Fall 2011

Business Implications of the 2011 Leahy-Smith America Invents Act

On September 16, 2011, the Leahy-Smith America Invents Act (AIA) became law and subsequently made extensive changes to the practice of patent law in the United States for the first time in decades.[1] The AIA is divided into thirty-seven sections, of which approximately only half will be of substantive consequence for most corporate IP departments.[2] Described below are the more relevant provisions of the new law and their business implications. The default effective date is one year from enactment – or September 16, 2012. For the sake of corporate preparedness, individual sections are grouped according to temporal applicability of either immediate or delayed relevance.[3]

Immediate Relevance: Effective as of September 16, 2011

- **Best Mode** – Failure of a patent applicant to describe the best mode shall no longer be a basis "on which any claim of a patent may be canceled or held invalid or otherwise unenforceable."[4] *While corporations need not worry about post-issuance patent invalidations due to alleged violations of the best mode requirement, a description of the best mode is still required during pre-issuance patent prosecution.*
- **Joinder** – Plaintiffs are explicitly barred from filing a single lawsuit on multiple defendants if the sole justification for joinder is that all defendants have allegedly infringed the same patent(s). The law also bars case consolidation absent waiver from any defendant(s).[5] *While affording some relief from frivolous non-practicing entity (NPE) infringement actions, other pragmatic issues such as court ordered consolidation of discovery may temper the potency of this provision for patent holders.*
- **False Marking** – *Qui tam* actions will be eliminated for most false marking suits. While only the U.S. government may sue for statutory damages, persons who have suffered a "competitive injury" may bring a civil action for damages "adequate to compensate for the injury."[6] *Corporations will now be afforded relief from many false marking lawsuits.*
- **Prior User Defense** – Applicable to new patents, AIA will expand "good faith" prior "commercial use" defenses to presumably all types of patents.[7] The prior user defense cannot be used for most

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[1] Otherwise known as H.R. 1249. Section 30 of H.R. 1249 states that "[i]t is the sense of Congress that the patent system should promote industries to continue to develop new technologies that spur growth and create jobs across the country which includes protecting the rights of small businesses and inventors from predatory behavior that could result in the cutting off of innovation."

[2] The listed provisions are only a subset of the entire Act. We encourage all stakeholders to carefully read and interpret H.R. 1249 as enacted.

[3] Corporations should realize that delayed changes becoming effective September 16, 2012 and beyond should be addressed as soon as possible to allow for timely corporate implementation.

[4] *Id.* at §15. While the best mode invalidity defense against infringement has been eliminated, 35 U.S.C. §112 best mode violations will remain a basis for claim rejection at the United States Patent & Trademark Office (PTO).

[5] *Id.* at §19. Parties may be joined as defendants (including counterclaim defendants) in an action for infringement only if they may be liable "jointly, severally, or in the alternative" and "questions of fact common to all defendants . . . will arise in the action." The result of this provision will ostensibly raise litigation costs for non-practicing entities (i.e., NPEs or patent trolls), as lawsuits will have to be filed separately, thereby increasing judicial burden. Notably, actions based on 35 U.S.C. §271(e)(2) (i.e., ANDA proceedings) are exempt from this provision.

[6] *Id.* at §16. As this section is immediately effective for all pending and future cases, it appears that most current false marking lawsuits will be dismissed. Additionally, marking with an expired patent number is no longer a statutory violation.

[7] *Id.* at §5. Previously, this defense was only available for business method patents. This defense is applicable only if such commercial use, proven by clear and convincing evidence, occurred in the U.S. at least 1 year before the earlier of either: (i) the effective filing date or (ii) the date of public disclosure. While the scope of "commercial use" is not explicitly defined, both

patented subject matter developed at institutions of "higher education".[8] *Corporate entities are now generally immune from infringement allegations if qualifying prior commercial use, including "internal commercial use" (e.g., trade secret use), can be established.*

