

The Leahy-Smith America Invents Act: Innovation Issues

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Summary

Following several years of legislative discussion concerning patent reform, the Congress enacted P.L. 112-29, signed into law on September 16, 2011. The Leahy-Smith America Invents Act makes significant changes to the patent system, including:

- *First-Inventor-to-File Priority System*. The America Invents Act shifts the U.S. patent priority rule from the current "first-to-invent" system to the "first-inventor-to-file principle" while allowing for a one-year grace period.
- *Prior User Rights*. The legislation establishes an infringement defense based upon an accused infringer's prior commercial use of an invention patented by another.
- *Assignee Filing*. Under the America Invents Act, a patent application may be filed by the inventor's employer or other entity to whom rights in the invention are assigned.
- *Post-Grant Review Proceedings*. The America Invents Act changes the current system of administrative patent challenges at the U.S. Patent and Trademark Office (USPTO) by establishing post-grant review, *inter partes* review, and a transitional program for business method patents.
- *Public Participation in USPTO Procedures*. The legislation allows members of the public to submit pertinent information to the USPTO concerning particular applications both before and after patent issuance.
- *USPTO Fees.* The new law stipulates fees for USPTO patent services and allows the agency to adjust the fees in order to cover its costs. It also requires that fees collected above the amount provided for in the appropriations process be used only for the USPTO.
- *Patent Marking*. The America Invents Act limits lawsuits challenging patent owners with false patent marking and allows for virtual, Internet-based marking.
- *Patentable Subject Matter*. The America Invents Act prevents patents claiming or encompassing human organisms and limits the availability of patents claiming tax strategies.
- *Best Mode*. The statute maintains the requirement that patents describe the best mode, or superior way for practicing the claimed invention, but eliminates failures to do so as a basis for invalidating the patent.

The America Invents Act introduces a number of additional changes to the patent law, including changes to the venue statute, the introduction of supplemental examination, and a clarification of the law of willful infringement.

Although the America Invents Act arguably makes the most significant changes to the U.S. patent statute since the 19th century, the legislation does not reflect all of the issues that were the subject of legislative discussion including the assessment of damages during infringement litigation and the publication of all pending patent applications prior to grant.

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Introduction

P.L. 112-29, the Leahy-Smith America Invents Act, arguably makes the most significant changes to the patent statute since the 19th century. Among other provisions, the statute introduces into U.S. law a first-inventor-to-file priority rule, an infringement defense based upon prior commercial use, and assignee filing. The legislation prevents patents from claiming or encompassing human organisms, limits the availability of patents claiming tax strategies, and restricts the best mode requirement. The America Invents Act also makes notable reforms to administrative patent challenge proceedings at the U.S. Patent and Trademark Office (USPTO) and to the law of patent marking. Along with numerous other changes to patent laws and procedures, these reforms were intended to modernize the U.S. patent system and to improve its fairness and effectiveness.

Congressional interest in patent reform is evidenced by sustained legislative activity over the last four Congresses.[1] There is broad agreement that more patents are sought and enforced than ever before; that the attention paid to patents in business transactions and corporate boardrooms has dramatically increased; and that the commercial and social significance of patent grants, licenses, judgments, and settlements is at an all-time high.[2] As the United States becomes even more of a high-technology, knowledge-based economy, the importance of patents may grow even further in the future.

Most experts agree that patent ownership is an incentive to innovation, the basis for the technological advancement that contributes to economic growth. It is through the commercialization and use of new products and processes that productivity gains are made and the scope and quality of goods and services are expanded. Award of a patent is intended to stimulate the investment necessary to develop an idea and bring it to the marketplace embodied in a product or process. Patent title provides the recipient with a limited-time monopoly over the use of his discovery in exchange for the public dissemination of information contained in the patent application. This is intended to permit the inventor to receive a return on the expenditure of resources leading to the discovery but does not guarantee that the patent will generate commercial benefits. The requirement for publication of the patent is expected to stimulate additional innovation and other creative means to meet similar and expanded demands in the marketplace.

Passage of the America Invents Act was preceded by several years of legislative debate about the current workings and future direction of the U.S. patent system. Although the discussion was wide-ranging, several points of concern were frequently mentioned. One was the recognition that differences between U.S. patent laws and global patent norms might increase the difficulty of domestic inventors in obtaining rights abroad. Another was that poor patent quality and high costs of litigating patent disputes might encourage speculation, or "trolling," by entrepreneurs that

[1] See CRS Report R41638, *Patent Reform in the 112th Congress: Innovation Issues*, by Wendy H. Schacht and John R. Thomas; CRS Report R40481, *Patent Reform in the 111th Congress: Innovation Issues*, by Wendy H. Schacht and John R. Thomas; CRS Report RL33996, *Patent Reform in the 110th Congress: Innovation Issues*, by John R. Thomas and Wendy H. Schacht; and CRS Report RL32996, *Patent Reform: Innovation Issues*, by John R. Thomas and Wendy H. Schacht.

