

2007 Patent Reform Bill: Will it Benefit Nanotechnology?

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ABSTRACT

The Patent Reform Act of 2007 is stirring debate, not only in both houses of Congress, but also within the pharmaceutical, biotechnology, software, and electronics industries. Nanotechnology companies too must be aware of what is at stake. In this article, Washington, DC patent attorney Stephen Maebius discusses the potential impact of the pending legislation on nanotechnology. The proposed changes would affect everything from who is entitled to receive a patent (first-to-invent or first-to-file) all the way to how infringement damages are calculated. Because they rely so heavily on the value of their patent portfolio, nanotech companies should form a collective voice to communicate a position in this important debate.

I. INTRODUCTION

On April 18, 2007, Congress introduced twin bills in the House and Senate proposing sweeping revisions to patent law.¹ On the House side, Representatives Berman and Smith introduced H.R. 1908 and on the Senate side, Senators Leahy and Hatch introduced S. 1145. Independently and over a short period of time prior to the introduction of the 2007 patent reform bill, the Supreme Court issued a series of patent-related decisions that effectively reduce the strength of patents. The enactment of some or all of the provisions contained in the 2007 patent reform bill, together with the impact of the recent Supreme Court patent decisions, will have an impact on the valuation of nanotechnology patents, the extent to which investors may rely on the strength of patents to bring a return on risky investments, and the balance of power between innovation and competition.

The community of nanotechnology companies and research institutions has so far not participated in an organized fashion in the debate over patent reform, a debate which is currently dominated by the pharmaceutical industry, the biotechnology industry, the software industry, and several coalitions and bar groups. In the months ahead, as hearings take place on Capitol Hill to examine the proposed reforms in

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¹ Rep. Berman just announced on May 10, 2007 that he intends for the House IP Subcommittee to conduct a markup of the bill, even though consensus among industry groups has not yet been reached and key industry groups have announced opposition to certain portions as discussed herein.

greater detail, it will be important for the nanotechnology community to understand what is at stake, adopt positions on provisions that will impact nanotechnology, form a collective voice to communicate a position in this important debate, and prepare to adopt new strategies to maximize the value of nanotechnology patent portfolios based upon the changes already made by the Supreme Court and any further ones enacted by Congress.

This article will summarize key provisions of the 2007 patent reform bill, highlight some positions taken on key provisions by other industries, review the recent series of Supreme Court decisions in patent cases, and discuss the potential impact of patent reform and Supreme Court decisions on nanotechnology.

II. UNDERSTANDING FORCES BEHIND THE PATENT REFORM MOVEMENT

A number of provisions contained in the 2007 patent reform bill have their genesis in recommendations that grew out of a series of hearings held on the patent system in 2002 by the Federal Trade Commission (FTC).² The hearings brought together representatives from industry, academia, the U.S. Patent Office, and private practitioners.³ The end result was a lengthy report prepared by the FTC containing ten recommendations for patent reform.⁴ The ten reforms recommended in the report are summarized as follows:

Creating a new administrative procedure that will make it easier for firms to challenge a patent's validity at the U.S. Patent and Trademark Office (PTO), without having to raise an expensive and time-consuming federal court challenge; and

Allowing courts to find patents invalid based on the preponderance of the evidence, without having to find that clear and convincing evidence compels that result. The current standard of "clear and convincing evidence" undermines courts' ability to weed out questionable patents. This is especially troubling, since certain PTO procedures and rules tend to favor the issuance of patents.

The report also recommends that Congress limit the award of treble damages for willful patent infringement. Some hearings participants explained that they do not read their competitors' patents because of concern that learning about others' innovations will expose them to treble damages infringement liability. Failure to read competitors' patents, however, can harm innovation and competition. The FTC's recommended legislative change would allow firms to read patents to learn about new innovations and to survey the patent landscape to assess potential infringement issues, yet would retain a viable willfulness doctrine that protects both wronged patentees and competition.⁵

The NAS followed with its own report of recommended patent reform, which contained many of the same suggestions, but also differed in some respects.⁶ Many commentators expressed a view during these

² See Federal Trade Commission, *Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy*, <http://www.ftc.gov/opp/intellect/> (last visited May 18, 2007) (final report and testimony of various parties who participated in the hearings).

