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The America Invents Act: Changes in the Patent Laws of Special Interest to the Life Sciences Industry




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Introduction

After several years of unsuccessful attempts, Congress recently passed the Leahy-Smith America Invents Act (the ''AIA''),[1] containing the most significant changes to the Patent Act in more than 60 years. President Obama signed the AIA into law on Sept. 16.[2] This article presents an overview of the major provisions that are significant for practitioners in the life sciences.[3]

A Brief History of the AIA

The AIA is the result of Congress's several past attempts to address perceived inefficiencies in the U.S. patent system. Rep. Lamar Smith (R-Texas) first advanced a bill aimed at comprehensive ''patent reform,''[4] contrasting in scope to the piecemeal amendments over the years since the 1952 Patent Act.[5] Submitted in re-

[1] H.R. 1249 (112th Congress).
[2] Pub. L. No. 112-29.
[3] The authors recognize that there is no monolithic ''life sciences industry'' that speaks with one voice on all issues, but instead use this term to address views that may be common or shared among individuals and entities advancing or using technologies in the biomedical or biotechnological sciences.
[4] H.R. 2975 (109th Congress).
[5] Act of July 19, 1952, codified as Title 35 of the United States Code.

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sponse to reports by the Federal Trade Commission and National Academy of Sciences, the 2005 bill contained numerous changes to the patent laws, including, among other things, moving the United States to a first-to-file system. Other significant changes were proposed: allowing for third-party ''protests'' during the application process; creating a system for post-grant oppositions; limiting willful infringement claims to only when a plaintiff notifies the defendant of infringement and the defendant is found to infringe; eliminating the claim of inequitable conduct, and replacing it with a duty of candor with the U.S. Patent and Trademark Office (USPTO); and adding a ''fairness'' requirement to the injunction analysis. Congress did not act on this proposed legislation.

Similar bills were introduced in the House of Representatives and the Senate two years later.[6] Additional provisions were proposed that went beyond the reforms contained in the 2005 bill, including:

- requiring a court determination of the patent's contribution over the prior art for the damages analysis;
- allowing third parties to submit prior art during the application process;
- expanding venue to districts where either party resides;
- defining ''inventor'' to include joint inventors and co-inventors; and
- banning tax planning patents.

Responding to growing damages awards in several high-profile patent infringement lawsuits concerning consumer electronics and telecommunications technologies, the 2007 bills proposed and sought comment on the statutory limitations to patent infringement damages. But the life sciences industry expressed concern about provisions limiting patent damages and claimed those provisions were lowering the disincentive for infringement, especially because many life-science patents are the result of years of research.[7] Other aspects of the 2007 bills drew criticism from those in the life sciences, including lower standards for post-grant review and permitting the USPTO to make substantive interpretations of patent law.[8]

The 2007 bills therefore exposed considerable differences between the life sciences and electronics industries over the most pressing problems in the laws that needed reform—differences that continue to exist to a certain extent today. Life sciences companies generally advocated for stronger patent rights to protect pipelines of high-cost pharmaceutical products and medical devices resulting from billions of dollars of prior investment. Those operating in the world of consumer electronics, on the other hand, sought more limits on damages that had grown to gargantuan proportions because of the multiplier effect from high-volume sales of relatively low-cost infringing products. Perhaps because the competing views of these major stakeholders proved irreconcilable, even though the House bill passed, the Senate never took it up.

In 2009, the Senate made a third attempt at patent reform, led by Sens. Orrin G. Hatch (R-Utah) and Patrick Leahy (D-Vt.). Although this bill largely resembled Congress's two prior efforts, it included some major changes. It omitted provisions related to inequitable conduct and USPTO's ability to make substantive rules related to patent law. The bill contained provisions that were designed to limit patent damages, such as broadening the venue statute, tightening restrictions on findings of willful infringement that could give rise to enhanced damages, and establishing statutory criteria for proving a ''reasonable royalty'' as a damages benchmark. The 2009 bill also proposed expanding invalidating ''public uses'' to occur anywhere in the world, allowing for patent reexamination based on prior use or sale, and permitting third parties to submit relevant prior art during prosecution. As it had before, practitioners in the life sciences maintained their opposition to limitations on patent damages and any provision that would restrict patent strength and potentially encourage infringement.

The call for patent reform was revived in the 112th Congress. Bills introduced in House[9] and Senate[10] committees were heavily debated and were the target of extensive lobbying efforts. The Senate bill passed on March 8 and the House bill passed on June 23. On Sept. 8, the Senate voted 89-9 to send H.R. 1249 to the White House; President Obama signed the AIA into law, stating that this ''much-needed reform will speed up the patent process so that innovators and entrepreneurs can turn a new invention into a business as quickly as possible.''[11]

The history of the AIA's passage reveals that many of the provisions those in life sciences objected to are absent in the final law. Perhaps most importantly to the biomedical community, provisions limiting damage awards were excluded, along with provisions that would have expanded the rulemaking authority of the USPTO. Yet the industry was unsuccessful in persuading Congress to keep the standard for post-grant review at ''substantial question of patentability.'' Overall, the AIA was well-received by the representatives of large life sciences institutions as providing a transparent, predictable and objective patent system that would help boost innovation and jobs in America.[12]

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[6] H.R. 1908 (110th Congress), S. 1145 (110th Congress).

[7] ''Patent Reform Act Favors High Tech Over Bio Tech,'' Sept. 7, 2007, available at http://www.infoworld.com/t/tech-industry-analysis/patent-reform-favors-high-tech-over-biotech-746; The Statement of the Biotechnology Industry Organization on H.R. 1908, The Patent Reform Act of 2007, April 26, 2007, available at http://www.bio.org/node/796.

[8] The Statement of the Biotechnology Industry Organization on H.R. 1908, The Patent Reform Act of 2007, April 26, 2007, available at http://www.bio.org/node/796.

[9] H.R. 1249 (112th Congress).

[10] S. 23 (112th Congress).

[11] Press release, White House Office of the Press Secretary, Sept. 16, available at http://www.whitehouse.gov/the-press-office/2011/09/16/president-obama-signs-america-invents-act-overhauling-patent-system-stim.

[12] Passage of America Invents Act to Result in Biotech Jobs, March 10, available at http://www.pharmaceutical-jobs.com/pharmaceutical-news/passage-of-america-invents-act-to-result-in-biotech-jobs; Life Technologies Applauds Signing of Patent Reform Bill, Sept. 16, 2011, available at http://www.prnewswire.com/news-releases/life-technologies-applauds-signing-of-patent-reform-bill-129943938.html; BIO Praises Final Passage of Patent Reform Legislation, Sept. 8, available at http://www.bio.org/media/press-release/bio-praises-final-passage-patent-reform-legislation.

