



Pre-Issuance Submissions under the America Invents Act

By Alan Kendrick, J.D., Nerac Analyst

The Leahy-Smith America Invents Act (AIA) was signed into law By President Obama in September 2011 and the final provisions became effective on March 16th, 2013. The AIA's various provisions have been implemented by the US Patent & Trademark Office (PTO) in stages over the 18 months following its enactment.

Significant Provisions of the America Invents Act

The Act has significantly changed many aspects of the US patent system. Some of the most significant changes include;

A First-Inventor-to-File (FITF) Regime: Replacement of a first-to-invent system with a first-to-file system. Priority is given to the first inventor to file the patent application, or to the first inventor who publicly discloses the invention within 1 year prior to filing.

Limitation on Joinder of Parties: Limits how accused infringers may be joined in one action as defendants. Accused infringers may not be joined in one action as defendants or counterclaim defendants, or have their actions consolidated for trial, based solely on allegations that they each have infringed the patent or patents in suit.

Restrictions on False Marking Claims: Prior to the AIA, an individual could bring a *qui-tam* action based on products that are mismarked as protected by a patent. The statute provided for substantial statutory fines of \$500 per offense. Under the AIA, only the United States will be able to sue for statutory damages for false marking. Private parties will be entitled only to compensatory damages based on the "competitive injury" that was the direct result of the false marking.

Elimination of the Best Mode Defense: The best mode defense in patent litigation is eliminated. Patentees are still required to comply with the best mode requirement, however an alleged infringer is prevented from claiming a failure by the patentee to disclose the best mode as a defense to infringement.

Procedural Changes

The AIA also establishes several new PTO proceedings regarding pre issuance submissions and post-grant reviews, and implements changes to several existing procedures such as inter partes and ex parte re-examination reviews.

Post-Grant Review: A patent may be challenged by any non-owner during the nine months after grant or issuance, on any grounds that would be available in district court litigation.

Inter Partes Review: The new inter partes review, along with changes to the post-grant review, will replace existing inter partes re-examination. Review will be based on prior art patents or publications and grounds will be limited to anticipation or obviousness. The third-party petitioner must show that it is more likely than not that at least one of the claims challenged in the petition is unpatentable and that the petitioner would prevail with respect to at least one of the claims challenged. The review becomes available after the nine-month post-grant review window has expired or after termination of an actual post-grant review.

Supplemental Review Proceedings: A patent owner may request a supplemental examination to consider, reconsider or correct information believed to be relevant to the patent. A supplemental examination request is no longer limited to prior art patents and printed publications, but may be based on any information believed relevant to the patent. If a determination is made that a substantial new question of patentability is raised, the Director shall order reexamination of the patent.

Transitional Post-grant Review for Covered Business Method Patents: The AIA creates a special invalidity procedure for challenging the validity of covered business method patents that claim a method or corresponding apparatus for performing data processing or other operations used in the practice, administration or management of a financial product or service. It relaxes timing restrictions and allows an accused infringer of business method patents to bring a post-grant review proceeding until September 16, 2020.

Pre-Issuance Submissions: Section 8 of the AIA amends the patent laws to provide a mechanism for third parties to submit to the Office, for consideration and inclusion in the record of a patent application, any patents, published patent applications, or other printed publications of potential relevance to the examination of the application. The statutory provisions are intended to improve the quality of the examination and issued patents by promoting the efficient processing of submissions and ensuring that the most relevant documents have been considered during the prosecution of the application.

Nuts & Bolts of Pre-Issuance Submissions

As of September 16, 2012, anyone has standing to submit documents to the USPTO that are relevant to a pending patent application. Pre-issuance submissions provide a means by which a third party may participate in the original patent examination process. Section 8 of the AIA amends the patent laws to provide a procedure for third parties to submit relevant publications to the Office “for consideration and inclusion in the record of a patent application, any patent, published patent application, or other printed publication of potential relevance to the examination of the application.” *AIA Section 8(a)(1) implemented by 35 U.S.C. 122(e)*. This provision provides a mechanism for third parties to contribute to the quality of issued patents by drawing the examiner’s attention to relevant prior art that may have been missed or not given thorough or proper consideration, and by providing a means for the third party to comment on the relevance of the prior art. A third party may file a submission in any non-provisional utility, design, or plant application, as well as in any continuing application, including abandoned applications or those not yet

published. Third-party submissions may not be filed in any issued patent, reissue application, or reexamination proceeding.