³ The author testified in one of the hearings held by the FTC to examine differences between the post-grant opposition systems of other countries and the reexamination system used in the U.S.

⁴ See FEDERAL TRADE COMMISSION, *TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY*, Oct. 2003, available at <http://www.ftc.gov/os/2003/10/innovationrpt.pdf>.

⁵ See Federal Trade Commission, *FTC Issues Report on How to Promote Innovation Through Balancing Competition with Patent Law and Policy*, <http://www.ftc.gov/opa/2003/10/cpreport.shtm> (posted Oct. 28, 2003).

⁶ See *A PATENT SYSTEM FOR THE 21ST CENTURY* (Stephen A. Merrill, Richard C. Levin & Mark B. Myers, eds. 2004), available at http://www.nap.edu/catalog.php?record_id=10976 (last visited May 18, 2007).

hearings that patents were sometimes harming innovation in certain areas, rather than promoting innovation, which is the core mission of the patent system.

More recently, the highly publicized patent litigation between NTP and RIM over RIM's Blackberry email devices further cast patents in a negative light when an injunction threatened to disrupt Blackberry service in the U.S. After a court upheld the patents' validity and after the failure of a belated attempt to have the Patent Office revoke the patents through a slow-moving reexamination proceeding (which still continues today without a final decision as this article goes to print), RIM was forced to pay more than \$600 million to settle the case and avoid an injunction that would have shut down its service in the U.S.

Compounding this negative image of patents, a growing number of patent holding companies with little or no internal research and development operations (sometimes referred to as "patent trolls") have been filing more and more patent litigation, often suing a large group of companies in the same industry in a single lawsuit filed in a jurisdiction perceived to offer favorable outcomes to patent owners, such as the Eastern District of Texas, where one report indicates an 88% success rate for plaintiffs.⁷ Large companies, such as Microsoft, have been ordered to pay large sums of damages, such as \$500 million in the *Eolas v. Microsoft* decision. The Business Software Alliance and similar groups believe that patent reform is needed to end the perceived abuses of the patent system by "patent trolls." Many of these groups associated with the software industry generally support efforts to reign in the injunctive power of patents, limits to the size of damages awards in patent cases, provisions to inhibit forum shopping by patent holding companies, and a meaningful post-grant opposition system that would be an alternative to costly and time-consuming litigation for weeding out patents that should not have been granted in the first instance.

On the other side of the spectrum, pharmaceutical and biotechnology companies depend vitally on patents to recoup the huge costs of drug development. They rely on the absolute power of an injunction to deter generic companies from entering the market before patent expiration. Groups associated with the pharmaceutical and biotechnology companies support many aspects of the patent reform bill, but oppose other parts of it. For example, the BIO association recently issued a press release that stated the following in relation to the proposed 2007 patent reform bill:

The Patent Reform Act of 2007 would create a new post-grant opposition system, under which a patent is given no presumption of validity and could be broadly challenged administratively throughout its term—even years after the patentee and the public have come to rely on it, and years after biotech companies have invested hundreds of millions of dollars to bring a patented invention through clinical trials and regulatory approval. Under such a scheme, patents will have less value and investment predicated upon them will diminish.

The bill also would change the way damages against patent infringers are calculated in a way that would de-value the contribution of many biotechnology patents. The right to fair compensation for infringement, and the right to fairly stop infringers from future infringing acts, are of paramount importance to the biotechnology industry and must be part of any legislation.

