low to begin with. The NRC asked whether or not a decline in patenting was expected to continue. They noted that public funding was not declining, nor was research productivity and that it was unlikely that the economic environment played a role, at least not initially, because patents that issued after 2000 derived from applications filed two or more years earlier.[89] The NRC acknowledged that, while hard to assess, greater conservatism on the part of USPTO is almost certainly a factor in the decline.[90] So it seems, that in spite of the claimed inability of the NAS to assess the impact of the USPTO's utility guidelines, that their implementation in which the claimed utility of an invention must be "specific, substantial and credible" [91] (these guidelines were mentioned above) might be having an effect on the numbers of patents issued and the quality of issued patents.

A Small Survey of University Licensing of Selected Categories of Patents

Obtaining information on licensing is not easy as firms and universities consider licenses and licensing terms proprietary information that they voluntarily disclose very selectively and only when it is to their advantage. Nevertheless, the NRC references a survey done at the beginning of 2003 on 30 US academic institutions owning 75 or more of the DNA-based patents.[92] Nineteen institutions provided data on licensing frequency for about 2,700 patents. In sum, the survey found that "interview respondents reported practices broadly consistent with the NIH guidelines issued in 1998 and with the Guidelines for Licensing of Genomic Inventions, which were in draft form and published for comment at the time the survey was conducted and the results analyzed. Further, university

[87] Supra note 9 at 107.
[88] We have used this database in our research and are uncomfortable with its maintenance.
[89] Supra note 9 at 110.
[90] Id.
[91] Supra note 9 at 64.
[92] Pressman et.al. *Patenting and Licensing Practices for DNA Based Patents at US Academic Institutions*. 24 Nature Biotechnology 31-39 (2006).

technology transfer offices reported considering the NIH guidelines de facto regulations binding on grantee institutions."[93]

The NRC also conducted its own small survey. It obtained the cooperation of the five universities assignees with the most patents (in all but one case) related to the three molecular pathways (identified above) to supply data on the licensing of these inventions. The NRC reports results were similar to the survey discussed above – that is, broadly consistent with the NIH guidelines.[94]

A Survey of Biomedical Research Scientists to Ascertain Their Experience with Intellectual Property and its Effects on Research

To collect more extensive (but still preliminary data)[95] on the whether or not patents contribute to the problems associated with an anti-commons the NRC arranged with Walsh and colleagues to undertake a more extensive survey than the one described above. This study is referred to as the second Walsh study. A sample of 1,124 persons included, among others, included investigators in universities, government laboratories, and other non-profit institutions; 563 industry scientists; and 299 researchers working on one of the signaling proteins. Industry researchers were over-sampled to ensure they made up one third of the total. And to ensure that the survey respondents contained sufficient numbers of individuals who work in the fields of biomedical sciences of high commercial interest (because of their association with normal and disease-associated cellular processes) a specially selected sample of approximately 100 researchers working on each of the three molecular pathways (EGF, CTLA4 and Nf-kB) was also included.[96] The unadjusted response rate was 33%.[97]

The findings of the second Walsh study are similar to the first Walsh study. For instance, drawing from the responses, those whose research goals were "drug discovery" "basic research" or "other" (to differentiate them from survey respondents working on the three molecular pathways) yielded a sample of 274 persons. In this sample, Walsh found that the top five reasons for project abandonment, were, in order of frequency, "lack of funding" (62%), "conflict with other priorities" (60%), "a judgment that the project was not feasible" (46%), "not scientifically important (40%)," and "not that interesting" (35%).[98]

Technology access issues (issues associated with a patent thicket or poor quality patents) were cited much less frequently as a reason for project abandonment across all types of scientists and researchers. For instance, in the sample above, "unreasonable terms for obtaining research inputs" was cited by 10% of survey respondents and "too many

[93] Supra note 9 at 110-111.
[94] Supra note 9 at 119.
[95] Supra note 9 at 119
[96] Supra note 9 at 120.
[97] Id.
[98] Supra note 9 at 123-124.

