Patent Reform: Is The Cure Worse Than The Disease?

The America Invents Act changes to priority of filing and the definition of prior art could lead to unintended consequences for the medical device industry.

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Now that the dust has is settling on the passage of U.S. patent reform legislation, the medical device industry will need to determine exactly what legal challenges may arise once the law and its general provisions go into effect. Industry executives certainly understand that the patent system is poised for dramatic change under the Leahy-Smith America Invents Act of 2011 (AIA). What remains to be seen, however, is whether the changes can cure what is ailing the U.S. patent system.

This article examines two key aspects of the AIA: The first-inventor-to-file patent scheme and what constitutes prior art after patent reform is fully implemented. AIA simplifies identification of activities that constitute prior art and transforms the U.S. patent system to give priority to inventors who are the first to file patent applications rather than to those who are the first to invent. Given the rapid pace of innovation in the medical technology field, companies in the near future will be pressured to file patent applications as quickly as possible in order to maintain competitive advantage.

This simplification has also broadened the scope and content of prior art that can be utilized against patents and patent applications in the medical device industry. It also puts limits on the one-year grace period between the creation of prior art and the patent application filing.

The first-to-file and prior art provisions of the AIA will take effect March 16, 2013. It is not too early, therefore, to begin considering the implications of the new patent scheme for device companies.

Major Departures

The U.S. Patent and Trademark Office (USPTO) will no longer grant patents to the first person to invent a new medical device. Instead, the patent will be granted to the first inventor who files for a patent on that new device. A patent for a new human organ, however, will not be granted to anyone—it is specifically barred from issuance under the AIA.

If that inventor inadvertently fails to describe the best mode of the device’s construction or manufacture as required in a patent application, that omission will not be held against the inventor so as to render the patent unenforceable.

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Should a competitor know of prior art that might invalidate or prevent the granting of the patent, that competitor can use administrative mechanisms in lieu of litigation to challenge the patent. During the pendency of the application and after the patent is granted, competitors can submit prior art for consideration by the examiner or the USPTO’s Patent Trial and Appeal Board. After the patent is granted, competitors can invoke two different yet similar mechanisms to invalidate the patent.

Post-grant review, which is the first of the two mechanisms available chronologically, can be used to invalidate the patent on a wide array of grounds, but only if a review request is filed for within the first nine months after the patent is granted. Inter partes review, the second of the two mechanisms, can be initiated at any time after the post-grant review time period has lapsed.

Finally, should the inventor decide to enforce the patent against perceived infringers, no longer can the inventor hold an entire industry hostage by filing one lawsuit naming all the industry’s players. Rather, naming multiple defendants is permitted only where the infringement results from the same transaction or a series of transactions or occurrences—or both situations—that relate to the same product or process. Should the accused infringer have previously and commercially used the patented device...
at least a year prior to the filing of the application that resulted in the patent, then the accused infringer will have a broader scope of prior user rights to assert as a defense to the accused infringement.

A Broader View

With the implementation of the AIA, the exclusively American concept of awarding a patent to the invention’s first inventor will disappear. Before lamenting the demise of this American ideal, we should recognize that this concept instilled a significant level of uncertainty in U.S. patents. A patent could always be later held invalid if it was shown that others in the United States had known of or used the invention described in the patent before the first inventor created the invention.

As set out in current Section 102(g), a person is entitled to a patent unless

“Before such person’s invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.”

This first part of Section 102(g)(2), not only established the U.S. patent system as a first-inventor entitlement scheme but also imputed uncertainty into the validity of all issued patents. With implementation of the AIA, this uncertainty about the possible existence of a prior inventor is eliminated. As stated in Section 102(a)(2) of the AIA, a person is entitled to a patent unless the claimed invention is disclosed in an issued patent or published application that names another inventor and was filed before the filing date of the claimed invention. This stipulation creates what some have deemed to be a race to the USPTO to obtain the patent.

That race also exists, to a certain extent, under the current law. In the above-quoted portion of Section 102(g)(2), reduction to practice (putting an invention to practical use), or due diligence in reducing the invention to practice, is required when considering prior inventorship. One means for constructively reducing an invention to practice is to file a patent application on the invention. Conception of an invention, coupled with prompt filing of a patent application, is therefore encouraged under the current system. The current system’s one-year period, prior to filing, for the exclusion of prior art, also encourages the faster filing of patent applications as a means to exclude the availability of additional prior art.

In addition to this uncertainty concerning prior inventors, the application and qualification of prior art under the current statute is complicated, because not all prior art is treated equally. Even after practicing patent law for many years, a seasoned patent attorney will likely refer to the text of current Section 102(a)(g) when determining whether a reference will constitute prior art against a given patent application. The section is convoluted and always requires detailed consideration.