We look forward to working with Senators Leahy and Hatch, Congressmen Berman and Smith, and the full Congress to ensure that any patent reform legislation truly

⁷ Roderick R. McKelvey, *Forum Selection in Patent Litigation: A Traffic Report for 2006*, AIPLA Spring 2007 Meeting, at 5, available at <http://www.cov.com/files/Publication/eb4ec296-744c-469f-bd1b-21fff9c4435f/Presentation/PublicationAttachment/d415bbc0-58b1-43ca-bbfe-27af8f4214f9/801.pdf> (citing LegalMetric's December 2005 report which stated that plaintiffs in the eastern district of Texas had won 88% of all jury trials since 1994).

improves the system and does not undermine a patent system that has been the driving force behind lifesaving and life-enhancing biotechnology breakthroughs.⁸

III. KEY PROVISIONS OF THE 2007 PATENT REFORM BILL

There are many important changes contained in the 2007 patent reform bill, but this article will focus on the four most important provisions that could have the greatest impact on nanotechnology: (a) post-grant opposition, (b) switching from a first-to-invent system to a first-to-file system, (c) patent damages reform, and (d) choice of venue for patent litigation.

1. Post-Grant Opposition

Currently, the U.S. has two types of post-grant opposition already available known as *ex parte* and *inter partes* reexamination. They may be initiated at any time during the enforceable life of a U.S. patent, but they may only be based on “printed publications or patents” that support an argument of unpatentability based on anticipation or obviousness. They may not be used to argue that a patent claim is unpatentable on the basis of lack of enablement (scope of claim broader than what is supported by the examples) or other statutory requirements for patentability.

The 2007 patent reform bill would create a third type of post-grant opposition proceeding that permits challenges of patents on the full range of patentability requirements. In addition, the existing *inter partes* reexamination proceeding, where a requester is permitted to participate in the proceeding after filing the request, would be enhanced by narrowing the scope of estoppel for a failed bid to revoke a patent to the actual grounds of unpatentability raised in the proceeding. Currently, a requester who files an *inter partes* reexamination request and is unsuccessful would be subsequently estopped from attacking the validity of the same patent in litigation on any grounds that “could have been” raised in the reexamination proceeding. This broader scope of estoppel has inhibited the use of *inter partes* reexamination proceedings.

2. Switching from First-to-Invent to First-to-File

The U.S. is currently the only country in the world that uses a first-to-invent system to determine who should be awarded a patent when two or more parties file overlapping applications around the same point in time. In such cases, the U.S. Patent Office may declare an “interference”, which is a miniature trial-like proceeding that takes place administratively within the U.S. Patent Office, allowing the parties to present evidence such as lab notes to try to prove they were the first to actually invent the subject matter at issue. Whichever party puts on the most persuasive case of being a prior inventor is awarded the patent, even if they filed their patent application after another party.

The 2007 patent reform bill would switch the U.S. to a first-to-file system, putting us on par with the rest of the world, which awards the patent to the first party to file an application regardless of when the subject matter was actually invented. At the same time, the bill provides a defense for someone who actually invented the subject earlier but filed later than the patent owner, known as a “prior user” defense. The prior user defense ensures that someone who had been using the subject matter of the patent before another party filed the application can continue to practice the invention when certain conditions are met.

3. Patent Damages Reform

The 2007 patent reform bill would also attempt to reign in damages awards in patent litigation. One provision would limit damages by specifying for the case of a patented invention that represents only one part of a larger product, damages must be apportioned to the significance of that one part in the overall

⁸ BIO Press Release, dated April 18, 2007 (www.bio.org).

product. Another provision would reduce the situations in which enhanced damages would be awarded by requiring the infringer to have actual notice of a patent before enhanced damages could be awarded.

4. Choice of Venue for Patent Litigation

Another series of provisions in the 2007 patent reform bill would try to limit the extent to which patent owners can shop for the most favorable forum in which to bring a patent infringement lawsuit. For example, the plaintiff would have to have a place of business in the court district where the lawsuit is initiated. Critics have pointed out that this may not be much of a deterrent because patent owners can easily open an office in the location where they prefer to file suit.

IV. SUMMARY OF RECENT SUPREME COURT PATENT DECISIONS

The Supreme Court has shown an unprecedented interest in patent law over the last few years. In particular, there are four recent Supreme Court patent decisions that may have the most impact on the patent reform debate as it relates to nanotechnology. As these are recent decisions, the full impact of these cases may not be realized for years and years, as lower courts work to apply the Supreme Court's rulings and determine the boundaries. Yet, it is essential to understand that the Supreme Court has already re-shaped the patent system through these decisions in a way that may lessen the need for patent reform legislation in some respects and increase the need for patent reform legislation in other respects. Moreover, these Supreme Court decisions also need to be understood in relation to nanotechnology, so that companies can adjust their patent claiming strategies and licensing strategies to maximize the value of their technologies. The following section summarizes the four cases and their impact on nanotechnology.