patents covering needed research inputs" was cited by only 3% of survey respondents as reasons for project abandonment.[99]

Overall, that is across all types of respondents, the number of projects abandoned or delayed as a result of technological access difficulties is extremely small, as is the number of occasions in which investigators revise their protocols to avoid intellectual property issues or pay high costs to obtain one.[100] For instance, no academic respondent abandoned work as a consequence of either delay or inability to receive permission.[101] Of those seeking permission from a patent owner (24 out of 32 academic respondents) only one encountered a demand for licensing fees, in the range of $1 - $100.[102]

But even though this report produced no evidence of a patent thicket or that researchers were being unreasonably challenged by questionable patents, the NRC echoes the concerns voiced by both the FTC report and the NAS report in regard to the *Madey* case. (The concerns being that *Madey* might cause academic researchers and industry participants to become more proactive in asserting their intellectual property rights, thus allowing a patent thicket or anti-commons to emerge.)

THE RECOMMENDATIONS OF THE REPORTS

The three reports we have discussed above were written from different perspectives and with differing goals. But common themes emerge. All three reports were concerned with issues associated with the possibility of an anti-commons emerging and ensuring patent quality and so avoiding uncertainty, potential litigation, and other unnecessary costs associated with poor quality patents.

Despite no evidence, the FTC report concludes that poor quality patents are being issued and urges a number of reforms to address the potential problems. These reforms that are aimed directly at improving the issuance of quality patents include:

1. Enact legislation to create a new administrative procedure to allow post-grant review and opposition to patents;
2. Enact legislation to specify that challenges to the validity of a patent are to be determined based on a "preponderance of evidence" rather than presuming an issued patent is valid;
3. Tighten certain legal standards to evaluate whether a patent is obvious;
4. Provide adequate funding for the USPTO;
5. Modify certain USPTO rules and implement portions of the USPTO's 21st Century Strategic Plan[103]

[99] Id.
[100] Supra Note 9 at 123.
[101] Id.
[102] Id.
[103] Supra note 7 at 1-16 for the recommendations.

Similarly, despite evidence that shows that there is no anti-commons, the NAS proposes addressing the issues of an anti-commons and patent quality through:

1. Reinvigorating the non-obvious standard
2. Creating a procedure for third parties to challenge patents for a limited time after their issuance
3. Providing more resources for the USPTO[104]

The NRC report, although concerned only with genomics and proteomics, contains a recommendation that non-obviousness should not be based on the absence of structurally similar molecules and instead should be evaluated:

> "by considering whether the prior art indicates that a scientist of ordinary skill would have been motivated to make the invention with a reasonable expectation of success at the time the invention was made."[105]

In addition, the NRC also encouraged universities to be:

> "…familiar with the USPTO utility guidelines and should avoid seeking patents on hypothetical proteins, random single nucleotide polymorphisms and haplotypes, and proteins that have only research, as opposed to therapeutic, diagnostic, or preventive, functions."[106]

Although this analysis focuses on issues associated with an anti-commons or patent thicket and poor quality patents, it should be noted that some of the recommendations of the reports have found their way into proposed legislation. For instance, both the FTC and the NAS reports recommend creating a post-grant opposition proceeding and both the FTC and NAS reports favor limitations on when damages may be trebled for willfulness.

PATENT REFORM: LACK OF EMPIRICAL JUSTIFICATION

A problem that has not been adequately addressed is that the call to overhaul the patent system to date is based more on conjecture, anecdote, and individual publicized cases, rather than upon reality. This may be particularly the case when it comes to patents in the biotechnology industry such as those involving genes. Caufield and colleagues point out that in biotechnology areas such as gene patenting, where ethical, legal, and economic concerns proliferate, the timing of major policy documents illustrates that policy has largely been driven by social unease, preliminary data, and literature on adverse practical ramifications, as well as several highly publicized patent protection controversies.[107]

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[104] Supra note 8 at 81-83.
[105] Supra note 9 at 142.
[106] Supra note 9 at 144.
[107] T. Caulfield, R.M. Cook-Deegan, F.S. Kieff, J.P. Walsh. *Evidence and Anecdotes: Analysis of Human Gene Patenting Controversies.* 24 Nature Biotechnology 1091-1094 (2006).