For example, under current Section 102, prior art is treated differently depending on whether it predates the applicant’s invention date or occurred more than a year before the date on which the applicant filed for a U.S. patent. Regarding the former, current Section 102(a) states:

A person shall be entitled to a patent unless. . . (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or …

Regarding the latter, current Section 102(b) states:

The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than a year prior to the date of the application for patent in the United States, or …

Thus, knowledge and use would be considered prior art if they occurred before the applicant’s invention date. Prior patenting, publication, public use, and on-sale activities are considered prior art only if they occur more than a year before the applicant’s U.S. filing date.

In addition to the timing of the prior art, under paragraphs (a) and (b) of the current Section 102, prior art is currently treated differently depending on the nature of the prior art itself and where it exists. Knowledge and use are important only if the knowledge or use occurred in the United States, whereas a printed publication or a patent is considered prior art regardless of where it is published or granted. Prior use and on-sale activities must occur in the United States to be considered as prior art.

The remaining paragraphs of current Section 102, paragraphs (c)-(g), provide additional exclusions for the obtaining of a patent. Specifically, prior art is excluded if the invention was abandoned by the inventor; if prior application for a patent in a foreign country occurred more than 12 months before filing in the United States; if an application was published by another or granting of a patent to another was filed before the U.S. applicant’s invention date; if a noninventor filed for a patent; or if prior invention was established by another who did not abandon, suppress, or conceal the invention.

Prior Art Simplified

Under the AIA, the complicated application of current Section 102 is eliminated and the definition of prior art is simplified. The key new to whether an item is considered prior art is to determine whether it existed before the effective filing date of the claimed invention. Section 102 of the AIA recites in part:

A person shall be entitled to a patent unless—

(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention; or...

Simply stated, under the AIA prior art to a claimed invention is that which, before the effective filing of the claimed invention, was patented, described in a printed publication, in public use, on sale, or otherwise available to the public anywhere in the world. This single
definition replaces Sections 102(a)-(d), (f), and (g) of the current law. Eliminated from the analysis are the separate considerations of whether the prior art predated the filing date of the claimed invention or a date one year prior to the filing date of the claimed invention.

Also eliminated from the analysis is consideration of the nature of the prior art. Patents, printed publications, public use, and on-sale activities are all treated similarly whether they occurred in the United States or in a foreign country. In other words, no geographic limitation would exclude or otherwise limit consideration of any form of prior art. Going forward, the removal of this geographic limitation vastly enlarges the scope of prior art that can be considered by an examiner weighing patentability and by an adversary investigating invalidity of a medical device patent.

**Various Exceptions**

A discussion of the AIA’s changes to Section 102 would be incomplete if it did not mention the existence of various exceptions under the new law. These exceptions are intended to grant to the inventor or owner of the claimed subject matter some relief from the application of the new Section 102.

Generally, such disclosures by the inventor or a joint inventor (or another who obtained the disclosed subject matter from the inventor or joint inventor) are not considered to be prior art against the claimed invention if they occur within one year of the effective filing date of the claimed invention. Under the AIA this exception continues the current law’s one-year grace period. This grace period will protect the inventor from third-party disclosures only if subject matter disclosed by a third party had already been publicly disclosed by the inventor or joint inventor. The rationale behind this exception is that, once begun, the one-year grace period being afforded to the inventor should not be limited or cut off as a result of the activities of a third party. A significant downside, however, is that such a disclosure by the inventor would prevent patenting of the subject matter in foreign countries in almost all cases.

Another exception, to which the one-year limitation does not apply, relates to disclosures appearing in other patents or patent applications. These disclosures will not be considered prior art if the disclosed subject matter was obtained from the inventor, previously disclosed by the inventor, or commonly owned. A claimed invention and disclosed subject matter will be considered as commonly owned if the claimed invention was made by and the disclosed subject matter was developed by or on behalf of at least one party to a joint research agreement. To avail oneself of this definition, the joint research agreement must have been created before the effective filing date of the claimed subject matter; the claimed invention must have been the result of activities under the joint research agreement; and the patent application for the claimed invention must disclose the names of the parties to the joint research agreement.

Notably absent from the list of exceptions is an express exception for experimental use. The courts had previously held that the experimental use is an exception to otherwise public use. New Section 102(1) includes identical language relating to “in public use” as is found in current Section 102(b). This favors an argument that prior case law relating to the experimental use exception should continue to apply under the AIA.

Note that Section 102 has been completely rewritten, not edited. However, the absence of express language in the AIA can be construed as intent to exclude an experimental use exception under the new law. It could further be argued that experimental use was intended to fall within, and therefore be excluded by, the new language of Section 102(a)(1) relating to a claimed invention being “otherwise available to the public.” This new language is not defined in the AIA, but is widely viewed as a catchall for establishing prior art.

As discussed above, the determination of what constitutes prior art has been simplified under the AIA and the new law fundamentally alters the patent filing scheme. When reform is conducted on such an extensive scale, trade-offs are expected, but the unintended consequences are sometimes harsh. As the AIA begins to take effect, one question is inevitable: Is the cure worse than the disease?

**Reference**


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