

## The Patent Reform Act of 2007: Potential Impact on Patent Rights

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On April 18, 2007, leaders from the United States Senate and the House of Representatives introduced identical patent-reform legislations, collectively referred to as the Patent Reform Act of 2007 (“the Reform Act”).<sup>1</sup> The Reform Act proposes significant changes to the United States patent laws that would overhaul the U.S. patent system, which has remained essentially the same since 1952.<sup>2</sup>

The Reform Act evidences great congressional effort to harmonize United States patent laws with that of the rest of the world, reduce excessive patent litigation, and improve quality of issued patents. The Reform Act broadly resembles legislations that have been tried in years past but never succeeded.<sup>3</sup> However, the Reform Act is for the first time bicameral and bipartisan,<sup>4</sup> and has the backing of numerous corporations and industry groups. As such, the likelihood that the Reform Act be enacted appears very high. This article discusses some of the significant changes proposed in the Reform Act and how these changes may potentially impact patent rights, particularly biotechnology patent rights.

### Transitioning to a first-to-file patent system

One of the most significant changes introduced by the Reform Act is a transition from the first-to-invent patent system to a first-to-file system. This change would bring the United States to be in conformity with the rest of the world.

Presently, the United States is the only country that grants patents to the first inventor, rather than to the first person who files the patent application. What this means is that diligent inventors get the patent if they can prove they had the idea first and worked on the invention diligently, even if they are not the first to file a patent application. When two or more inventors file for patent applications on the same invention, the United States Patent and Trademark Office (USPTO) invokes an “interference” proceeding to determine the first inventor who would be entitled the patent rights.

The interference proceeding is a lengthy process which in many aspects resembles a litigation process. It involves multiple steps such as declaration of the interference, motion, discovery, testimony, hearing, and judgment. In order for a party to show that it is the first to invent, it needs to present clear and convincing evidence that it is the first to come up with the idea, and that it has worked diligently to make the invention work. Because the determination of first to invent is highly fact-specific, the interference proceeding usually requires parties to submit a huge number of documents from previous years and is highly costly.

Under the proposed first-to-file system, patent rights are granted to the first person who files the patent application.<sup>5</sup> A party who has independently developed the invention prior to the invention date of the first filer but failed to timely file a patent application would no longer be able to claim patent rights. Of course, if his invention is public used or sold, that activity may constitute prior art against the first filer’s patent application.

Since patent right is no longer granted to the first party to invent, the interference proceeding would be eliminated in the Reform Act. Instead, the Reform Act has created a “derivation proceeding” that allows inventors in dispute to determine whether the patent applicant is a proper filer.<sup>6</sup> For example, if a party believes that the patent filer has misappropriated the invention from him, that party can assert right to the patent in the derivation proceeding. Similarly, issues such as whether a joint inventor should be included in the patent application can be addressed in the derivation proceeding.

One consequence of switching to the first-to-file system is that the nature of the prior art will change. The Reform Act has provided several provisions that significantly alters the scope of prior art. Presently, prior public uses or sales of the invention only constitute prior art if these activities occurred in the United States. Under the Reform Act, even public uses and sales occurring abroad would become prior art. Furthermore, under current patent law, there is a one-year “grace period” during which the applicant can “swear behind” a prior art reference or activity by showing that the applicant came up with the invention prior to the prior art reference or activities. Under the Reform Act, the one-year grace period remains only as to the applicants’ own disclosure, joint research disclosures, and disclosure by the applicant’s assignee. Any third party reference or activities before the filing date of a patent application will be prior art that must be distinguished by the applicant.

Transitioning from first-to-invent to first-to-file would significantly reduce the uncertainty as to the ownership of patent rights. This is particularly important in the biotechnology industry, because investors in biotechnology industry rely heavily on whether the patent holder can exclude others from the invention in many years to come in making an investment decision. Without the certainty, there would be little incentive for investors to fund high risk biotechnology products.

Opponents of the first-to-file system have contended that the first-to-file system puts small entities in great disadvantage. They argue that small entities tend to be less experienced with the patent application system and thus will likely lose in a “race to the mail box.” Supporters of the first-to-file system, on the other hand, have countered that the current first-to-invent system is even more unfair to small entities due to its costs and complexities. Under the first-to-invent system, an invention dispute is addressed in a costly interference proceeding. Small entities without knowledge of patent laws at the time of invention often do not have the records to support their invention dates. The limited resources of small entities pose a hindrance under the current system given the costly litigation associated with interference proceedings.

Although it is generally believed that the transition from first-to-invent to first-to-file will eventually occur in the United

States, it is unclear when such transition will be made. Department of Commerce and, in particular, its component the USPTO, for example, have noted that the conversion to a first-to-file system is an overriding consideration in ongoing substantial patent law harmonization discussions between the United States and foreign patent offices. They urge that any commitment by the United States to convert to first-to-file should be contingent on significant progress and international agreement in those harmonization discussions. It thus remains to be seen whether the provision will be put in effect in the very near future.

