What's Next for the U.S.—The Metric System?: A Quick Look at the "Imminent" Major U.S. Patent Law Reform

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Introduction

After five attempts in just as many years, the U.S. Congress is finally a vote away from sending a sweeping patent law reform bill to the President for his signature. On March 8, 2011, the Senate passed the America Invents Act ("AIA") by a 95-5 margin, and the House of Representatives Judiciary Committee approved corresponding legislation by a wide 32-3 margin on April 14, 2011. All signs suggest that the House will pass the bill, and the legislation could be enacted as early as later this year.

Seeking to harmonize U.S. patent laws with other systems around the world and promote strong patents to spur economic growth, the AIA represents the first major overhaul to the U.S. patent system in sixty years. Among other changes, the AIA abolishes the U.S.'s longstanding first-to-invent system in favor of a first-inventor-to-file ("FITF") system and implements a correlative derivation proceeding; introduces post-grant review, similar to European opposition practice; eliminates the Hilmer doctrine and introduces other potential earthshaking territorial practice considerations; creates a supplemental examination procedure to cure inequitable conduct; provides a method for third party submissions of prior art during the pendency of an application; and amends current inter partes reexamination.[1] In many ways, this legislation represent a tectonic shift in U.S. patent law, and this review discusses each of these major changes and provides initial thoughts on how practice before the U.S. Patent and Trademark Office ("USPTO"), and patent practice in general, may change after the AIA is enacted.

First-Inventor-to-File and So Much More

While first to file or the U.S. version, FITF, gets all the headlines, many of the other proposed changes to the definition of prior art, including removal of territorial restrictions and elimination of the Hilmer doctrine, will have a more substantial effect on your day to day practice.

FITF Amendments

The AIA replaces the U.S.'s cherished first-to-invent system with a FITF system by amending 35 U.S.C. § 102 of the Patent Act to do away with current sections (a)-(g):

> 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 . . . .[2]

This section alone would move the U.S. to a first-to-file system with absolute novelty requirements. But the AIA goes much further. For example, the act keeps a more limited type of grace period by amending § 102 to except from § 102(a)(1) only disclosure made within one year prior to the effective filing date by the inventor, coinventor, or any third party who obtained the disclosed subject matter either directly or indirectly from an inventor.[3] As a consequence, even an independent third party disclosure within the one year grace period will not jeopardize the patentability of a claimed invention if an inventor, coinventor, or connected third party made an even earlier disclosure during the same grace period.[4]

The move away from first to invent also means that prior art under proposed § 102(a)(2), which is similar to current § 102(e), can only be removed as prior art in limited circumstances. Thus, a U.S. patent application of a third party that publishes after your effective filing date, but has an earlier effective filing date, is prior art for both novelty and obviousness. The new § 102, however, maintains the intent of the CREATE Act and removes certain patents and applications as prior art under § 102(a)(2), where the subject matter was developed under a joint research agreement.[5] Likewise, section 102(b)(2)(C) also eliminates patents and applications as prior art where the disclosed subject matter and claimed inventions were commonly owned or subjected to common assignment by the time of the effective filing date. But to benefit from any collaborative efforts, proposed § 102(c) requires that 1) the joint research agreement be in force by the effective filing date; 2) that the claimed invention is a result of the joint research efforts; and 3) the application discloses the parties to the research agreement.

Elimination of the Hilmer Doctrine

The AIA rights the unequal treatment of U.S. provisional applications and foreign priority documents by legislatively reversing *In re Hilmer*.[6] In *Hilmer*, a U.S. appeals court held that a patent application's foreign filing date under § 119 could be used to antedate prior art but could not be used as affirmative prior art under § 102(e). This shield-sword distinction disadvantages foreign inventors who file an application first in their home country and rely on Art. 4 of the Paris Convention to file a U.S. patent application within a year. Under these circumstances, the foreign application is not effective prior art against any other U.S. application under § 102(e) because it was not "filed in the United States." As a result, entities choosing to file only foreign priority applications gain no offensive benefit from their early disclosure. Thus, *Hilmer* led foreign inventors to either abolish their foreign filings altogether in favor of filing U.S. provisional applications or to file concurrent foreign and U.S. provisional applications.