1. *eBay v. MercExchange*

In *eBay v. MercExchange*, the Supreme Court weakened the power of injunctions by holding that a district court has discretion to determine whether an injunction is appropriate. The Court of Appeals for the Federal Circuit (CAFC) ruled that injunctions in a patent infringement case should almost automatically be granted upon a finding of infringement and validity. The Supreme Court reversed the CAFC, noting that the statute states that injunctions "may" be granted, but they are not automatic or required. In particular, the Supreme Court found that it may be appropriate to consider the degree to which the patent owner makes use of the patented invention when deciding the appropriateness of injunctive relief. Several district court cases following the Supreme Court decision in *eBay* have demonstrated that injunctions may be denied even after a finding of infringement and validity. However, the recent CAFC decision the PLAVIX drug litigation reveals that injunctions still may be granted in pharmaceutical cases.⁹

The Supreme Court reminded us that injunctions are not automatic and the four factors (irreparable harm would result if not granted, remedy at law such as money damages is inadequate, balance of hardships weighs in favor of it, public interest would not be served without it) must be clearly explained in any motion seeking an injunction in a patent case, as required in every kind of non-patent case where injunctions are sought. In general, the decision offers flexibility to a district court to potentially deny an injunction if the factors weight against it in a given case.

⁹ To review a scorecard of post-*eBay* decisions where injunctions have and have not been granted, see Joseph Scott Miller, *The Fire of Genius*, at <http://www.thefireofgenius.com/injunctions> (last visited June 4, 2007).

2. *KSR v. Teleflex*

In *KSR v. Teleflex*, the Supreme Court decided that the determination of whether a claimed invention is unobvious (one of the core requirements for obtaining a patent) should not be the prisoner of a rigid formula. The Court found that, while there must be explicit reasoning to support combining prior art references that teach separate elements of a claimed combination, there need not be an explicit teaching, suggestion or motivation (TSM) in the references themselves. While the Court sought to create flexibility in the manner in which the TSM test is applied, the opinion at the same time reminds us that certain pathways remain valid approaches for overcoming obviousness.¹⁰

One such pathway for arguing non-obviousness on which the *KSR* opinion commented favorably is the “teaching away” approach, which should be especially applicable to nanotechnology.¹¹ In *KSR*, the Supreme Court looked favorably on situations “when the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be non-obvious,” citing *United States v. Adams*.¹² Patentees and inventors should study *Adams* and its implications.

The *Adams* case, now more than 40 years old, related to the obviousness of a “wet battery.” The battery was unusual because it contained water and different electrode materials than normal. In *Adams*, the Supreme Court found the invention to be non-obvious. In *KSR*, the Supreme Court said about *Adams*:

When Adams designed his battery, the *prior art warned that risks were involved* in using the types of electrodes he employed. The fact that the elements worked together *in an unexpected and fruitful manner* supported the conclusion that Adam’s design was not obvious to those skilled in the art. (emphasis added)

Nanotechnology finds many applications in similar types of devices such as light emitting diodes, solar cells, sensors, transistors, batteries, etc. In this new regime, we advise nanotechnology clients to focus when they can on an “Adams approach.” Look for demonstrated advantages if not unexpected results. And perhaps most important, *study the prior art and understand why the art teaches against what you are inventing.*

During prosecution at the U.S. PTO, many examiners and applicants (unnecessarily) restrict themselves to debating over art cited by the examiner. Applicants need to have a broader approach and cite art that helps their case, even if not cited by the examiner. And applicants should cite to *KSR* and its approval of *Adams*. Declaration evidence about how the uncited prior art teaches away may be particularly persuasive. Thus, the *KSR* opinion reinforces for us that innovative nanotechnology will continue to be patentable when attention is focused on the proper analysis. At the same time, the *KSR* opinion creates flexibility for the manner in which the TSM test will be applied. Ultimately, in some cases, more work may be required to obtain a patent.

