Impact of America Invents Act on Biotech Intellectual Property

Amanda Murphy, Michael Stramiello, Jonathan Stroud, Stacy Lewis, and Tom Irving

Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, Washington, D.C. 20001-4413

Correspondence: amanda.murphy@finnegan.com

This review introduces the America Invents Act (AIA), a comprehensive reform of U.S. law on patentability and patent enforceability that Congress enacted in 2011. The AIA's most publicized change transforms the United States from a "first-to-invent" system to a "first-inventor-to-file" regime, bringing U.S. patent law more in line with the patent systems of nearly every other industrialized country in the world. This new system requires small companies and independent inventors to toe the line against larger competitors in what many have called a "race to the patent office." But a closer look at the AIA reveals several opportunities for smaller entities that may even the playing field, particularly for innovators in the biotech sector. This article addresses changes that the AIA brings to U.S. patent law, keeping an eye toward issues relevant to biotech companies.

The America Invents Act (AIA),¹ signed into law on September 16, 2011, marked the first major patent reform in the United States since the 1952 Patent Act. The AIA fundamentally transformed the U.S. landscape on patentability and patent enforceability. For some patents and applications, however, the old law (pre-AIA 35 U.S.C. §100 et seq.) will remain in effect until approximately 2034.² To effectively formulate patent filing strategies and evaluate existing portfolios, innovators and attorneys alike must do their best to understand the interplay of the old and new law. Such understanding is dif-

ficult to attain in this early period when the judiciary has construed very few provisions of the AIA.

As illustrated in Figure 1, the pre-AIA "first-to-invent" system gave inventors leeway to seek patent protection later in development. This is because when separate inventors independently invented the same invention, those having the earlier date of invention generally received patenting rights. The AIA, however, established a "first-inventor-to-file" system. Under it, inventors having the earlier filing date generally prevail—even if they lack an earlier date of invention.

Although the AIA's first-inventor-to file system may force innovators to seek patent protection sooner, a closer look reveals certain counterbalances that help to level the playing field in this "race to the patent office": a preserved,

¹The full text of the AIA can be found at 125 Stat. 284 (Pub. L. No. 112-29, Sept. 16, 2011). Unless otherwise specified herein, all citations to 35 U.S.C. refer to AIA 35 U.S.C.

²Those patents and applications in which all claims have an effective filing date before March 16, 2013.

Editors: Salim Mamajiwalla and Rochelle Seide

Additional Perspectives on Intellectual Property in Molecular Medicine available at www.perspectivesinmedicine.org

Copyright © 2015 Cold Spring Harbor Laboratory Press; all rights reserved; doi: 10.1101/cshperspect.a020784

Cite this article as *Cold Spring Harb Perspect Med* 2015;5:a020784

A. Murphy et al.

Figure 1. Representative time line illustrating hypothetical inventive activities by two different inventors. Under the pre-AIA first-to-invent system, Inventor #1 could prevail over Inventor #2, even after filing second. Under the AIA's first-inventor-to-file system, Inventor #2, who invented later but filed first, may more easily prevail.

albeit narrowed, prior art grace period; derivation proceedings³; and broadened exceptions for joint research and common ownership. Surely, mastering the new law will require practitioners to remain familiar with old tools.

This article discusses the AIA's expanded definition of prior art and what it means for biotech companies. It also briefly describes other AIA changes, such as supplemental examination and other new post-grant proceedings.

CHANGES TO PATENTABILITY

Pre-AIA §102 contained subsections (a)–(g), whereas AIA §102 contains subsections (a)–(d). The AIA amendments to 35 U.S.C. §102 took effect on March 16, 2013.⁴ And until approximately March 2034, parallel 35 U.S.C. §102 universes will exist: one containing pre-AIA (a)–(g) and one containing AIA (a)–(d).

Although the new statutory definitions of prior art contained in AIA §102 will surely have a dramatic impact on U.S. patent law, its full effect will remain unclear until courts interpret those new provisions. For now, we merely strive to unravel the new statute—and in the process, hopefully shed some light on AIA's likely impact on biotech innovation.

First-Inventor-to-File

Most notably, the AIA calls for a transition from the old first-to-invent system to a new first-in-

ventor-to-file system. This brings U.S. patent law closer to the regimes of most other industrialized countries. The pre-AIA first-to-invent system typically protected an earlier inventor's right to receive a patent—even if a later, independent inventor first filed a patent application on the same invention.⁵ In contrast, the AIA's first-inventor-to-file system will typically protect whichever independent inventor first files a patent application. The new first-inventor-to-file regime applies to any patent having at least one claim with an effective filing date after March 15, 2013.⁶

The scientific community holds mixed views on this transition (Lewis 2013; Nagesh Rao 2013). Critics see it as biased toward large corporations. They argue that the first-inventor-to-file system unfairly tilts the playing field toward companies with well-established and heavily funded patent departments that better enable them to file first. This may ring true to many in the biotech industry, in which small start-up companies often rely on outside investors and patent experts only once the need arises.

But supporters of the first-inventor-to-file system note that the AIA preserves key features of the old system, including aspects of the 1-year grace period that protects inventors who file a patent application within 1 year of publicly disclosing their invention. Supporters also point out that the new system relaxes requirements for establishing common ownership under joint research agreements (JRAs). Moreover, the new system creates a microentity discount for innovators who lack sufficient funding.

³The authors note, however, that derivation proceedings are difficult. To date, public records indicate that only six such proceedings have been filed.

⁴AIA Sec. 3(n).

⁵See Figure 1.

⁶AIA Sec. 3(n).

And, as discussed in greater detail below, the U.S. Patent and Trademark Office (USPTO) has taken the position that the AIA removed certain categories of secret prior art that would have prevented patentability under the old law.

The authors of this article acknowledge that large organizations might have an advantage in winning the purported “race to the patent office.” Still, one can argue that the costs and unpredictability of establishing first-to-invent status (under the old system) typically offset any practical advantage of that system to small organizations. Moreover, as discussed below, the AIA preserves opportunities for smaller organizations to strategically disclose inventions to potential investors before filing a patent application. As a result, we are at least hopeful that most biotech companies, large and small, will notice little impact from the new first-inventor-to-file provisions of the AIA.

Expanded Definitions of Prior Art in AIA §102(a)

AIA 35 U.S.C. §102(a) redefines “prior art.”⁷ Prior art is the universe of information that will prevent patentability of an invention or invalidate or cancel claims of an issued patent. Prior art under the new law, absent an admission,⁸ includes both public disclosures (under §102(a)(1)) before a claim’s effective filing

Impact of America Invents Act on Biotech IP

date (EFD) and patent disclosures (under §102(a)(2)) that are effectively filed before a claim’s EFD but published after that EFD. AIA §102 also includes categorical exceptions that negate the effects of what would otherwise be prior art events.

§102(a)(1)

At a glance, 35 U.S.C. §102(a)(1) sets forth categories of prior art that resemble those of pre-AIA §102: patents, printed publications, public uses, and sales.⁹ Yet AIA §102(a)(1) contains important changes. Some broaden the scope of prior art, while others narrow it.

The broadening effects of AIA §102(a)(1) include, for example, removing pre-AIA geographic and language restrictions on certain prior art events. This means that prior art may now arise from a disclosure anywhere and in any language. Likewise, the AIA defines prior art relative to a claim’s EFD, rather its date of invention, which almost always comes earlier.

This focus on EFD, however, also narrows the scope of prior art. For instance, another’s earlier invention no longer serves as prior art, as it would under pre-AIA §102(f) and (g), unless an event associated with that earlier invention falls under AIA §102(a)(1) or §102(a)(2).

In addition, the phrase “or otherwise available to the public” in AIA §102(a)(1) is viewed by many as having added an overarching requirement of “public accessibility” to the definition of prior art. As a result, the AIA may shield secret sale or use activity from the scope of prior art. According to the USPTO, the phrase “or otherwise available to the public” modifies the scope of prior art under AIA §102(a)(1) such that it “does not cover secret

⁷35 U.S.C §102:

Conditions for patentability; novelty (a) NOVELTY; PRIOR ART.—A person shall be entitled to a patent unless—

1. the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention; or
2. the claimed invention was described in a patent issued under section 151, or in an application for patent published or deemed published under section 122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.

⁸See *In re Nomiya* (509 F.2d 566, 571) (C.C.P.A. 1975); Examination Guidelines, 78 Fed. Reg. 11061 at 11064 and 11075 (Feb. 14, 2013) (“Office does not view the AIA as changing the status quo with respect to the use of admissions as prior art”). Thus, admissions should remain as non-statutory prior art, and such admissions should be avoided.

⁹As a result, inventors should take care when publicly sharing their findings. Although a presentation including a transient display of slides will not necessarily count as a “printed publication,” continuously displaying slides on a poster for two and a half days at a conference has barred at least one inventor from patenting. See *In re Klopfenstein* (380 F.3d 1345) (Fed. Cir. 2004). Of course, the best advice is to file a provisional application before making any public disclosures of an invention. See discussion of provisional applications in Murphy et al. (2014).