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Becoming a First-to-File Patent System

One of the major changes in the AIA is to move the U.S. patent system from first-to-invent toward a first-to-file system consistent with other major patent systems around the world.[13] The first thing to note is that the provision will not go into effect until March 16, 2013. Until then, patent applications will be examined under current laws. Those inventors with an early date of conception which is well documented should consider filing an application prior to March 16, 2013, to obtain the benefit of the old patent laws, such as the first-to-invent standard.

After March 16, 2013, a claimed invention is not patentable if it ''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 described in a patent or application that ''names another inventor and was effectively filed before the effective filing date of the claimed invention.''[14]

The move to the first-to-file system will eliminate the traditional interference proceeding to determine inventorship, a mainstay of the patent system for decades.[15] Disputes over inventorship will now be resolved in derivation proceedings, discussed later. Under a first-to-file regime, first conception and reduction to practice will not govern entitlement to a patent. Instead, the first-filed patent application will be entitled to patent protection.

Supporters of this fundamental change believe that the bright-line first-filing rule will bring transparency and predictability to the patent system because parties will not have to worry about the additional costs and uncertainty surrounding proving conception and reduction to practice before another alleged inventor.[16] Opponents, on the other hand, argue that small companies and individual inventors will be at a disadvantage because in general, limited resources will constrain the number and frequency of their patent applications. Both sides in this debate draw parallels with Canada's experience of switching from a first-to-invent to a first-to-file patent system in 1989,[17] yet it remains unclear how this change will manifest itself in the United States. Specifically for the life sciences, a major concern may arise for small, spin-off businesses from universities and companies that are based on a single or small number of inventions. University spin-off companies, for example, may want to consider requiring the university or parent corporation to pay for the filing of a patent application before or at the time of spin-off to provide the small company with the patent protection that it will need to become a valuable and viable venture. In addition, those companies may face additional concerns regarding ''public disclosure'' of their inventions in order to raise capital or investments. Those disclosures may become prior art against a later-filed application if the companies are not diligent in seeking patent protection.

Opponents also point to the concern that patent applications will be hastily drafted to get an application on file as soon as possible. A premature application may lack the detail necessary to satisfy strict written description requirements under 35 U.S.C. § 112, first paragraph.[18] For patents in the life sciences, the amount and detail of description provided in the application is critical to not only obtaining a single patent, but also to the development of a comprehensive estate protecting a family of related inventions, obtained through continuation and divisional applications.

In implementing the first-to-file system, the AIA considerably broadens the scope of anticipatory prior art. Previously, the prior use and on-sale bar provisions of 35 U.S.C. § 102(b) provided for anticipation when ''the invention was . . . in public use or on sale *in this country*.''[19] After amendment, however, anticipation occurs when ''the claimed invention was . . . in public use, on sale, or otherwise available to the public before the effective filing date,''[20] meaning that an invalidating use or sale of an invention could occur anywhere in the world.

In addition, the Federal Circuit has held that a sale under Section 102(b) ''is not limited to ultimate users of the product,'' and has ''rejected the argument that sales activity kept secret from the trade does not trigger the on-sale bar.''[21] This interpretation is consistent with the goal requiring prompt invention disclosure as a condition for patentability as promoting of the progress of science and the useful arts, a goal confirmed by more than 200 years of Supreme Court interpretation of Constitutional and statutory provisions for patent protection.[22]

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[13] *E.g.*, AIA, § 3(p) (''SENSE OF CONGRESS.—It is the sense of the Congress that converting the United States patent system from 'first to invent' to a system of 'first inventor to file' will improve the United States patent system and promote harmonization of the United States patent system with the patent systems commonly used in nearly all other countries throughout the world with whom the United States conducts trade and thereby promote greater international uniformity and certainty in the procedures used for securing the exclusive rights of inventors to their discoveries.'').

[14] AIA, § 3(b) (amending 35 U.S.C. § 102).

[15] AIA, § 3(j) (eliminating references to interference in applicable sections of Title 35).

[16] *E.g.*, AIA, § 3(o) (''SENSE OF CONGRESS.—It is the sense of the Congress that converting the United States patent system from 'first to invent' to a system of 'first inventor to file' will . . . provide inventors greater certainty regarding the scope of protection provided by the grant of exclusive rights to their discoveries.'').

[17] *See, e.g.*, 157 Congressional Record S1178-79, daily edition March 3, 2011, (remarks of Sen. Coons), Hearing on H.R. 1249 before the House Subcommittee on Intellectual Property, Competition and the Internet, 112th Congress (2011) (statement of David J. Kappos, undersecretary of Commerce for intellectual property and director of the USPTO); *but see e.g.*, 157 Congressional Record H4428-29, daily edition June 22, 2011, (remarks of Rep. Manzullo), 157 Congressional Record S1094, daily edition March 2, 2011 (remarks of Sen. Feinstein).

[18] *See e.g.*, *Ariad Pharms. Inc. v. Eli Lilly & Co.*, 595 F.3d 1329, 1352-53 (Fed. Cir. 2009) (noting reference to the written description requirement as a super-enablement or heightened disclosure requirement targeted at biotechnology inventions).

[19] Unless indicated otherwise, all emphasis is added.

[20] AIA, § 3(b) (amending 35 U.S.C. § 102).

[21] *Brasseler U.S.A. I L.P. v. Stryker Sales Corp.*, 182 F.3d 888, 891 (Fed. Cir. 1999) (citations omitted).

[22] *E.g.*, *Pennock v. Dialogue*, 27 U.S. (2 Peters) 1, 4 (1829) (Story, J.) (confirming the unavailability for patent protection where an invention was ''known or used by the public'' prior to application, and affirming a decision where a jury charge stated that ''if the public, with the knowledge and the tacit consent of the inventor, is permitted to use the invention without opposition, it is a fraud upon the public afterwards to take out a patent''); *see also*, *Woodbridge v. United States*, 263 U.S. 50,

The AIA construction departs from this interpretation, however, as the inclusion of the phrase ''*or otherwise available to the public*'' suggests that invalidating sales must be at least as public as invalidating public uses. It remains to be seen what issues of statutory interpretation emerge from newly-amended 35 U.S.C. § 102(a)(1). Further, this new language in the AIA includes public disclosure anywhere in the world, while the prior on-sale bar was limited to sales in the United States. As companies have an ever-growing global reach, they must be aware of any such public disclosures of the invention anywhere in the world that may occur before filing the application. This new provision may have an impact on known business strategies of introducing products in foreign markets prior to introduction in the United States.

At the end of the day, adopting a first-to-file system is, without doubt, a fundamental change to the patent system. All companies, including those in the life sciences, should analyze and reevaluate their patent practices. Initially, it may be worthwhile to accelerate the filing of patentable ideas in a company's pipeline before the change to get the benefit of the first-to-invent priority—especially in cases where strong evidence of an early conception and reduction to practice exists.