The primary empirical studies offered by the FTC, NRC, and NAS reports are the first and second Walsh studies discussed above which investigated the biotechnology industry, which has been perceived to be the industry most likely to suffer from an anti-commons. Although both studies report subjective findings based on interviews and surveys, both studies concluded that an anti-commons is being avoided in the industry. We note that qualitative studies such as this are often used in order to better understand a perceived problem or to gain a new perspective.[108] Thus, qualitative methods are appropriate in situations where one might need to first identify the variables that could later be quantitatively studied. None of the reports relied upon to justify overhaul are based on objective, empirical data, other than the NRC's commissioned study limited to DNA patents, which found issued patents declining in this area. *And, it should be noted that the entire FTC's report was, in fact, a qualitative study.*

As discussed above, the first Walsh study involved interviews of a small sample of intellectual property attorneys, business managers and scientists, with 24 from the pharmaceutical industry, representing 10 firms, 18 from biotech, representing 15 firms, 13 from six universities and 15 others. While the small number of individuals interviewed means that it is impossible to determine if the results are representative of the national experience, the study found no evidence that the proliferation of patents was causing an anti-commons in the biotechnology industry. [109]

While the second Walsh study suffers from a modest response rate, again putting into question whether the existing research truly represents the national experience, the second study supports the findings of the first study, namely that there is no evidence that the proliferation of patents was causing an anti-commons in the biotechnology industry.

These studies, while limited in that the data are not combined with objective data, do not indicate that there is an anti-commons in the biotechnology industry, and therefore, they do not justify support for the proposed patent system overhaul. However, given the methodological issues associated with the studies and the lack of any objective empirical data, it is impossible to categorically state what is or is not occurring with absolute certainty. Further, there is another problem. Court cases recently decided have now changed the landscape significantly. The impact of such decisions has not been studied or was studied too soon after the decisions to draw certain conclusions.

RECENT COURT CASES THAT MAY ALTER PATENT ENVIORNMENT

Madey v. Duke University

John Madey was employed by Duke University to direct a lab using equipment developed from his two patents related to free electron laser technology. Following

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[108] A Strauss, & J. Corbin, J. *Basics of Qualitative Research: Grounded Theory Procedures and Techniques*. Newbury Park, CA: Sage Publications, Inc. (1990).

[109] In addition, methods describing the study period, questions posed, the sampling method to select respondents, or rate of those agreeing to be interviewed are not provided in the publication describing the results which makes it difficult to assess the validity of the findings.

internal disagreements, Duke removed him as a director but continued to use his patents. Madey sued claiming patent infringement. The lower court dismissed his claim based on the common law experimental use doctrine. (The experimental use exemption was articulated in 1813 by Judge Story. In *Whittemore v. Cutter,* Judge Story used the term "philosophical" instead of "scientific" to describe the experimental use exemption from patent infringement. The essential component of the court's reasoning was that those skilled in such "useful arts" are free to use the knowledge imparted by a patent disclosure for amusement, to satisfy idle curiosity or for strictly philosophical inquiry.)[110] On appeal, the U.S. Court of Appeals for the Federal Circuit reversed and remanded.[111] The U.S. Supreme Court in 2002 denied Duke's petition seeking review of the Federal Circuit's decision in the University's case with John Madey. [112]

The Federal Circuit Court held that the experimental use exemption does not apply to research that furthers universities' "business objectives," including research, educating and enlightening students and faculty, holding that "so long as the act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense."[113] Moreover, the profit or non-profit status of the user is not relevant.[114]

