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Patent Updates

The America Invents Act and Its Importance to Patent Prosecution in the Biotech Sector

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On September 16th, 2011, President Barack Obama signed the *The Leahy-Smith America Invents Act* (AIA) into law. With enactment of the AIA, the US patent system will undergo the most significant reform that it has experienced since enactment of the Patent Act of 1952. In a press release issued by the Biotechnology Industry Organization (BIO) following final passage of the AIA, BIO President and CEO Jim Greenwood stated that "[t]he improvements made by the bill will benefit all sectors of the national economy by enhancing patent quality and the efficiency, objectivity, predictability and transparency of the U.S. patent system."[1] Greenwood went on to say that "[s]mall biotechnology companies rely heavily on their patents to attract investment," and "they will benefit from the improvements to our nation's patent system made by this legislation." Changes under the new rules could have a significant impact on the biotechnology industry, and there is debate over whether those changes will help or hinder the sector's efforts to obtain and enforce patents.

Perhaps the most notable feature of the AIA is that as of March 16, 2013, the US patent system will shift from the current "first-to-invent" system to a "first-inventor-to-file" system, bringing the priority establishment of the US patent system into accord with that of other industrialized nations.

The First Person to File Wins the Race to the Patent Office

In the new first-inventor-to-file system under the AIA, the first inventor to file a patent application on a new invention will get the right to attempt to obtain a patent, regardless of who first discovered the invention. However, much like under current US patent laws, inventions described in US patent applications filed on or after March 16, 2013 will not qualify for US patent protection if the invention has been earlier disclosed in an issued US patent, a published US patent application, or an international patent application designating the US that names another inventor and has an effective filing date prior to the effective filing date of the application.[2] Thus, under the new patent laws, a person who invents first, but files an application after someone else files a patent application on the same subject matter will not have the right to a patent (*Fig. 1*).

However, the AIA also provides three exceptions to this strict rule: prior disclosure will not bar patentability of the invention if the subject matter of the disclosure was obtained from any of the inventors; the disclosure was preceded by a public disclosure of the invention prior to the effective filing date of the application by the inventors or by another who obtained the subject matter from any of the inventors; or the subject matter of the disclosure and the invention were commonly owned by the same person or subject to an obligation of assignment to the same person (for example, as under a joint research agreement) on or before the effective filing date of the patent application.[2]

Per the AIA, the term "inventor" is explicitly defined as the individual or *the individuals collectively* (in the case of a joint invention) who invented or discovered the subject matter of an invention.[3] This means that a prior disclosure can be used against a later patent application if the inventorship for the application and the prior disclosure differ at all, even if the two documents have one or more inventors in common. Under the current system, so-called "interference" proceedings can be used to determine who first invented an invention when it has been claimed by two different inventors who each filed their own patent application. [4] Patent applications filed in the US before March 16, 2013 will continue to be governed by such proceedings. However, under the AIA, the date of the invention is no longer relevant, and only the application filing date is considered. Thus, an interference proceeding is no longer relevant, and these types of proceedings will go the way of the dinosaur once there are no longer any applications pending that were filed under the old laws.

The Prior Art Expanded

The AIA also expands the definition of what types of documents and information can be used to invalidate a patent or prevent a patent application from issuing as a patent. Such documents and information, as well as other types of public disclosures, are called "prior art." After March 15, 2013, the AIA further stipulates that an invention will no longer be eligible for patentability if the invention has been patented or published; is in public use or on sale; or is otherwise available to the public *anywhere in the world prior to the effective filing date* of the patent application.[2] Under current US patent laws, publications made after the invention date and *domestic* public uses and offers for sale within one year of the filing date are not deemed prior art. In contrast, under the new US patent laws, publications, public uses and sales, and offers for sale anywhere in the world before the effective filing date of the patent application are considered when assessing patentability. Thus, prior art searches must now be done in an even more comprehensive way than was sufficient in the past.

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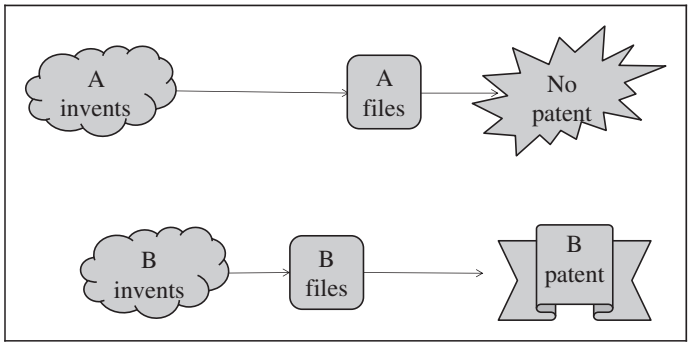

Fig. 1. A patent applicant who invents first, but files second (A) will not have the right of priority over a second party who invents second, but files first (B).