The AIA amends 35 U.S.C. 122 by adding paragraph (e), which governs the conditions that apply to third-party pre-issuance submissions to the PTO in a patent application. A pre-issuance submission must be timely filed, in writing, and contain the following:

- (1) A list identifying the items being submitted,
- (2) A concise description of the relevance of each item listed,
- (3) A legible copy of each non-U.S. patent document listed,
- (4) An English language translation of any non-English language item listed,
- (5) A statement by the party making the submission that the submission complies with the statute and the rule;
- (6) Payment of the required fees.

Additionally, any submission made under §122(e) must be made before the earlier of

- (a) the date of notice of patent allowance, or
- (b) the later of
 - (i) 6 months after the application's publication, or
 - (ii) the date of first rejection of any claim by the examiner.

Practical Application of the Pre-Issuance Submission

Claims restriction, denial and application rejection.

A third party may submit prior relevant art along with a concise explanation of relevance as a means to persuade the examiner to limit or deny patent application claims or to reject the application outright. The concise description of relevance is limited to a factual description of a submitted document's relevance and may only set forth facts regarding the listed item's relevance to the examination of the subject patent application. The concise description of relevance does not allow third parties to propose rejection of claims, submit arguments against patentability or to state conclusions as to the patentability of any claim. Any such submissions will be found non-compliant and discarded and the submission fee will be forfeited. Amendments to non-compliant submissions are not allowed, however a party may file a new submission within the statutory filing period and pay the applicable fees.

It is not necessary that the submitted published document be one that is new to the prosecution. The submission could include a document already discovered by the examiner or one submitted by the applicant. The submission of such publications allows a third party to highlight relevant items of a

submitted publication along with a description designed to draw the examiner's attention to those relevant issues that may have been overlooked or to facts that support an alternative interpretation of the claims.

Determination of risk and litigation avoidance

A pre-issuance submission allows a competitor to submit facts that could potentially invalidate or restrict claims of an application providing the competitor with greater certainty of the risks associated with pending patent applications in relation to the competitor's product. This is particularly important where the competitor's product is still in the developmental stages and may, as designed, infringe elements of the subject application if granted. A pre-issuance submission by a competitor that is relied on by the examiner to narrow, restrict or reject the application claims provides an offensive means to avoid future infringement litigation. Given the relatively low submission fees, \$180 for every ten documents listed or fraction thereof, a pre-issuance submission may be an attractive means to limit a competitor's exposure to expensive infringement litigation. And if the submission contains three or fewer documents, a third party is exempt from paying the submission fees provided it is the party's first submission and the party declares that the submission is the first and only submission under 35 U.S.C. 122(e) filed in the application by the party.

Another benefit of a pre-issuance submission with respect to litigation is the lower burden of proof in showing that a claim is unpatentable in view of the submitted items. The burden of proof in pre-issuance submission is a preponderance of the evidence, whereas in litigation the granted patent is given a presumption of validity and the burden of proof to support invalidity is clear and convincing evidence.

Potential disadvantages to third parties submitting pre-issuance submissions

An unsuccessful submission may strengthen the subsequently granted patent because the submitted items will become part of the patent's file wrapper and hence part of the patent record. This will likely prevent any pre-issuance submissions from being relied upon to invalidate the granted patent in any subsequent post-grant review, inter partes review or litigation.

