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What You Should Know About Patent Reform

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I. Introduction

Patent reform has been a heavily debated topic since the introduction of the Patent Reform Act of 2005. There have been no comprehensive changes in patent law since the passing of the 1952 Patent Act, which has been the foundation for more than fifty years. Though recent attempts to overhaul the patent system have failed, the current legislation is the closest Congress has ever come to successfully passing legislation that would dramatically alter some of the most important aspects of patent law.

The advocates for patent reform are led by the Coalition for Patent Fairness, a collection of companies that mostly specialize in computing and software technology. The Coalition believes that the current patent system produces too many questionable patents, abusive lawsuits, and oversized damage awards. The Coalition seeks to change patent law provisions relating to (1) the calculation of damages for patent infringement, (2) the options for challenging the validity of an issued patent, and (3) the choice of location for a patent infringement action. Many organizations, including the Medical Device Manufacturers Association, oppose aspects of the patent reform sought by the Coalition. Whether Congress can find sufficient compromises on the most divisive provisions will determine whether comprehensive patent reform will happen this year.

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Recent developments indicate that Congress is as close as it has ever been to reaching a compromise. This year, the Senate has been the first to act in moving forward with its bill; the Senate was the roadblock for the Patent Reform Act of 2007. On April 2, the Senate Judiciary Committee took a large step toward reform when the Committee passed an amended version of its bill, S. 515 (3 MELR 237, 4/8/09). The optimism for patent reform advocates, however, has been tempered after the House Judiciary Committee held hearings to consider its version of the Act on April 30 (3 MELR 315, 5/6/09). At these hearings, many House members were skeptical about adopting wholesale the provisions from the amended Senate bill. Still, the amended Senate bill is the strongest sign yet that patent reform will become a reality in 2009. Therefore, it is vital for every participant in the medical device industry to understand what is at stake in the most recent patent reform efforts. The following is an overview of the most important provisions of the Patent Reform Act of 2009.

II. New Control on Damages for Patent Infringement

No issue is more polarizing for reform advocates and opponents than how trial courts should calculate damages for patent infringement. Currently, juries have wide discretion in that calculation. The patent law only requires that the damages be ''adequate to compensate for the infringement but in no event less than a reason-

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able royalty for the use made of the invention by the infringer.'' A list of 15 factors, known as the *Georgia Pacific* factors, often serve as guidelines for determining how much compensation is adequate. Within this framework, the most common damage award relies on the reasonable royalty. For calculating a reasonable royalty, juries use a hypothetical licensing negotiation to determine what the patentee and the infringer would have agreed to if they had actually reached a licensing agreement. Whether this ''hypothetical negotiation'' is an accurate method for determining a reasonable royalty is a source of debate about the current damages scheme. Additionally, juries have wide latitude in determining whether the royalty base in the damages calculation is the specific improvement that distinguishes the patented invention from conventional technology, or whether it is the entire patented invention as claimed.

The Patent Reform Act of 2009 originally imposed strict rules for calculating damages. A judge would have to choose one of three methods for determining damages listed in the damages provisions. The first prescribed method allows a jury to consider a reasonable royalty based on the entire value of the infringing product only if the patentee can show to the satisfaction of the court that the infringed patented invention was the predominant basis for demand of the infringing product. Second, if the patentee or infringer can show the existence of licenses for either the claimed invention or noninfringing substitutes, then royalty damages may be based upon the value of those licenses. Finally, if neither of the first two methods are available, then the court must ''ensure that [a] reasonable royalty is applied only to the portion of the economic value. . .properly attributed to the claimed invention's specific contribution over the prior art.'' A judge would have discretion in considering ''any other relevant factors under applicable law.'' The judge would then direct the jury on how to calculate damages based on the judge's chosen method. This damages scheme reflects the Coalition's priorities of making it tougher for a patentee to obtain a large damages award, and to give juries less discretion in the damages calculation.