A. Murphy et al.

sales” or uses unless they “make the invention available to the public.”¹⁰

The USPTO has indicated that its determinations of whether a prior art event made an invention available to the public will rely on pre-AIA case law regarding public accessibility and availability.¹¹ Federal Circuit case law teaches that an invention’s public accessibility ultimately turns on whether it was “available to the extent that persons interested and ordinarily skilled in the subject matter or art[,] exercising reasonable diligence, can locate it” (*Voter Verified, Inc. v. Premier Election Solutions, Inc.* (698 F.3d 1374) (Fed. Cir. 2012)). Therefore, in the USPTO’s interpretation, disclosures withheld from the public domain (e.g., those subject to a confidentiality agreement) should not qualify as prior art under the AIA.

Based on this commentary, some argue, and the USPTO agrees, that the AIA legislatively overruled the forfeiture doctrine of *Metallizing Engineering Co. v. Kenyon Bearing & Auto Parts Co.* (153 F.2d 516) (2d Cir. 1946), under which secret uses, secret offers for sale, and other secret activities by an inventor could bar patenting.¹² That interpretation of AIA §102(a)(1) will no doubt be litigated, and the Federal Circuit will not necessarily defer to the USPTO’s interpretation.

¹⁰USPTO’s AIA Examination Guidelines, 78 Fed. Reg. 11059 (Feb. 14, 2013).

¹¹*Id.*

¹²See Intellectual Property Owners Association (IPO) and American Intellectual Property Law Association (AIPLA) submissions to USPTO: Comments on Proposed Rules and Examination Guidelines for Implementing the First Inventor to File Provisions of the Leahy-Smith America Invents Act 77, Fed. Reg. 43742 and 43759 (July 26, 2012). IPO letter, Oct. 5, 2012, <http://www.ipso.org/wp-content/uploads/2013/03/IPOCommentsToFITFFRN10-5-12.pdf>; AIPLA letter, Oct. 5, 2012, <http://www.aipla.org/advocacy/executive/Documents/AIPLA%20Comments%20to%20USPTO%20on%20First-Inventor-to-File%20-%202010.5.12.pdf>. In addition, commentary in the USPTO’s final rules seems to indicate that the Office will operate as if *Metallizing Engineering* has in fact been overruled when it states: “some of the purposes ascribed to these doctrines in case law appear to be ill-suited to or inconsistent with the AIA. The problem of delayed filing of applications is unique to pre-AIA 35 U.S.C. 102, under which an applicant can rely on a secret invention date in order to establish a priority date.” USPTO Examination Guidelines, p. 11062.

The Federal Circuit generally seeks to resolve statutory ambiguity by examining Congress’s intent (*Hoechst Aktiengesellschaft v. Quigg* (917 F.2d 522, 526) (Fed. Cir. 1990)). In this case, the AIA’s legislative history, which provides at least some informational value, may align with the USPTO’s interpretation of §102(a)(1). Senator Kyl, for example, addressed this issue from the Senate floor: “Once an invention has entered the public domain, by any means, it can no longer be withdrawn by anyone. But public uses and sales are prior art only if they make the invention available to the public.”¹³ Likewise, Senator Leahy explained that “new paragraph 102(a)(1) imposes an overarching requirement for availability to the public . . . which will limit paragraph 102(a)(1) prior art to subject matter meeting the public accessibility standard that is well-settled in current law, especially case law of the Federal Circuit.”¹⁴

Still, critics question the weight of this legislative history.¹⁵ And the Federal Circuit may, as in *Hoechst*, ultimately disregard it.¹⁶ According to Supreme Court Justice Antonin Scalia, “[t]he statute is what Congress voted on, not what some committee member said he thought it meant.”¹⁷ Thus, whether the AIA truly imposes “an overarching requirement for availability to the public” remains to be seen.

If the AIA did overrule *Metallizing Engineering*, anyone seeking to patent a secret process would benefit—even if the product of that secret process has been commercialized. Likewise, the inventor’s confidential commercial agreements (e.g., concerning manufacturing or distribution) would not constitute prior art, even if they were interpreted as sales of the invention. Biotech companies should closely monitor de-

¹³*Cong. Rec.*, S5431 (Sept. 8, 2011).

¹⁴*Cong. Rec.*, S1496 (March 9, 2011).

¹⁵Daniel Taskalos, Note, “*Metallizing Engineering*’s forfeiture doctrine after the America Invents Act,” 16 *Stan. Tech. L. Rev.* 657, 661 (2013); Ron Katznelson, “The America Invents Act may be constitutionally infirm if it repeals the bar against patenting after secret commercial use,” 13 *Engage* 73 (2012).

¹⁶*Hoechst* at 529.

¹⁷Robert Barnes, “Supreme Court lawyers cautious when offering one specific piece of evidence,” *Washington Post*, Apr. 22, 2012 (quoting Justice Scalia).

velopments in this area, as they often hire third parties to manufacture prototypes and test inventions.¹⁸

§102(a)(2)

AIA §102(a)(2) defines a specific subcategory of prior art relating to published patent documents. Such documents are prior art if they are effectively filed before someone later files a patent application containing relevant claims, and if they publish after the effective filing date of the relevant claims. To qualify as prior art under AIA §102(a)(2), any of three types of documents must publish: (1) a U.S. patent, (2) a U.S. patent application, or (3) a Patent Cooperation Treaty (PCT) application designating the United States.

For the third type, AIA §102(a)(2) uses the phrase “deemed published under 35 U.S.C. §122(b).” This links AIA §102(a)(2) to §374 (concerning PCT filings designating the United States) and renders as prior art all published, U.S.-designating PCT applications—in any language—as of the PCT’s effective filing date, even if no entry into the U.S. national stage is ever made. Thus, AIA §102(a)(2) defines a broader scope of prior art than its counterpart, pre-AIA §102(e), which required publication in English. Recall, however, that AIA §102(a)(1) defines as prior art any publication of an effectively filed relevant patent document before the effective filing date of a claimed invention. Thus, if a PCT or any other patent document publishes *before* a claimed invention’s effective filing date, that PCT is prior art under AIA §102(a)(1)—even if it fails to designate the United States.

AIA 35 U.S.C. §102(d)¹⁹ further defines the effective prior art date of a published patent

document under 35 U.S.C. §102(a)(2) that is effectively filed before the effective filing date of a claimed invention but published after that effective filing date. Specifically, following publication of one of the three types of §102(a)(2) documents, such document has retroactive availability as prior art for novelty and obviousness purposes as of its filing date, if the document was “effectively filed” before the “effective filing date” of the claimed invention. Thus, AIA §102(d) is somewhat like pre-AIA 35 U.S.C. §102(e). But under AIA, the retroactive availability of a published patent document aligns with the date the earlier patent document was effectively filed in any country and in any language, effectively mooted the pre-AIA *Hilmer I* and *Hilmer II* decisions, as discussed below. And unlike pre-AIA §102(e), new §102(d)/102(a)(2) prior art generally cannot be antedated by proving an earlier invention. Such prior art is removed only if an exception applies under 35 U.S.C. §102(b)(2).

As indicated above, AIA §102(d) legislatively overruled *Hilmer I* and *Hilmer II*.²⁰ The *Hilmer* doctrine allowed applicants to use a foreign priority date as a shield to defend against intervening prior art arising before filing in the United States, but barred its use as a sword to attack another under 35 U.S.C. §102(e) or 35 U.S.C. §102(g). As illustrated in Figure 2, under AIA, the sword is now available for prior art falling within 35 U.S.C. §102(a)(2).

As illustrated in Figure 2, under *Hilmer* (pre-AIA), a foreign priority application could serve as a shield to overcome intervening prior art but could not serve as a §102(e) prior art

¹⁸For now, the possibility that secret prior art will not bar future patenting places a premium on confidentiality agreements and trade secrets. In the event a company comes to learn that a competitor is coming close to reverse engineering their trade secret, the company can then seek patent protection for the invention. Biotech companies should consider this when evaluating the risks and expenses typically associated with maintaining trade secrets.

¹⁹35 U.S.C. §102(d):

PATENTS AND PUBLISHED APPLICATIONS EFFECTIVE AS PRIOR ART.—For purposes of determining whether a patent or application for patent is

prior art to a claimed invention under subsection (a)(2), such patent or application shall be considered to have been effectively filed, with respect to any subject matter described in the patent or application—

1. if paragraph (2) does not apply, as of the actual filing date of the patent or the application for patent; or
2. if the patent or application for patent is entitled to claim a right of priority under section 119, 365(a), or 365(b), or to claim the benefit of an earlier filing date under section 120, 121, or 365(c), based upon 1 or more prior filed applications for patent, as of the filing date of the earliest such application that describes the subject matter.

²⁰*In re Hilmer* (359 F.2d 859) (C.C.P.A. 1966); *In re Hilmer* (424 F.2d 1108) (C.C.P.A. 1970).