The *Madey* court did not provide any examples of the types of uses that would qualify for the experimental use defense (those acts performed solely for amusement, to satisfy idle curiosity or for strictly philosophical inquiry). It did, however, delineate the boundaries of the defense by examining what uses would not qualify for the experimental use defense. The court found that the experimental use exception should not insulate commercial research from claims of patent infringement. This applied to Duke who as Judge Gajarsa noted, was "…not shy in pursuing an aggressive patent licensing program from which it derives a not insubstantial revenue stream."[115]

Moreover, the Court reasoned that the experimental use exemption might unfairly advance Duke's business interests. The court used a broad definition of business interest:

> [M]ajor research universities, such as Duke, often sanction and fund research projects with arguably no commercial application whatsoever. However, these projects unmistakably further the institution's legitimate business objectives including educating and enlightening students and faculty participating in these projects….(which) serve to increase the status of the institution and lure lucrative research grants, students and faculty.[116]

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[110] Whittemore v. Cutter, 29 F. Cas. 1120 1121 (C.C.D. Mass 1813)
[111] Madey v. Duke University, 307 F.3d 1351 (Fed. Cir. 2002).
[112] Cert. denied 123 S. Ct. 2639 (2003)
[113] 307 F. 3d. at 1362.
[114] Id.
[115] 307 F. 3d. at 1367 at n.7.
[116] 307 F. 3d. at 1362

The FTC, NAS and NCR reports as well as the Walsh reports question whether the absence of an observed anti-commons is associated with researchers' lack of knowledge about the *Madey* decision. The speculation is that as more researchers and their institutions become more knowledgeable about the decision, they, as well as private industry, may become more proactive in protecting their intellectual property rights, allowing an anti-commons to emerge. The NAS states that:

> An informal poll of research institutions reported to a September 30, 2002, meeting organized by the Association of American Universities, American Association of Medical Colleges, Council on Government Relations, and National Association of State Universities and Land Grant Colleges revealed that a number of institutions were receiving more notification letters with respect to patent infringement in the aftermath of the decision. The organizations have arranged with the American Association for the Advancement of Science to continue to monitor universities' experience in this regard.[117]

We are, however, unaware of any follow-up on the part of these organizations.

But it should be noted that just as before the *Madey* decision when people posited that the possibility of anti-commons was occurring with no empirical evidence, in the aftermath of the *Madey* decision people are once again positing that an anti-commons may occur with no empirical evidence.

eBay Inc. v MercExchange, LLC

In *eBay Inc. v MercExchange, LLC* [118] a patent owner alleged patent infringement for a method of conducting internet sales. The lower court found the patent had been infringed but denied permanent injunctive relief. The U.S. Court of Appeals reversed, finding the District Court abused its discretion by denying the permanent injunction, applying its general rule of granting injunctions against patent infringement except in exceptional circumstances. On appeal to the U.S. Supreme Court, the Court found that the District Court was incorrect in its categorical denial of injunctive relief and likewise the Court of Appeals erred in categorically granting such relief. Accordingly, the Court remanded the case ordering that the traditional four-factor framework that governs the award of injunctive relief be applied. This four-pronged test requires a plaintiff to demonstrate that: 1) it has suffered irreparable injury; 2) remedies available at law are not adequate to compensate for the damage incurred; 3) Upon balancing hardships between plaintiff and defendant, a remedy in equity such as injunctive relief is warranted, and 4) that the public interest would not be disserved by granting injunctive relief.

This ruling is most problematic for patentees who do not themselves practice their inventions and who have in the past relied on the high likelihood of an injunction following a finding of infringement.

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[117] Supra note 8 at 76

[118] *Ebay Inc., et al., Petitioners v. MerEchange, L.L.C.* 547 U.S. (2006) Kennedy J. concurring

KSR International Co. v. Teleflex Inc. et al.