The amended Senate bill voted out of committee represents a middle-of-the-road compromise that significantly modifies the original damages calculation scheme in the Act. Instead of requiring a judge to choose between statutorily prescribed methods of calculating damages, the bill has a ''gatekeeper provision'' that would require a judge to take a more active role in damages calculations. Before any party could introduce evidence regarding damages, the judge would decide whether a party's calculation method has a legally sufficient basis. Next, the judge would only allow the jury to hear evidence on damages when the evidence is used to support the pre-approved calculation method. Unlike the original reform provision, the gatekeeper provision would give a judge greater authority in determining which calculation methods are proper. The amended provisions do not appear to change the standards for calculating a reasonable royalty, but only require the judge to exercise a firmer hand in the damages determination.

III. New Avenue for Challenging a Patent

Currently, there are only two options for a third party desiring to challenge the validity of an issued patent without resorting to litigation. First, an *ex parte* reexamination request can be filed by any third party wanting the Patent & Trademark Office (PTO) to reconsider the validity of the patent based on prior art that raises a substantial new question of patentability. If the PTO grants the request, only the patent owner can correspond with the PTO, leaving the third-party requester on the sideline without any ability to further participate in the reexamination proceeding. The second option, an *inter partes* reexamination request, also can be initiated by a third party wanting the PTO to reconsider the validity of a patent based on a substantial new question of patentability. In this proceeding, however, the third party requester is *not* anonymous, and *does* participate in the proceeding. If the third-party requester is unsuccessful in challenging the validity of the patent, and the third party is sued for infringement by the patent owner, the third party is prevented, or estopped, from using any grounds of defense that were raised or could have been raised during the *inter partes* reexamination proceeding. This estoppel does not apply to *ex parte* reexaminations. In both cases, the proceeding concludes with the patent owner either obtaining a reissued patent, with amended or intact claims, or relinquishing all patent rights.

Patent reform advocates believe that these two options are ineffective for those who want to challenge the validity of a patent. The original legislation catered to these concerns by instituting a third option called a cancellation proceeding. Any third party would be able to challenge a patent's validity within twelve months of issuance of the patent based on any evidence that raises a substantial question as to the patentability of the recently issued patent. The question of patentability would not need to be new, as in current reexamination proceedings, and apparently may even ask for a reevaluation of issues that arose during the original prosecution. The third party would not be anonymous and would participate in the proceeding, but the third party would only be estopped in a subsequent litigation from using grounds of defense that *were* raised in the cancellation proceeding, and not grounds that *could* have been raised. The original legislation also strengthens current *ex parte* and *inter partes* reexaminations by expanding the types of prior art that could be used to attack the validity of a patent, and by narrowing the estoppel effect of *inter partes* reexamination to grounds that *were* raised during the proceeding (similar to the cancellation proceeding). The amended Senate bill mostly keeps intact the original post-grant review provisions, but does, however, eliminate the expansion of prior art available to attack the validity of a patent.

There is no doubt that the new cancellation proceeding would be a powerful weapon for third parties wishing to defeat a recently issued patent. The overall effect of the original legislation and the amended Senate bill would be to bolster the ability of third parties to challenge the validity of a patent, and to significantly weaken the value of an issued patent during its first year of existence while a cancellation proceeding is still possible.

IV. Further Limit on the Location of a Patent Lawsuit

Currently, a plaintiff (usually the patent owner) has broad latitude in deciding where a patent infringement lawsuit will take place. Given this latitude, patent owners unsurprisingly initiate lawsuits in forums that are

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viewed as ''friendly'' to the patent owner, such as the U.S. District Court for the Eastern District of Texas. Advocates for patent reform call this ''forum shopping.''

The original legislation would have restricted the forums available for a patent owner to file a patent infringement lawsuit. In general, the legislation would require that infringement suits to be brought only in states where the defendant is incorporated, has a principal place of business, or has an ''established physical facility'' that constitutes a ''substantial portion'' of its operations. The original legislation also would prevent a party from ''manufacturing'' venue by assigning patents to other entities or by incorporating a new entity in a patentee-friendly venue.