[2] Statistics from the United States Patent and Trademark Office (USPTO) support this account. In 1980, 104,329 utility patent applications were received at the U.S. Patent and Trademark Office (USPTO); by 2009, this number had more than quadrupled to 456,106 applications. During the same time period, the number of U.S. utility patents granted grew from 61,819 to 167,349. U.S. Patent and Trademark Office, *U.S. Patent Statistics, Calendar Years 1963-2009*, available at http://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.pdf.

acquire and enforce patents. Congress also recognized that individuals, universities, and small entities play a role in the technological advancement and economic growth of the United States. A number of provisions of the America Invents Act address these issues and concerns in different ways.

As ultimately enacted, the America Invents Act also reflects the reality that the courts have been active in making changes to important patent law principles. Some observers believe that several court decisions addressed the same concerns that had motivated earlier legislative reform proposals, thereby obviating or reducing the need for congressional action. For example, judicial opinions issued in the past several years have addressed the availability of injunctive relief against adjudicated patent infringers,[3] the standards for deciding which venue is appropriate for conducting a patent trial,[4] and the assessment of damages in patent infringement cases.[5] As a result of these and other developments, several provisions found in predecessor versions of the America Invents Act were not included in the final version of the statute.[6]

This study provides an overview of the America Invents Act. It begins by offering a brief overview of the patent system. The specific components of this legislation are then identified and reviewed in greater detail. The report closes with further considerations.

Patent System Fundamentals

The patent system is grounded in Article I, Section 8, Clause 8 of the U.S. Constitution, which states that "The Congress Shall Have Power ... To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries...." As mandated by the Patent Act of 1952,[7] U.S. patent rights do not arise automatically. Inventors must prepare and submit applications to the U.S. Patent and Trademark Office (USPTO) if they wish to obtain patent protection.[8] USPTO officials known as examiners then assess whether the application merits the award of a patent.[9] The patent acquisition process is commonly known as "prosecution."[10]

In deciding whether to approve a patent application, a USPTO examiner will consider whether the submitted application fully discloses and distinctly claims the invention.[11] In addition, the application must disclose the "best mode," or preferred way, that the applicant knows to practice the invention.[12] The examiner will also determine whether the invention itself fulfills certain substantive standards set by the patent statute. To be patentable, an invention must consist of a

[3] eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388 (2006).

[4] In re TS Tech USA Corp., 551 F.3d 1315 (Fed. Cir. 2008).

[5] Lucent Technologies, Inc. v. Gateway, Inc., 580 F.3d 1301 (Fed. Cir. 2009).

[6] See papers cited in footnote 1.

[7] P.L. 82-593, 66 Stat. 792 (codified at Title 35 United States Code).

[8] 35 U.S.C. § 111.

[9] 35 U.S.C. § 131.

[10] John R. Thomas, "On Preparatory Texts and Proprietary Technologies: The Place of Prosecution Histories in Patent Claim Interpretation," 47 *UCLA Law Review* (1999), 183.

[11] 35 U.S.C. § 112.

[12] *Ibid*.

process, machine, manufacture, or composition of matter that is useful, novel, and nonobvious. The requirement of usefulness, or utility, is satisfied if the invention is operable and provides a tangible benefit.[13] To be judged novel, the invention must not be fully anticipated by a prior patent, publication, or other state-of-the-art knowledge that is collectively termed the "prior art."[14] A nonobvious invention must not have been readily within the ordinary skills of a competent artisan at the time the invention was made.[15]

If the USPTO allows the patent to issue, the patent proprietor obtains the right to exclude others from making, using, selling, offering to sell, or importing into the United States the patented invention.[16] Those who engage in these acts without the permission of the patentee during the term of the patent can be held liable for infringement. Adjudicated infringers may be enjoined from further infringing acts.[17] The patent statute also provides for the award of damages "adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer."[18]

The maximum term of patent protection is ordinarily set at 20 years from the date the application is filed.[19] At the end of that period, others may employ that invention without regard to the expired patent.

Patent rights are not self-enforcing. Patentees who wish to compel others to observe their rights must commence enforcement proceedings, which most commonly consist of litigation in the federal courts. Although issued patents enjoy a presumption of validity, accused infringers may assert that a patent is invalid or unenforceable on a number of grounds.[20] The U.S. Court of Appeals for the Federal Circuit (Federal Circuit) possesses national jurisdiction over most patent appeals from the district courts.[21] The U.S. Supreme Court enjoys discretionary authority to review cases decided by the Federal Circuit.[22]

[13] 35 U.S.C. § 101.

[14] 35 U.S.C. § 102.

[15] 35 U.S.C. § 103.

[16] 35 U.S.C. § 271(a).

[17] 35 U.S.C. § 283.

[18] 35 U.S.C. § 284.

[19] 35 U.S.C. § 154(a)(2). Although patent term is based upon the filing date, the patentee gains no enforceable legal rights until the USPTO allows the application to issue as a granted patent. A number of Patent Act provisions may modify the basic 20-year term, including examination delays at the USPTO and delays in obtaining marketing approval for the patented invention from other federal agencies.

[20] 35 U.S.C. § 282.

[21] 28 U.S.C. § 1295(a)(1).

[22] 28 U.S.C. § 1254(1).