A. Murphy et al.

Figure 2. Representative time line illustrating hypothetical foreign-filing activities. Under a pre-AIA application of the *Hilmer* doctrine, the '001 foreign priority date could be used as a shield to defend against intervening prior art, but it could not be used as a sword under §102(e) to prevent the '002 patent from issuing. Under the AIA, the '001 foreign priority date serves as a shield to defend against intervening prior art and as a sword to prevent the '002 patent from issuing, regardless of whether the effective filing date of the '002 patent is January 18, 2000, or October 17, 2000. The only way for the '002 applicant to remove the '001 patent document from the universe of prior art is to find an exception under AIA 35 U.S.C. §102(b).

sword against later-filed patent applications. Under AIA §102(d), however, the foreign priority application may serve as a §102(a)(2) prior art sword against a later-filed patent application unless one of the exceptions of §102(b)(2) (discussed below) applies.

Thus, AIA §102(d) should eliminate the need to file U.S. provisional applications based on non-U.S. applications as a means of sidestepping *Hilmer I* and *Hilmer II* to create prior art. As Figure 3 illustrates, a priority applica-

tion filed in any country or language, upon its publication, retroactively becomes available—as of its filing date—as prior art for novelty and obviousness purposes. This means that all patent filing documents will be prior art under §102(a)(2) as of the date they are effectively filed, rather than when they published (like patent documents under pre-AIA §102(e))—as long as they end up publishing as one of the three accepted types of documents explained in AIA §102(a)(2) and in AIA §102(d).

Figure 3. Exemplary prior art events under AIA §102(a)(2) and §102(d). Following publication, all three patent documents have retroactive availability as prior art for novelty and obviousness purposes as of their original effective filing dates (designated as stars). No geographical or language distinctions exist under AIA §102(a)(2) and §102(d). PCT, Patent Cooperation Treaty; des. U.S., designating the United States; USPAT, U.S. patent granted.

Comment on the New Prior Art Definitions in AIA §102

The new first-inventor-to-file regime removes certain opportunities that applicants had under the old system to antedate certain types of prior art events. This change should motivate innovators to diligently seek patent protection for new inventions. Still, applicants should carefully weigh the benefits of filing early against the time required for the more heightened searching that might be needed in view of the AIA's broadened definition of prior art, and the greater demand for relevant experimental data to support the utility, written description, and enablement of biotech inventions, as indicated by recent Federal Circuit decisions (although, of course, those decisions were limited to the facts of those cases).²¹

In light of this Federal Circuit trend—and many other countries' strict requirements concerning experimental data—life sciences applicants should give due consideration before rushing to the USPTO with an application that may lack sufficient disclosures. By filing a comprehensive patent application containing substantiating data, a biotech applicant may be able to maximize her opportunities for obtaining meaningful patent protection worldwide. Besides, a more comprehensive application having abundant fallback positions stands a better chance of distinguishing (and thus withstanding) prior art events unknown at the time of filing.

New Prior Art Exceptions in AIA §102(b)

As discussed above, AIA §102(b) sets out exceptions to the prior art definitions in AIA §102(a). These exceptions may be particularly important to those in the life sciences, who often rely on public disclosures and press announcements to encourage financial investment.

²¹See, e.g., *Rasmussen v. SmithKline Beecham Corp.* (413 F.3d 1318) (Fed. Cir. 2005); *Janssen Pharmaceutica N.V. v. Teva Pharms. USA, Inc.* (583 F.3d 1317, 1327) (Fed. Cir. 2009); and *Eli Lilly and Co. v. Teva Pharms. USA, Inc.* (619 F.3d 1329, 1342) (Fed. Cir. 2010).

§102(b)(1)

AIA §102(b)(1) sets out certain exceptions to the prior art defined in AIA §102(a)(1).²² Of note, §102(b)(1) maintains for U.S. patent applications the pre-AIA 1-year grace period for some prior art. During that time an inventor can seek protection for an invention following a public disclosure of the invention if he, his joint inventor, or someone who obtained the disclosed subject matter from them made the §102(a)(1) public disclosure.

Because many biotech companies rely on outside investors to fund research and development, they often publicly announce new inventions while hoping to retain the possibility of obtaining U.S. patent protection. Thus, AIA's preservation of a 1-year grace period for U.S. patent applicants might seem to offer a welcome relief. In practice, however, it should be used with caution. The USPTO has warned that the AIA §102(b)(1) exceptions apply only for the "same" subject matter (in a novelty sense) earlier disclosed.²³ According to the USPTO, "related" subject matter (in an obviousness sense) could still be used against the inventor. A best practice, then, would be to file for patent pro-

²²35 U.S.C. §102(b):EXCEPTIONS.—

(1) DISCLOSURES MADE 1 YEAR OR LESS BEFORE THE EFFECTIVE FILING DATE OF THE CLAIMED INVENTION.—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 under subsection (a)(1) if—

A. the disclosure was made by the inventor or joint inventor or by another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor; or

B. the subject matter disclosed had, before such disclosure, been publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor.

²³Examination Guidelines, p. 11061: "The Office also indicated in the proposed examination guidelines that the subject matter in the prior disclosure being relied upon under AIA 35 U.S.C. 102(a) must be the same 'subject matter' as the subject matter previously publicly disclosed by the inventor for the exceptions in AIA 35 U.S.C. 102(b)(1)(B) and 102(b)(2)(B) to apply. . . . These examination guidelines maintain the identical subject matter interpretation of AIA 35 U.S.C. 102(b)(1)(B) and 102(b)(2)(B)." See also p. 11066.

A. Murphy et al.

Figure 4. Definition of prior art, Scenario 1: Patent application publications as prior art under the AIA. Under pre-AIA law the inventor on the bottom could attempt to antedate the inventor on the top by showing prior conception and diligence or reduction to practice. Under the AIA, because the inventor on top filed first, she created a prior art event to the inventor on the bottom under §102(a)(2), unless a §102(b)(2) section applies.

tion before making or authorizing any public disclosures.

§102(b)(2)

AIA §102(b)(2)²⁴ sets out three exceptions to the prior art defined in §102(a)(2), each relating to subject matter “obtained from” the inventor or someone who owns the invention. It creates exceptions for:

1. subject matter obtained directly or indirectly from the inventor or a joint inventor;
2. the inventor’s (or a joint inventor’s) public disclosure, or subject matter disclosed by another who obtained it directly or indirectly from the inventor (or joint inventor);

3. certain subject matter commonly owned.

Unlike those in AIA §102(b)(1), these exceptions do not include a 1-year grace period for U.S. patent applicants. But the USPTO has taken a similar position regarding the interpretation of AIA §102(b)(1) and (b)(2) in terms of “disclosed” versus “related” subject matter. Again, a best practice would be to file for patent protection before any of the prior art events defined in §102(a)(2) occur.

The series of examples illustrated in Figures 4–10 should help illustrate the new definition of prior art and the exceptions.

Comment on Exceptions

The exceptions under 35 U.S.C §102(b)(1) and (b)(2), depending on circumstances, might offer a vital tool for salvaging patentability of inventions that otherwise would have been lost to prior art. Still, biotechnology innovators should tread carefully: As noted above, the USPTO has signaled a narrow construction of AIA §102(b)(1) and (b)(2) that will not cover obvious variations of the disclosed subject matter. In light of the USPTO’s construction, a best practice would be to avoid publicly disclosing an invention before filing for patent protection.

As with pre-AIA attempts to “swear behind” a prior art reference, best practice under the AIA

²⁴35 U.S.C. §102(b)(2):

DISCLOSURES APPEARING IN APPLICATIONS AND PATENTS.— A disclosure shall not be prior art to a claimed invention under subsection (a)(2) if—

A. the subject matter disclosed was obtained directly or indirectly from the inventor or a joint inventor;

B. the subject matter disclosed had, before such subject matter was effectively filed under subsection (a)(2), been publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor; or

C. the subject matter disclosed and the claimed invention, not later than the effective filing date of the claimed invention, were owned by the same person or subject to an obligation of assignment to the same person.

Figure 5. Definition of prior art, Scenario 2: Foreign sales as prior art under the AIA. Under pre-AIA law, the foreign sale was not prior art to the later-filed application. Under AIA §102(a)(1), the foreign sale is prior art.

is to argue the merits of a rejection (or invalidity contention) rather than relying on a prior art exception. Biotech organizations should avoid, if possible, relying on any of the §102(b)(1) and (b)(2) exceptions and, if possible, instead prove that claimed subject matter is in fact patentably distinct over putative AIA §102(a)(1) or (a)(2) prior art. Proving separate patentability should eliminate any issues that might later arise if the facts ultimately fail to warrant application of a §102(b)(1) or (b)(2) exception. But if one seeks to avail herself of a §102(b)(1) or (b)(2) exception, she should know and present all relevant facts to the USPTO in an accurate and complete way.

AIA §102(b)(2)(C) and §102(c)

Of particular relevance to the biotech and life sciences fields, AIA §102(b)(2)(C) and §102(c)²⁵ expand the provisions of the Cooperative Research and Technology Enhancement (CREATE) Act of 2004 and the American Inventors Protection Act (AIPA) of 1999. The AIPA provides that disclosures contained in certain commonly assigned applications cannot be

used as prior art relevant to the obviousness of a claimed invention in a later patent filing. The CREATE Act provides that subject matter developed under joint research agreements (JRAs) that leads to patent filings could be treated as “commonly assigned” for the purpose of obviousness under the AIPA.

