Bloomberg Law Reports[®]

Intellectual Property

Patent Law

Patent Reform

"America Invents Act": The Impact of Patent Reform



Contributed by John Garretson and Ben Tabor, Shook, Hardy & Bacon LLP

When Congress returns from recess after Labor Day, patent reform will be in the spotlight. The Senate is scheduled to vote on the "Leahy-Smith America Invents Act," which would make significant changes to substantive patent law, procedures for challenging issued patents, and Patent Office funding. If enacted, many changes will take place immediately. Others will be phased in over 18 months. All will affect company decision-making and budgeting for patent procurement, licensing, and enforcement.

The key legislative provisions are summarized below, with an emphasis on those immediately applicable. Their impact is also addressed in light of recent Congressional and public debate.

Legislative History

The Act is intended to streamline and simplify the patent system to promote innovation and stimulate the economy. If passed, it will be the first major overhaul of the patent system in 60 years. It comes in response to escalating calls for quicker and better patent examination, as well as reduced and more cost-effective litigation.

Some industry concerns have already been addressed. The U.S. Court of Appeals for the Federal Circuit recently strengthened damages and inequitable conduct standards, with the result that the former is no longer included in the proposed legislation. The U.S. Supreme Court has also shown increased interest in patent cases. Since 1996, it has issued more decisions in this area than in the previous 30 years combined, on topics such as patentable subject matter, regulatory "safe harbor" immunity, rights exhaustion, obviousness, declaratory judgment jurisdiction, and injunctive relief. Nevertheless, many issues remain.

On the legislative front, there are presently two parallel versions of the Act. The Senate Bill (S.23) passed on March 8, 2011 and was sponsored by Sen. Patrick Leahy [D-VT]. The House Bill (H.R. 1249) passed on June 23, 2011 and was sponsored by Rep. Lamar Smith [R-TX]. They differ in several important respects. For example, under the House Bill, Congress would authorize Patent Office spending through a yearly appropriations process, rather than by establishing a revolving fund (as in the Senate Bill). Although fees collected by the Office cannot be diverted, there is no guarantee Congress will approve their full expenditure every year.

The Senate is now acting to resolve these differences. Sen. Harry Reid [D-NV] has filed a cloture motion that would end Senate debate and put the House Bill to a vote. This vote would take place in early September, shortly after the Senate reconvenes. If approved by the Senate, the House Bill would go directly to the President's desk and likely be signed into law.

Originally published by Bloomberg Finance L.P. in the Vol. 5, No. 36 edition of the Bloomberg Law Reports–Student Edition. Reprinted with permission. Bloomberg Law Reports® is a registered trademark and service mark of Bloomberg Finance L.P.

This document and any discussions set forth herein are for informational purposes only, and should not be construed as legal advice, which has to be addressed to particular facts and circumstances involved in any given situation. Review or use of the document and any discussions does not create an attorney-client relationship with the author or publisher. To the extent that this document may contain suggested provisions, they will require modification to suit a particular transaction, jurisdiction or situation. Please consult with an attorney with the appropriate level of experience if you have any questions. Any tax information contained in the document or discussions is not intended to be used, and cannot be used, for purposes of avoiding penalties imposed under the United States Internal Revenue Code. Any opinions expressed are those of the author. Bloomberg Finance LP. and its affiliated entities do not take responsibility for the content in this document or discussions and do not make any representation or warranty as to their completeness or accuracy.

Immediate Changes Upon Enactment

Some of the new provisions will be effective upon President Obama's signature. They include changes to: (1) existing patent litigation; (2) parties, defenses, and jurisdiction in newly-brought actions; (3) current and prospective re-examination proceedings; and (4) calculating the time period for filing a patent term extension application. Additional changes to the Patent Office's fee schedules, including a fee for prioritized examination and a 15 percent increase in most other fees, will take effect shortly after enactment.

- Existing Patent Litigation

The major changes to pending litigation involve the marking of patent numbers on products. This affects recoverable infringement damages and false marking claims.¹ Upon enactment, "virtual marking" (with a web address containing patent information) will be sufficient to comply with the marking requirement. Furthemore, a private litigant will have to show competitive injury to maintain a false marking action, with compensatory damages the measure of recovery. Only the U.S. government will be able to sue for statutory civil penalties.

These provisions are clearly designed to reduce the recent surge in false marking litigation, while still providing recourse for competitor cases.

Parties, Defenses, and Jurisdiction in Newly-Filed Actions

Litigation commenced upon or after enactment will be subject to several new conditions, apart from the statutory changes effective 12-18 months later (discussed below).