The Leahy-Smith America Invents Act

First Inventor to File

The America Invents Act shifts the U.S. patent priority rule from the current "first-to-invent" principle to the global norm of the "first-inventor-to-file" principle.[23] Within the patent law, the priority rule addresses the circumstance where two or more persons independently develop the identical or similar invention at approximately the same time. In such cases the patent law must establish a rule as to which of these inventors obtains entitlement to a patent.[24]

Prior to the enactment of the America Invents Act, the United States was the only patent-issuing state to follow the "first-to-invent" rule. Under this principle, when more than one patent application was filed claiming the same invention, the patent would be awarded to the applicant who was the first inventor in fact. This conclusion holds even if the first inventor was not the first person to file a patent application directed towards that invention.[25] Within this "first-to-invent" system,[26] the timing of real-world events, such as the date a chemist conceived of a new compound or a machinist constructed a new engine, is of significance.

In contrast, priority of invention under the "first-inventor-to-file" principle is established by the earliest effective filing date of a patent application disclosing the claiming invention.[27] Stated differently, the inventor who first files an application at the patent office is presumptively entitled to the patent. Whether or not the first inventor applicant is actually the first individual to complete the invention in the field is irrelevant. This priority system follows the "first-inventor-to file" principle.

A simple example illustrates the distinction between these priority rules. Suppose that Inventor A synthesizes a new chemical compound on August 1, 2010, and files a patent application on November 1, 2010, claiming that compound. Suppose further that Inventor B independently invents the same compound on September 1, 2010, and files a patent application on October 1, 2010. Inventor A would be awarded the patent under the first-to-invent rule, while Inventor B would obtain the patent under the first-inventor-to-file principle.

The "first-inventor-to-file" rule established by the America Invents Act becomes effective 18 months after the statute's date of enactment. Notably, the America Invents Act does not allow one individual to copy another's invention and then, by virtue of being the first to file a patent application, be entitled to a patent. All patent applicants must have originated the invention themselves, rather than derived it from another.[28] In order to police this requirement, the new legislation provides for "derivation proceedings" that would allow the USPTO to determine

[23] P.L. 112-29 at § 3(b).

[24] *See* Roger E. Schechter & John R. Thomas, *Principles of Patent Law* § 1.2.5 (2d ed. 2004).

[25] In addition, the party that was the first to invent must not have abandoned, suppressed or concealed the invention. 35 U.S.C. § 102(g)(2).

[26] *See* Charles E. Gholz, "First-to-File or First-to-Invent?," 82 *Journal of the Patent and Trademark Office Society* (2000), 891.

[27] *See* Peter A. Jackman, "Adoption of a First-to-File System: A Proposal," 26 *University of Baltimore Law Review* (1997), 67.

[28] 35 U.S.C. § 101.

which applicant is entitled to a patent on a particular invention.[29] It is expected that this provision will reduce the costs associated with determining when an invention was first made in a dispute under the previous system.

Grace Period

The America Invents Act continues to provide inventors with a one-year period to decide whether to pursue patent protection after disclosing their inventions to the public. Current U.S. patent law essentially provides inventors with a one-year period to decide whether patent protection is desirable, and, if so, to prepare an application. Specified activities that occur before the "critical date"—patent parlance for the day one year before the application was filed—will prevent a patent from issuing.[30] If, for example, an entrepreneur first discloses an invention by publishing an article in a scientific journal, she knows that she has one year from the publication date in which to file a patent application. Importantly, uses, sales, and other technical disclosures by third parties will also start the one-year clock running. As a result, inventors have a broader range of concerns than merely their own activities.[31]

Suppose, for example, that an electrical engineer files a patent application claiming a new capacitor on February 1, 2010. While reviewing the application, a USPTO examiner discovers an October 1, 2008, journal article by any author disclosing the identical capacitor. Because the article was published prior to the critical date of February 1, 2009, that publication will prevent or "bar" the issuance of a patent on that capacitor.

Under the America Invents Act, the grace period operates similarly. The statute stipulates that a disclosure "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" would not be patent-defeating, provided it was made "1 year or less before the effective filing date of a claimed invention." In contrast, disclosures qualify as prior art, and are therefore potentially patent-defeating, if they were made either by (1) the inventors and their associates more than one year before the patent application's filing date; or (2) anyone else prior to the filing date, provided that such a disclosure occurred prior to the inventor's own disclosure. These amendments in essence protect the patent positions of individuals who disclosed their inventions up to one year before they filed a patent application and encourage publication so as to put the information before the public.

Marking

The America Invents Act introduces reforms to the legal rules governing the practice of "marking" articles with the numbers of particular patents. The U.S. patent laws have long encouraged patent proprietors that manufacture their patented inventions to notify the public of their patent rights.[32] Section 287(a) of the Patent Act of 1952 provides that patent owners should place the word "patent," or the abbreviation "pat.," along with the number of the patent, on

[29] P.L. 112-29 at § 3(h).

[30] 35 U.S.C. § 102(b).

[31] Schechter & Thomas, *supra*, at § 4.3.1.