- **Venue** – Applicable to any currently pending or subsequent appeal, certain PTO appellate Board decisions (including ex parte reexaminations) may only be appealed to the Court of Appeals for the Federal Circuit, and not a district court.[9]
- **Reexamination Standard** – The standard for new requests for *inter partes* reexamination will change to "a reasonable likelihood that the requestor would prevail" with respect to at least one claim challenge.[10] *Corporations should realize that the current new standard is a higher burden of proof for* inter partes *reexamination patent challenges.*
- **Patentable Subject Matter** – No patent will be granted for pending "tax-strategy" applications or pending applications encompassing "a human organism."[11]
- **Patent Term Extension (PTE) Requests** – Applicable to any pending or subsequent case, the calculation of the 60-day time period for applying for PTE has been modified to exempt a day when FDA marketing approval is transmitted after 4:30 PM Eastern Time on a business day.[12] *Corporations are afforded more time for PTE requests when FDA marketing approval occurs after traditional business working hours.*
- **Advice of Counsel** – Failure to obtain the advice of counsel may not be used to prove that the accused infringer (i) willfully infringed the patent or (ii) intended to induce infringement.[13] *It is presently unclear how this provision affects determination of enhanced damages.*

Delayed Relevance: Effective as of September 16, 2012 or March 16, 2013 [14]

- ***Inter Partes* Review** – Retroactively effective September 16, 2012, petitions for *inter partes* review by a person who is not the patent owner shall (i) be based on patents or printed publications for an issue actionable under 35 U.S.C. §102 or §103 and (ii) be filed after the later of 9 months after patent/reissue grant or termination of any post-grant review proceeding.[15] *Corporate defendants*

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premarketing regulatory review (e.g., FDA) and continued non-profit laboratory use are available for the prior commercial use defense. Assignee limitations and other exceptions apply.

[8] University inventions not eligible for federal funding (e.g., certain stem cell research) are subject to the prior user defense.

[9] *Id.* at §9. 35 U.S.C. §146 civil interference proceedings, §145 civil actions, §32 suspension from practice, §293 nonresident patentee and §154 PTA adjustments proceedings shall be appealed to the District Court of Eastern Virginia (formerly, the U.S. District Court for the District of Columbia).

[10] *Id.* at §6. Previously, the standard for any reexamination request was "a substantial new question of patentability". This will soon be referred to as "Inter Partes Review".

[11] *Id.* at §§14 and 33, respectively. Tax preparation and financial management inventions are still patentable.

[12] *Id.* at §37. Thus, FDA approval at 4:31 PM Eastern Time on a Friday would allow sponsor to wait until the next following business day (e.g., Monday if it is not a national holiday) to begin calculation of the 60-day PTE request period.

[13] *Id.* at §17. This section of the AIA merely codifies the well-settled rule of In re Seagate Tech., LLC, 497 F.3d 1360 (Fed. Cir. 2007) where a failure to obtain an opinion of counsel shall not be considered when adjudicating willful infringement.

[14] Depending on the specific subsection of the AIA, the delayed statutory effective dates are either 12 months or 18 months after enactment of the AIA.

[15] *Id.* at §6. Printed publications additionally include "affidavits or declarations of supporting evidence and opinions, if the petitioner relies on expert opinions." Inter partes review (IPR) petitions must identify each claim challenge with particularity and demonstrate that a "*reasonable likelihood* that the petitioner would prevail with respect to at least 1 of the claims challenged . . . ." The previous lower standard for any reexamination request was "a substantial new question of patentability." IPR will replace *inter partes* reexamination and all IPR petitions will be made publically available. Patent owners are afforded a right to file a preliminary response. The determination by the PTO on whether to institute an IPR shall be final and nonappealable. Patent owners may file one motion to amend patent. IPR review is barred by earlier civil actions. Later filed civil actions may be automatically stayed. Counterclaim validity challenges are not similarly restricted. IPR is barred if requested more than one year after petitioner is sued for infringement. PTO joinder of multiple IPR petitioners is discretionary. IPR is conducted by the Patent Trial and Appeal Board (PTAB) and will allow for limited discovery, oral hearings, settlement and protective orders. Appeal of PTAB decisions are directed to the CAFC. IPR affords intervening rights to qualifying parties. The PTO may limit the number of IPR proceeding during the first four 1-year periods. Estoppel applies to any ground that petitioner "raised or reasonably could

should begin monitoring third party patent applications (and patents issued before November 29, 1999) in anticipation of making the difficult decision whether to file an inter partes *review request or a declaratory judgment claim of invalidity. Corporations should realize that (i) the new standard is a higher burden of proof for patent challengers, (ii) there is no longer the requirement for the question of patentability to be "new", and (iii) patents subjected to* inter partes *review may emerge stronger.*