The need for such filing strategies will no longer be required under the AIA because the AIA maintains U.S. patents and published applications as prior art documents but eliminates the U.S. filing date requirement. In particular, § 102(d) establishes that an application is "effectively filed" for the purposes of § 102(a)(2) (analogous to current § 102(e)) on the date of actual filing in the U.S. or on the date that an application under § 119 was filed. Thus, the USPTO may expect a steep decline in U.S. provisional applications after the enactment of the AIA.

Other Territorial Considerations - the On-sale Bar

Current § 102(b) bars a patent if a claimed invention is on sale *in the* U.S. more than one year prior to the filing of a U.S. patent application for the claimed invention. Proposed § 102(a), however, removes the "in this country" language, begging the question whether non-public offers for sale outside the U.S. will become prior art under the AIA.

Right now, "on sale" includes commercial offers for sale whether public or not.[7] § 102(a)(1) bars patentability if

> 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 . . .

Because Congress has removed the "in this country" language but retained the modifier "public" for use and not "on sale," U.S. statutory interpretation precedent suggests that confidential offers for sale anywhere in the world may become relevant patent bars.[8] But before panic sets in, the authors note that § 102(a)(1) also includes the proviso "or otherwise available to the *public*," (emphasis added) suggesting that Congress intends for only public publications and events, such as sales, to be covered by the AIA. Since the statutory language is new and the territory-defining language has been deleted, we counsel caution in making any assumptions one way or the other before the issue is litigated. As a result, inventors and companies should ensure that they have filed patent applications before drumming up business, even confidentially, for their inventions anywhere in the world.

Derivation Proceedings

The newly proposed derivation proceedings appear to be a necessary corollary to the inventor-publication grace period, but in reality amended § 135 may simply represent the U.S.'s desire to hold on to its first-to-invent roots.[9] If an opportunist files an application that is based on an inventor's research paper before the inventor files his own application, on its face, § 102(b)(2)(B) seems to obviate the need for derivation proceedings in such a situation. It is unlikely, however, that a savvy invention-miner will simply copy an inventor’s original disclosure, perhaps necessitating derivation proceedings in nuanced circumstances where the disclosures are substantially the same but not identical. Thus, § 102(b)(2)(B) appears to be applicable only to situations where it is clear that the patent application and the research publication disclose identical subject matter, leaving murkier questions of overlap for derivation proceedings.

But where a prior research paper is the only evidence of a "communication" to the alleged deriver, the USPTO will not likely initiate a derivation proceeding. As a result, § 135 is most likely directed to situations where derivation occurs in the absence of any public disclosure or in situations where there is a research paper and additional evidence of communication between the petitioner and the alleged deriver. For example, one company may disclose information to a potential partner, who then files an unauthorized patent application based on those business discussions. In either situation, the AIA gives an inventor an opportunity to challenge a deriver—whether the invention was published or not—by filing a petition for a derivation proceeding.

Starting the Proceedings

An inventor may file a petition in the USPTO to institute a derivation proceeding for relief against the owner of an earlier-filed application as long as the invention claimed in the earlier-filed application was derived from the petitioning inventor.[10] The petitioner must file his petition within one year of the publication of a claim to the invention or to a substantially similar invention.[11] The petition must be supported by substantial evidence and set forth with particularity the basis for finding that the earlier applicant derived the claimed invention and, without authorization, filed an application to it.[12] If the USPTO determines that a petition meets the requisite standards, the Director then has final and non-appealable discretion to institute a derivation proceeding.[13]

Once this legislation is enacted, patent practitioners will, no doubt, closely watch the case law as it develops to see what constitutes sufficient particularity and substantial evidence. Since derivation proceedings will likely incorporate—or at least start with—existing § 102(f) case law, at the very least a petitioner will need to outline that the subject matter at issue was conceived in its entirety by another, and that this idea was conveyed to the applicant with enough detail to enable the claimed invention.[14] As mentioned above, merely stating that the petitioner previously published an enabling research article is likely insufficient to meet the proposed threshold because under current § 102(f) case law, access to information alone is not enough to prove derivation.[15]