For obvious reasons, once implemented, this new first-to-file system rewards earlier disclosures and filings more than the previous first-to-invent system, placing greater pressure on internal practices and procedures for filing patent applications. It almost certainly will be beneficial to establish new procedures that encourage inventors to work with patent counsel as an invention is reduced to practice to increase the efficiency of filing. Patent counsel may need to be involved in the early strategic planning stages of development in order to identify patentable inventions early on and prepare applications that meet the drafting requirements of Section 112. Existing practices likewise will require modification to fully protect inventive subject matter. Depending on the particular field, or the complexity or life cycle of the planned commercial embodiment, these changes may include filing more provisional, partial applications, and/or continuation-in-part applications. Regardless, companies in the life sciences should revisit and pay close attention to internal patent strategies and procedures in light of the first-to-file system under the AIA provisions.

Prior Art Exceptions

The AIA replaces the blanket one-year ''grace period'' in former 35 U.S.C. § 102(b) with a narrower exception for disclosures made within one year of the effective filing date. But this exception applies only if one of the following situations is present: 1) the disclosure was made by the inventor or someone who obtained the information directly or indirectly from the inventor; or 2) the subject matter had been disclosed by the inventor or obtained directly or indirectly from the inventor.[23] An inventor may disclose the claimed invention before filing the application, but the AIA requires the inventor to file the application within one year of that disclosure.

The exceptions offer some advantages and disadvantages to the life sciences industry. On the one hand, the amendment encourages inventors to publish information that may disclose the claimed invention before filing an application, because that publication would have an earlier effective date than a competitor's later-filed application. Consistent with current practice, the exception provides the inventor with one year to file an application and obtain a patent on his or her own work disclosed in a publication. This incentive to publish furthers the policy aim of fostering public disclosure consistent with the notice function of patents. Moreover, given the pressure to publish results that is characteristic of research and development efforts in the life sciences, the ability to more freely disseminate information and still retain the right to patent may be a welcome change for technical personnel.

On the other hand, such additional disclosures carry additional administrative costs associated with monitoring the timing and content of disclosures. Particular care must be taken when deciding to publish reports describing even a portion of inventive subject matter before a patent application filing. As researchers issue publications on the progress of their research, there is a concern that such disclosures may preclude obtaining a patent if the proper controls are not in place to file a timely application. Given the potential problem of losing out on a valuable patent, life sciences companies must carefully evaluate their policies and practices governing pre-patent application publication.

The courts ultimately will determine the scope of a ''disclosure'' under this exception.[24] Like the phrase ''or otherwise available to the public,'' discussed above, the term ''disclosure'' is not specifically defined beyond the reference to Section 102(a)(1), and therefore the scope of public uses or sales constituting a disclosure is not clear. One key question to be resolved is whether, according to the new statute, a development agreement is a disclosure that would trigger the application of the exception. It is difficult to understate the importance of

56 (1923) (Taft, C.J.) (Any practice by the inventor and applicant for a patent through which he deliberately and without excuse postpones beyond the date of the actual invention, the beginning of the term of his monopoly, and thus puts off the free public enjoyment of the useful invention, is an evasion of the statute and defeats its benevolent aim.''); *Metallizing Eng'g Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516, 520 (2d Cir. 1946) (Hand, J.) (''It is a condition upon the inventor's right to a patent that he shall not exploit his discovery competitively after it is ready for patenting; he must content himself with either secrecy or legal monopoly.'').

[23] AIA, § 3(b) (amending 35 U.S.C. § 102).

[24] *Id.* (stating in new Section 102(a)(1) that a ''*disclosure* made 1 year or less before the effective filing date of a claimed invention shall not be prior art to the claimed invention.''). Addressing questions of this nature raised during debate, AIA cosponsor Rep. Smith stated that

> contrary to current precedent, in order to trigger the bar in the new 102(a) in our legislation, an action must make the patented subject matter ''available to the public'' before the effective filing date. Additionally, subsection 102(b)(1)(B) is designed to make a very strong grace period for inventors that have made a disclosure that satisfies 102(b). Inventors who have made such disclosures are protected during the grace period not only from their own disclosure but from other prior art from anyone that follows their disclosure. This is an important protection we offer in our bill.

157 Congressional Record, daily edition June 22, 2011 (remarks of Rep. L. Smith).

Whether this statement is sufficient to crystallize Congressional intent regarding ''disclosures'' remains to be established in future litigation.

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development agreements to many life sciences organizations, a common tool for sharing resources, raising capital, and developing useful and marketable products. Until some clarity emerges from courts, companies are well-advised to be cautious in the early days of the first-to-file system, and to file applications in a timely manner before potential disclosures are made in executing a development agreement.

The AIA also carves out patents and applications that will not be prior art under Section 102(a)(2) if the subject matter disclosed was obtained from the inventor, publicly disclosed by the inventor, or was owned by the same person or subject to assignment to the same person at the time of the effective filing date.[25] Under this provision, one's own patents and applications are not prior art, a benefit to inventions in life sciences characterized by a relatively long patent cycle in which a single product may feature several different inventions claimed in multiple patents.

Barriers to Filing on Behalf of Inventors

Having the power ''[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries,''[26] Congress squarely vested rights in an invention to the inventor.[27] The Patent Act furthermore establishes certain obligations that an inventor must fulfill to secure his or her right to the invention, including making a written application, or authorizing one to be made, accompanied by the inventor's oath and the filing fee.[28]

The AIA amends 35 U.S.C. § 115, the provision for the inventor's oath or declaration, to include several new features that may streamline the process of patenting inventions in the life sciences. The AIA maintains the current practice that ''each individual who is the inventor or joint inventor of a claimed invention in an application shall execute an oath or declaration in connection with the application.''[29] Consistent with the preexisting law, the oath or declaration must contain a statement of original inventorship, but adds a requirement that ''the application was made or was authorized to be made by the affiant or declarant.''[30] The AIA allows a patent applicant to submit a ''substitute statement'' under certain circumstances, including at least[31] the inability of an inventor to file an oath or declaration,[32] or, importantly, their refusal to do so when under an obligation to assign the invention.[33] The substitute statement must simply identify the individual and detail the circumstances that make the substitute statement necessary.[34]

Although the patent rules previously permitted filing when an inventor refused to sign or could not be reached,[35] the new subsections remove all procedural barriers to institutional entities filing patent applications to protect the inventions of their employees, or indeed any person under an obligation to assign rights in an invention. Innovation in the life sciences depends on and thrives in a collaborative environment, where many different contributions synergize to reveal novel practical biological and medical applications of technology. After the AIA, companies, research institutions, and universities need only ensure that comprehensive agreements to assign are in place that specify a present intention to convey rights to the invention[36] to avoid an inability to file a patent application on a later invention should any inventor in the collaboration be unable or unwilling to execute the required oath.