Although a party that submits a pre-issuance submission may do so with anonymity, a pre-issuance submission heightens the applicant's awareness of a competitor or potential infringer's interest. This may provide the applicant with impetus to keep the claims as broad as possible or lead the applicant to file divisional applications and keep them pending in order to subsequently broaden the patent scope. The patent applicant may have another advantage in that any claims affected by items presented in a pre-issuance submission may be easily amended at this early stage in the prosecution.

Nerac provides identification to submission support

Nerac can provide research and support services through the entire pre-issuance submission process. Nerac analysts work with the client to establish a competitor and technology watch list relevant to the client's products and technology. The watch list would include patent applications filed by competitors that produce identical or similar products, and patent applications the subject of which relates to relevant client technologies. Nerac analysts will work with the client to establish alert strategies designed to identify published applications to which the client may want to take exception through the use of a pre-issuance

submission. Nerac analysts will then monitor and review the weekly patent publications and send a feed of any publications that meet the client's criteria as identified by the alerts.

If the client subsequently decides to file a pre-issuance submission to an identified patent application, Nerac can further assist in the pre-issuance process by reviewing the subject patent file wrapper and determining whether the time and first rejection requirements of §122(e) (1)(A) & (B) have been met. If the pre-issuance submission is so authorized, Nerac analysts would then perform detailed relevant prior art and invalidity research on the proposed patent and provide the results in a form acceptable for a pre-issuance submission. Analysts will provide a final report listing the relevant prior art, copies of the relevant publications highlighting the relevant items, and the associated concise statement of relevance.

Nerac's identification to submission support for pre-issuance submissions is an efficient means for clients to monitor, identify and submit pre-issuance submissions on proposed patents that may have an impact on their products and technologies.

About the Analyst

Alan Kendrick, J.D.

Alan Kendrick specializes in mechanical and aerospace systems and provides clients with technical and intellectual property support. He worked for the systems engineering division of NASA's Ames Research Center in Northern California for twelve years as a mechanical/aerospace design engineer. While at NASA, Alan worked on a variety of design projects including wind tunnel design, modification and modernization, design and structural analysis of aircraft modification projects, biomedical and human habitat research equipment, electro-mechanical hardware modernization, design, selection and integration with mechanical systems, space flight hardware, and large facility piping and piping structure analysis and design. He has worked at Boeing/Hughes Satellite Systems as a mechanical/aerospace satellite systems design engineer where he designed component equipment for the Anik F2 communications satellite. Recently, Alan has worked in the solar industry in the design of large scale photovoltaic systems (200kW+) for industrial commercial applications. He has experience in the installation and operation of various mechanical, electro-mechanical, aerospace, hydraulic and R&D facility designs, hardware, equipment and models.

Mr. Kendrick also holds a Juris Doctor degree from the University of San Francisco and has been a California licensed attorney since 1998. His practice focused on intellectual property matters including patent, trademark, copyright, trade secret and unfair competition. He worked for the intellectual property law firm of Čermák, Hořejš Myslíl in Prague, Czech Republic from 2001 to 2004 and he has seven years of international legal experience.

Credentials

J.D. University of San Francisco

B.S. *Magna Cum Laude*, Aerospace Engineering, San Jose State University

Bar Member, U.S. District Court - Northern District of California

Bar Member, U.S. District Court - Southern District of California

Bar Member, Supreme Court of California

Bar Member, Czech Republic (Česká Advokátní Komora) – admitted as a foreign attorney 2002-2006.

About Nerac

Nerac Inc. is a global research and advisory firm for companies developing innovative products and technologies. Nerac provides expert insights that equip clients with the knowledge to develop or refine a technology, explore market growth opportunities, evaluate intellectual property strategies and respond to

Nerac Inc.

1 Technology Drive
Tolland, Connecticut 06084-3900

www.nerac.com

860.872.7000 telephone
860.872.6026 facsimile

regulatory changes. Nerac has approximately 1,000 clients worldwide and a long, successful consulting history in a wide-range of industries with a strong focus in the areas of pharmaceutical, medical devices, engineering, energy, food and nutraceuticals and specialty chemicals.