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The Changing Patent Landscape

Jonathan R. Sick

The patent reform legislation introduced in Congress last year was the result of building concerns in the United States over patent quality, the high cost of patent litigation, and the perceived need for patent harmonization with the rest of the world. The highly publicized Blackberry dispute between RIM and NTP focused further attention on issues such as patent quality and potential abuses of the system by patent speculators.¹ Patent reform is coming—it's just a question of when and in what form.

The Patent Reform Act was first introduced in the House in June 2005. It has undergone two revisions since that time, and a competing bill was introduced just this April.²⁻⁵ Although the legislation is in a state of flux, certain features persist throughout the various versions. What follows is a high-level introduction to these features, with a particular focus on how they are likely to affect the medical technology industry.

The Establishment of a First-to-File System

If two individuals independently come up with the same invention,

current law favors granting the patent to the individual who invented first. The proposed reform legislation would award the patent to the individual who was the first to file a patent application—regardless of who was the first to invent.

This reform would harmonize the U.S. patent system with the rest of the world, which already operates under a first-to-file system. The change is expected to ease the administrative burdens on global companies because they will no longer need to treat U.S. patent applications differently from applications filed in other countries. The change would also eliminate interferences—the sometimes-complicated proceedings that decide who was the first inventor.

If a first-to-file system is adopted, medical technology companies will want to revisit their patent filing strategies. To reduce the likelihood that a competitor will file first and thus walk away with the patent rights, it will be important for companies to file patent applications as quickly as possible. To preserve their patent rights as a technology evolves, companies may want to consider filing provisional patent applications at regular intervals during the development



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process. Smaller entities may find themselves at a disadvantage because they may not have the resources to engage in such aggressive filing strategies. Indeed, individual inventors vehemently oppose this proposed reform for that very reason.

Prior User Rights

To counterbalance the change to a first-to-file system, the reform proposal provides for prior user rights. This reform would establish a defense against patent infringement for an

entity that independently completes an invention and takes steps toward commercializing it before another entity files a patent application for that same invention. In other words, even if company A beats company B to the U.S. Patent and Trademark Office (PTO), company B may still be free to use the invention if it took steps toward commercialization prior to company A filing its patent application.

Drafters of the reform bill did not overlook the fact that medical technology companies may be subject to lengthy regulatory approval periods prior to commercialization. For any medical device that is subject to a pre-marketing regulatory review period to establish safety or efficacy, commencement of human clinical trials will constitute commercial use.

Elimination of Best-Mode Requirement

Current law requires patent applicants to disclose the best mode known to them of carrying out their invention. This requirement has often led to litigation over the subjective question of what a particular inventor thought was best at the time the patent application was filed. The proposed reform bill would drop the best-mode requirement altogether, removing it as an issue in litigation and eliminating another difference between U.S. law and international law.

This reform may encourage a strategy of describing an invention generally in the patent application while deliberately holding back, as a trade secret, the very best way of practicing the invention. For example, an application describing a medical device may disclose general operating ranges, while omitting the specific parameters within those ranges that have been found to work best.

All Patent Applications Published

Most U.S. patent applications are automatically published 18 months after they are filed. An applicant who waives the right to file for patent protection outside the United States, however, can opt out of the publication process and keep the application secret until the patent issues. These secret patent applications—sometimes referred to as submarine patents—have caused problems in many industries because of the inability of businesses to make preparations for their arrival.

The reform proposal would require all patent applications to be published within 18 months; applicants could no longer opt out of publication. Such a change will make patent searching more effective, allowing a searcher to get a heads-up on all potentially problematic U.S. patents before they arrive. This promises to be of particular benefit to the regulatory-intensive medical technology industry, where there is a premium on accurate strategic planning.

Heightened Willful Infringement Standard

Currently, one who willfully infringes a patent may be liable for treble damages. But one cannot willfully infringe a patent of which one is not aware. For this reason, the threat of treble damages is often viewed as a deterrent to comprehensive patent searching and effective strategic planning; the more patents reviewed, the greater the chances of willful infringement liability.

The reform proposal would require, as a prerequisite for a willfulness charge, that the patent owner provide an alleged infringer with written notice of specific allegations

of infringement. As a result, a potential infringer will no longer be exposed to the risk of treble damages by simply searching for, and identifying, patents that may pose an infringement risk. Again, this may be a boon for the medical technology industry, where strategic planning is so important.

Postgrant Opposition Proceeding

One of the more significant reform proposals is the implementation of a postgrant opposition procedure—an adversary proceeding for challenging the validity of a granted patent in an administrative setting before the PTO. This proposed reform is intended to serve as a quality-control mechanism for granted patents and to provide a less-expensive alternative to litigation.

There appears to be fairly widespread support for a postgrant opposition proceeding, although some question how the already-overloaded PTO would be able to handle the increased work load. Additionally, the pharmaceutical industry and the software industry sharply disagree over when an opposition proceeding could be instituted. Pharma favors a limited nine-month window after a patent issues, whereas the software industry advocates an additional second window that would be opened once a patent infringement suit is filed.^{6,7}

This is another reform under consideration that will hopefully benefit industries (such as the medical technology industry) that rely on significant strategic planning. Assuming the procedure works as intended, it will provide a cost-effective mechanism for preemptively challenging patents that may threaten products that are under development or already in clinical trials.

Inequitable Conduct Defense Limited

A defendant in a patent infringement suit will almost always assert that the patent is unenforceable because the plaintiff has committed inequitable conduct—that is, the plaintiff intentionally withheld material information from the PTO during the application process that led to the patent. This litigation strategy invariably leads to significant expense, and the Federal Circuit has gone so far as to characterize the practice as “an absolute plague.”⁸

The reform proposal would greatly reduce a defendant’s ability to raise the inequitable conduct defense during litigation. While many favor this change, some believe it removes one of the few disincentives that discourage patent owners from filing frivolous infringement suits.

Injunctions

The injunction issue has been brought front and center by the Blackberry dispute between RIM and NTP.¹ The basic question is this: Should a patent-holding company (one that doesn’t sell the patented product) be able to enjoin the activities of an infringer that is actually providing the patented product to the public? Historically, the answer has been yes. Proposed reform language would encourage courts to consider fairness in deciding whether to issue an injunction or whether, for example, to impose a forced royalty instead. This proposed language has engendered much debate and has even been omitted from some versions of the proposed legislation. This reform may be moot in view of the

Supreme Court’s May 15 decision in the *Ebay v. MercExchange* case, which instructed courts to be more equitable in deciding whether to grant an injunction in a patent case.⁹

Conclusion

For the most part, the proposed reforms will affect the medical technology industry in the same way as the rest of U.S. industry as a whole. However, the changes to the publication and willful infringement rules, as well as the implementation of a postgrant opposition proceeding, will present a real opportunity for medical technology entities to improve strategic planning and manage business risks throughout the lengthy commercialization process. Given the fluctuating state of the legislation, it is unlikely that any of the patent reforms discussed above will make their way into law this year. Next year, on the other hand, is a real possibility.

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Jonathan R. Sick is a shareholder at the law firm of McAndrews, Held & Malloy (Chicago), where he counsels and assists clients on a variety of intellectual property matters. He can be contacted by phone at 312/775-8000, or via e-mail at jsick@mhmlaw.com.