Regulatory News

Patents

House Passes Modified Patent Reform Bill, Adopting Manager's Amendment, Five Others

The House on a vote of 220 to 175 passed legislation (H.R. 1908) Sept. 7 to overhaul the ailing U.S. patent system.

Following a contentious debate about both procedure and substance, the lawmakers agreed to a manager's amendment that made changes to the underlying bill's provisions on damages, willful infringement, prior user rights, and post-grant review of patents.

The House also adopted four amendments: on publication of patent applications, rulemaking authority for the Patent and Trademark Office, infringement damages calculations, and the best-mode patentability requirement.

Among other things, the bill would convert the U.S. patent system from a first-to-invent priority standard to a first-inventor-to-file standard.

The lawmakers earlier rejected an attempt to overturn a House Rules Committee resolution that allowed only one hour of floor debate and five amendments to the landmark reform. Opponents complained during the day-long proceedings that the legislation was being ''rushed to the floor.''

AdvaMed: Bill 'Weakens' Patent Protections. ''This law contains some of the most sweeping changes America's patent system since the 1950s,'' according to Christopher White, general counsel for the Advanced Medical Technology Association (AdvaMed). The legislation ''weakens important patent protections by making patents easier to challenge and cheaper to infringe at a time when America's innovators, manufacturers and workers need stronger patent protections to compete internationally,'' White said in Sept. 7 release.

The closely divided vote in the House ''demonstrates the significant bipartisan opposition to the patent reform plan as currently written,'' White added. ''AdvaMed urges the Senate to delay further patent legislation until important improvements can be made to protect America's workers, inventors and investors.''

Administration Gives Qualified Endorsement. On the eve of the House action, the Bush administration weighed in with a statement of administration policy. In the statement, the Office of Management and Budget expressed the administration's general support for the bill's objectives and praised language to refine the patent application process and increase the regulatory authority of the PTO.

However, the statement voiced the administration's serious concerns about the bill's limits on a court's discretion to decide damages for patent infringement, and warned the administration will oppose the bill if that provision is not fixed.

The manager's amendment is available at http://www.rules.house.gov/110/amendments/hr1908/12-110_hr1908_berman.pdf.

Patents

PTO Issues Final Patent Claim Rules Allowing '2 Plus 1' Continuation Applications

The Patent and Trademark Office Aug. 21 finalized its long-awaited rules intended to rein in patent applicants' practice of filing multiple continuation patent applications and large numbers of claims.

Following months of criticism and commentary from the patent community, the final rules package relaxes some of the more controversial requirements originally proposed in early 2006. The agency said the rules will allow it to continue to make the patent examination process more effective and efficient by encouraging applicants to use greater precision in describing the scope of inventions.

The new rules will allow applicants to file two continuing applications and one request for continued examination as a matter of right (a 2+1 limit on continuations). Abandoning the proposed requirement that applicants designate certain ''representative claims'' in applications with multiple claims, the final rules instead allow a threshold of 25 claims and five independent claims before requiring an additional support document.

The new rules were published in the Aug. 21 *Federal Register* (72 Fed. Reg. 46716), and take effect Nov. 1.

Placing Boundaries on Process. PTO Director Jon Dudas said in an Aug. 21 statement on the agency Web site that the new rules ''better focus examination and will bring closure to the examination process more quickly, while ensuring quality and maintaining the right balance between flexibility for applicants and the rights of the public.''

''Placing conditional boundaries on a previously unbounded process provides for more certainty and clarity in the patent process,'' according to the PTO statement. ''The result is that application quality will be improved and piecemeal or protracted examination will be avoided, enhancing the quality and timeliness of both the examination process and issued patents,'' the statement said.

The rule changes initially were proposed in January 2006, and quickly faced stiff resistance from IP groups and small businesses. The American Intellectual Property Law Association, the Intellectual Property Owners Association, and the Small Business Association all pressed for amendments to the proposed rules.

On July 25, the PTO announced that the White House Office of Management and Budget had concluded its review of the controversial patent rule changes, and that

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the final rules would be made public later in the summer.

Uncertainty Remains. Steven Maebius, with Foley & Lardner LLP, in Washington, called the final rules a ''definite'' improvement over the proposed rules, which would have cut off the number of continuations at one. But, he said, a remaining area of uncertainty is under what condition will PTO allow the filing of additional continuations beyond the 2+1 limit.

Continuations allow the inventor to exchange additional information with the patent office necessary to get to the proper scope of patentability, Maebius said. They allow a further ''back and forth of information'' between the applicant and the patent examiner, and allow applicants to try out a slightly modified claim version to see if that will satisfy the examiner.