Thus, in the pre-AIA world, common ownership could be used only to overcome an obviousness rejection. Under the AIA, however, common ownership can be applied to overcome *both* novelty and obviousness. Specifically, AIA §102(b)(2)(C) creates an exception to AIA §102(a)(2) if, not later than the EFD of the claimed invention, the subject matter disclosed in an item of §102(a)(2) prior art and a later claimed invention were owned by the same person or subject to an obligation of assignment to the same person.

And importantly, the AIA now recognizes common ownership as long as that ownership exists at the effective filing date of the claimed invention. Under the pre-AIA regime, common

²⁵35 U.S.C. §102(c):

COMMON OWNERSHIP UNDER JOINT RESEARCH AGREEMENTS.—Subject matter disclosed and a claimed invention shall be deemed to have been owned by the same person or subject to an obligation of assignment to the same person in applying the provisions of subsection (b)(2)(C) if—

1. the subject matter disclosed was developed and the claimed invention was made by, or on behalf of, one or more parties to a joint research agreement that was in effect on or before the effective filing date of the claimed invention;
2. the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and
3. the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement.

A. Murphy et al.

Figure 6. Definition of prior art, Scenario 3: Public use outside the United States as prior art under the AIA. Under pre-AIA law, the public use outside the United States was not prior art. Under AIA §102(a)(1), the prior public use is prior art wherever it occurs, unless an exception applies under §102(b)(1) or unless the applicant can patentably distinguish over the public use.

ownership had to exist at the date of invention. Because a date of invention almost always precedes a claimed invention's effective filing date, the AIA provides additional time for establishing common ownership of inventions before filing a patent application.

Similar comments apply to AIA §102(c). Therein, subject matter disclosed in an item of §102(a)(2) prior art and a later-claimed invention shall be deemed to have been owned by the same entity if the subject matter disclosed and the claimed invention were made by, or on behalf of, one or more parties to a JRA that was in effect by the effective filing date of the claimed invention. Pre-AIA, the relevant date was "at the time the invention was made," leaving a much smaller window of time for formalizing JRAs.

The prior art exceptions defined in AIA §§102(b)(2)(C) and 102(c) apply only to AIA

§102(a)(2) prior art. But because many biotech innovations come from collaborative efforts, such as between academia and industry or small start-ups and established companies, these exceptions may have a beneficial broadening effect for the biotech industry compared to their pre-AIA counterparts.

Indeed, the AIA's change to "on or before the effective filing date" may sometimes allow applicants to proactively cure a potential §102/103 prior art problem—perhaps even by purchasing the potential prior art before filing a patent application. For example, assume University X invents and files a patent application for compounds A and B. University X then approaches Company Y to license compounds A and B. Prior to being approached by X, Company Y invented compounds C to E and plans to file a patent application disclosing those new

Figure 7. Definition of prior art, Scenario 4: Public use in the United States as prior art under the AIA. Under pre-AIA law, the applicant could attempt to antedate the prior public use if it occurred within 1 year of filing. Under AIA §102(a)(1), the prior public use is prior art whenever it occurred prior to the filing date, unless an exception applies under §102(b)(1) or unless the applicant can patentably distinguish over the public use.

Figure 8. The new U.S. grace period under AIA §102(b)(1)(A). In this scenario the applicant makes a public disclosure of the invention and, within a year, files an application in a foreign country. The applicant then makes a second public disclosure of the invention and, within a year, files a U.S. application that claims priority to the foreign application. Neither of the public disclosures is a prior art event for novelty purposes under §102(a)(1) in this scenario. For the first, we assume that the AIA §102(b)(1)(A) exception applies. For the second, we assume the effective filing date (EFD) of the relevant claimed subject matter is found in the foreign application. Hence, the second is not a “disclosure” before the EFD of the relevant claimed subject matter. The same analysis would apply if the applicant had filed a U.S. provisional application rather than a foreign application.

Figure 9. The new U.S. grace period under AIA §102(b)(1)(A) and (b)(1)(B). In this scenario the applicant makes a public disclosure of the invention that is followed by a second public disclosure by a third party. Because the applicant filed within 1 year of both disclosures, neither is a prior art event for novelty purposes, assuming the exceptions can properly be taken.

A. Murphy et al.

Figure 10. Public disclosure as a sword and a shield under the AIA. In this scenario Inventor B publicly discloses her invention before Inventor A files his patent application. Inventor B files her patent application within 1 year of her public disclosure. Inventor A's application later publishes, but Inventor B's public disclosure serves as a shield to protect against Inventor A's earlier effective filing date. In addition, Inventor B's public disclosure also serves as a sword to prevent Inventor A from receiving a patent, assuming that neither of the §102(b)(1) exceptions is available to Inventor A. Thus, in this scenario, the first-inventor-to-file *loses* to the first-inventor-to-disclose. This demonstrates that the earlier filer under AIA does not always get a patent relative to a later filer.

species and claiming a genus that encompasses compounds A and B in addition to C to E. If Company Y purchases compounds A and B prior to filing its application to compounds C to E and the genus encompassing A and B, Company Y will jointly own both inventions prior to the effective filing date of Company Y's application. Thus, Company Y should be able to eliminate the prior art effect of University X's patent application under the new §102(b)(2)(C) exception if University X's patent application matures into §102(a)(2) prior art through one of the three types of designated publications under new §102(a)(2).

Thus, in the above example, if University X and Company Y desire a JRA rather than a transfer of ownership, the parties could draft a JRA that has within its scope the discovery, synthesis, and testing of all compounds A to E. If carefully crafted, the JRA (or common ownership agreement) should allow Company Y to remove the anticipatory effects of University X's patent application under AIA §102(a)(2) by invoking the AIA §102(b)(2)(C) exception.

And what if Company Y filed its patent application prior to finding out about University X's application? Perhaps all is not lost. Depending on the circumstances, Company Y may be able to abandon its application and refile it after

perfecting the common ownership or JRA. This is because nothing in the CREATE Act prohibits its application to research activities that have already produced potentially patentable inventions at the time the JRA or common ownership agreement is executed. Indeed, Congress included a section in the AIA explicitly noting that AIA §102(c) should continue to be interpreted with same intent as under the CREATE Act (i.e., promote joint research).²⁶

Company Y's genus application would not have been similarly protected in any of these scenarios under the pre-AIA CREATE Act. First, the pre-AIA version only provided a shield for obviousness, not loss of novelty. Second, the

²⁶125 Stat. 287, Sec. 3(b)(2):

CONTINUITY OF INTENT UNDER THE CREATE ACT.—The enactment of section 102(c) of title 35, United States Code, under paragraph (1) of this subsection is done with the same intent to promote joint research activities that was expressed, including in the legislative history, through the enactment of the Cooperative Research and Technology Enhancement Act of 2004 (Public Law 108-453; the “CREATE Act”), the amendments of which are stricken by subsection (c) of this section. The United States Patent and Trademark Office shall administer section 102(c) of title 35, United States Code, in a manner consistent with the legislative history of the CREATE Act that was relevant to its administration by the United States Patent and Trademark Office.

pre-AIA CREATE Act would not have applied to the University X/Company Y scenario, because the generic invention had already been made as of the date of the JRA. AIA's changes certainly favor collaboration and, as explained above, could provide a critical advantage for biotech inventions.

TRANSITION PROVISIONS AIA SEC. 3(n)(1) AND 3(n)(2)

When do the prior art provisions of AIA §102(a) and the prior art exceptions of AIA §102(b) discussed in the preceding sections apply? To assist the patent practitioner in answering that question, AIA provides two important transition provisions: AIA Sec. 3(n)(1) and 3(n)(2).²⁷ These transition provisions are not codified in 35 U.S.C. Instead, they are found *only* in the public law. AIA Sec. 3(n)(1) defines

²⁷ 125 Stat. 293: AIA Sec. 3(n) (emphasis and commentary added):

EFFECTIVE DATE.—

1. IN GENERAL.—Except as otherwise provided in this section, the amendments made by this section shall take effect upon the expiration of the 18-month period beginning on the date of the enactment of this Act, and shall apply to any application for patent, and to any patent issuing thereon, that *contains or contained at any time—*

A. a claim to a claimed invention that has an effective filing date as defined in section 100(i) of title 35, United States Code, that is on or after the effective date described in this paragraph; or

B. a specific reference under section 120, 121, or 365(c) of title 35, United States Code, to any patent or application that contains or contained at any time such a claim.