Another important amendment to Section 115 includes a liberal standard for withdrawing, replacing, or correcting an oath, declaration, or substitute statement ''at any time.''[37] The AIA also goes further and expressly precludes invalidity or unenforceability of a patent as long as any failure to comply with the oath requirements is remedied.[38] These provisions will almost certainly assist the development of the comprehensive patent families critical for protecting complex inventions in the life sciences such as pharmaceutical products and methods of their use because companies will not have to obtain consent for correcting an oath from a disgruntled researcher or have to worry about possible challenges on the validity or enforceability during litigation for failure to obtain a proper oath.

Complementary amendments to 35 U.S.C. § 118 further ease procedural burdens by broadening existing law relating to filing an application. After amendment, any ''person to whom the inventor has assigned or is under an obligation to assign may make an application for patent.''[39] Moreover,

> [a] person who otherwise shows *sufficient proprietary interest in the matter may make an application* for patent on behalf of and as agent for the inventor on proof of the pertinent facts and a

[25] AIA, § 3(b) (amending 35 U.S.C. § 102).

[26] U.S. Constitution Article I, § 8, clause 8.

[27] 35 U.S.C. § 101 (''Whoever invents or discovers any new or useful process, machine, manufacture, or composition of matter . . . may obtain a patent therefor.''); *Bd. of Trs. of the Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc.*, 563 U.S. ___, 131 S.Ct. 2188, 2194 (2011) (''[a]lthough much in intellectual property law has changed in the 220 years since the first Patent Act, the basic idea that inventors have the right to patent their inventions has not.''); *Gayler v. Wilder*, 51 U.S. (10 How.) 477, 493 (1851) (''the discoverer of a new and useful improvement is vested by law with an inchoate right to its exclusive use, which he may perfect and make absolute by proceeding in the manner which the law requires.''); *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 188 (1933) (an inventor owns ''the product of [his] original thought.'').

[28] 35 U.S.C. § 111(a).

[29] AIA, § 4(a) (amending 35 U.S.C. § 115).

[30] *Id.*

[31] *Id.* (providing that the Director (the ''Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office'') may specify additional circumstances by regulation).

[32] *Id.* (providing death, legal incapacity or ''cannot be found or reached after diligent effort'' as examples).

[33] *Id.* (permitting a substitute statement for an individual who ''is under an obligation to assign the invention but has refused to make the oath or declaration required'').

[34] *Id.* (providing that the Director may specify additional requirements).

[35] *See* 37 C.F.R. § 1.47(a).

[36] *See FilmTec Corp. v. Allied-Signal Inc.*, 939 F.2d 1568, 1572 (Fed. Cir. 1991) (indicating that language in a contract that an inventor ''agrees to assign'' fails to indicate a present intent to convey a future right, requiring instead a statement that the inventor ''do[es] hereby assign [his] right, title and interest'' in any invention).

[37] AIA, § 4(a) (amending 35 U.S.C. § 115).

[38] *Id.*

[39] AIA, § 4(b) (amending 35 U.S.C. § 118).

showing that such action is appropriate to preserve the rights of the parties.[40]

This provision of Section 118 seems to indicate that an actual assignment or obligation to assign may not be necessary to permit a sponsoring organization from filing an application. Finally, Section 118 confirms that if a patent issues from an application filed by a party with proprietary interest, ''the patent *shall be granted* to the real party in interest,''[41] ostensibly obviating the need for any subsequent assignment from an inventor.

Together with provisions for satisfying the oath or declaration requirement, this filing and granting provision takes a recalcitrant inventor out of the loop, and greatly reduces the possibility that an inventor can deprive a sponsoring institution of rights to an invention developed within the scope of the relationship governed by an obligation to assign. But in general, these new provisions are designed to facilitate filing, which helps foster the successful implementation of the new first-to-file regime.

The protections provide a palpable benefit to large sponsoring institutions that produce the majority of inventions in the life sciences. For one, the new legislation lessens the pre-filing burden of investigating all possible inventors that must sign on to an application if defects are curable any time after filing. The new law almost certainly means the end of the ''omitted co-inventor'' problem that extensive pre-filing investigation was meant to prevent. As an example of this scenario, an exclusive licensee to a patent naming a sole inventor sues a competitor for infringement. As the lawsuit unfolds, however, the competitor learns that another person was a co-inventor, was not under an obligation to assign his rights, and was not named on the patent. The competitor confirms that the omitted co-inventor does not consent to the exclusive licensee's lawsuit, and for good measure, obtains a retroactive license from the omitted co-inventor. In a case with these facts, the Federal Circuit dismissed the exclusive licensee's lawsuit for failing to obtain the participation of the co-inventor.[42]

What the AIA does not do, however, is establish the criteria necessary to place an inventor under an ''obligation to assign'' to another entity for purposes of filing a patent application or subsequent patent ownership under Section 118. In 1991, the Federal Circuit held in *FilmTec Corp. v. Allied-Signal Inc.* that a present assignment of a right in a future invention (as opposed to a promise to assign future rights) is necessary to transfer legal title to the assignee upon making that invention.[43] The Federal Circuit continues to confirm that the language of a contract is dispositive in determining whether a contractual provision is either a present assignment of future rights effecting a transfer of legal title, or merely a promise to assign rights in the future that may only convey equitable rights,[44] insufficient for full enforcement.[45] In the recent *Stanford* case involving the reach of the Bayh-Dole Act, the Supreme Court did not address the validity of the Federal Circuit's rule in *FilmTec*.[46] The extent to which the terms of any particular agreement oblige an employee or contractor to assign an invention to his or her employer or sponsor is an issue that will continue to be resolved in the courts.

Post-Issuance Review Procedures

The AIA institutes post-issuance procedures available to both patent owners and other parties under the Patent Laws. Four procedures are discussed below: post-grant review, inter partes review, supplemental examination, and derivation proceedings.[47] Collectively, these procedures not only challenge the USPTO to implement effective mechanisms for invalidating bad patents and strengthening good ones, but also promise to transform the practice of patent law for many years to come.

Post-Grant Review and Inter Partes Review

Current law[48] provides for inter partes reexamination,[49] under which ''[a]ny third party requester at any time may file a request for inter partes reexamination'' based on prior art patents or printed publications that have a bearing on that claim's patentability.[50] Amendments in the AIA partition the post-issuance period to accommodate two mutually exclusive review mechanisms, each designed to challenge issued patent claims: post-grant review in the first nine months after issuance, and thereafter, inter partes review.[51] These two

[40] *Id.* (emphasis added).

[41] *Id.* (emphasis added) (also requiring ''such notice to the inventor as the Director considers to be sufficient'').

[42] *Ethicon Inc. v. United States Surgical Corp.*, 135 F.3d 1456 (Fed. Cir. 1998); *see Schering Corp. v. Roussel-UCLAF SA*, 104 F.3d 341, 345 (Fed. Cir. 1997) (stating that ''one co-owner has the right to impede the other co-owner's ability to sue infringers by refusing to voluntarily join in such a suit'').