[32] For further discussion of current patent marking issues and proposed legislation, see CRS Report R41418, *False Patent Marking: Litigation and Legislation*, by Brian T. Yeh.

patented goods. If the nature of the article does not allow this notice to be placed directly upon it, then a label may be placed on its packaging. This practice is commonly termed "marking."[33]

There is no absolute duty to mark. If a patent proprietor fails to mark in the specified manner, however, then it may receive damages only for infringing acts that occur after the infringer receives actual notice of infringement.[34] Filing an infringement lawsuit is considered to provide such actual notice. Less severely, a patent owner may issue a specific charge of infringement, commonly by sending a cease and desist letter to the infringer. The marking statute is said "to give patentees the proper incentive to mark their products and thus place the world on notice of the existence of the patent."[35]

The Patent Act also addresses the issue of "false marking." Section 292 prohibits marking a product with the number of another's patent, the name of another patent owner, or a patent or application number where no such patent or application exists. Prohibited marks also include the number of expired patents and patents that do not cover the marked product, provided such marks were affixed for the "purpose of deceiving the public." The Patent Act mandates a maximum fine of $500 for "every such" offense. According to the statute, "any person may sue for the penalty, in which event one-half shall go to the person suing and the other to the use of the United States."[36]

The America Invents Act alters the Patent Act's false marking provision by stipulating that the statute may only be privately enforced by a "person who has suffered a competitive injury as a result of the violation...."[37] Damages in such cases would also be limited to those "adequate to compensate for the injury." This amendment would change previous law, which allows any private person to bring a civil action for false marking, whether or not they have been negatively affected. These provisions do not apply to the U.S. government. Under the provisions of the America Invents Act, the U.S. government would continue to bring false marking suits without regard to competitive injury, and also would retain the ability to recover a maximum fine of $500 per each falsely marked article.

The America Invents Act also allows for "virtual marking." Under this proposal, the marking standard would be fulfilled if the product or its packaging included the word "patent" or the abbreviation "pat.," together with an Internet address that provided the number of the patent associated with the patented article.[38]

Prior Commercial Use Defense

The American Inventors Protection Act of 1999, P.L. 106-113, allowed an earlier commercial user of a "method of doing or conducting business" that was later patented by another to claim a defense to patent infringement in certain circumstances. The America Invents Act expands the

[33] *See* Schechter & Thomas, *supra*, at § 9.2.3.

[34] It should be further appreciated that under 35 U.S.C. § 286, "no recovery shall be had for any infringement committed more than six years prior to the filing of the complaint or counterclaim for infringement in the action."

[35] Laitram Corp. v. Hewlett-Packard Co., 806 F. Supp. 1294, 1296 (E.D. La. 1992).

[36] 35 U.S.C. § 292(b). This sort of proceeding is termed a *qui tam* action.

[37] P.L. 112-29 at § 16(b).

[38] P.L. 112-29 at § 16(a).

range of individuals who may assert this defense in court. Even more significantly, the new legislation eliminates the current restriction of the prior commercial use defense to business method patents. Under the America Invents Act, a patent claiming any type of invention may be subject to the prior commercial user defense.

The prior commercial user defense accounts for the complex relationship between the law of trade secrets and the patent system. Trade secrecy protects individuals from misappropriation of valuable information that is useful in commerce. One reason an inventor might maintain the invention as a trade secret rather than seek patent protection is that the subject matter of the invention may not be regarded as patentable. Such inventions as customer lists or data compilations have traditionally been regarded as amenable to trade secret protection but not to patenting.[39] Inventors might also maintain trade secret protection due to ignorance of the patent system or because they believe they can keep their invention as a secret longer than the period of exclusivity granted through the patent system.[40]

The patent law does not favor trade secret holders, however. Well-established patent law provides that an inventor who makes a secret, commercial use of an invention for more than one year prior to filing a patent application at the USPTO forfeits his own right to a patent.[41] This policy is based principally upon the desire to maintain the integrity of the statutorily prescribed patent term. The patent law grants patents a term of 20 years, commencing from the date a patent application is filed.[42] If the trade secret holder could make commercial use of an invention for many years before choosing to file a patent application, he could disrupt this regime by delaying the expiration date of his patent.

Settled patent law principles established that prior secret uses would not defeat the patents of later inventors.[43] If an earlier inventor made secret commercial use of an invention, and another person independently invented the same technology later and obtained patent protection, then the trade secret holder could face liability for patent infringement. This policy is based upon the reasoning that once issued, published patent instruments fully inform the public about the invention, while trade secrets do not. Between a subsequent inventor who patented the invention, and thus had disclosed the invention to the public, and an earlier trade secret holder who had not, the law favored the patent holder.

An example may clarify this rather complex legal situation. Suppose that Inventor A develops and makes commercial use of a new manufacturing process. Inventor A chooses not to obtain patent protection, but rather maintains that process as a trade secret. Many years later, Inventor B independently develops the same manufacturing process and promptly files a patent application claiming that invention. In such circumstances, Inventor A's earlier, trade secret use does not prevent Inventor B from procuring a patent. Furthermore, if the USPTO approves the patent application, then Inventor A faces infringement liability should Inventor B file suit against him.

The American Inventors Protection Act of 1999 somewhat modified this principle. That statute in part provided an infringement defense for an earlier user of a "method of doing or conducting

[39] Restatement of Unfair Competition § 39.

[40] David D. Friedman, "Some Economics of Trade Secret Law," 5 *Journal of Economic Perspectives* (1991), 61, 64.

[41] 35 U.S.C. § 102(b). *See* Metallizing Engineering Co. v. Kenyon Bearing & Auto Parts, 153 F.2d 516 (2d Cir. 1946).