2. INTERFERING PATENTS.—The provisions of sections 102(g), 135, and 291 of title 35, United States Code, as in effect on the day before the effective date set forth in paragraph (1) of this subsection, shall apply to each claim of an application for patent, and any patent issued thereon, for which the amendments made by this section also apply [Authors' note: In other words, AIA Sec. 3(n)(1) also applies], if such application or patent *contains or contained at any time—*

A. a claim to an invention having an effective filing date as defined in section 100(i) of title 35, United States Code, that occurs before the effective date set forth in paragraph (1) of this subsection; or

B. a specific reference under section 120, 121, or 365(c) of title 35, United States Code, to any patent or application that contains or contained at any time such a claim.

the effective date of the AIA's amendments to 35 U.S.C. §§ 102 and 103. AIA Sec. 3(n)(2) addresses circumstances under which parts of the pre-AIA law will continue to operate simultaneously with AIA §§ 102 and 103 for certain patents and applications.

Figure 11 depicts the impact of transition provisions 3(n)(1) and 3(n)(2). The simple message is this: If the EFD of *all* claims that a patent or application contains (or contained at any time) is after March 15, 2013, then the prior art provisions, exceptions, and definitions of AIA apply to all claims through transition provision AIA Sec. 3(n)(1).

Conversely, if *all* claims that a patent or application contains have an effective filing date before March 16, 2013, only the pre-AIA prior art provisions apply.

If, however, an application contains (or contained at any time) at least one claim with an effective filing date before March 16, 2013, *and* at least one claim with an effective filing date after March 15, 2013, transition provision 3(n)(2) establishes that all of the claims of that application are subject to the AIA's §§ 102 and 103 prior art provisions *plus* pre-AIA §§ 102(g), 135, and 291.²⁸

The authors of this article fancifully call such applications containing at least one claim with an effective date prior to March 16, 2013, and at least one claim having an effective date after March 15, 2013, a “Jedi Master Mixer,” or less glamorously, a JMM application.²⁹ Because both AIA Sec. 3(n)(1) and 3(n)(2) apply to such applications, the JMM patent applicant receives at least the following benefits of AIA for *all claims* in the JMM application:

²⁸ AIA Sec. 3(n); see also 78 Fed. Reg. 11030 (Feb. 14, 2013).

²⁹ The USPTO uses the term “transition application” to broadly refer to any patent application that has bridged the transition between the pre-AIA and AIA regimes. Thus, the USPTO's term “transition application” broadly encompasses any application that was pending when AIA went into effect, regardless of the effective filing dates of the claims contained therein. The term “Jedi Master Mixer” (JMM), in contrast, more precisely identifies applications that contain claims that have both pre-AIA and AIA effective filing dates and, therefore, invoke both transition provisions 3(n)(1) and 3(n)(2).

A. Murphy et al.

Figure 11. Applying transition provisions 3(n)(1) and 3(n)(2) to determine which law applies (FITE, first-inventor-to-file). In the first scenario the priority date and the application filing date are both before March 16, 2013. Thus, the application is examined under pre-AIA law. In the third scenario the application filing date and the priority date are both after March 15, 2013. Thus, the application is examined under the AIA. In the second scenario the choice of law depends on whether the application contains, or contained at any time, a claim having an effective filing date after March 15, 2013. If not, the application is examined under pre-AIA law. If so, the application is examined under the AIA, subject to the applicability of provision 3(n)(2).

- elimination of certain types of secret prior art (at least according to the USPTO's interpretation of AIA §102(a));
- liberalized application of the common ownership/CREATE Act prior art exceptions for both AIA §§ 102 and 103.

Thus, there could be an enormous benefit to bringing pre-AIA claims into our new AIA world by filing a JMM application under AIA Sec. 3(n)(2).³⁰ Specifically, applicants should be able to use the JMM application strategy to avoid certain pre-AIA bars to patentability of the claimed invention that are not also AIA bars to patentability. Thus, a JMM application can be used to secure whatever benefits (and

drawbacks) might exist in both the pre-AIA first-to-invent and the AIA first-inventor-to-file worlds. Figure 12 depicts one example of how and why an applicant might create a JMM application.

However, the JMM will not cure all prior art and other pre-AIA issues for pre-AIA claims. As noted, transition provision 3(n)(2) expressly pulls pre-AIA §§ 102(g), 135, and 291 into our new AIA world. Thus, JMM applications are still subject to secret prior art in the form of prior invention by another, and can still be dragged into interference proceedings either in the USPTO or in a federal district court. Under those circumstances it may be necessary, and is certainly allowed, to prove an earlier date of invention in the JMM application to avoid the work of others under pre-AIA 35 U.S.C. §§102(g), 135, and/or 291.

Thus, inventors should continue to maintain good laboratory notebooks, even in our

³⁰See U.S. Patent No. 8,598,219 for an example of a JMM. And, of course, "same invention" type double patenting is the same pre-AIA or AIA. So the JMM application must have claims that are patentably distinct from any co-pending applications to avoid same invention type double patenting.

Impact of America Invents Act on Biotech IP

Figure 12. One mechanism for creating a Jedi Master Mixer application is to file a continuation-in-part of a pre-AIA application after March 15, 2013, in which the applicant adds new matter and recites a claim that is supported, at least in part, by that new matter. If the applicant also presents a claim that is exclusively supported by the pre-AIA disclosure, the application will trigger transition provisions 3(n)(1) and 3(n)(2). One possible benefit of such an application is that it may allow the applicant to avoid the prior art effect of a private sale that occurred more than 1 year before the original pre-AIA filing date.

new AIA first-inventor-to-file regime. Such records, for example, might someday be required to prove an earlier date of invention for JMM applications subject to pre-AIA §§ 102(g), 135, and 291, and they could be critical for establishing actual inventorship.

The authors note that although a JMM application can provide important benefits for certain pre-AIA inventions, it is not an appropriate strategy for all applications. Practitioners should carefully analyze the effective filing dates of each claim presented in a patent application. To avoid stumbling into an AIA regime for those inventions that would not benefit from the transition provisions of 3(n)(1) and 3(n)(2), practitioners should check that every claim in a transition application (i.e., a pre-AIA application that is still pending in our new AIA world) stays on the pre-AIA side of the effective date divide between our pre-AIA and AIA worlds. A final caution from the authors: If you mix pre-AIA and AIA claims in a JMM application, do so deliberately—once you invoke transition provisions 3(n)(1) and 3(n)(2), you can never revert to the pre-AIA regime in that application or in its descendants.

PRIOR USER RIGHTS

The AIA made significant changes to the prior user rights defense to patent infringement encompassed in pre-AIA §273. A prior user rights defense is based on a party's earlier use of an invention that is later patented by someone else.

Pre-AIA, an accused infringer's prior use of later-patented technology was not an independent defense to patent infringement except for patents directed to methods of conducting business.³¹ AIA §5 amended pre-AIA §273³² to

³¹See American Inventors Protection Act of 1999, Pub. Law 106-113 (later amended by the Intellectual Property and High Technology Technical Amendments Act of 2002, Pub. Law 107-273).

³²AIA 35 U.S.C. §273:

Defense to infringement based on prior commercial use

(a). IN GENERAL.—A person shall be entitled to a defense under section 282(b) with respect to subject matter consisting of a process, or consisting of a machine, manufacture, or composition of matter used in a manufacturing or other commercial process, that would otherwise infringe a claimed invention being asserted against the person if—

1. such person, acting in good faith, commercially used the subject matter in the United States, either in

A. Murphy et al.

expand the prior user rights defense to include other technologies and to provide protection for trade secrets. These changes largely harmonized U.S. law with that of other industrialized countries.

Effective September 16, 2011, the prior user defense applies to any technology patented after that date, as long as the prior commercial use has been occurring for at least 1 year before the earlier of either the effective filing date of the claimed invention or the date of public disclosure that qualified for an exception from prior art under AIA §102(b). But interpretation of the prior user rights provision is more complicated than it may seem.

Although AIA §273 went into effect September 16, 2011, AIA §102(b) did not come into effect until March 16, 2013. So it might be unclear exactly when the opportunity for prior user rights began.

In addition, §273 does not specify which subsection of §102(b) provides “the exception from prior art.” Thus, determining whether a prior user rights defense is available can, for events occurring before September 16, 2013, require retroactively applying the definitions of prior art set forth in AIA §102(a) to see if any of the AIA §102(b)(1) and §102(b)(2) prior art exceptions apply to the events occurring before September 16, 2013.

Although AIA expanded the prior user rights defense, the new law does not automatically provide a general license to all claims of the patent; rather, it merely provides a defense to patent infringement. In addition, to access the defense, companies will need to keep sufficient records to establish clear and convincing evidence of their good faith prior commercial use of the patented invention in the United States.

In addition, the new law makes certain exceptions for nonprofit and university entities. For example, a prior user rights defense is not available if the claimed invention was owned by a university at the time of invention, unless the reduction to practice could not have been undertaken using federal government money.³³

In addition, for nonprofit entities, the use of a claimed invention shall be deemed a commercial use for the purposes of raising a prior user rights defense as long as the defense is asserted for continued and noncommercial use only.³⁴ Because much biotech research and development occurs in nonprofit university settings, these exceptions could have an important impact on patent litigation in that field.