In 2002, Teleflex filed suit against KSR International for patent infringement of its electronic floor pedals. KSR argued that the pedals were nothing more than a combination of existing technologies and were therefore obvious and unenforceable. The District Court found for KSR, holding that the patent was obvious. The Court of Appeals reversed, holding that if the "Teaching, Suggestion, Motivation" (TSM) test for obviousness were appropriated applied, the patent would have been found to be non-obvious. Applying this test means a patent is obvious only if prior art, the problem's nature, or knowledge of a person with ordinary skill in the art indicate motivation or suggestion to combine the prior art teachings. The Supreme Court reversed, holding that the patent was invalid because it was obvious to a person of ordinary skill in the field to combine the existing technologies, finding that KSR provided convincing evidence that combining the existing technologies was well within the grasp of a person of ordinary skill in the field and the benefit of doing so was obvious.[119] While acknowledging that the TSM test provides helpful insight in that a patent existing of combined elements is not obvious merely by proving that each element was independently known as prior art, the Court, counseled against confining the obviousness analysis to a formal conception of "teaching, suggesting, and motivation." Thus, the Supreme Court effectively raised the bar for obviousness and new guidance to the USPTO examiners can be expected.[120]

CONCLUSION

As demonstrated above, there is a lack of evidence that justifies overhauling the patent system in a way that could potentially disrupt the incentives of industries that rely on patents to innovate. Indeed, the Walsh studies suggest that there is no basis to believe that the proliferation of patents is hindering research. Moreover, the courts, particularly the Supreme Court, have taken the lead in initiating reforms to the patent system and the industries that are affected by it. The *Madey* decision blurred the boundaries between universities and their missions and industry. But, despite the worry voiced by the reports discussed above, the only evidence we have that the consequences of *Madey* might contribute to an anti-commons through increased litigation activities is an informal poll showing that some universities have received more notification letters warning of infringement.

In both *eBay* and *KSR*, the Supreme Court has increased uncertainty in the business environment. As to *eBay*, there is now less certainty as to whether injunctive relief will be granted when patents are infringed. And while this might weaken patent rights it should effectively have eased the concerns of some of the FTC panelists, particularly those in the computer hardware and semi-conductor industries, who are concerned that findings of infringement could result in automatic injunctive relief. And the KSR decision has, in essence, agreed with one of the major recommendations for patent reform

[119] *KSR International Co. v. Teleflex Inc. et al* 127 S. Ct. 1727, 2007.
[120] USPTO, Draft KSR Training Guidelines Under OMB Review
http://usasearch.gov/search?affiliate=uspto.gov&v%3Aproject=firstgov&query=KSR

made by the FTC, the NAS, and the NRC -- that the obvious standard should be strengthened.

We don't know how these judicially-enacted patent reforms will play out. Theoretical arguments can be made on both sides of the anti-commons and patent quality debate. Most observers of the patent system welcome and acknowledge the need for patent reform in some areas, such as ensuring the USPTO has the resources it needs to ensure patent quality. But overhauling the patent system in a way that would weaken patent rights is controversial and should be carefully assessed and balanced with the potential untoward impact such changes may have on various industry sectors, particularly those whose primary assets are patents, not manufactured products. In these sectors, significant changes that introduce uncertainty and weaken patent rights may reduce investment in these industries, which in turn may adversely impact innovation and successful commercialization.

There is no doubt that the explosion of innovation which has resulted in large numbers of patents being issued has strained the patent system. But, the patent system supports and protects innovation by providing the incentives for innovation, and legal mechanisms protect intellectual property rights. We have seen that as innovation cycles have occurred, the system has shown itself to be resilient and self-correcting. For instance, as mentioned by the reports, discussed above, the USPTO has revised its guidelines in response to criticisms and will be implementing new standards to accommodate the *KSR* ruling. And as mentioned by the reports, industry participants are finding solutions to problems associated with possible patent thickets and poor quality patents. Implementing overhaul measures aimed at weakening patent rights and enforcement mechanisms is dangerous because innovation often depends on strong patent rights and enforcement mechanisms. The danger to innovation increases when overhaul is implemented without methodologically sound empirical data that also adequately takes into account the effect of confounding variables such as recent court decisions.