[42] 35 U.S.C. § 154.

[43] W.L. Gore & Associates v. Garlock, Inc., 721 F.2d 1540 (Fed. Cir. 1983).

business" that was later patented by another. By limiting this defense to patented methods of doing business, Congress responded to the 1998 Federal Circuit opinion in *State Street Bank and Trust Co. v. Signature Financial Group*.[44] That judicial opinion recognized that business methods could be subject to patenting, potentially exposing individuals who had maintained business methods as trade secrets to liability for patent infringement.

Again, an example may aid understanding of the prior commercial user defense. Suppose that Inventor X develops and exploits commercially a new method of doing business. Inventor X maintains his business method as a trade secret. Many years later, Inventor Y independently develops the same business method and promptly files a patent application claiming that invention. Even following the enactment of the American Inventors Protection Act, Inventor X's earlier, trade secret use would not prevent Inventor Y from procuring a patent. However, should the USPTO approve Inventor Y's patent application, and should Inventor Y sue Inventor X for patent infringement, then Inventor X may potentially claim the benefit of the first inventor defense. If successful,[45] Inventor X would enjoy a complete defense to infringement of Inventor Y's patent.

Prior to the America Invents Act, the prior commercial user defense could "be asserted only by the person who performed the acts necessary to establish the defense...."[46] The America Invents Act would also allow the defense to be asserted by "any other entity that controls, is controlled by, or is under common control with such person...."[47]

In addition, the America Invents Act eliminates the restriction of the prior commercial user defense to business method patents. As a result, any type of patented invention would be subject to the prior commercial user defense. The new legislation also exempts patents held by universities from the prior commercial user defense when it stipulates that this is not available if "the claimed invention ... was made, owned or subject to an obligation of assignment to either an institution of higher education ... or a technology transfer organization whose primary purpose is to facilitate the commercialization of technologies developed by one or more such institutions of higher education."

Inventor's Oath and Assignee Filing

As the law stood prior to enactment of the American Invents Act, a patent application had to be filed by the inventor—that is, the natural person or persons who developed the invention.[48] This rule applied even where the invention was developed by individuals in their capacity as employees. Even though rights to the invention usually have been contractually assigned to an employer, for example, the actual inventor, rather than the employer, must be the one that applies for the patent. In particular, Section 115 of the Patent Act obliges each applicant also to submit an

[44] 149 F.3d 1368 (Fed. Cir. 1998).

[45] As presently codified at 35 U.S.C. § 273, the prior commercial user defense is subject to a number of additional qualifications. First, the defendant must have reduced the infringing subject matter to practice at least one year before the effective filing date of the application. Second, the defendant must have commercially used the infringing subject matter prior to the effective filing date of the patent. Finally, any reduction to practice or use must have been made in good faith, without derivation from the patentee or persons in privity with the patentee.

[46] 35 U.S.C. §273(b)(6)

[47] P.L. 112-29 at §5.

[48] 35 U.S.C. § 111.

oath or declaration stating that he believes himself to be the "original and first inventor" of the subject matter for which he seeks a patent. Section 118 of the Patent Act allowed a few exceptions to this general rule. If an inventor cannot be located, or refuses to perform his contractual obligation to assign an invention to his employer, then the employer may file the patent application in place of the inventor.

The America Invents Act modifies these rules by incorporating the exceptions found in current Section 118 into Section 115 of the Patent Act.[49] This reform appears to be primarily technical in nature, although a few differences between the new statute and prior law exist. First, the new law requires inventors to declare only that they are the "original inventor"—rather than the "original and first inventor"—in keeping with the proposed shift to a first-inventor-to-file priority system. Second, the new law allows an "individual who is under an obligation of assignment for patent [to] include the required statements ... in the assignment executed by the individual, in lieu of filing such statements separately." This provision comports with the allowance of the filing of patent applications by employers and other assignees of patent rights.

The America Invents Act further stipulates that a "person to whom the inventor has assigned or is under an obligation to assign the invention may make an application for patent." Individuals who otherwise make a showing of a "sufficient proprietary interest in the matter" may also apply for a patent on behalf of the inventor upon a sufficient show of proof of the pertinent facts. Under the new law, if the USPTO "Director grants a patent on an application filed under this section by a person other than the inventor, the patent shall be granted to the real party in interest and upon such notice to the inventor as the Director considers to be sufficient."

Willful Infringement/Advice of Counsel

The patent law of the United States allows a court to "increase the damages up to three times the amount found or assessed."[50] An award of enhanced damages, as well as the amount by which the damages will be increased, is committed to the discretion of the trial court. Although the statute does not specify the circumstances in which enhanced damages are appropriate, the Federal Circuit recently explained that "a patentee must show by clear and convincing evidence that the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent."[51] This circumstance is termed "willful infringement."[52]

Courts will not ordinarily enhance damages due to willful infringement if the adjudicated infringer did not know of the patent until charged with infringement in court, or if the infringer acted with the reasonable belief that the patent was not infringed or that it was invalid. Prior to the 2007 decision in *In re Seagate Technology*, Federal Circuit decisions emphasized the duty of someone with actual notice of a competitor's patent to exercise due care in determining if his acts will infringe that patent.[53] In *Seagate Technology*, however, the Federal Circuit opted to "abandon

[49] P.L. 112-29 at § 4.