With respect to parties, many plaintiffs have filed infringement actions joining multiple, unrelated defendants accused of infringing a particular patent. Under the Act, such joinder would not be permissible unless: (1) redress is sought for the same activities relating to the same accused product or process; or (2) fact issues common to all defendants will arise during the litigation.² This reduces the logistical difficulties experienced by courts and defendants in responding to, and resolving, infringement allegations.

Regarding defenses, failure to disclose the "best mode" of practicing an invention will no longer be a basis for asserting patent invalidity during litigation.³ On the flip side, a new "prior user" defense will be available against patents issuing on or after the enactment date, as long as the patented subject matter was not developed using government or certain non-profit funding.⁴ This addresses the concern some have expressed recently about so-called "submarine" patents.

As for jurisdiction, two new provisions merit special mention. First, the venue for litigation against the Patent Office will change from the District of Columbia to the Eastern District of Virginia.⁵ The Virginia court's docket typically progresses much more quickly, which should help expedite patent term and other case resolutions. Second, state court jurisdiction will be definitively abolished for "any claim for relief arising under any Act of Congress relating to patents, plant variety protection, or copyrights."⁶ This will promote consistent adjudication of all such claims, both initially and upon appeal to the Federal Circuit.

Re-examination Proceedings

Inter partes re-examination in the Patent Office is a viable alternative to litigation. Its major downside has been time to resolution, including appeals within the Patent Office and to the federal courts.

Under the Act, inter partes re-examination will no longer be available, effective one year after enactment. It will be supplanted by several new, expedited post-grant proceedings (discussed below). In the interim, inter partes re-examination requests can still be filed, but a heightened standard will apply. Instead of "a *substantial new question* of patentability affecting any claim," the threshold will be "a *reasonable likelihood that the requester would prevail* with respect to at least one of the claims challenged."⁷ Also, upon enactment district courts will no longer review re-examination decisions.⁸

- Patent Term Extension

The Act contains a provision clarifying when the 60-day period begins to run for filing an application to extend patent term. According to this revision, the trigger – "the date the product received permission" – depends on the time that the FDA approval letter was transmitted.⁹ This is particularly important for pharmaceutical companies seeking to maximize branded-drug patent protection.

Longer-Term Changes and the Road Ahead

If the House Bill is enacted, many additional, longer-term changes will take effect during the next 12 to 18 months. A full discussion of each is beyond the scope of this article. However, highlights include: (1) adoption of a modified "first inventor to file" patent grant system closer to those in other countries (without requiring that the EU or Japan adopt U.S.-style "grace periods"); (2) new supplemental patent examination, post-grant review and inter partes review proceedings in the U.S. Patent Office; (3) expansion of the definition of prior art under 35 U.S.C. § 102(a) to include others' "effectively filed" applications as of their foreign priority dates, as well as foreign public use and/or sale of patented inventions; and (4) priority U.S. examination for technologies "that are important to the national economy or national competitiveness." The first-to-file system and new review proceedings will have particularly profound effects on patent challenges and enforcement.

- The "First Inventor to File" System

Perhaps the most publicized change is the transition from the present first-to-invent system to one that grants rights to the first inventor filing a patent application. Interference proceedings would no longer be available, although a similar (but narrower) "derivation" proceeding could be brought. Small entities and individual inventors have expressed concern that this will create a "race to the Patent Office," in which better-funded business entities will have the advantage.

The current legislation addresses this issue in several ways. One is small- and micro-entity fee schedules incorporating 50-75 percent reductions. Another is limited prior art exclusion for an applicant's own work. Furthermore, the Patent Office is tasked with studying the system's effect on small entities' ability to procure patents. In conjunction with the Office's Patent Ombudsman Program, which provides small-entity support and services, there is reason to believe the Act will provide a level playing field for all interested parties.

- Post-Grant Proceedings

There are several provisions in the Act that pertain to new post-grant proceedings. The current ex parte re-examination procedure will still be available, but will probably be superseded as a practical matter by post-grant review, inter partes review and supplemental examination. These procedures collectively replace inter partes re-examination, which will no longer exist as of one year post-enactment.

By way of background, U.S. patent revocation proceedings have evolved considerably since ex parte re-examination was introduced in 1980. As originally contemplated, third parties would present relevant patents or printed publications raising a substantial new question of patentability. A dialogue would then ensue between the patent owner and the Patent Office, without further involvement by the third party. This proved insufficient to resolve most invalidity disputes without litigation. Absent participation in the process, third parties saw little reason to file for re-examination.