The proceedings and ramifications of a final decision

Once instituted, the newly minted Patent Trial and Appeal Board ("Board") will conduct the derivation proceeding. The Board has significant discretion to defer action on a petition or stay a proceeding until termination of ex parte reexamination, inter partes review, or post-grant review.[16] However, once underway, a derivation proceeding will probably closely resemble current interference

practice where § 102(f) has been raised. In particular, we expect that the Board will still require a petitioner to prove by clear and convincing evidence the two-part test for derivation, namely that 1) the petitioner first conceived of the invention and 2) that the petitioner communicated his invention to the alleged deriver with enough particularity to enable the claimed invention.[17]

Although the proposed legislation brings the U.S. closer to Europe's first-to-file system, the U.S.'s reluctance to completely eviscerate the concept of inventorship is clear from the provisions for a FITF system and derivation proceedings. As a result of the U.S.'s deep patent law roots, European patent applicants and practitioners are faced with learning another, albeit similar, system. A particular challenge will be to juggle the old and new system since the changes to § 102 will not be retroactive and the new FITF system will only apply to applications filed after the effective date.

Post-grant Review Proceedings

Who may challenge and what can be challenged

Under the proposed legislation, any party besides the patent owner may file a petition to institute post-grant review so long as it is not challenging the patent's validity in a civil action.[18] The petitioner may request cancellation of one or more claims on any basis set forth in § 282(b) ¶¶ 2 or 3 for invalidity, including for example, novelty, obviousness, written description, enablement and statutory subject matter.[19] The petition must be filed within nine months from grant or reissue of a patent.[20]

Initiation of post-grant review

Upon receipt of a post-grant review petition, and any preliminary response by the patentee,[21] the USPTO may only institute post-grant review if unrebutted information presented in the petition demonstrates that it is more likely than not that at least one of the claims challenged is unpatentable or if "the petition raises a novel or unsettled legal question that is important to other patents or patent applications."[22] The USPTO has discretion to determine standards for whether these requirements are met, and any decision to refuse initiation of the proceeding is "final and non-appealable."[23]

Because post-grant review is a new process, it is difficult to say how high the USPTO will set the bar to initiate a proceeding. In view of the statutory definition, it seems likely that the USPTO will set the bar relatively high, which will effectively control the number of frivolous proceedings. This is in drastic contrast to the standards at the European Patent Office for initiating an opposition, which in essence only require that an issue be raised.

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The AIA charges the Board with conducting the post-grant review proceedings, giving it significant discretion to determine the course of post-grant review, including authority to stay, transfer, consolidate, or terminate the proceedings.[24]

To be successful, the petitioner must prove the invalidity of challenged claims by a preponderance of the evidence.[25] As a result of this lower standard of proof than that required in a typical district court litigation, post-grant review is an attractive alternative. However, a final decision estops a petitioner during any subsequent proceeding from asserting what it actually asserted during post-grant review. As a result of this estoppel, an important strategic consideration will be whether to save validity challenges for subsequent litigation.[26] Petitioners should also be aware that a final decision under post-grant review estops the petitioner from raising any defense, in a proceeding before the USPTO, that could have been raised during post-grant review.[27] As a result, after post-grant review, it is unlikely that the same challenger will overcome the "could have been" barrier and institute an inter partes review.

Like derivation proceedings, parties in a post-grant review proceeding may terminate the proceedings if the parties reach a settlement. Unless the Board has already decided the merits, the Board must terminate post-grant review.[28] The USPTO also has

discretion to terminate post-grant review if no petitioner remains.[29] The Act provides for appeal only to the Federal Circuit.[30]

The institution of post-grant review in the U.S. means that all competitive inventors and companies should implement issued patent monitoring systems as is already done with regards to European patents to ensure that they can timely challenge their competitors' patents. Moreover, companies should not lose sight of the fact that their own patents may face post-grant review challenges and should continually evaluate known art (which if material should be submitted to the USPTO) to prepare for such challenges. In the case of important patents, companies may want to consider conducting prior art searches once a patent issues to develop defensive strategies similar to pre-litigation investigations. These due diligence investigations could serve a dual purpose of forming the basis of an offensive post-grant review challenge in the event that a competitor obtains a patent for similar subject matter.