''The rules give you three guaranteed bites at the apple,'' he told BNA in an Aug. 21 interview. ''But what happens if you find yourself in a situation where you need that fourth bite.'' Right now, the criteria needed to apply for a fourth application are largely ''a black box.''

Under the new rules, a company wanting to submit additional continuation applications will have to explain why the extra continuation is necessary, and the PTO will decide each additional application on a case-by-case basis, he said. There is ''an amount of fear'' in not knowing in which situations the PTO will accept additional continuations.

Impact on Device Industry. Andrew E. Rawlins, also with Foley & Lardner in Washington, said that placing a limit on the number of continuation applications may hinder an applicant's ability to get broad patent protection on fundamental technologies.

Continuations often are necessary to help an applicant obtain the broadest possible protection for their innovation, Rawlins said. An applicant that ''pushes the boundary'' with a broad claim may need to do a lot more explaining to the patent examiner, which usually means more continuations, Rawlins explained. While it is not typical for an applicant to go over three continuations, Rawlins said, it also is not uncommon.

In the medical device industry there are more small and mid-sized companies, Rawlins continued. These companies ''can live or die by the breadth of their patent protection,'' he said.

Companies can help reduce the need for continuations by doing more of their own prior art research in advance of filing a patent application and by personally meeting with the patent examiner to try to work out what subject matter is patentable, Rawlins said. Both options will be effective, he said, but they also will cost more money.

That is an ''interesting effect of these new rules,'' Rawlins added. ''There's a push back of expenses to the applicant, and those [smaller companies] that are impacted the most are probably in the worst position to pay,'' he said.

More Appeals Possible. In Maebius's view, the limitation on continuations also could lead to more appeals questioning a patent examiner's ruling.

The ''stated purpose of the new rules was to reduce the number of unnecessary continuations and to try to squeeze the process a little to make it more efficient on both sides,'' Maebius said. The new rules likely will eliminate a certain number of continuations for which applicants did not have a strong need, Maebius acknowleged. The long-term effect is unclear, however, because there could be an increase in the number of appeals.

In fact, Maebius noted, the PTO has said they are prepared to deal with an increase in appeals and have taken steps to do so. For example, in late July, the PTO proposed several changes to the rules governing practice before the Board of Patent Appeals and Interferences in ex parte patent appeals (72 Fed. Reg. 41,472). The proposed rules would require applicants seeking review of adverse decisions by patent examiners to offer more information in their appeals briefs to minimize further proceedings (1 MELR 349, 8/15/07).

Legal Challenge Filed. Nevertheless, legal challenges to the new rules already have been filed. On Aug. 22, an individual inventor filed a lawsuit in the U.S. District Court for the Eastern District of Virginia challenging the validity of the new rules (*Tafas v. Dudas*, E.D. Va., No. 07–846, *complaint filed* 8/22/07). Dr. Triantafyllos Tafas, a Connecticut inventor who currently has more than 17 patents pending before the patent office, filed the declaratory action against the PTO and its director, Jon W. Dudas. The complaint asks for court declaration that the new rules are in conflict with the Patent Act and thus invalid.

It will be interesting to see whether the court accepts that Tafas has standing to sue, because the rule has yet to go into effect, and there is no immediate injury to redress, Maebius said. Nevertheless, he said, it is possible that other groups will follow Tafas' lead and challenge the rules in court.

Advertising and Marketing

Senators Introduce Bill to Require Drug, Device Makers to Report Gifts to Doctors

Sens. Charles E. Grassley (R-Iowa) and Herb Kohl (D-Wis.) Sept. 6 introduced legislation (S. 2029) to require manufacturers of pharmaceutical drugs, devices, and biologics to disclose the amount of money they give to doctors through payments, gifts, honoraria, travel, and other means.

The Physician Payments Sunshine Act would require drug and device manufacturers to disclose to the secretary of Health and Human Services, on a quarterly basis, anything of value given to doctors.

Along with the gift value, these companies would be required to report the name of the physician and the date of the gift, its purpose, and what, if anything, was received in exchange.

''Right now the public has no way to know whether a doctor's been given money that might affect prescribing habits,'' said Grassley, ranking member of the Senate Finance Committee. ''This bill is about letting the sun shine in so that the public can know.''

If enacted, the new requirements would apply to manufacturers with $100 million or more in annual gross revenues. Penalties for not reporting payment would range from $10,000 to $100,000 per violation.

The bill also would require the HHS secretary to create a Web site and post payment information in a clear and understandable manner.