The America Invents Act and Your Biotech-Based Business

Sandra P. Thompson

Buchalter Nemer, Irvine, CA

The America Invents Act (AIA), commonly referred to as the "patent reform bill," was signed into law late last year, and business owners are still wondering what, if anything, it means to them. Many biotech-based businesses have been operating in an international patent protection space, and therefore, many of these concepts are not new. However, several of the new pieces of the AIA that appear to be the same as what the rest of the world already does are not quite the same, and the distinctions are important. One good example of that is the First-to-File system, covered in another article in this issue (*p. 66)*.

Since patent reform has been discussed for the last 6-10 years, there are also several aspects of the AIA that are being misunderstood or exaggerated. Again, one of the key misunderstandings is the ramification of the US First-to-File system; companies, especially those with technical teams who regularly publish or present at outside meetings, must be careful to understand the pitfalls and issues with this section of AIA.

Overall, it is important to know that AIA will be implemented over an 18-month period with some provisions that took effect immediately and others that will be put into practice in 2012 or 2013. The First-to-File provision, for example, does not take effect until March 2013. Therefore, it is important to review any questions or concerns about whether aspects of the AIA apply to your business, patents, or patent applications before considering amending your company's best practices or implementing new policies.

Fee Increase, Effective Immediately

Almost all patent fees collected by the United States Patent & Trademark Office (USPTO) have increased by 15%. The fee increase applies to fees for both patent applications and issued patents, such as maintenance fees. An application can be prioritized by the USPTO by paying a flat fee of $4,800 in addition to other ordinary fees. Finally, a $400 fee will be applied to those matters that are not filed electronically with the USPTO. One interesting fee-related provision relates to the creation of a "Microentity" designation. Currently, patent applicants are either designated large entities or small entities, with the latter getting a 50% decrease on most USPTO patent fees. The Microentity designation would mean a 75% decrease on most USPTO patent fees and is reserved for institutions of higher education or small entities with four or fewer previously filed patent applications and gross income less than three times the median household income. As of this article, information regarding the Microentity status has been sent out by the USPTO for comment but has not been implemented.

Business Practice Point. Biotech businesses that routinely include patent filings in their annual budgets should consider doing several things to reduce their patent fee burden. First, break out the budget into legal fees and government fees. In this instance, the "government fees" portion should be determined annually and then a 10% buffer applied. Patent offices throughout the world are shortening the timeline between patent fee increases, and therefore, it is smart to be proactive on this point in budgets. Second, if a particular biotech company files more than 10 US patent applications a year, it may be wise to negotiate a cap on legal fees per application with the company's patent professional. This cap better allows a company to determine a patent budget for a year without too many surprises.

Post-Grant Review, Effective September 2012

Under the AIA, any party will be able to petition the USPTO for a post-grant review of any issued US patent within nine months of its issue. The standard for granting review is "more likely than not that at least one of the claims challenged is unpatentable," which is much broader than the current standard for reexamination ("substantial new question of patentability"). This new process is similar to the Opposition Proceeding currently used in Europe.

Business Practice Point. Businesses must do three things under this new review petition: A) track and monitor patent applications on significant inventions; B) collect and document any information that can be used to show that any of the claims are unpatentable; and B) be prepared to file a petition quickly when one of these patents issues. A company's intellectual property committee that includes members of management, technical, sales, and legal staff should meet on a regular basis to help with this process.

Prior Use Defense, Effective Immediately

Before the AIA, the "prior use defense" was available to those defendants being sued for patent infringement of a business method patent if the defendant could prove that he/she reduced the subject matter to practice at least one year before the effective filing date of the patent and commercially used the subject matter before the effective filing date of the patent. The AIA opens the prior use defense up to all patents issued on or after September 2011 and requires clear

DOI: 10.1089/ind.2012.1517

and convincing evidence of commercial use in the US at least one year before the earlier of the filing date of the patent application or the date the invention was disclosed to the public. This provision puts a company's trade secrets and trade secret protection policy back into play. In the past, a company may have disclosed a trade secret or filed a patent application for it in order to keep a competitor from obtaining a patent on the same technology and blocking them from using it. Now, as long as the company can provide clear and convincing evidence as to the commercial use and timeline, the company may be able to use the prior use defense in patent infringement cases.