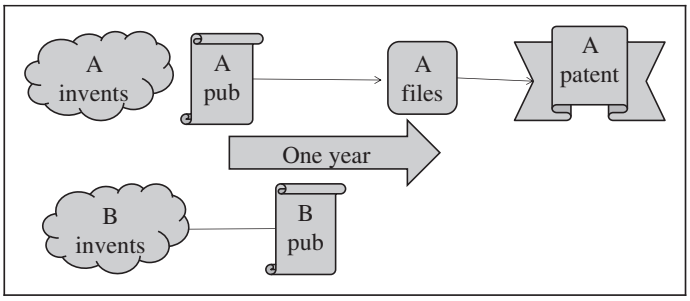

Fig. 3. A publication that occurs between a patent applicant's public disclosure and the filing date of the patent application will not be considered prior art as long as the applicant's public disclosure is within one year of the filing date of the application.

The new patent laws still provide a one-year grace period during which an inventor can seek protection of his invention following a public disclosure of the invention if either the disclosure was made by the inventor himself (or a joint inventor) or by another who obtained the subject matter disclosed from the inventor (or a joint inventor); or the disclosure was preceded by a public disclosure of the invention by the inventor himself (or a joint inventor) or by another who obtained the subject matter of the disclosure from the inventor (or a joint inventor).[2] In other words, an inventor will still have a one-year grace period from the date that he publicly discloses his invention to seek US patent protection of that invention, as is the case under the current patent laws. However, this grace period is subject to different conditions than that of the current patent laws, which provide a one-year grace period for filing a patent application with respect to *all* disclosures, not just those disclosures made by the inventor. Therefore, in situations where another party publishes a reference describing the invention within one year of the filing date of the patent application, the applicant will no longer be able to "swear behind" the reference (*Fig. 2*) as is possible under the current laws. What remains unclear according to the wording of the AIA is whether or not public uses or offers for sale by the inventor are also considered as disclosures.

For example, under the new patent laws, a patent applicant that makes a public disclosure within one year before filing the patent application will not be prohibited from obtaining a patent on the invention if the invention is published by another between the date of the public disclosure and the filing date of the patent application (*Fig. 3*). However, such a public disclosure will negatively affect foreign patent rights, and so one should always seek to file a patent application before making a public disclosure anywhere in the world if foreign patent rights are desired.

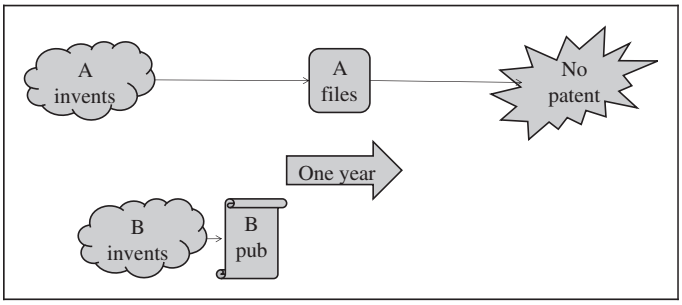

Fig. 2. A patent applicant (A) can no longer swear behind a publication by another (B) within one year of the filing date.

The first-to-file change will also affect the non-obviousness requirement of claimed inventions, specifically with respect to biotechnological processes. Under current US patent laws, a biotechnological process using or resulting in a composition that is patentable can itself be considered non-obvious if claims to both the process and the composition are contained in the same patent application or contained in separate patent applications having the same effective filing dates *as long as* both the composition and the process, at the time the process was invented, were owned by the same person or company.[5] This effectively limits the body of prior art that can be used to bar patentability of certain claimed biotechnological process inventions. However, effective March 16, 2013, these special provisions for biotechnological process inventions will be abolished, and the non-obviousness requirement of the US patent system will be simplified to bar patentability of an invention if the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the relevant field.[6] Thus, implementation of the first-to-file rule shifts the application of non-obviousness forward from the date of the invention to the *effective filing date* of the patent application for that invention. Common ownership of an invention on or before the effective filing date of the patent application may, however, shield the application against obviousness rejections over some prior disclosures.