Overall, however, it is unclear to what extent AIA’s changes to the prior user rights defense will impact the biotech industry. On one hand, because biotech innovation tends to progress more slowly than that in other fields, prior user rights could serve as an important part of a biotech inventor’s intellectual property toolkit. For example, inventors could choose to keep an invention as a trade secret and to rely on prior user rights as a defense to any later-filed patents. This approach avoids the burdens of filing and prosecuting a patent application, as well as publicly disclosing the invention and starting a 20-year period of exclusivity.

On the other hand, trade secrets are difficult to protect in the biotech industry, where innovators often rely on outside vendors and third-party investors. Plus, the requirement for secret commercial use for more than 1 year will make it particularly difficult for small start-ups to establish prior user rights, especially because many end up selling their innovations (or their companies) before commercializing their products. In addition, prior user rights and trade secrets are expensive to maintain and difficult for investors to evaluate—a major concern for start-ups.

It may be unlikely that companies will choose to rely on trade secrets and prior user

connection with an internal commercial use or an actual arm’s length sale or other arm’s length commercial transfer of a useful end result of such commercial use; and

2. such commercial use occurred at least 1 year before the earlier of either—

A. the effective filing date of the claimed invention; or
B. the date on which the claimed invention was disclosed to the public in a manner that qualified for the exception from prior art under section 102(b).

³³35 U.S.C. §273(e)(5); 125 Stat. 298–299.

³⁴35 U.S.C. §273(c)(1); 125 Stat. 297.

rights in typically competitive markets, such as the biotech industry. Biotech companies generally may choose patent protection because of the availability of money damages, injunctions, and other remedies. Only time will tell whether the AIA's changes in prior user rights will actually change the behavior of patentees and potential infringers in the biotech field.

SUPPLEMENTAL EXAMINATION AND REISSUE

One of the most powerful litigation tools available to an accused infringer is the equitable defense of inequitable conduct,³⁵ which seeks to ensure against misrepresentations or bad faith during the procurement of patents. Every individual associated with the filing and prosecution of a U.S. application owes to the USPTO a duty of candor and good faith.³⁶ A finding that one has breached this duty renders a patent unenforceable against all past, present, and future infringers,³⁷ and it might even affect the enforceability of related patents.³⁸

In biotech patent litigation, allegations of inequitable conduct are unusually prevalent. For example, in 2008, more than 51% of all pharmaceutical patent cases involved issues of inequitable conduct, whereas the defense was raised in fewer than 13% of all other patent

litigations.³⁹ Moreover, the defendant established inequitable conduct in more than 25% of the pharmaceutical cases in 2008.⁴⁰ This threat of unenforceability because of inequitable conduct drastically complicates patent valuation and investment in cutting-edge technology—it thus places a particularly heavy burden on biotech companies that rely on external funding.

AIA §257, however, offers patent owners an opportunity to reduce this uncertainty through a new procedure called supplemental examination. This new procedure allows any patent owner to file a petition requesting that the USPTO consider, reconsider, or correct information in the patent or its file history.⁴¹ Within 3 months, the USPTO will determine whether the information presented in the request raises a substantial new question of patentability.⁴² If so, it will order ex parte reexamination in view of the submitted evidence, during which the patent owner can argue for patentability of the claimed invention.⁴³ Importantly, the AIA bars as the basis for a finding of inequitable conduct anything considered in the request for supplemental examination or during the ensuing ex parte reexamination.⁴⁴

Still, there are important limitations to what supplemental examination can accomplish. For instance, supplemental examination becomes unavailable once inequitable conduct has been raised in either a paragraph IV notice letter⁴⁵ or a pending litigation.⁴⁶

³⁵*Therasense, Inc. v. Becton, Dickinson and Co.* (649 F.3d 1276) (Fed. Cir. 2011) (en banc), discussing how “[t]his judge-made doctrine evolved from a trio of Supreme Court cases that applied the doctrine of unclean hands to dismiss patent cases involving egregious misconduct: *Keystone Driller Co. v. General Excavator Co.* (290 U.S. 240) (1933), *Hazel-Atlas Glass Co. v. Hartford-Empire Co.* (322 U.S. 238) (1944), overruled on other grounds by *Standard Oil Co. v. United States* (429 U.S. 17) (1976), and *Precision Instruments Manufacturing Co. v. Automotive Maintenance Machinery Co.* (324 U.S. 806) (1945).”

³⁶See 37 C.F.R. §1.56 (2014) (“Duty to disclose information material to patentability”).

³⁷*J. P. Stevens & Co. v. Lex Tex Ltd.* (747 F.2d 1553, 1561) (Fed. Cir. 1984): “Once a court concludes that inequitable conduct occurred, all the claims—not just the particular claims in which the inequitable conduct is directly connected—are unenforceable.”

³⁸See, e.g., *Consolidated Aluminum Corp. v. Foseco Int’l Ltd.* (910 F.2d 804, 808–812) (Fed. Cir. 1990) (finding allegations of misconduct may spread across entire patent families).

³⁹Source: www.patstats.org (calculated by dividing the total number of pharmaceutical cases by the number of those cases involving inequitable conduct and comparing to the total number of nonpharmaceutical cases divided by the number of those cases involving inequitable conduct).

⁴⁰*Id.*

⁴¹37 C.F.R. §1.605 (2014) (“Items of information” including anything containing information believed to be relevant to the patent that the patent owner requests the Office to consider, reconsider, or correct).

⁴²35 U.S.C. §257(a) (2012).

⁴³*Id.* §257(b).

⁴⁴*Id.* §257(c).

⁴⁵The term “paragraph IV notice letter” refers to a notice received by a patent owner under §505(j)(2)(B)(iv)(II) of the Federal Food Drug and Cosmetic Act (21 U.S.C. 355(j)(2)(B)(iv)(II)), notifying the patent owner that a ge-

A. Murphy et al.

Moreover, the cleansing effect of a supplemental examination occurs only once the proceeding and any ex parte reexamination ordered therefrom has drawn to a close,⁴⁷ which could take years. So if the patent becomes involved in litigation before the USPTO completes its review, the accused infringer may raise an inequitable conduct defense regarding any information that the patent owner asked the USPTO to consider in its request for supplemental examination.⁴⁸

Patent owners, therefore, ought to carefully consider the timing of any effort at supplemental examination if they might soon seek to enforce the patent. A decision on the request for supplemental examination must be made in 3 months,⁴⁹ but the patent could be tied up in the Patent Office for years if the Office orders ex parte reexamination—historical data show pendency averaging 27.8 months.⁵⁰ And appealing an adverse decision in the ex parte reexamination could delay any effort to enforce a patent for at least another year.

The patentee should assess the enforceability of valuable patent portfolios as early as possible to determine whether to request supplemental examination. In the pharmaceutical industry, patent holders might want to make such an analysis when listing a patent in the FDA's Orange Book. Patent owners can be fairly certain that an Orange Book-listed patent will be litigated, but usually not immediately—providing some chance that a supplemental exam-

ination (and any subsequent ex parte reexamination) would run its course before the patent owner seeks to enforce the patent against accused infringers.

A “fraud” exception also limits supplemental examination. If the director learns that a material fraud had been committed on the USPTO during patent prosecution, the matter will be referred to the attorney general for disciplinary proceedings against the patent attorney. The patent owner may also face criminal and anti-trust claims under §257(f).

The USPTO places high burdens on patent owners seeking supplemental examination. First, it has set a steep fee for the procedure.⁵¹ Second, it requires patent owners to make, on the record, fairly substantial admissions regarding errors made during prosecution.⁵² For example, for errors involving omitted references,

⁵¹See Changes To Implement the Supplemental Examination Provisions of the Leahy-Smith America Invents Act and To Revise Reexamination Fees, 77 Fed. Reg. 48828 (Aug. 14, 2012):

This final rule requires the following supplemental examination fees:

1. A fee of \$5140.00 for processing and treating a request for supplemental examination;
2. a fee of \$16,120.00 for an ex parte reexamination ordered as a result of a supplemental examination proceeding; and
3. for processing and treating, in a supplemental examination proceeding, a non-patent document over 20 pages in length, a fee of \$170.00 for a document of between 21 and 50 pages, and a fee of \$280.00 for each additional 50 pages or a fraction thereof.

This final rule also requires the following reexamination fees:

1. \$17,750.00 for filing a request for ex parte reexamination;
2. \$1,930.00 for filing a petition in an ex parte or inter partes reexamination proceeding, except for those specifically enumerated in 37 CFR 1.550(i) and 1.937(d); and
3. \$4,320.00 for a denied request for ex parte reexamination under 37 CFR 1.510 (*this amount is included in the request for ex parte reexamination fee, and is the portion not refunded if the request for reexamination is denied*).

⁵²37 C.F.R. §1.605 (2014): “(b) An item of information includes a document submitted as part of the request that contains information, believed to be relevant to the patent, that the patent owner requests the Office to consider, reconsider, or correct.”

neric pharmaceutical company has filed an Abbreviated New Drug Application (ANDA) requesting FDA approval to market a generic version of a patent-protected drug.

⁴⁶35 U.S.C. §257(c)(2)(A).

⁴⁷*Id.* §257(c)(2)(B).

⁴⁸*Id.* §257(c)(2)(B).