Business Practice Point. The prior use changes under the AIA make biotech companies especially susceptible when having trade secrets within the company or when employees leave the company. It is always important to document and put procedures in place to protect trade secrets, but biotech companies must not fall into the trap of believing that trade secrets are now an attractive, low-cost option for them in view of the AIA. Employee turnover should be the primary consideration for a biotech company. If it is moderate-to-high, then the company should consider weighting the intellectual property portfolio toward patent applications. If employee turnover is small, then the company should consider incorporating trade secrets into its intellectual property portfolio. However, it is important to remember that once a trade secret is disclosed, it is lost. So, core technologies and inventions should always be patent protected.

Inventor Oaths, Effective September 2012

Under the current patent system, each inventor must sign an oath/declaration stating that he/she conceived of the invention either alone or jointly with other inventors. If the inventor could not be found or refused to sign the paperwork, the owner or other inventors had to institute a proceeding whereby the owner or other inventors had to prove to the USPTO that they actively tried and failed to find the inventor or get the inventor to sign. This process is expensive and delays patent examination until resolved. Under AIA, the person or company who is considered the assignee of the patent application may now file the patent application with a substitute oath (statement) for those inventors who are deceased, legally incapacitated, or cannot be found. The assignee may also file a substitute statement if the non-signing inventor is under an obligation to assign the application but refuses to sign the oath/declaration.

Business Practice Point. It is very important that businesses review their employment and independent contractor agreements to ensure that their employees and independent contractors have a duty to assign any inventions conceived during their employment or contract period.

Patent Marking, Effective Immediately

Section 16 of AIA relates to patent marking, which is regularly contested in litigation proceedings. This section favors businesses by allowing patent owners to satisfy the marking requirement by referencing a publically available internet address or website. This concept is something that new small and mid-size businesses should pay close attention to, because products and services must be marked with your patent numbers. In addition, the AIA states that only the US or a person suffering competitive injury can sue for false marking. These sections apply to currently pending cases.

Business Practice Point. Biotech companies should ask their intellectual property committees to regularly review what is being marked and whether the marking is proper. In addition, companies should have or develop a database to track markings.

Best Mode Requirement, Effective Immediately

The AIA eliminated another long-standing provision of US patent law—the Best Mode Requirement, which required the patentee to provide the best mode for practicing the invention at the time of filing in the patent application. While this requirement has been dropped for future patent applications, it still stands to reason that the strongest patents have supporting examples and information as to the best way to practice the invention. At this point, it remains to be seen whether this update will affect the quality of patent applications, but it can no longer be used as a way to attack patents in litigation.

Conclusions

There will continue to be a significant amount of commentary and information coming out over the next 36 months on the provisions and implementation of AIA. Therefore, businesses should stay in touch with intellectual property counsel and ensure that technical teams, sales teams, and management have an understanding of how new patent laws apply to them. Biotech companies should also be working with their outside legal team to institute a regular employee training program on intellectual property issues and initiatives, along with monthly alerts and articles.

Sandra P. Thompson, J.D., Ph.D., is a shareholder in the Orange County (Irvine, California, USA) office of Buchalter Nemer (www.buchalter.com). Her practice areas include intellectual property, specifically, patents and trademarks. She completed doctoral studies in analytical chemistry, during which period she worked at the US Environmental Protection Agency. Phone: +1 (949) 224-6282. Email: sthompson@buchalter.com

The content of this article is not intended as legal or financial advice. Views expressed are those of the author and should not be construed as necessarily representative of those of Buchalter Nemer, *Industrial Biotechnology* journal, Mary Ann Liebert, Inc., publishers, or their affiliates. No endorsement of any entity or technology is implied.