In 1999, inter partes examination was introduced. This allowed a third party to challenge an issued patent using the same threshold as in ex parte re-examination, while participating in the arguments before the Patent Office. In exchange for the opportunity to directly affect the outcome, a third party was estopped from later asserting in litigation an invalidity defense that could have been raised during re-examination.

Inter partes re-examination has proved attractive, but it typically takes several years to resolve. This has influenced some courts to deny stays of litigation pending re-examination. This reduces the incentive for an accused infringer to request re-examination, and raises the specter of parallel, inconsistent, and inefficient outcomes. Upon passage of the Act, new procedures will replace inter partes re-examination, although ex parte re-examination will remain substantially intact.

First, there will be a nine-month period after patent issuance during which post-grant review may be sought. The threshold is essentially: (1) a facial likelihood that at least one claim is unpatentable based on the assertions in the request; or (2) a novel or unsettled legal question important to other applications. The challenger will bear the burden of proof by a preponderance of the evidence, with limited discovery available. The request will be decided by a Patent Trial and Appeal Board within one year (or six additional months with good cause), followed by direct appeal to the Federal Circuit.¹⁰

Second, "inter partes review" will be available nine months after a patent is granted or reissued. This review is limited to patents and printed publications, and is subject to the same time constraints, burden of proof, and decision process as post-grant review.¹¹ Together, these changes will expedite the examination process and address the current issues with inter partes re-examination.

Third, the patent owner will be able to request supplemental examination after patent issuance. This allows the Patent Office to consider or correct information believed by the patentee to be relevant to the patent, and that raises a substantial new question of patentability. Unlike inter partes review, any type of prior art may be raised. Moreover, information considered, reconsidered, or corrected during this process *cannot* be used to hold a patent unenforceable during litigation, unless the request for supplemental examination followed a particularized allegation or defense in litigation.¹²

Taken together, these new proceedings – plus the expansion of prior user and prior art defenses described above – are intended to provide a clearer, quicker, and more cost-effective process for achieving patent clarity short of litigation.

Conclusion

The "America Invents Act" is far-reaching, comprehensive legislation that will have a profound impact on our patent system. If enacted, its full range of effects will not be apparent for several years, although some changes will take place immediately. Upon initial analysis, the Act appears likely to advance its stated purpose – to simplify and streamline the process of procuring, and enforcing, strong intellectual property rights.

John Garretson is a Partner at Shook, Hardy & Bacon L.L.P., a national litigation firm recognized for its expertise in intellectual property law. Mr. Garretson's practice emphasizes patent litigation and counseling in the areas of pharmaceuticals, biotechnology and medical devices, with a focus on Hatch-Waxman litigation. He has successfully handled cases in federal courts across the country, including trials and appeals to the Federal Circuit. Mr. Garretson is a frequent speaker and author in the U.S., Japan and Europe on pharmaceutical and biotechnology patent issues. He can be reached at jgarretson@shb.com<mailto:jgarretson@shb.com> or 816-559-2539.

Ben Tabor is an Associate at Shook, Hardy & Bacon L.L.P. in the firm's Intellectual Property Practice Group. As a former electrohydraulic design engineer, Ben leverages his technical background to provide his clients legal counsel in technology fields that include cloud-computing networks, telecommunications, medical hardware and software, and handset applications. His experience includes prosecuting patent applications both in the United States and internationally; conducting patentability, patent infringement, and patent validity analyses; as well as performing offensive and defensive patent portfolio reviews. Ben can be reached at btabor@ shb.com<mailto:btabor@shb.com> or 816-559-2136.

 135 U.S.C. §§ 287 and 292, as prospectively amended by Section 16 of the Act (Section numbers hereinafter refer to H.R. 1249).

²35 U.S.C. § 299 (new); Section 19(d).

³35 U.S.C. § 282; Section 15.

⁴35 U.S.C. § 273; Section 5.

⁵35 U.S.C. §§ 32, 145, 146, 154(b)(4)(A) and 283; Section 9.

⁶ 28 U.S.C. § 1338(a); Section 19.

⁷35 U.S.C. §312(a); Section 6(c)(3) (emphasis added).

⁸35 U.S.C. § 145; Section 6(h).

⁹35 U.S.C. §156(d)(1); Section 37.

¹⁰ 35 U.S.C. §§ 321-329 (new); Section 6(d).

¹¹ Replacing <u>35 U.S.C. §§ 311-319;</u> Section 6(a).

¹² 35 U.S.C. §282 (invalidity); Section 10.