[43] 939 F.2d 1568, 1573 (Fed. Cir. 1991)

[44] *E.g.*, *Speedplay, Inc. v. Bebop, Inc.*, 211 F.3d 1245, 1253 (Fed. Cir. 2000); *see also*, *Stanford*, 131 S.Ct. at 2203 (Breyer, J. dissenting) (noting that ''a present assignment of future inventions . . . conveyed equitable, but not legal, title'') (citations omitted).

[45] *E.g.*, *Arachnid Inc. v. Merit Indus. Inc.*, 939 F.2d 1574, 1578-79 (Fed. Cir. 1991) (citing *Crown Die & Tool Co. v. Nye Tool & Mach. Works*, 261 U.S. 24, 40-41 (1923)).

[46] *Stanford*, 131 S.Ct. at 2194 n.2.

[47] The AIA provides an important fifth post-issuance review mechanism, the Transitional Program for Business Method Patent Review, not discussed in this article because of its limited relevance to the life sciences. AIA, § 18.

[48] Provisions for post-grant review and inter partes review take effect one year after enactment, on Sept. 16, 2012. AIA, §§ 6(c)(2), 6(f)(2).

[49] It is important to note that the AIA does not alter the availability of ex parte reexamination. 35 U.S.C. §§ 302-307. But in an amendment relevant to ex parte reexamination, the AIA broadened 35 U.S.C. § 301—''citation of prior art''—to permit, in addition to patents or publications, submission of inventor statements that were filed with the PTO or a federal court in which ''the patent owner took a position on any claim of a particular patent.'' AIA, § 6(g) (amending 35 U.S.C. § 301). Amended Section 301 now requires the submitter to ''include any other documents, pleadings, or evidence from the proceeding in which the statement was filed that addresses the written statement.'' *Id.* This section limits these statements and related documents to be used to determine the proper meaning of a patent claim in reexaminations or other post-issuance reviews. *Id.* It will be interesting to see how broadly courts interpret the phrase ''took a position on any claim,'' given the current practice of maintaining large patent families in which applications frequently claim priority to or share disclosures with patents that may have been the subject of litigation.

[50] 35 U.S.C. § 311 (citing 35 U.S.C. § 301).

[51] AIA, § 6.

  LSLR ISSN 1935-7257

procedures are similar to each other but differ in their timing, standard to initiate, and scope.

The new post-grant review provides that any person, other than the owner of a patent, may file a petition to cancel as unpatentable one or more claims of a patent on any ground of invalidity.[52] A petition seeking post-grant review must be filed within nine months of issuance. Proponents of the measure believed that post-grant review by third parties, a common feature of European patent systems, could be a useful mechanism to ''both help screen out bad patents while bolstering valid ones.''[53] Opponents argued that adoption of a mechanism akin to the European opposition would prompt a litigation boom in the USPTO that would consume scarce resources.[54]

Under the new procedure, the USPTO director[55] will determine whether to institute a post-grant review within three months after receiving a patent owner's response to a petition.[56] The standard of the director's review of the petition is a preponderance of the evidence: post-grant review is warranted if ''it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable.''[57] Alternatively, the law provides that a petition may be granted if it ''raises a novel or unsettled legal question that is important to other patents or patent applications.''[58] The director's decision of whether to institute a post-grant review may not be appealed. If granted, the post-grant review proceeding is conducted before a new body called the Patent Trial and Appeal Board (''PTAB'').[59]

The AIA provides that most of the details of post-grant review proceedings before the PTAB are to be prescribed by the director through rulemaking.[60] But the law does list certain important requirements, including the public availability of the proceedings; provisions for discovery; protections from abuse, including sanctions and protective orders; and permitting the patent owner to amend or cancel a challenged claim.[61] Perhaps betraying a slight bias in favor of rooting out bad patents, the law also provides that the ''petitioner shall have the burden of proving a proposition of unpatentability by a preponderance of the evidence.''[62] This evidentiary standard places significantly more pressure on a patentee to put forward sufficient evidence of an issued claim's validity than the Federal Circuit's clear and convincing evidence standard requires for invalidity in district court patent litigation.[63]

Practitioners now familiar with inter partes reexamination will find the AIA's inter partes review procedure to be a similar mechanism for post-issuance review of patents.[64] As before, any party other than the patentee may file a petition for inter partes review. While post-grant review must be sought within nine months after issuance, inter partes review can occur any time following nine months after issuance or the conclusion of post-grant review, if later.

Consistent with current practice in inter partes reexamination, inter partes review involves canceling an invalidity claim ''only on a ground that could be raised under section 102 or 103 and only on the basis of prior art consisting of patents or printed publications.''[65] This narrower scope distinguishes inter partes review from the more broad-ranging post-grant review procedure, which is available within the first nine months after patent issuance.

By and large, however, the procedure for an inter partes review closely resembles the provisions for post-grant review. A petition seeking inter partes review should be granted if ''there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.''[66] This standard is slightly lower than the preponderance of the evidence standard for post-grant review, and wholly replaces the ''substantial new question of patentability affecting a claim of a patent'' standard required to grant a petition seeking inter partes reexamination.[67] It will be interesting to see how, if at all, the USPTO interprets these different statutory standards.[68]

The jurisdiction of the PTAB extends to proceedings for granted petitions[69] for inter partes review,[70] with details of the procedure to be determined by rulemaking, but includes at least provisions for discovery, sanctions, and non-broadening amendments, as with post-

[52] AIA, § 6(d). The statute provides for invalidity under Section 282(b), which reflects a technical amendment of Section 282. See AIA, § 20. There is no substantive change in the availability of invalidity defenses in a patent infringement action.

[53] 157 Congressional Record H4425, daily edition June 22, 2011 (remarks of Rep. Goodlatte).

[54] *Id.* at H4428 (remarks of Rep. Manzullo) (noting that 5 percent of patents in Europe are opposed versus the 1.5 percent of U.S. patents that are challenged in patent litigation, and that Japan dropped its post-grant review provisions in 2004 because they consumed 20 percent of its patent office resources). Although not addressed in this article, it is interesting that congressional proponents pressed to house such sweeping new administrative procedures in the USPTO while at the same time resisting legislation that would stabilize the agency's budgets in part by ending the long-standing practice of fee diversion.

[55] Various sections of the AIA vest power in the director of the USPTO to devise rules and regulations governing disposition of petitions and the conduct of proceedings. *E.g.*, AIA, § 6(f).

[56] AIA, § 6(d) (amending 35 U.S.C. § 324). In addition, the director has the discretion to join multiple petitioners and consolidate granted petitions into a single post-grant review proceeding. *Id.* (amending 35 U.S.C. § 325).

[57] *Id.* (amending 35 U.S.C. § 324).