[50] 35 U.S.C. § 284.

[51] *In re Seagate Technology*, 497 F.3d 1360 (Fed. Cir. 2007) (en banc).

[52] *See* Beatrice Foods Co. v. New England Printing & Lithographing Co., 923 F.2d 1576, 1578 (Fed. Cir. 1991).

[53] *See, e.g.,* Jon E. Wright, "Willful Patent Infringement and Enhanced Damages—Evolution and Analysis," 10 *George Mason Law Review* (2001), 97.

the affirmative duty of due care."[54] The court of appeals instead explained that "proof of willful infringement permitting enhanced damages requires at least a showing of objective recklessness."[55]

Prior to 2004, the Federal Circuit held that when an accused infringer invoked the attorney-client or work-product privilege, courts should be free to reach an adverse inference that either (1) no opinion had been obtained or (2) an opinion had been obtained and was contrary to the infringer's desire to continue practicing the patented invention.[56] However, in its decision in *Knorr-Bremse Systeme fuer Nutzfahrzeuge GmbH v. Dana Corp.*,[57] the Federal Circuit expressly overturned this principle. The Court of Appeals further stressed that the failure to obtain legal advice did not occasion an adverse inference with respect to willful infringement either. Following the *Knorr-Bremse* opinion, willful infringement determinations are based upon "the totality of circumstances, but without the evidentiary contribution or presumptive weight of an adverse inference that any opinion of counsel was or would have been unfavorable."[58]

The America Invents Act includes language specifying that the "failure of an infringer to obtain the advice of counsel ... may not be used to prove that the accused infringer willfully infringed the patent...."[59] This provision appears essentially to codify the holding of *Knorr-Bremse* described above.

Inter Partes and Post-Grant Reviews

The America Invents Act mandates changes to the options available for post-grant USPTO review proceedings by (1) replacing the existing *inter partes* reexamination system with *inter partes* review proceedings;[60] and (2) introducing a new proceeding titled "post-grant review."[61] Both *inter partes* and post-grant reviews are patent revocation proceedings administered by the USPTO. They would operate similarly to the existing reexamination system, which has been part of U.S. law since 1981. The USPTO currently administers two types of reexamination proceedings, termed *ex parte* and *inter partes*.

Under the reexamination statute, any individual, including the patentee, a competitor, and even the USPTO Director, may cite a prior art patent or printed publication to the USPTO. If the USPTO determined that this reference raised a "substantial new question of patentability" with respect to an issued patent, then it would essentially reopen prosecution of the issued patent. Traditional reexamination proceedings were conducted in an accelerated fashion on an *ex parte* basis—that is to say, as a dialogue between applicant and examiner without extended participation by others. Following the American Inventors Protection Act of 1999,[62] an *inter*

[54] *Seagate Technologies*, *supra*.

[55] *Id.*

[56] *See, e.g.,* Fromson v. Western Litho Plate & Supply Co., 853 F.2d 1568, 1572 (Fed. Cir. 1988).

[57] 383 F.3d 1337 (Fed. Cir. 2004).

[58] *Ibid* at 1341.

[59] P.L. 112-29 at § 17.

[60] P.L. 112-29 at § 6(a).

[61] P.L. 112-29 at § 6(d).

[62] The American Inventors Protection Act of 1999, P.L. 106-113, was part of the Intellectual Property and Communications Omnibus Reform Act of 1999, attached by reference to the Consolidated Appropriations Act for Fiscal Year 2000. President Clinton signed this bill on November 29, 1999.

partes reexamination allowed the requester to participate more fully in the proceedings through the submission of arguments and the filing of appeals. Either sort of reexamination may have resulted in a certificate confirming the patentability of the original claims, an amended patent with narrower claims, or a declaration of patent invalidity.

Congress intended reexamination proceedings to serve as an inexpensive alternative to judicial determinations of patent validity.[63] Reexamination also allows further access to the legal and technical expertise of the USPTO after a patent has issued.[64] However, some commentators believe that reexamination proceedings have been employed only sparingly and question their effectiveness.[65]

The America Invents Act establishes a new proceeding termed a "post-grant review." Unlike previous reexamination proceedings, petitioners may challenge validity based upon on any ground of patentability in a post-grant review. A post-grant review must be filed within nine months of the date of patent grant. To initiate a post-grant review, the petitioner must present information that, if not rebutted, would demonstrate that it is more likely than not that at least one of the claims is unpatentable. A post-grant review must be completed within one year of its commencement, with an extension of six months possible for good cause shown. As well, the individual who commenced the proceeding, along with his privies (people who have a legal interest in the patent), are barred in the future from raising issues that were "raised or reasonably could have been raised" during the post-grant review.

The new law also replace existing *inter partes* reexamination proceedings with a similar system termed "*inter partes* review." A notable difference between the old and new proceedings is that the USPTO will be required to complete the proceeding within one year of its commencement, with an extension of six months possible for good cause shown. In broad outline, the law allows a person who is not the patent owner to file a petition requesting *inter partes* review nine months after a patent issues or reissues, or the conclusion of any post-grant review, whichever occurs later. In contrast to the post-grant review, the basis for requesting an *inter partes* review is restricted to patents or printed publications. As a result, patent challenges under *inter partes* review are limited to the patentability issues of novelty and nonobviousness.[66] Post-grant reviews allow a patent challenger to raise additional patentability issues, such as unpatentable subject matter or lack of enablement, that are not based upon a patent or printed publication.