3. *Medimmune v. Genentech*

In *Medimmune v. Genentech*, Medimmune had obtained and maintained a license to a patent owned by Genentech relating to antibody production. Medimmune filed a declaratory judgment (DJ) action challenging the license after a second patent issued that was included in the license, which would have extended the royalty period. Genentech argued that Medimmune could not maintain a DJ action while

¹⁰ The following discussion is excerpted from “The Impact of *KSR v. Teleflex* On Nanotechnology,” by J. Steven Rutt and S. Maebius, distributed at the 2007 Annual USPTO Nanotechnology Customer Partnership Meeting.

¹¹ Other pathways include size-dependent unexpected results that can occur due to quantum effects and absence of an enabling method for producing nanoscale materials of certain properties, as discussed in Vivek Koppikar, Stephen B. Maebius & J. Steven Rutt, *Current Trends in Nanotech Patents: A View From Inside the Patent Office*, 1 NANOTECH. L. & BUS. 24, 30 (2004).

¹² *United States v. Adams*, 383 U.S. 39 (1966).

continuing to enjoy the security of the license agreement—in other words, it could only sue if it repudiated the agreement and lost its protection. However, the Supreme Court reversed, noting that nothing in the license agreement prevented Medimmune from filing the DJ action to challenge the patent's validity and that Medimmune potentially might be able to establish jurisdiction based on Genentech's conduct despite its continued payment of royalties, constituting a real dispute between the two parties.

It may be possible, in some circumstances, to file and maintain a DJ action attacking a patent's validity while continuing to pay royalties under a license agreement for that patent, but each case must be carefully analyzed to determine the risks and benefits. Licensors should consider new strategies for licensing agreements to reduce the incentives for a validity challenge by a licensee, taking care to avoid unenforceable provisions under *Lear* and patent misuse.

4. *Merck v. Integra*

In *Merck v. Integra*, the Supreme Court rejected a pre-clinical boundary on the safe harbor from patent infringement that exists when a party utilizes a patented invention for the purpose of obtaining information that may be used in connection with FDA approval.¹³ The end result is that the safe harbor may extend further upstream in the product development cycle.

V. NANOTECHNOLOGY COMPARED TO OTHER INDUSTRIES

As noted above, the software industry and biotechnology/pharmaceutical groups have very different viewpoints about certain parts of the 2007 patent reform bill that are not easy to reconcile. In 2006, a similar package of patent reforms never made it out of committee due to the clash between these opposing industry groups. Despite the opposing views, the new Democrat-controlled Congress seems eager to find common ground and to pass a patent reform bill.

Nanotechnology includes a diverse array of companies at different stages of development focusing on different industries, such as drug delivery, electronics, energy, and medical devices. Despite this diversity, the majority of nanotechnology companies are characterized by long product development cycles and significant expenditures on research. Patents are highly valued by nanotechnology companies and provide a significant stimulus for venture capital firms to invest money in them. Without a guaranteed period of exclusivity, there would not be a strong incentive to invest in risky nanotechnology. For these reasons, the nanotechnology community may fall closer to the biotechnology and pharmaceutical end of the spectrum in the patent reform debate.

VI. CONCLUSIONS

The chorus of voices calling for patent reform is putting pressure on Congress to do something. The community of nanotechnology start-ups, publicly traded companies, universities, and research organizations has not yet spoken up in the ongoing debate, but it is now prime time to express their views. Because nanotechnology is an important economic sector that is creating high-tech jobs in the U.S. and is helping the U.S. to remain competitive in many vital areas such as defense, medicine, and clean energy, legislators and policymakers will listen to the nanotechnology community if it chooses to make itself heard in the ongoing patent reform debate.

¹³ For a more complete discussion of this case, see Stephen B. Maebius & Harold C. Wegner, *Merck v. Integra: The Impact of a Broader "Safe Harbor" Exemption on Nanobiotechnology*, 2 NANOTECH. L. & BUS. 254 (2005).