[58] *Id.*

[59] AIA, § 7 (replacing the Board of Patent Appeals and Interferences by amendment to 35 U.S.C. § 6).

[60] *Id.*, § 6(d) (amending 35 U.S.C. § 326).

[61] *Id.* The statute provides that amendments ''may not enlarge the scope of the claims of the patent or introduce new matter.'' *Id.*

[62] *Id.*

[63] *Hybritech Inc. v. Monoclonal Antibodies Inc.*, 802 F.2d 1367, 1375 (Fed. Cir. 1986) (noting that the ''burden of proof never shifts to the patentee to prove validity'' and that the ''presumption [of validity] remains intact and [the burden of proof remains] on the challenger throughout the litigation, and the clear and convincing standard does not change'').

[64] *Id.*, § 6(a) (amending 35 U.S.C. § 311).

[65] *Id.*

[66] *Id.* (amending 35 U.S.C. § 314).

[67] AIA, § 6(c); supra; see also 35 U.S.C. § 313.

[68] Manual of Patent Examining Procedure § 2642 (discussing the criteria for assessing the presence or absence of a substantial new question of patentability).

[69] As with post-grant review, the director's decision on the sufficiency of the petition is not subject to appeal. AIA, § 6(a) (amending 35 U.S.C. § 314).

[70] *Id.* (amending 35 U.S.C. § 316).

grant review.[71] Also similar to post-grant review, the petitioner has the burden of proving ''a proposition of unpatentability'' in an inter partes review proceeding by a preponderance of the evidence.[72]

For both post-grant review and inter partes review, a petitioner or real party in interest is not entitled to either PTAB procedure if it has brought a civil action challenging the validity of that patent.[73] The AIA also provides that any civil action will be automatically stayed if the petitioner brings a civil action challenging the validity of the petitioned patent until either: (1) the patent owner moves to lift the stay; (2) the patent owner asserts infringement against the petitioner in a counterclaim; or (3) the petitioner moves to dismiss the civil action.[74] Both review procedures may be terminated by written settlement at any time before a decision on the merits is received from the PTAB.[75] Both post-grant review and inter partes review result in a final, written decision from the PTAB regarding the patentability of challenged claims, and the issuance of a certificate reflecting claim cancellation or patentability, with or without amendment.[76] This final written decision may be appealed directly to the Federal Circuit.[77]

The AIA provides a strong and explicit estoppel provision for both post-grant review and inter partes review.[78] A petitioner for either procedure who receives a final written decision cannot assert invalidity of reviewed claims before the USPTO, a federal district court, or the International Trade Commission on the ground raised in the petition or any other ground that ''reasonably could have been raised'' during the review.[79] Estoppel may therefore persuade a petitioning party asserting invalidity by anticipation or obviousness to wait and file for inter partes review, which, if decided in favor of patentability, would leave non-prior art-based invalidity defenses available for presentation at a subsequent litigation. The same would not be true for an adverse decision under post-grant review, as estoppel requires raising all bases of invalidity that could have been raised. It remains to be seen whether such strong estoppel provisions will prevent the wholesale adoption of these new post-grant review and inter partes review procedures; the prospect, however, of invalidating claims by a preponderance of the evidence may provide adequate incentive in particular cases.

A party's decision to proceed under a post-grant review should be carefully considered. On the one hand, the post-grant review superficially allows a party access to fire a ''quick shot'' that might invalidate a patent and avoid the considerable costs and uncertainty associated with a district court proceeding. Importantly, a party may challenge validity without meeting the strict personal or subject matter jurisdiction requirements to sustain a patent validity challenge that in the absence of a civil action alleging infringement must be brought pursuant to the Declaratory Judgment Act. On the other hand, the diligence of the petitioning party in monitoring pending applications may be insufficient to permit adequate preparation to mount an effective post-grant review challenge in the nine-month window on grounds other than anticipation or obviousness. An unprepared challenger that receives a final written decision in the USPTO is estopped from a second invalidity attack in a district court.

Overall, post-grant review and inter partes review provide parties with potentially potent weapons in the arsenal for challenging the validity of a competitor's patent. The utility of these tools for patents and parties in the life sciences remains to be determined, and time will reveal the extent to which these mechanisms are put to actual use.

Supplemental Examination

The AIA provides for supplemental examination, a new procedure under which ''[p]atent owners will be able to improve the quality of their patents''[80] by asking the USPTO ''to consider, reconsider or correct information believed to be relevant to the patent.''[81] Sen. Hatch explained that,

> supplemental examination provision satisfies a long-felt need in the patent community to be able to identify whether a patent would be deemed flawed if it ever went to litigation and enables patentees to take corrective action.[82]

The legislative history makes it clear that supporters of this provision were most interested in having an error correction mechanism to address those flaws that could render a patent unenforceable for inequitable conduct in a litigation.[83]

The statute does not specify a time limit for requesting supplemental examination, although one may be

[71] *Id.*

[72] *Id.* The present reexamination statute does not contain an express evidentiary standard. 35 U.S.C. § 314.

[73] AIA. §§ 6(a) (amending 35 U.S.C. § 315(a)), 6(d) (amending 35 U.S.C. § 325(a)). Counterclaims are expressly not civil actions for purposes of post-grant review. Therefore, a defendant may submit invalidity counterclaims in addition to invalidity defenses in response to a complaint for patent infringement and sill retain the right to post-grant review of that patent.

[74] *Id.*

[75] *Id.*, §§ 6(d) (amending 35 U.S.C. § 327), 6(a) (amending 35 U.S.C. § 317).

[76] *Id.*, §§ 6(d) (amending 35 U.S.C. § 328), 6(a) (amending 35 U.S.C. § 318).

[77] *Id.*, §§ 6(d) (amending 35 U.S.C. § 329), 6(a) (amending 35 U.S.C. § 319), 7(c) (amending 35 U.S.C. § 141).

[78] *Id.*, §§ 6(d) (amending 35 U.S.C. § 325(e)), 6(a) (amending 35 U.S.C. § 315(e)).

[79] *Id.* The AIA maintains the broad ''raised or could have been raised'' standard that governs estoppel for inter partes reexamination decisions under 35 U.S.C. § 315(c). MPEP § 2686.04.

[80] 157 Congressional Record S951, daily edition Feb. 28, 2011 (remarks of Sen. Hatch).

[81] AIA, § 12 (amending 35 U.S.C. § 257(a)).

[82] 157 Congressional Record S1097, daily edition March 2, 2011 (remarks of Sen. Hatch).