Supplemental Examination

The AIA adds § 257 by amendment to provide patentees with the opportunity to supplement the USPTO record and potentially expunge inequitable conduct. In particular, a patentee can request that the USPTO consider, reconsider, or correct information that may be relevant to the validity of a patent.[31] Within three months after receiving the request, the USPTO must decide whether the patentee's request raises a substantial new question of patentability.[32] If it does, the request for supplemental examination is granted, and the USPTO will conduct a traditional reexamination in view of each issue raised in the request.[33] Unlike a traditional reexamination proceeding, though, the patentee cannot file a responsive statement.[34] As a result, a petitioner will probably want to include the relevant art or other information and a statement regarding why the patent claims remain valid despite this newly raised information.

A reexamination resulting under this section will bar a finding of unenforceability in a district court action for conduct that occurred during the original prosecution that is corrected during the reexamination.[35] Consequently, supplemental examination has the powerful potential to short circuit unenforceability challenges to a patent. In reality, however, the window of opportunity to use supplemental examination is narrow. Supplemental examination cannot be used if a challenger has already raised the issue of inequitable conduct in either a paragraph IV notice letter or if a patent enforcement action is already under way.[36] Therefore, if the patent covers an innovative drug compound or it is a critical patent in a company's portfolio, a careful review of all sources of potential inequitable conduct-raising defenses should be performed as soon after issuance as possible and well in advance of the receipt of paragraph IV letters or the initiation of district court proceedings.

Because § 257 allows for the consideration of all "information" believed to be relevant, supplemental examination need not be limited to circumstances where patentees uncover additional uncited art. Supplemental examination could also be used to correct misstatements or omissions, such as the failure to provide contradictory research and development data, during prosecution.

Other Miscellaneous Provisions: Third Party Pre-issuance Submissions, Inter Partes Review, and Prior User Rights

Third Party Pre-Issuance Submissions

The AIA adds § 122(e) to encourage submission of prior art by third parties during the pendency of patent applications. Under this section, any third party may submit any printed publication that has potential relevance to the examination of the application within a certain time period. Specifically, the submission must be made before a first rejection or within six months of the date the application is first published, whichever is later, and before a notice of allowance is given or made.[37] For most applications, the cut-off will be the date of the first rejection. The required submission, which becomes part of the public file history, must also include a "concise description of the asserted relevance of each submitted document."[38]

Inter Partes Review

The AIA does away with inter partes reexamination, currently conducted by Examiners in the Central Reexamination Unit, and adds an inter partes review procedure to be conducted by the Board.[39] Effectively, the combination of post-grant review and inter partes review augments the current inter partes reexamination by allowing additional attacks on a patent's validity during the period for post-grant review with less restrictive estoppels. While post-grant review provides a petitioner a forum to challenge a patent on any basis of patentability, inter partes review is limited to novelty and non-obviousness.[40] The period for petitioning begins after the period during which post-grant review may be initiated or, if post-grant review is initiated, at the conclusion of the post-grant review.[41] A party challenging the validity of a patent in a declaratory judgment action cannot seek inter partes review, but a petitioner who has been accused of infringement can seek review within six months of receiving a filed complaint.[42]

The basis for review is limited to patents or printed publications, as is current inter partes reexamination, although supporting evidence and opinions may be submitted in the form of affidavits or declarations.[43] Inter partes review also has a greater estoppel effect than post-grant review; in addition to estoppel in district court for issues actually raised, an inter partes review, like current inter partes reexam proceedings, also estops the party from raising any issue that could have been raised.[44] Thus, potential challengers should carefully consider the pros and cons of filing an inter partes review petition.

A significant change is that the AIA raises the bar of entry making initiating an inter partes review much more difficult than initiating a current inter partes reexamination. In particular, the AIA mandates that the Director can only institute inter partes review if there is a reasonable likelihood that the petitioner will prevail in the proceeding.[45] This standard appears much higher than the current standard that a substantial new question of patentability is raised, which is met in over 90% of the reexams filed. Just like with post-grant review, the USPTO's decision whether to institute a review is final and non-appealable.[46]

If a decision is made to institute review, the proceedings will be conducted in a manner similar to post-grant review proceedings. Obviously, these proceedings will differ from the current inter partes reexamination conducted by Examiners, with possible appeal to the Board, in that inter partes review will be conducted by the Board in the first instance. As with post-grant review, the Board has significant discretion to structure and conduct the proceedings, and to adopt settlements. As with post-grant review, the AIA provides for appeal only to the Federal Circuit.

