

Patent Reform Uncertainties

With the political shake-up in the House and Senate, the future of patent reform proposals is somewhat uncertain. There has been bipartisan support for patent reform in general, but the new leaders in Congress may very well rework the details of the legislation. And as everyone in the medical device industry knows, the devil is in the details.

One of the more significant reform proposals is the implementation of a postgrant opposition procedure. Specifically, the proposal calls for the adoption of an adversary proceeding for challenging the validity of a granted patent in an administrative setting before the U.S. Patent and Trademark Office (PTO). The proposed proceeding is intended to serve as a quality-control mechanism for granted patents and to provide a less expensive alternative to litigation. The adoption of a postgrant opposition or review proceeding may create an opportunity for medtech organizations to enhance their strategic planning efforts and bring products to market with less risk of facing patent infringement actions.

On the House side, it is unclear who will take over leadership of the IP Subcommittee from Representative Lamar Smith (R-TX). The ranking Democrat is Representative Howard Berman (D-CA), but it has been rumored that he may pass the position to the next Democrat in line, Rick Boucher (D-VA). Berman has been a long-standing proponent of patent reform. Berman and Boucher jointly introduced the Patents Depend on Quality (PDQ) Act in April 2006. The PDQ Act included provisions for a postgrant opposition procedure quite similar to that which had been proposed by Smith in his Patent Reform Act of 2005 (HR 2795). However, Berman and Boucher reintroduced the controversial second window for filing an opposition request, which Smith had written out of his bill.

In the Senate, Orrin Hatch (R-UT) was the IP Subcommittee chair during the previous Congress. On August 3, 2006, Hatch introduced the Patent Reform Act of 2006 (S 3818) jointly with the ranking Democrat on the subcommittee, Patrick Leahy (D-VT). Leahy is taking over leadership of the Senate Judiciary Committee, and it is expected that S 3818 will be a starting point for patent reform discussions. It is unclear at this point who will replace Hatch as the chair of the IP Subcommittee.

Although Leahy cosponsored S 3818, the bill was a legislative compromise in which Hatch had more say than Leahy. Therefore, it is uncertain whether the bill will survive in its current form with the new leadership in the Senate. It is worth noting,

however, that the postgrant review provisions of S 3818 were distinct from House versions of the postgrant opposition legislation in the following respects.

- In S 3818, the PTO director is given much wider authority to establish regulations governing the details of the proceeding. Issues such as what must be set forth in the postgrant review petition, how the proceeding will relate to other PTO proceedings, and procedures for discovery are all left to the discretion of PTO.
- The normal window for filing a petition for postgrant review is 12 months, as opposed to nine months in House versions of the legislation.
- S 3818 establishes a second window for filing a postgrant review petition that is open to anyone who “establishes a substantial reason to believe that the continued existence of the challenged claim causes or is likely to cause the petitioner significant economic harm.” The downside to using the second window is that a “could have raised” estoppel will apply to the petitioner in subsequent proceedings, including litigation, whereas the normal petitioner will be subject to estoppel only for specific invalidity grounds raised and specific claims targeted during the proceeding.

One generalization that can be made is that the Democrats involved up to this point have favored the second window more than the Republicans. So if, indeed, we see a postgrant review procedure come out of the Democrat-controlled 110th Congress, it will likely include a second window provision in one form or another.—*Jonathan R. Sick, shareholder, McAndrews, Held & Malloy (Chicago)*

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