- **Post-Grant Review** – Effective September 16, 2012 for patents granted under the first-to-file system (March 16, 2013), any petition for post-grant review by a person who is not the patent owner must be "identified, in writing and with particularity . . ." and filed within 9 months of patent/reissue grant date. Post-grant review may be based on *any* statutory grounds of invalidity with a final decision to be issued in 1 year.[16] *Corporations should begin monitoring competitor's pending applications in anticipation of filing a broad array of post-grant review challenges. Stakeholders should realize that patents subjected to post-grant review might emerge stronger. Current patent seekers should file before the effective date to avoid future post-grant review.*
- **Supplemental Examination** – Retroactively effective September 16, 2012, patent owners may be granted "supplemental examination" if the request "raises a substantial new question of patentability".[17] *Corporations are encouraged to promptly request supplemental examination to "cleanse" any patent that may arguably have a defective prosecution history (e.g., due to inequitable conduct).*
- **Preissuance Submissions** – Effective September 16, 2012 and applicable to any pending application, any third party may submit any printed publication "of potential relevance" with a "concise description" of relevance before the earlier of: (i) the date of Notice of Allowance or (ii) the later of (a) 6 months after date of publication or (b) the date of the first Office Action.[18] *While submissions with commentary may be used to prevent issuance of a patent, surviving patents will emerge stronger.*
- **Patent Trial and Appeal Board (PTAB)** – Effective September 16, 2012, the PTAB will (i) review adverse decisions of examiners, (ii) review appeals of reexaminations, (iii) conduct derivation proceedings, and (iv) conduct inter partes and post-grant reviews.[19] The PTAB will replace the Board of Patent Appeals and Interferences (BPAI).

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have raised" during IPR. Note that *ex parte* reexamination is still available to challenge patentability under the less rigorous "substantial new question of patentability" threshold.

[16] *Id.* at §6. Similar to European opposition practice, petitions must be from "a person who is not the owner of a patent" and will become publically available. Citations may be based on patents, printed publications and affidavits or declarations of supporting evidence and opinions, if the petitioner relies on "*other factual evidence"* or on expert opinions (italicized language differs from allowable IPR citations). Patent owner has the right to file a preliminary response. Post-grant review (PGR) is conducted by the PTAB and will allow for discovery, oral hearings, settlement and protective orders. PGR is available if "it is *more likely than not* that at least 1 of the claims challenged in the petition is unpatentable." Particularly relevant to the biotechnology and chemical arts, PGR is available for alleged violations of 35 U.S.C. §§101, 102, 103 and 112 Written Description, Enablement, and issues of "unsettled legal question[s] . . . important to other patents or patent applications", but not Best Mode. Earlier filed civil actions will bar PGR. Later filed civil actions will be automatically stayed. Multiple petitions for PGR may be consolidated. Limitations on PGR of Reissue patents exist. PGR is conducted by the PTAB. Patent owners may file one motion to amend patent. PGR affords intervening rights to qualifying parties. Appeal of PTAB decisions are directed to the CAFC. The PTO may limit the number of PGR proceeding during the first four 1-year periods. Estoppel applies to any ground that petitioner "raised or reasonably could have raised" during PGR.

[17] *Id.* at §12. Patentees may not file a reexamination statement pursuant to 35 U.S.C. §304. With the exception of (i) a civil suit pled with particularity or (ii) a notice received by patentee during a ¶4 ANDA proceeding before the date of a supplemental examination request, a patent shall not be held unenforceable due to conduct related to information that was unconsidered, inadequately considered or incorrect in a prior examination if corrected during a supplemental examination. Patent owners also cannot rely on a pending supplemental exam to defeat defenses raised in an infringement or §337(a) ITC action filed before completion of the supplemental examination.