[83] *E.g.*, 157 Congressional Record S5319, daily edition Sept. 6, 2011 (remarks of Sen. Jon Kyl, R-Ariz.) (''It is often the case that startup companies or university researchers cannot afford to hire the very best patent lawyers. Their patents are prosecuted by an in-house attorney who does a good enough job but who is unfamiliar with all of the sharp corners and pitfalls of the inequitable conduct doctrine, such as the need to present cumulative studies and prior art. Later, when more legally sophisticated investors evaluate the patent for potential investment or purchase, these minor flaws in prosecution can deter the investor from purchasing or funding the development of the invention. An investor would not risk spending hundreds of millions of dollars to develop a product if a potential inequitable conduct attack may wipe out the whole investment.'').

  LSLR ISSN 1935-7257

provided through the USPTO's rulemaking.[84] Upon review of a patent owner's petition for supplemental examination, the director may issue a certificate indicating that a ''substantial new question of patentability is raised by 1 or more items of information'' in a petitioner's request.[85] The statute commands the USPTO director to address each substantial new question of patentability in an ex parte reexamination ''notwithstanding the limitations'' prescribed by statute in Sections 301-307.[86] Taken as a whole, there is no limit to the patentability issues that may be addressed in supplemental examination.

Perhaps most strikingly, Congress provided for blanket protection from later charges of inequitable conduct based on a patentee filing a petition for supplemental examination. Under the new law,

> [a] patent shall not be held unenforceable on the basis of conduct relating to information that had not been considered, was inadequately considered, or was incorrect in prior examination of the patent if the information was considered, reconsidered, or corrected during a supplemental examination of the patent.[87]

In other words, any basis for unenforceability may be cured through supplemental examination if that basis is addressed in the petition. Protection from subsequent inequitable conduct claims is not available if inequitable conduct allegations had been pleaded with particularity in another proceeding, or if an earlier-filed litigation incorporates an invalidity defense based on the information that was considered, reconsidered, or corrected by a supplemental examination request.[88] Because of this provision, a patentee must seek supplemental examination before filing a patent infringement action to avoid liability for inequitable conduct.[89]

Nevertheless, supplemental examination, once in effect, will provide a new post-issuance avenue for correcting various errors made during prosecution that might otherwise invalidate issued claims or render a patent unenforceable. As originally proposed in the Senate and House bills, opponents of this measure were up in arms that supplemental examination could reward patent holders that knowingly falsify or intentionally omit information in an original application and will have a second chance to cure without consequence.[90] Perhaps in response, Rep. Smith submitted a manager's amendment that inserted the fraud provision, which permits cancellation of claims of a patent, or referral of the case to the attorney general for criminal prosecution, if a director ''becomes aware'' of evidence of ''a material fraud'' on the USPTO ''committed in connection with the patent that is the subject of the supplemental examination.''[91] Nevertheless, opponents remain skeptical, noting that this fraud provision ''tasks [the USPTO], which was unable to identify the original misrepresentation, with identifying deceptive conduct in a supplemental examination.''[92]

While supplemental examination holds out the significant benefit of strengthening a patent and correcting errors that may render it unenforceable, as with all post-issuance mechanisms advanced in the AIA, it remains to be seen whether it will enjoy widespread use. Perhaps the rules that will be promulgated to govern the conduct of supplemental examination will yield a clue as to whether parties reserve use of the procedure in limited cases to correct the most glaring errors or freely use it as a litmus test to evaluate a patent's strength in advance of an infringement suit.

Derivation Proceedings

In connection with the change to a first-to-file system, interferences have been substantially narrowed to cover only derivation proceedings that resolve prior inventorship.[93] Indeed, interference proceedings were only necessitated by a first-to-invent regime. By enacting the first-to-file system, the AIA eliminates all references to interferences in Title 35.[94]

Procedurally, a petition to institute a derivation proceeding must be filed within a year of publication of the same or substantially same claim.[95] The petition should show with particularity facts setting forth a basis for finding both that the named inventor on a patent derived that invention from the petitioner and filed the earlier application without authorization. The AIA requires a petitioner to submit these facts under oath, supported by substantial evidence, for the PTAB's consideration, which issues a final decision that may be appealed to the Federal Circuit.[96] As with an interference, if derivation is found, the PTAB may correct inventorship in any application or patent or deny the petition. A written statement of settlement may terminate a derivation proceeding as long as it is consistent with the evidence of record.[97] Additionally, the parties may voluntarily submit to arbitration for part or all of the contest where the award is dispositive of the issues that are raised.[98] Notwithstanding this new section, civil actions in the district courts still exist for derivation proceedings as they did for interferences.[99]

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[84] AIA, § 12 (amending 35 U.S.C. § 257(a)).

[85] *Id.* (amending 35 U.S.C. § 257(b)).

[86] *Id.* 35 U.S.C. § 307 provides for issuance of a certificate cancelling unpatentable claims, confirming patentable claims, and incorporating any proposed amended or new claim determined to be patentable. Intervening rights may be available to an accused infringer with respect to amended claims. 35 U.S.C. § 307(b).

[87] *Id.* (amending 35 U.S.C. § 257(c)).

[88] *Id.*

[89] 157 Congressional Record S1097, daily edition March 2, 2011 (remarks of Sen. Hatch) (''The request must be made before litigation commences. Therefore, supplemental examination cannot be used to remedy flaws first brought to light in the course of litigation, nor does it interfere with the court's ability to address inequitable conduct.'').

[90] 157 Congressional Record E1208, extensions of remarks June 24, 2011 (speech of Rep. Henry A. Waxman (D-Calif.)) (stating that supplemental examination ''amounts to a 'get out jail free card' for any company fearful of having their patent invalidated because they deceived the PTO'').

[91] AIA, § 12(a) (amending 35 U.S.C. § 257(e)).

[92] Letter from Robert Billings, executive director, Generic Pharmaceuticals Association, to Reps. Lamar Smith and John Conyers Jr., H.R. Judiciary Committee (May 3, 2011), available at http://www.gphaonline.org/sites/default/files/GPhA%20letter%20on%20H.R.%201249%2005.03.11.pdf.

[93] AIA, §§ 3(h), 3(i).

[94] AIA, § 3(j).

[95] AIA, § 3(i) (amending 35 U.S.C. § 135(a)).

[96] *Id.* (amending 35 U.S.C. §§ (a), (b)).

[97] *Id.* (amending 35 U.S.C. § 135(e)).

[98] *Id.* (amending 35 U.S.C. § 135(f)).

[99] AIA, §§ 3(h) (amending 35 U.S.C. § 291), 3(j) (amending 35 U.S.C. § 146).

Subject Matter Limitations

One of the three subject matter limitations provided for in the AIA may be of interest to practitioners in the life sciences: a codification of the Weldon Amendment[100] that prohibits the patenting of human organisms:

> (a) LIMITATION.—Notwithstanding any other provision of law, no patent may issue on a claim directed to or encompassing a human organism.[101]

The legislative history of this section indicates that this prohibition does not extend to chemical compounds; cells, tissues, or organs produced through human intervention; methods for creating human organisms, including methods such as in vitro fertilization, or a non-human organism incorporating one or more human genes.[102] Yet the broad language of the amended provision, in particular the ambiguous term ''directed to,'' suggests that further interpretation of the scope of this prohibition may follow from the USPTO and courts.

