America Invents Act: Start Planning Now

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On September 16, 2011, the America Invents Act (the “Act”) was signed into law, marking arguably the most significant modification to the U.S. patent system since 1952. Although the default effective date is September 16, 2012, medical device companies should start making adjustments to their patent strategies now to better protect their investments in the future. In this article, three main modifications are discussed: the systematic change to first-to-file system; a broadening of applicable prior art; and additional patent office proceedings to challenge patentability.

The most publicized change in the Act was the shift from a “first-to-invent” to a “first-to-file” patent system. This change may be interpreted as allowing for a patent to be awarded to the first inventor to file an application, regardless of who invented it first. However, this is overly simplistic. While a claim of prior invention is arguably no longer relevant, the Act does not usher in a pure first-to-file system. Instead, the new U.S. patent system is more appropriately described as awarding a patent to the first-to-disclose. A disclosure of the claimed invention in a provisional patent application, or a “public disclosure” of the claimed invention, starts a one-year countdown for which the inventor may file an application with priority over other inventors (including first-filers). In a simple example, if a professor from University A publishes a paper disclosing an invention, University A has one year to file a patent application to receive priority to the invention, regardless of whether another entity (e.g., company B) files first. One can thus use a public disclosure or provisional patent application as a “placeholder” to beat other entities in the race to the Patent Office.

Medical device companies can begin preparing a shift in strategy to facilitate more frequent provisional applications and to expedite the transition from innovation to application or (in certain circumstances) disclosure. However, planning to seek patent protection for every innovation will not always be appropriate. Some developments may be better off protected as trade secrets, and disclosure (including disclosure due to an unsuccessful patent application) would defeat that protection. But if the invention is appropriately protected by a patent, provisional applications may be filed early and often (hopefully only after the appropriate level of a “supporting” disclosure can be achieved).

In conjunction with the shift toward a first-to-file system, the scope of prior art (i.e., prior publicly available technology) available to demonstrate an invention was previously known is arguably broadened. First, prior to the Act, the temporal benchmark for determining whether an invention qualified as prior art was measured from an applicant’s date of invention. Under this system, the activities of third parties which describe an invention occurring prior to an applicant’s filing date, but after an applicant’s invention date, were not considered prior art. The Act changed the pertinent date to the effective filing date, thus eliminating opportunity to disqualify third party invention based on an applicant’s prior invention. In

practice, the date on which a product or process is considered “invented” is necessarily on or before (and often a good deal of time before) the date a patent application is filed. Second, prior to the Act, technology which was “known or used by others” could qualify as prior art. The Act amended this language to encompass technology “available to the public.” While the precise effect of this amendment is yet to be determined, the drafters of the Act have indicated “available to the public” was “added to clarify the broad scope of relevant prior art, as well as to emphasize the fact that it must be publicly accessible.” Third, prior to the Act, public uses or sales were required to have occurred in the United States only. The Act removed this limitation, thus expanding the scope of prior art to include public uses or sales (otherwise qualifying as prior art) anywhere in the world. With at least the above expansions in the scope of invalidating material, taking early action to protect innovations is of the utmost importance.

Finally, the Act creates a new post-grant review proceeding to challenge the patentability of issued patents. Any patent containing a claim with an effective filing date on or after March 16, 2013, may be subject to review. When used, this proceeding will permit petitioners to challenge patent claims with a broader scope of prior art previously unavailable before the Patent Office, while maintaining a significantly lower cost than litigation in the Courts. Specifically, unlike other reexamination or review proceedings limited to only “prior art consisting of patents or printed publications,” a petitioner in a post-grant review can challenge patentability on any ground of invalidity that could be raised under 35 U.S.C. §§ 282(b)(2) or (3), which adds lack of written description, enablement, and indefiniteness under 35 U.S.C. § 112, and a prior use or sale under 35 U.S.C. 102. The drafters made the intent for this provision clear: to “serve as an effective and efficient alternative to often costly and protracted district court litigation.”

Post-grant review is not without certain drawbacks. If a final decision (or an appeal therefrom) affirms patentability, the petitioner is precluded from asserting that the claims are “invalid on any ground that the petitioner raised or could have raised during the post-grant review.” After the Act was signed into law, an amendment was proposed to limit the breadth of estoppel, by deleting the “could have raised” language. The preclusion applies before the Patent Office, in courts, and before the International Trade Commission. Thus, a company may have just one shot to invalidate a competitor’s patent. The drawback is potentially further exacerbated by the fact that parties to a post-grant review are limited to discovery of “evidence directly related to factual assertions advanced by either party in the proceeding.” This scope is narrower than the standard in a civil action.

For medical device companies, the Act affords certain incentives (e.g., encouraging habitual provisional application filings), expands available prior art, and creates a new vehicle for challenging competing patents. A shift in a company’s patent strategy may be necessary to better protect its own innovations and more efficiently challenge the patents of third parties.

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