Under the America Invents Act, the petitioner must demonstrate that there is a "reasonable likelihood" that he would prevail with respect to at least one claim in order for the *inter partes* proceeding to begin. Under the time frames established, the effective result is that a patent may be challenged at the USPTO on any basis of any patentability issue within nine months from the date it issued (via post-grant review). Thereafter, and throughout its entire term, the patent may be challenged at the USPTO on the grounds of novelty and nonobviousness (via *inter partes* review).

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[63] Mark D. Janis, "Inter Partes Reexamination," 10 *Fordham Intellectual Property, Media & Entertainment Law Journal* (2000), 481.

[64] Craig Allen Nard, "Certainty, Fence Building and the Useful Arts," 74 *Indiana Law Journal* (1999), 759.

[65] *See* Schechter & Thomas, *supra*, at § 7.5.4.

[66] Notably, the proposed restriction of *inter partes* review to patents and printed publications limits the grounds on which a patent challenger may request such a review. Once a patent is subject to *inter partes* review, the USPTO may potentially consider other pertinent patentability issues, such as claim definiteness.

The new law stipulates that an accused infringer may not seek *inter partes* review if he has already filed a lawsuit challenging the patent or more than six months have passed since the date the accused infringer was served with a complaint alleging infringement of that patent. The law affords the patent proprietor a single opportunity to amend its patent during the proceeding, with further opportunities available with good cause shown. Should the patent survive the *inter partes* review proceeding, the individual who commenced the proceeding, along with his privies, are barred in the future from raising issues that were "raised or reasonably could have been raised."

Post-Grant Citation of Prior Art

The USPTO has long allowed any person at any time to bring to the agency's attention "patents or printed publications" believed to "have a bearing on the patentability of any claim of a particular patent."[67] That person may also include a written statement explaining the relevance of the cited document to the patent. This sort of "prior art citation" does not provoke any sort of administrative proceeding. However, the USPTO will place these submissions within the official file of the relevant patent, where they are accessible to the public. Prior art that potentially has a negative impact upon the patent's validity may be of considerable interest to the patent owner, its customers and competitors, and possibly others. The name of the person who files a prior art citation may be kept confidential by request.

The ability of members of the public to cite to the USPTO information that may be pertinent to the validity of a granted patent would be augmented under the provisions of the America Invents Act. The new law also allows the citation of written statements that the patent owner has filed before a federal court or the USPTO regarding the scope of the patent's claims.[68]

Preissuance Submissions

The America Invents Act expands the possibilities for members of the public to comment upon pending applications at the USPTO. Prior to this legislation, interested individuals could file a "protest" at the agency. Such a protest was required to identify the application specifically and be served upon the applicant. The protest had to include a copy and, if necessary, an English translation, of any patent, publication, or other information relied upon. The protester was required to explain the relevance of each item.[69]

Protest proceedings have traditionally played a small role in U.S. patent practice. Until Congress enacted the American Inventors Protection Act of 1999, the USPTO maintained applications in secrecy. Therefore, the circumstances in which members of the public would learn of the precise contents of a pending patent application were relatively limited. Following the 1999 legislation, the USPTO began to publish many pending patent applications. Seemingly aware of this possibility, the 1999 Act provided that the USPTO shall "ensure that no protest or other form of pre-issuance opposition ... may be initiated after publication of the application without the express written consent of the applicant."[70] Of course, the effect of this provision was to eliminate the

[67] 35 U.S.C. § 301.

[68] P.L. 112-29 at § 6(g)

[69] 37 C.F.R. § 1.291.

[70] 35 U.S.C. § 122(c).

possibility of protest in exactly that class of cases where the public was most likely to learn of the contents of a pending application.

Through rulemaking, the USPTO had nonetheless established a limited mechanism for members of the public to submit information they believe is pertinent to a pending, published application. The submitted information must consist of either a patent or printed publication, and it must be submitted within two months of the date the USPTO published the pending application. Nondocumentary information that may be relevant to the patentability determination, such as sales or public use of the invention, will not be considered.[71] In addition, because Congress stipulated that no protest or pre-grant opposition may occur absent the consent of the patent applicant, the USPTO had explained that it will not accept *comments* or *explanations* concerning the submitted patents or printed publications. If such comments were attached, USPTO staff would redact them before the submitted documents were forwarded to the examiner.[72]

The America Invents Act expands the possibility for preissuance submissions. Under the legislation, any person may submit patent documents and other printed publications to the USPTO for review. Such prior art must be submitted within the later date of either (1) the date the USPTO issues a notice of allowance to the patent applicant; or (2) either six months after the date of pre-grant publication of the application, or the date of the first rejection of any claim by the USPTO examiner. Such a submission must include "a concise description of the asserted relevance of each submitted document."