Litigation-Related Amendments

The AIA includes several provisions proposed to correct inefficiencies in patent litigation, both perceived and real. Some of these amendments are considered below.

Years of intense lobbying by computer technology companies had sensitized the drafters of the AIA to the growing number of patent infringement lawsuits naming several defendants whose only connection is a plaintiff's allegation that each infringes the same patent or patents.[103] Often, these lawsuits would be brought by a non-practicing entity. The suits would be filed frequently in jurisdictions thought to be ''plaintiff-friendly'' such as the Eastern District of Texas and the Central District of California.[104]

New Joinder Provision

In an effort to minimize the impact of the lawsuits, the AIA includes new subsection 35 U.S.C. § 299(a), which expressly restricts the filing of patent infringement lawsuits against multiple defendants unless the requirements consistent with rules governing permissive joinder[105] have been met.[106] As if to underscore the intent of Congress concerning this point, the AIA also amends the Patent Laws to include new subsection 35 U.S.C. § 299(b), which states,

> (b) ALLEGATIONS INSUFFICIENT FOR JOINDER.—For purposes of this subsection, accused infringers may not be joined in one action as defendants or counterclaim defendants, or have their actions consolidated for trial, based solely on allegations that they each have infringed the patent or patents in suit.[107]

Although ultimately intended to increase the procedural burden and cost to plaintiffs associated with bringing multiple lawsuits each naming a single defendant, it is not clear whether this new provision will affect the volume of patent infringement lawsuits.[108] Moreover, experience will show whether this new statutory provision may in fact increase costs for accused defendant-infringers, as oftentimes those defendants form joint defense groups to reduce and spread attorneys' fees and costs among them.

Patent infringement lawsuits involving life sciences generally do not feature such multiple-defendant lawsuits, however. The one exception may be lawsuits under the Hatch-Waxman Act where generic drug companies are often joined as defendants in a suit and consolidated trials are conducted. The AIA could limit that practice. Still, it remains to be seen whether the new joinder provisions will affect parties who turn to Multidistrict Litigation rules for relief.[109]

A Broad Prior Use Defense

Since its introduction in the Patent Laws, prior use rights protected entities that developed methods for doing and conducting business but kept those methods as trade secrets, rather than patenting them. If that commercially-used method became the subject of a later invention by another, Congress permitted the prior user to avoid infringement based on its prior use of the method.[110] But the prior use defense contained a number of significant limitations that restricted the application of the defense to a particular use, and importantly, did not establish patent invalidity by anticipation or obviousness solely because the patented business method had been used before the invention date.[111]

Perhaps to accompany the shift to a first-to-file regime, under which invalidity under 35 U.S.C. § 102(g) for prior invention is no longer viable, the AIA amended Section 273. But it is difficult to glean the justification for the substantial expansion of the availability and reach of the prior use defense to patent infringement, as the new law extends the prior use defense to all statutory classes of inventive subject matter, not just business methods.[112] Large companies may benefit from

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[100] The ''Weldon Amendment'' was a pro-life policy rider first introduced by Rep. David Weldon on July 22, 2003, in connection with the Commerce, Justice and Science Appropriations bill; the rider has passed in 2004 and every year since. 157 Congressional Record E1177-80, daily edition June 23, 2011 (speech of Rep. C. Smith) (appending the 2003 debate on the Weldon Amendment at E1178).

[101] AIA, § 33.

[102] 157 Congressional Record E1183, daily edition June 23, 2011 (speech of Rep. L. Smith)

[103] *See, e.g.*, *LVL Patent Group LLC v. Federal Express Corp.*, No. 11-cv-834 (D. Del. Sept. 15, 2011) (one of nine lawsuits alleging infringement of patents in a single family filed on the same day in the District of Delaware collectively naming 148 defendants).

[104] Despite the consideration of venue revisions in past patent reform efforts, substantive changes governing venue did not appear in the AIA. The one exception is a change in venue for lawsuits brought against the USPTO, which under the AIA, are to be brought in the Eastern District of Virginia. AIA, § 9.

[105] Fed. R. Civ. P. 20(a)(2) (stating that defendants may be joined if the right to relief (if not joint and several) arises from the same series of transactions or occurrences and questions of law or fact are common to all defendants).

[106] AIA, § 19(d).

[107] *Id.*

[108] By way of example, on Sept. 23, 2011, Network Signatures Inc. filed five complaints in the Central District of California alleging that five separate defendants infringed the same patent.

[109] 28 U.S.C. § 1407.

[110] 35 U.S.C. §§ 273(a)(3), (b)(1), (b)(3)(A).

[111] *Id.*, § 273(b)(3).

[112] AIA, § 5(a) (amending 35 U.S.C. § 273) (extending subject matter coverage to ''a process, or consisting of a machine,

  LSLR ISSN 1935-7257

this expansion by avoiding infringement of any process, machine or composition of matter upon a showing of its prior use, which, as with the original statute, may merely be connected with ''an internal commercial use.''[113] Put another way, products and processes put on the shelf may one day provide a freedom to operate despite a competitor's patent.

False Patent Marking

In another area less troublesome for life sciences than other industries, the AIA amended 35 U.S.C. § 292, the statute providing for liability for falsely marking a product with a patent with intent to deceive the public.[114] Previously, false-marking suits were brought as qui tam actions to recover a prescribed penalty of up to $500 per falsely-marked item on behalf of the United States. But after the AIA's amendment, only the United States may sue for that penalty.[115] In addition, only a ''person who has suffered a competitive injury'' may now bring a false-marking claim, but the amendment removes marking with expired patents as a basis for false-marking liability.[116] Finally, the amendments allow for virtual marking where a patentee can mark a product with ''patent'' or ''pat.'' and an address to a website that associates the patented article with the number of the patent.[117]

Conclusion

Practitioners and stakeholders in the life sciences may be split on whether the AIA will fulfill its promise of encouraging innovation, job creation, and economic growth. Political and policy considerations aside, the reforms will almost certainly usher in a new regime for patent practice before the USPTO and in the federal courts. Until the impact of those new procedures has been fully realized, those in the field would be well-advised to take a hard look at their current patent prosecution practices, monitor various enforcement options for existing patents, and implement strategies for ensuring that future inventions reap the benefits of patent protection in a substantially changed landscape.

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manufacture, or composition of matter used in a manufacturing or other commercial process'').

[113] *Id.*; *see also*, 35 U.S.C. § 273(a)(1).

[114] AIA, § 16(b) (amending 35 U.S.C. § 292).

[115] *Id.*

[116] *Id.*

[117] *Id.*, § 16(a) (amending 35 U.S.C. § 287(a)).