### **Establishing post-grant review proceedings**

Another significant change proposed by the Reform Act is the establishment of a new post-grant review proceeding, which provides a less expensive and more streamlined way for third parties to challenge issued patents. The post-grant review proceeding will be similar in many ways to the opposition procedures that are available in a number of foreign jurisdictions.

Presently, a party seeking to challenge the validity of an issued patent in the United States has two avenues: by reexamination proceeding at the United States Patent and Trademark Office or by litigation in a federal district court. The reexamination proceeding was considered not very effective, and the litigation is unwieldy and expensive.

Under the new post-grant review proceeding, any person can oppose the grant of an issued patent within twelve months after the patent is granted. Additionally, the Reform Act provides a “second window” beyond the initial one year time period. It allows a party to petition for cancellation of an issued patent at any time if the party can establish a “substantial reason” that the continuing existence of the issued patent would “cause or is likely to cause” the party “significant economic harm.”

The Reform Act does not specify grounds an opposition can proceed on, but it appears that any grounds for invalidity will support an opposition. The patentee is provided an opportunity to respond to the opposition, for example by making arguments, submitting factual evidence, or submitting expert opinions. The patentee may amend the patent claims, provided that the amendment does not enlarge the scope of the originally issued claims. The Reform Act mandates that the opposition proceed swiftly, requiring the patent office to make a final determination within about a year.

The post-grant review proceeding will have many characteristics of a patent litigation in a court, including discovery and protective orders. However, unlike patent litigation, there will be no presumption of patent validity in the post-grant review

proceeding. Instead, the validity of the patent is determined *de novo*. Additionally, the party seeking to cancel the issued patent will only be required to show that the patent is invalid by a preponderance of the evidence, not clear and convincing evidence, as is required in a court proceeding. The post-grant review proceeding therefore makes it much easier to invalidate an issued patent.

The post-grant proceeding does have a potential downside. If a party is unsuccessful in challenging a patent in a post-grant review proceeding, it would be precluded in subsequent litigation from challenging the patent on any ground it had raised during the post-grant review proceeding. Likewise, if a litigant has already lost on challenging the validity of a patent in court, he will not be permitted to file a post-grant review petition in the patent office to cancel the patent on the same basis.

The post-grant review proceeding is perhaps the most controversial change proposed in the Reform Act. Supporters believe that this new proceeding will allow a challenge to the validity of the patent to proceed in a relatively quick and inexpensive manner, thus ensuring quality of issued patents. Opponents, on the other hand, argue that this new proceeding would create uncertainty about the validity of patents and subject patent owners to increased costs to defend against challenges to issued patents. Opponents are particularly concerned about the second window in the proposed post-grant review proceeding, which allows a third party to challenge an issued patent at any time during the life of the patent. Opponents believe that this second window will create uncertainty of patent rights, and provide an effective vehicle for larger companies to force smaller companies to divert their limited resources to defend their patents.

### **Providing standard for determining damages for patent infringement**

The other significant change introduced in the Reform Act is to align damage awards for patent infringement more closely to the harm caused by the infringement.

Under current law, damages for patent infringement can be calculated either with respect to lost profits or a reasonable royalty. The lost profits analysis applies only to patent owners who make the patented products themselves and can prove lost sales, price erosion, or other lost profits resulting from the patent infringer's infringement. If the patent owner is not in the same business as the patent infringer, its damages will be calculated based on a reasonable royalty.

If a reasonable royalty is the measure of damages, the fact finder is required to determine damages by envisioning the result of the parties' hypothetical negotiation for a license to the claimed invention at the time infringement began. Courts

have great flexibility in determining a reasonable royalty based on multiple factors.<sup>7</sup> The question of what would be the reasonable royalty for a relatively small piece of patented technology when it is integrated as a component of a larger article has been subject to a lot of debates.

The Reform Act introduces a new mandatory procedure for determining and applying reasonable damages. Based on the argument that many patents cover only improvements on already-existing products or systems, the Reform Act seeks to limit damages by allowing for a reasonable royalty only for "that economic value properly attributable to the patent's specific contribution over the prior art," and exclude economic value attributable to the prior art and other features or improvements. Moreover, the Reform Act requires that damages not be based "upon the entire market value of that infringing product or process" unless the patent holder shows that his patented improvement "is the predominant basis" for the product's market demand.

These changes seek to ensure that damages are proportionate to the value of the component in question, rather than the entire product. Opponents of this provision believe that this proposed reform artificially reduces the value of patents. They believe that, basing reasonable royalty damages on the value of a component rather than that of the entire product would encourage patent infringement, making patent infringement merely a business decision. Furthermore, the apportionment of damages as proposed would be costly and time consuming. This is especially true for biotechnology products, where it would be extremely difficult to separate out contribution of a particular patent to the product from contribution from prior art. Opponents have also argued that the amount of reasonable royalty should turn on the facts of each particular case, and that courts have already had adequate guidance from the case law to make such determination. They believe that it would be unnecessary and improper for a legislative provision to codify or emphasize any one or more factors that a court must apply when determining reasonable royalty damages.