[18] *Id.* at §8. Currently, 37 C.F.R. §1.99 requires third party prior art submissions to be made within two months of publication and prohibits any discussion of prior art.

[19] *Id.* at §7. Administrative patent judges shall be persons of "competent legal knowledge and scientific ability . . . ." All proceedings will be held by at least three members and are appealable to the CAFC. Applicants or parties to a derivation proceeding may additionally have remedy by a civil action at the District Court of Eastern Virginia.

- **First Inventor to File** – Effective March 16, 2013, priority will be calculated from the first inventor's effective filing date with the PTO.[20] Foreign public knowledge, foreign public use or art "otherwise available to the public" is now available as prior art if they predate the effective filing date. *Corporations should consider (i) expanding the scope of prior art searches and (ii) filing fully enabled patent applications (including provisional applications) as early as possible to avoid the expanded pool of prior art. U.S. patents will be able to rely on a foreign filing date for priority purposes and to defeat later-filed applications. 35 U.S.C. §103 obviousness will be analyzed as of the effective filing date (and not the date of invention). Businesses should realize that strategic pre-filing disclosures might substantially negate foreign patent rights.*
- **Derivation Proceedings** – Effective March 16, 2013, derivation proceedings may be brought by a later inventor alleging that the earlier patent applicant derived the invention. Any petition must (i) be filed with the PTO within one year of first publication of a relevant claim and (ii) be supported "by substantial evidence."[21] *Corporations should have protocols in place to monitor newly published patent applications for inventions that may have been derived from corporate inventor(s).*
- **Assignee Application Filing** – Effective March 16, 2013, patent assignees may file patent applications.[22] *Corporate assignees no longer need to file a petition if the inventor(s) refuse to sign patent application oath/declaration.*
- **Deceptive Intent** – The requirement of no deceptive intent has been eliminated for correcting (i) errors in inventorship, (ii) errors in reissue corrections, and (iii) failures to obtain foreign filing licenses.[23] *Corporations will now be able to more freely amend some errors thereby eliminating several grounds of invalidity or unenforceability.*
- **Interference Proceedings** – Pending interference proceedings of 35 U.S.C. §§102(g), 135 and 291 will continue to apply to those applications with a priority date before March 16, 2013.[24]

Please note that the above commentary describes only the more generally applicable provisions of the America Invents Act of 2011. Other provisions in the AIA address: changes to prosecution fees, PTO funding, establishment of a "micro-entity" class, pro bono programs, priority examination, satellite PTO offices, administrative judge travel expenses, funding agreements, and U.S. government sponsored studies of (i) patent litigation, (ii) international patent protections for small businesses, (iii) applicant diversity, (iv) genetic testing, and (v) implementation issues.

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[20] *Id.* at §3(a-d). Previously, a "first-to-invent" standard permitted an applicant to antedate prior art with proof of earlier invention. A 1-year grace period will still apply for disclosures made only by the inventor(s) or someone who derived the inventor's subject matter. Importantly, non-derived third party disclosures prior to application filing date can negate patentability. "Effective filing date" means either (i) the actual filing date or (ii) the filing date of the earliest application for which the patent or application is entitled. Moreover, "[i]t is the sense of the Congress that converting the United States patent system from "first to invent" to a system of "first inventor to file" will improve the United States patent system and promote harmonization of the United States patent system with the patent systems commonly used in nearly all other countries throughout the world . . . ." *Id.* at §3(p).

[21] *Id.* at §3(h). The determination of whether to institute a derivation proceeding shall be final and nonappealable. The Patent Trial and Appeal Board (PTAB) is tasked with determining whether a claimed invention was derived. Parties may additionally settle or enter arbitration.

[22] *Id.* at §4(b).

[23] *Id.* at §20.

[24] In other words, those applications *not* affected by the first-to-file provisions. The PTO will determine the circumstances under which a pending interference proceeding may be dismissed without prejudice in favor of a post-grant review proceeding. v11

If you have any questions about this article, or would like to discuss this topic further, please feel free to contact:

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