⁴⁹See *Id.* §257(a); 37 C.F.R. §1.620 (2014): “Conduct of supplemental examination proceeding. (a) Within three months after the filing date of a request for supplemental examination, the Office will determine whether a substantial new question of patentability affecting any claim of the patent is raised by any of the items of information presented in the request.”

⁵⁰See U.S. Patent and Trademark Office, *Ex Parte* Reexamination Filing Data (Sept. 30, 2013), www.uspto.gov/patents/stats/ex_parte_historical_stats_roll_up_EOY2013.pdf.

parties must admit the document is “relevant to the patent” and must explain its relevance; however, they specifically do not have to address the item’s “materiality.”⁵³ Third, it limits the number of items that a patent owner may raise in a request for supplemental examination.⁵⁴ In view of these limitations, it is not surprising that patent holders have requested only 80 supplemental examinations during the first year and two-thirds that the procedure was available.⁵⁵ Note that as of this writing, at least three litigants chose to seek supplemental examination and requested stays of the related litigations—two that were contested.⁵⁶ Thus, it may be possible to seek a litigation stay related to supplemental examination just as with any other post-grant proceeding.

Interestingly, the AIA may have unintentionally provided other options for curing inequitable conduct. For instance, in amending the reissue sections of the statute, Congress removed the requirement that any errors corrected through reissue were made without deceptive intent.⁵⁷

The Federal Circuit has noted that inequitable conduct cannot be cured through reissue. But if the USPTO considers an item of information during a reissue proceeding and still reissues the patent, an accused infringer would be hard-pressed to prove an inequitable con-

duct defense under the Federal Circuit’s *Therasense* standard.⁵⁸ In the absence of affirmative egregious misconduct, the *Therasense* standard finds inequitable conduct only where the USPTO issues a claim that it would not have issued if it had known the withheld or misrepresented information.⁵⁹ Thus, Congress’s removal of the “without any deceptive intention” requirement from the pre-AIA reissue statute, along with the Federal Circuit’s en banc decision in *Therasense*, which generally requires “but-for” materiality to establish inequitable conduct,⁶⁰ arguably opens the door for patent owners to address questions of inequitable conduct via reissue.⁶¹ But, of course, reissues can sometimes linger through years of prosecution and appeal.

THIRD-PARTY PROCEEDINGS

The AIA dramatically changed the administrative options available to third parties. Pre-AIA, there were three limited alternatives:

- preissuance submissions (which allowed limited citation of printed publications);
- post-grant *ex parte* reexaminations (which could be requested by a third party, the patent owner, or the director, but did not allow third-party participation once instituted);
- post-grant *inter partes* reexaminations (which could only be requested by a third party).

The AIA expanded preissuance submissions, replaced *inter partes* reexaminations with *inter partes* review (IPR) (as of September 16, 2012), and established a new third-party proceeding called post-grant review (PGR). *Ex parte* reexaminations remain unchanged, although supplemental examination has potentially made them more useful.⁶²

⁵³77 Fed. Reg. at 48845: “The Office must determine whether any of the items of information raises a substantial new question of patentability, not whether any of the items of information is ‘material.’ Therefore, the Office is not adopting a requirement that the patent owner state whether or why an item of information is or is not material.”

⁵⁴37 C.F.R. §1.605 (2014) (“Items of information”) (limiting parties to 12 “items”).

⁵⁵As of June 30, 2014, the USPTO listed 80 Supplemental Examinations. U.S. Patent and Trademark Office, AIA Statistics, www.uspto.gov/aia_implementation/statistics.jsp.

⁵⁶See Order Granting Motion to Stay Pending Supplemental Examinations, *Eagle View Technologies, Inc. v. Aerialogics, LLC* (No. 2:12-cv-00618) (W.D. Wash. Nov. 19, 2012) and Memorandum & Order, *Englishtown, Inc. v. Rosetta Stone Inc.* (No. 2:12-cv-10636) (D. Mass. July 25, 2013). Others have requested stays related to Supplemental Examination that have been contested. See, e.g., *Tempnology v. Implus Footcare LLC* (No. 1:13-cv-00347) (D. N.H. Feb. 24, 2014).

⁵⁷35 U.S.C. §251 (2012).

⁵⁸*Therasense* at 1292 (Fed. Cir. 2011) (en banc).

⁵⁹See generally *Id.*

⁶⁰*Id.* at 1292–93.

⁶¹Note, however, that there is no way to address the deceptive intent prong of the inequitable conduct analysis through reissue.

⁶²See previous section.

A. Murphy et al.

Third-party submissions ostensibly provide a mechanism for interested parties to contribute to the quality of issued patents by submitting printed publications to the USPTO for consideration during examination. Pre-AIA, the USPTO accepted such submissions only during a 2-month window after the application published, and it barred any commentary regarding the submitted publications. Under the AIA, however, third-party submissions *must* include a concise description of the asserted relevance of each submitted publication. The AIA also broadened the window for filing such submissions, allowing them before the earlier of (1) a notice of allowance or (2) the later of either (a) 6 months after publication of the application or (b) the first rejection of the application.

Although the AIA improves the third-party submission process, it may be best practice to avoid using preissuance submissions unless the party cannot afford one of the other post-grant proceedings. Because preissuance submissions do not afford the submitter an opportunity to participate in the prosecution of the application, the submission may serve to strengthen the patent over the submitted references, making it harder to challenge the patent's validity in future proceedings (assuming that the patent issues).

The two new post-grant proceedings created by the AIA, IPR⁶³ and PGR,⁶⁴ are essentially patent cancellation proceedings. IPR is currently available for any issued patent⁶⁵ and allows a third party to challenge the patentability of the issued claims on the basis of prior art patents or printed publications.⁶⁶ PGR is available only for patents issued after March 15, 2013,⁶⁷ and for certain earlier-issued covered business method (CBM) patents⁶⁸ if the requestor has been sued

or threatened with assertion of such a patent. PGR permits a party to challenge the validity of a patent on most statutory bases.⁶⁹ Note, however, that the prior art available for CBM review is different than for a full PGR.⁷⁰

An integral part of these third-party cancellation proceedings is the replacement of the Board of Patent Appeals and Interferences with the Patent Trial and Appeal Board (PTAB). The PTAB, which generally sits as three-judge panels, is the forum of first instance for IPRs and PGRs. IPRs and PGRs also enjoy a statutorily mandated time frame for resolution by the PTAB—no longer than 18 months from filing the petition.⁷¹ For comparison, *ex parte* and *inter partes* reexaminations under pre-AIA law (challenges heard in the first instance by the USPTO's central reexamination unit) typically lasted for several years.⁷²

Legislative history indicates that Congress intended for IPRs and PGRs to provide an alternative to expensive and time-consuming district court litigation. So far, however, it appears that petitioners for IPR and PGR generally prefer to use those proceedings as parallel tools to infringement proceedings.

As of October 16, 2014, at least 1908 petitions for IPR and 241 petitions for PGR of CBM patents had been filed, along with two “true” PGRs (one of which is a pharmaceutical case). As Figure 13 illustrates, just over 5.7% of those petitions involved patents in the bio/pharma space and 7.2% involved chemical technologies.⁷³

⁶³35 U.S.C. §311 (“Inter partes review” (IPR)) (2012).

⁶⁴*Id.* §321 (“Post grant review” (PGR)).

⁶⁵*Id.* §311(c).

⁶⁶*Id.* §311(b).

⁶⁷AIA §6(f)(2)(A): “IN GENERAL.—The amendments made by subsection (d) shall take effect upon the expiration of the 1-year period beginning on the date of the enactment of this Act and, except as provided in section 18 and in paragraph (3), shall apply only to patents described in section 3(n)(1).”

⁶⁸AIA §18(a)(C) (2012).

⁶⁹37 C.F.R. §42.304(b)(2) allows challenges available under 35 U.S.C. §282(b)(2)–(3) (2012): “(2) Invalidity of the patent or any claim in suit on any ground specified in part II as a condition for patentability. (3) Invalidity of the patent or any claim in suit for failure to comply with—(A) any requirement of section 112, except that the failure to disclose the best mode shall not be a basis on which any claim of a patent may be canceled or held invalid or otherwise unenforceable; or (B) any requirement of section 251.”

⁷⁰AIA §18(a)(1)(C) (defining CBM prior art).

⁷¹35 U.S.C. §316(a) (2012).

⁷²See U.S. Patent and Trademark Office, *Ex Parte* Reexamination Filing Data (Sept. 30, 2013), www.uspto.gov/patents/stats/ex_parte_historical_stats_roll_up_EOY2013.pdf.

⁷³See U.S. Patent and Trademark Office, AIA Progress Statistics Graphic, www.uspto.gov/ip/boards/bpai/stats/01614_aia_stats_graph.pdf (posted Oct. 16, 2014).

Figure 13. AIA petition technology breakdown listing biotech/pharma patents at 122 out of the first 1908 petitions filed. See U.S. Patent and Trademark Office, AIA Progress Statistics Graphic, www.uspto.gov/ip/boards/bpai/stats/101614_aia_stat_graph.pdf.