Prior User Rights

Unlike the Senate version of the bill that does not account for prior user rights except to ask for a report on the necessity of them,[47] the House version of the AIA specifically amends § 273 to provide a defense to infringement challenges for prior use. In particular, prior users who reduce the invention to practice and commercialize it at least one year prior to the effective filing date of the patent at issue have a complete defense to infringement.[48] The House version does, however, carve out an exception to this defense for alleged infringers of patents developed with government funding.[49] Apparently, the debate regarding prior user rights and this carve-out, in particular, are on-going, so it is unclear whether prior user rights will even be among the text of any enacted bill.

Conclusion

Overall, the AIA represents a tectonic shift in U.S. patent law. It achieves many of the long sought after goals of global harmonization by implementing the FITF system and post-grant review proceedings. It also seeks to promote stronger patents and more certainty regarding intellectual property rights and along with the *Therasense* decision takes steps to address the plague of inequitable conduct allegations in U.S. litigation. In the coming months, look out for enactment of a final version of the AIA and more details with regards to how to navigate the new U.S. patent landscape. We will continue to provide more substantive details in this column and in a series of lectures this fall. As for the metric system—if the derivation proceedings are any indication—the U.S. is nowhere near measuring just how big a step this legislation represents in anything other than inches and feet.

You can find more information regarding U.S. Patent Law Reform 2011 at http://www.finnegan.com/patentlawreform2011/.

Endnotes

[1] The authors cite herein to only the AIA (the Senate version of the Bill). To the extent there are any notable differences between the Senate and House versions of the Bill, the authors specifically note them. Reference to sections of the U.S. code represent new or amended versions. Any reference to the current version of the U.S. code is specifically noted. Additional information regarding the U.S. patent law reform, including the proposed legislation, can be found at http://www.finnegan.com/patentlawreform2011/.

[2] § 102(a)(1).

[3] § 102(b)(1)(A).

[4] § 102(b)(1)(B).

[5] § 102(b)(2)(C).

[6] 359 F.2 859 (C.C.P.A. 1966) (hereinafter "*Hilmer*").

[7] *Pfaff v. Wells Elecs., Inc*., 525 U.S. 55, 67 (1998); *Hobbs v. United States*, 451 F.2d 849 (5th Cir. 1971).

[8] *Bragdon v. Abbott*, 524 U.S. 624, 645 (1998) ("If a phrase or section of a law is clarified through judicial construction, and the law is amended but retains that same phrase or section, then Congress presumably intended for the language in the new law to have the same meaning as the old.").

[9] § 135.

[10] § 135(a).

[11] *Id*.

[12] *Id*.

[13] *Id*.

[14] *Int'l Rectifier Corp. v. IXYS Corp*., 361 F.3d 1363, 1376 (Fed. Cir. 2004).

[15] *Hedgewick v. Ackers*, 497 F.2d 905, 908 (C.C.P.A. 1974).

[16] § 135(c).

[17] *Brand v. Miller*, 487 F.3d 862, 869-70 (Fed. Cir. 2007).

[18] § 321(a); § 325(a).

[19] § 321(b).

[20] § 321(c). The introduced House bill differs in extending the time period for filing to 12 months.

[21] § 323.

[22] § 324(a)-(b).

[23] § 324(e).

[24] § 325(a); § 6.

[25] § 326(e).

[26] § 325(e)(2).

[27] § 325(e)(1).

[28] § 327(a).

[29] *Id*.

[30] § 141(c).

[31] § 257(a).

[32] § 257(a)-(b).

[33] § 257(b).

[34] *Id*.

[35] § 257(c).

[36] § 257(c)(2).

[37] § 122(e).

[38] Id.

[39] § 311.

[40] § 311(b).

[41] § 311(c).

[42] § 315(a)-(b). The House version allows for nine months.

[43] § 312.

[44] § 315(e).

[45] § 314(a).

[46] § 314(d).

[47] AIA, p. 21.

[48] § 273(b).

[49] § 273(b)(2)(D).