### **Other significant changes**

The Reform Act also includes less controversial proposals in procuring patent rights. Among these are:

- \* Permitting an assignor to file a patent application on behalf of the inventor(s);
- \* Allowing substitute statement in lieu of inventors' oath if inventor is unable or unwilling to make oath;
- \* Allowing members of the public to submit prior art during examination of applications; and
- \* Providing for publication of applications even if the patent application is not filed abroad.

The Reform Act further includes several features that may

potentially impact the way patents are litigated in the courts. These include:

- \* Limiting venue for patent infringement actions to where either party resides or where the defendant has committed acts of infringement and has a regular and established place of business (28 USC 1400);
- \* Providing for interlocutory appeals to the Federal Circuit after a claim construction order by a district court; (28 USC 1292).
- \* Setting limitations on triggering and finding willful infringement and the subsequent trebling of damages (35 U.S.C. 284); and
- \* Expanding prior use right to all patents, making it a defense to infringement if the accused infringer had practiced the invention before the effective filing date of the patent application.

### What has not been included

The Reform Act drops many controversial provisions found in prior proposed patent reform legislations. For example, the Reform Act drops the previous proposal to raise the standard of finding a patent applicant's inequitable conduct before the Patent Office. Calling candor and truthfulness the "backbone of the patent application system," the legislators believed that raising standard of finding inequitable conduct "would have weakened that doctrine." The Reform Act also drops the previous proposal to eliminate the best mode requirement, an old requirement under U.S. patent law that has no counterpart in foreign law, according to which the inventor must describe the best mode of practicing his or her invention.

The Reform Act also leaves a number of issues untouched, with the hope that they will be addressed by the Supreme Court without the need for legislation. For example, absent in the Reform Act are clarification of the standard for awarding injunctive relief, a reform deemed unnecessary after the Supreme Court's ruling on that issue in *eBay Inc. v. MercExchange LLC*.<sup>8</sup> The Reform Act also lacks provisions amending language at 35 U.S.C. § 271(f) on extraterritorial infringement, which was at issue in *Microsoft Corp. v. AT&T Corp.*<sup>9</sup> The Reform Act also leaves the obviousness standard for evaluating an invention untouched, perhaps in light of the Supreme Court's review of the *KSR International v. Teleflex case*.<sup>10</sup> On April 30, 2007, the Supreme Court issued the landmark decision *KSR International v. Teleflex*, setting a lower standard for finding an invention obvious and making it significantly more difficult to obtain patents.

### Conclusion

Because the Reform Act is bicameral and bipartisan, it is highly likely that at least some of the proposed provisions in the Reform Act will be enacted. The new legislation would

make the requirements for obtaining a new patent more stringent, make it easier for rivals to challenge patents, and reduce the penalties for patent violation. Companies should pay close attention to the Reform Act and be prepared to adapt to whatever changes that will be introduced by the Reform Act.

If the Reform Act is enacted in its current form, biotechnology companies should keep a closer track of new research discoveries made in house and adopt a more aggressive patent filing strategy to ensure timely filing of patent applications. Companies should also be more diligent in monitoring patents coming out in their area of expertise and their competitors' intellectual property portfolio. The possibility of filing a post-grant review petition should be considered if an issued patent appears to create freedom-to-operate issues or otherwise looks close to what the company is doing. On the other hand, one needs to be aware that if he loses in an opposition proceeding, he cannot later seek to raise the same invalidity issue in a federal civil lawsuit. As a consequence, a company needs to fully balance the pros and cons of each option and be strategic in making a decision.

- 1 The Reform Act was introduced by Senators Patrick Leahy and Orrin Hatch together with Representatives Howard Berman and Lamar Smith. HR1908 and S1145.
- 2 The new law would apply to any patent issued on or after the new law's effective date.
- 3 The Reform Act is the sixth patent reform proposal put forward in the past two years, but the first that has the backing of both parties and to be introduced in both houses simultaneously.
- 4 The Reform Act is bicameral because it was introduced in the House and the Senate simultaneously. The Reform Act is bipartisan because it is sponsored jointly by the chairs and ranking minority members of the Senate Judiciary Committee and the House Judiciary Committee's Subcommittee on Courts, the Internet, and Intellectual Property.
- 5 Foreign patent filers can rely on the filing date of the priority application as their earliest filing date.
- 6 A derivation proceeding must be initiated within 12 months of publication of earlier application.
- 7 *Georgia-Pacific Corp. v. U.S. Plywood Corp.*, 318 F. Supp. 1116 (S.D.N.Y. 1970), modified and aff'd, 446 F.2d 295 (2d Cir.), cert. denied, 404 U.S. 870 (1971).
- 8 126 S. Ct. 1837 (2006).
- 9 *Microsoft Corp. v. AT&T Corp.*, No. 05-1056 (S.Ct. April 30, 2007).
- 10 *KSR International v. Teleflex*, No. 04-1350 (S.Ct. April 30, 2007).