Potential Loss of First-to-Invent Status in Continuation Applications

As noted above, the AIA's first-to-file provisions and prior art rules will go into effect on March 16, 2013. Any application filed before March 16, 2013 or a continuation application claiming priority to an application (a provisional, continuation, or divisional application) filed before March 16, 2013 will still benefit from the

present first-to-invent rules. However, the new (and sometimes less desirable) AIA's rules will strictly apply to any application that ***ever*** contains a claim that has an effective filing date on or after March 16, 2013, and any continuation or divisional application that claims priority to such an application. Since continuation and divisional applications and the amendment of claims are typical in biotech and chemical industry patent application filing and prosecution strategies under the current US patent laws, it is very important to learn of this potential pitfall before it is too late.

The new rules "shall apply to any application for patent, and to any patent issuing thereon, that *contains or contained at any time*… a claim to a claimed invention that has an effective filing date … that is on or after the effective date [March 16, 2013]."[7] This language in the new rules means that any application that claims priority from an earlier application filed prior to March 16, 2013 may nevertheless lose its first-to-invent status if the United States Patent and Trademark Office (USPTO) determines that at least one claim in the new application is not sufficiently supported in the earlier priority application. Importantly, the AIA does not indicate that the first-to-invent status can be reinstated after withdrawal of a new matter rejection, so cancelling the offending claim will not solve the problem. To make matters worse, the new rules indicate that not only would the rejected claim lose its first-to-invent status, but all the claims in the pending application *and* all future continuation and divisional applications based on that application would lose their first-to-invent status. It is clear that the new rules seek to reduce the number of applications pending that qualify for review under the old rules. Thus, great caution must be taken when adding new claims or revising existing claims in an application filed after March 16, 2013 that claims priority of an earlier application, especially in scenarios in which the applicant must rely on the date of invention to get behind and remove prior art, which would be impossible if the new rules were applied to the application.

Claims Directed to a Human Organism

The USPTO for a number of years has implemented a policy that human organisms are excluded from the scope of patentable subject matter under 35 U.S.C. § 101.[8] For example, the Manual for Patent Examination (M.P.E.P.) instructs that "[i]f the broadest reasonable interpretation of the claimed invention encompasses a human being, then a rejection under 35 U.S.C. 101 must be made indicating that the claimed invention is directed to nonstatutory subject matter."[9] The USPTO has implemented this policy without statutory or legal authority. However, the newly implemented AIA provides statutory support for the USPTO's position on this issue. Specifically, Section 33(a) of the AIA states that "[n]otwithstanding any other provision of law, no patent may issue on a claim directed to or encompassing a human organism." In drafting claims to cells, nucleic acids, and proteins, biotech applicants should take care to ensure that their claim language clearly excludes humans from the scope of the claims.

The USPTO and Personalized Medicine

Section 27 of the AIA is one of the few provisions that may impact the biotechnology industry directly and specifically. The "study on genetic testing" described in this section mandates that the Director of the USPTO conduct a study on "effective ways to provide independent, confirming genetic diagnostic test activity where gene patents and exclusive licensing for primary genetic diagnostic tests exist."[10] In particular, the study is required to include an examination of the following: the impact that the current lack of independent second opinion testing has had on the ability to provide the highest level of medical care to patients and recipients of genetic diagnostic testing, and on inhibiting innovation to existing testing and diagnoses; the effect that providing independent second opinion genetic diagnostic testing would have on the existing patent and license holders of an exclusive genetic test; the impact that current exclusive licensing and patents on genetic testing activity have on the practice of medicine, including but not limited to the interpretation of testing results and performance of testing procedures; and the role that cost and insurance coverage have on access to and provision of genetic diagnostic tests.[11]

This is one of the few provisions of the AIA that went into effect immediately upon enactment of the AIA, and requires that the USPTO provide a report and recommendations to Congress by June 2012. The USPTO is to use this genetic testing study to provide input on how gene patents affect personalized medicine. The design of the study has yet to be completed, and the USPTO is accepting comments on how to address the issue of independent second opinion genetic diagnostic testing and its relationship to medical care and medical practice, the rights of innovators, and considerations relevant to medical costs and insurance coverage, among other issues relevant to the study. The results of this study may stimulate additional further legislation in the area of patent law.

Conclusions

While the new patent laws under the AIA go a long way to harmonize the US patent laws with those in other countries, they are also filled with potential traps for the unwary once certain deadlines for implementation have passed. We have highlighted some of the provisions that will have an impact on the biotech sector, and while one can debate whether the new rules will makes things better or worse for obtaining and enforcing patents in this sector, patent applicants and patent owners are best served by learning how to use the new rules, which are here to stay for the foreseeable future, to their advantage.

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