The amended Senate bill eliminates these venue restrictions and contains a watered-down instruction for a district court to transfer patent litigation to a ''more convenient'' venue ''for the convenience of parties and witnesses'' and ''in the interest of justice.'' This soft language may have been part of a compromise in exchange for keeping meaningful damages and post-grant review provisions. Alternatively, patent reform advocates may have been more willing to back down on venue restrictions in light of the Federal Circuit's decision late last year in *In re TS Tech USA*, 551 F.3d 1315 (Fed. Cir. 2008). The Federal Circuit held that the Eastern District of Texas had clearly abused its discretion in not transferring a patent litigation to a different venue. The lawsuit's only connection to the Eastern District of Texas was the sale of some of the infringing products in the district. Neither party was incorporated in Texas or had offices in the venue, and all of the witnesses and evidence were located in other venues. It's possible that the *TS Tech* will be enough of a deterrent to ''forum shopping'' such that patent reform advocates would rather focus on other provisions.

V. Other Important Provisions

Though damages, post-grant review, and venue have garnered a lot of attention, the Patent Reform Act of 2009 has other important provisions, such as priority to the first to file, determination of willful infringement, assignee filing authority, pre-issuance third party prior art submissions, residency restrictions on Federal Circuit Judges, PTO fee setting authority, and interlocutory claim construction appeals, among others. Some of the more significant provisions will be briefly described.

The United States currently awards patent rights to the first person to make the invention, while other major industrial regions (e.g., Europe and Japan) award patent rights to the first person to file a patent application. The original Senate and House versions of the Act both have provisions that would change the U.S. to a ''first-to-file'' country in conformity with the other major industrial countries. The Senate bill, originally and as amended, does not put any conditions on the switch to a first-to-file system. The House bill's first-to-file provision, however, would only become effective when Europe and Japan adopt a one-year grace period for inventors to file an application after the inventor publicly discloses the subject matter of the claimed invention. The U.S. currently has such a grace period, while Europe and Japan do not award patent rights to an inventor if the invention was disclosed in any way before the filing of a patent application. Thus, the switch to a first-to-file system depends on the language used in a reconciliation of the House and Senate bills. Despite being a fundamental change to the U.S. patent system, the first-to-file provisions have not generated as much controversy, possibly because the potential effects do not evenly divide major U.S. industries. The change likely would favor large corporations that have the ability to quickly file multiple patent applications.

Another set of important provisions in the Patent Reform Act of 2009 codifies the Federal Circuit's important decision in *In re Seagate Technology*, 497 F.3d 1360 (Fed. Cir. 2007), regarding the law of willful infringement. Before *Seagate*, an accused infringer with notice of a patent had an affirmative duty of due care to avoid infringing activity, and a party that did not fulfill this duty could be liable for willful infringement and the treble damages that may accompany it. The Act adopts a much less patentee-friendly standard. It requires the patentee to show by clear and convincing evidence that the accused infringer acted with objective recklessness and (1) the patentee gave written, detailed notice of the allegedly infringing acts, (2) the infringer intentionally copied the patented invention with knowledge that it was patented, or (3) the infringer was previously found to have infringed the patent but nevertheless is engaging in conduct not colorably different from the previous infringement. The Act also codifies a ''good faith'' defense that would preclude a finding of willful infringement if the alleged infringer has a good faith belief that the patent is invalid, unenforceable, or not infringed.

Notably, the amended Senate bill includes an important partial repeal of the best mode requirement as a basis for invalidity of the patent. This current aspect of patent law requires an inventor to disclose in the patent the best way they know to practice the invention. While the inventor's contemplated best mode of practicing the invention is still required in a patent application, the amended Senate bill no longer allows a failure to disclose the best mode as a basis for invalidity in a patent action.

VI. Conclusion

Damages, post-grant review, and venue have proven to be the most controversial issues preventing significant overhaul of the patent system. As outlined above, the Senate Judiciary Committee has taken significant steps towards finding a compromise position by finding a middle road on damages, preserving strengthened post-grant review opportunities, and deferring to the recent status quo on venue determination. Though the House Judiciary Committee hearing on April 30 may have tempered the optimism created by the amended Senate bill, patent reform is close enough to reality that the medical device industry should thoroughly understand the effects of important provisions of the Act.