Once a petition is filed, the PTAB must decide whether it is more likely than not that at least one of the challenged claims is unpatentable (PGR),⁷⁴ or whether there is a reasonable likelihood that the petitioner will prevail in establishing unpatentability of at least one claim (IPR).⁷⁵ As of October 16, 2014, petitions have been quite successful in meeting these statutory thresholds, with the PTAB granting review in approximately 74% of all petitions.⁷⁶

For the PTAB to ultimately cancel a patent claim, the petitioner must prove the claim is unpatentable by a preponderance of the evidence, given all parties' arguments. As of October 16, 2014, the PTAB reported that they issued 157 final written decisions (and, in addition, 45 decisions granting adverse judgment).⁷⁷ Consolidating duplicate cases on the same patent, there were 131 unique final written decisions. Of those decisions, 116 (88.55%) canceled or amended at least some claims (see Fig. 14). In only 15 deci-

⁷⁴37 C.F.R. §42.208(c): "[T]he petition supporting the ground would, if un rebutted, demonstrate that it is more likely than not that at least one of the claims challenged in the petition is unpatentable."

⁷⁵37 C.F.R. §42.108(c): "[T]he petition supporting the ground would demonstrate that there is a reasonable likelihood that at least one of the claims challenged in the petition is unpatentable."

⁷⁶See U.S. Patent and Trademark Office, AIA Progress Statistics Graphic, www.uspto.gov/ip/boards/bpai/stats/101614_aia_stat_graph.pdf (posted Oct. 16, 2014).

⁷⁷*Id.*

Impact of America Invents Act on Biotech IP

Figure 14. AIA final written decision breakdown of case dispositions for IPR and CBM combined, excluding mixed outcomes. (Based on internal Finnegan data compiled by attorney Daniel Klodowski. Current as of Oct. 16, 2014. Used with permission.)

sions (11.45%), all instituted claims survived (see *id.*). In 99 (75.57%), all instituted claims were canceled (see Fig. 15). And parties have requested adverse judgment in 45 cases, canceling all claims. As of this writing, only one motion to amend has been granted.⁷⁸

This rate of cancellation of issued claims may not be a total surprise. In particular, once a post-grant proceeding is instituted, the patent claims, in contrast to district court litigation, are accorded no presumption of validity.⁷⁹ In addition, in contrast to *Markman*⁸⁰ hearings in district court litigation, the PTAB applies a "broadest reasonable interpretation" claim construction standard.⁸¹ And finally, the burden of proof on the petitioner to achieve claim cancellation is merely a preponderance

⁷⁸See *International Flavors & Fragrances Inc. v. U.S.A.*, IPR2013-00124, Paper 12 (P.T.A.B. May 20, 2014).

⁷⁹35 U.S.C. §282(a) and §326(e). District courts presume patents "valid" unless parties prove invalidity by clear and convincing evidence. At the Office, a petition must only show "unpatentability" by a preponderance of the evidence, given the patent owner's rebuttal evidence and arguments.

⁸⁰A claim construction or *Markman* hearing is based on the eponymous *Markman v. Westview Instruments, Inc.* (517 U.S. 370) (1996).

⁸¹37 C.F.R. §42.300(b): "A claim in an unexpired patent shall be given its broadest reasonable construction in light of the specification of the patent in which it appears." Note that the U.S. House of Representatives recently passed legislation (H.R. 3309) that would ban the broadest reasonable interpretation for claim construction in post-grant proceedings, and as of this writing, a companion Senate bill was emerging from committee.

A. Murphy et al.

Figure 15. AIA final written decision breakdown of case dispositions for IPR and CBM combined, including mixed outcomes. (Based on internal Finnegan data compiled by attorney Daniel Klodowski. Current as of Oct. 16, 2014. Used with permission.)

of the evidence, in contrast to the district court litigation standard of clear and convincing evidence.

Hence, compared to district court litigation, it should be easier for a post-grant petitioner to establish unpatentability. Indeed, in pre-AIA *inter partes* reexaminations (reminiscent of AIA's IPR proceedings), challengers experienced an overwhelming success rate—forcing patent owners to cancel or change patent claims in 88% of cases.⁸² If those statistics reflect success rates that petitioners can expect for the AIA's post-grant proceedings, patent owners beware.

The one notable drawback for IPR and PGR requestors is that after the PTAB issues a final written decision, the petitioner, real party-in-interest, or privy of the petitioner is estopped from challenging a claim on any ground that the petitioner raised or reasonably could have raised during the proceeding.⁸³ Still, it does not seem that this deters IPR challenges generally, or in the biotech field specifically. Apparently, the estoppel is claim-by-claim for only those claims

involved in the post-grant proceeding.⁸⁴ And, of course, for an IPR, no estoppel extends to invalidity arguments raised under §§ 101 and 112, obviousness-type double patenting (also true for a PGR), inequitable conduct (also true for a PGR), and noninfringement positions (also true for a PGR), because those allegations cannot be raised during IPR.⁸⁵

If the past is any indication, the average number of IPRs filed on biotech patents will rise in the coming years, and there will probably soon be the first biotech PGR. It appears that IPR has already become and PGR will likely become important tools in the biotech industry's toolbox when faced with freedom-to-operate obstacles and the specter of patent infringement.

REFERENCES

*Reference is also in this subject collection.

Lewis G. 2013. Opinion: Racing toward invention. *The Scientist* (July 23, 2013).

* Murphy A, Stramiello M, Lewis S, Irving T. 2014. Introduction to intellectual property: A U.S. perspective. *Cold Spring Harb Perspect Med* doi: 10.1101/cshperspect.a020776.

Nagesh Rao G. 2013. Opinion: AIA does not discriminate. *The Scientist* (August 21, 2013).

⁸²USPTO statistics: 45% of cases had all claims canceled; 43% of cases had claims changed. See www.uspto.gov/patents/stats/inter_parte_historical_stats_roll_up_EOY_2013.pdf.

⁸³35 U.S.C. §315(e) (2011).

⁸⁴“35 U.S.C. 315(e), as amended, and 35 U.S.C. 325(e) provide for estoppel on a claim-by-claim basis, for claims in a patent that result in a final written decision.” Changes to Implement Inter Partes Review Proceedings, Post-Grant Review Proceedings, and Transitional Program for Covered

Business Method Patents, 77 Fed. Reg. 48703 (Aug. 14, 2012).

⁸⁵37 C.E.R. §42.304(b)(2) only allows challenges available under 35 U.S.C. §282(b)(2)–(3) (2012) (i.e., not best mode, obviousness-type double patenting, or inequitable conduct).

Cold Spring Harbor Perspectives in Medicine

Impact of America Invents Act on Biotech Intellectual Property

Amanda Murphy, Michael Stramiello, Jonathan Stroud, Stacy Lewis and Tom Irving

Cold Spring Harb Perspect Med 2015; doi: 10.1101/cshperspect.a020784 originally published online April 27, 2015

Subject Collection [Intellectual Property in Molecular Medicine](#)

Patentability of Stem Cells in the United States

Sarah E. Fendrick and Donald L. Zuhn, Jr.

Inventorship and Authorship

Antoinette F. Konski and Linda X. Wu

The Patentability of Stem Cells in Australia

Jenny Petering and Prue Cowin

Impact of America Invents Act on Biotech Intellectual Property

Amanda Murphy, Michael Stramiello, Jonathan Stroud, et al.

Introduction to Intellectual Property: A U.S. Perspective

Amanda Murphy, Michael Stramiello, Stacy Lewis, et al.

The Role of Regulatory Agencies and Intellectual Property: Part I

Kevin E. Noonan

Canada's Patented Medicines (Notice of Compliance) Proceedings and Intellectual Property

Henry Bian and Conor McCourt

Patentability of Genes: A European Union Perspective

Paul Cole

The Impact of *Myriad* on the Future Development and Commercialization of DNA-Based Therapies and Diagnostics

Michele Wales and Eddie Cartier

Protecting Traditional Knowledge Related to Biological Resources: Is Scientific Research Going to Become More Bureaucratized?

Prashant Reddy and Malathi Lakshmikumaran

Protecting Trade Secrets in Canada

Noel Courage and Janice Calzavara

Inherent Anticipation in the Pharmaceutical and Biotechnology Industries

Michael Goldman, Georgia Evans and Andrew Zappia

The Role of Regulatory Agencies and Intellectual Property: Part II

Kevin E. Noonan

Baseball Bats and Chocolate Chip Cookies: The Judicial Treatment of DNA in the *Myriad Genetics* Litigation

Ian Binnie and Vanessa Park-Thompson

The Impact of *Myriad* and *Mayo*: Will Advancements in the Biological Sciences Be Spurred or Disincentivized? (Or Was Biotech Patenting Not Complicated Enough?)

Jennifer Gordon

Trade Secrets in Life Science and Pharmaceutical Companies

Tara Nealey, Ronald M. Daignault and Yu Cai

For additional articles in this collection, see <http://perspectivesinmedicine.cshlp.org/cgi/collection/>