Venue

The America Invents Act alters the venue provisions that apply to suits where the USPTO is a party—for example, appeals from inventors whose patent applications have been rejected.[73] Such cases are currently heard by the District Court for the District of Columbia. Under the new law, the District Court for the Eastern District of Virginia will hear such cases. This change in venue may reflect the fact that the headquarters of the USPTO is no longer located within Washington, DC, but rather in Alexandria, VA.

USPTO Fee-Setting Authority and Funding

The USPTO enjoys certain rulemaking authority provided by law. The USPTO may establish regulations that "govern the conduct of proceedings" before it, for example, as well as regulations that "govern the recognition and conduct" of patent attorneys.[74] However, the fees charged by the USTPO currently were determined by Congress.

[71] 37 C.F.R. § 1.99.

[72] U.S. Dept. of Commerce, U.S. Patent & Trademark Off., Manual of Patent Examining Procedure § 1134.01 (8th ed. July 2008).

[73] P.L. 112-29 at § 9.

[74] 35 U.S.C. § 2(b)(2). It should be appreciated that "Congress has not vested the [USPTO] with any general substantive rulemaking power.... " Cybor Corp. v. FAS Techs, Inc., 138 F.3d 1448, 1479 (Fed. Cir. 1998) (en banc) (Newman, J., additional views).

The America Invents Act grants the USPTO additional authority "to set or adjust by rule any fee established or charged by the Office" under certain provisions of the patent and trademark laws.[75] This appears to provide the USPTO with greater flexibility to adjust its fee schedule absent congressional intervention. The new law requries that "patent and trademark fee amounts are in the aggregate set to recover the estimated cost to the Office for processing, activities, services and materials relating to patents and trademarks, respectively, including proportionate shares of the administrative costs of the Office."

The America Invents Act additionally stipulates fees for patent services provided by the USPTO.[76] In general, the new law raises the fees slightly. For example, the fees for filing a patent application and for the issuance of an approved application were $300 and $1,400 respectively; the new fees are $330 and $1,510. As previously discussed, each of these fees would then presumably be subject to adjustment by the USPTO.

The new statute creates within the Treasury a "Patent and Trademark Fee Reserve Fund" into which fee collections above that "appropriated by the Office for that fiscal year" will be placed. These funds will be available to the USPTO "to the extent and in the amounts provided in appropriations Acts" and may only be used for the work of the Office.[77]

The America Invents Act also establishes a new "micro entity" category of applicants.[78] A micro entity must make a certification that it qualifies as a small entity, has not been named on five previously filed patent applications, does not have a gross income exceeding three times the average gross income, and has not conveyed an interest in the application to another entity with an income exceeding that threshold. Micro entities would be entitled to a 75% discount on many USPTO fees. The USPTO Director is given authority to limit those who qualify as a micro entity if such limitations "are reasonably necessary to avoid an undue impact on other patent applicants or owners and are otherwise reasonably necessary and appropriate." The USPTO must inform Congress at least three months in advance of imposing such limitations.

Supplemental Examination

The America Invents Act establishes a new post-issuance administrative proceeding termed "supplemental examination."[79] This proceeding appears to be based upon a need to address concerns over the legal doctrine of inequitable conduct, a topic that bears some explanation. The administrative process of obtaining a patent from the USPTO has traditionally been conducted as an *ex parte* procedure. Stated differently, patent prosecution involves only the applicant and the USPTO. Members of the public, and in particular the patent applicant's marketplace competitors, do not participate in patent acquisition procedures.[80] As a result, the patent system relies to a great extent upon the applicant's observance of a duty of candor and truthfulness towards the USPTO.

[75] P.L. 112-29 at § 10.

[76] P.L. 112-29 at § 11.

[77] P.L. 112-29 at § 22.

[78] P.L. 112-29 at § 10(g)

[79] P.L. 112-29 at § 12.

[80] 35 U.S.C. § 122(a) (stating the general rule that "applications for patents shall be kept in confidence by the Patent and Trademark Office and no information concerning the same given without authority of the applicant.... ").

An applicant's obligation to proceed in good faith may be undermined, however, by the great incentive applicants might possess not to disclose, or to misrepresent, information that might deleteriously impact their prospective patent rights. The patent law therefore penalizes those who stray from honest and forthright dealings with the USPTO. Under the doctrine of "inequitable conduct," if an applicant intentionally misrepresents a material fact or fails to disclose material information, then the resulting patent will be declared unenforceable.[81] Two elements must exist before a court will decide that the applicant has engaged in inequitable conduct. First, the patentee must have misrepresented or failed to disclose material information to the USPTO in the prosecution of the patent.[82] Second, such nondisclosure or misrepresentation must have been intentional.[83]

During patent infringement litigation, an accused infringer has the option of asserting that the plaintiff's patent is unenforceable because it was procured through inequitable conduct. Some observers have expressed concerns that charges of inequitable conduct have become routine in patent cases. As one commentator explains:

> The strategic and technical advantages that the inequitable conduct defense offers the accused infringer make it almost too attractive to ignore. In addition to the potential effect on the outcome of the litigation, injecting the inequitable conduct issue into patent litigation wreaks havoc in the patentee's camp. The inequitable conduct defense places the patentee on the defensive, subjects the motives and conduct of the patentee's personnel to intense scrutiny, and provides an avenue for discovery of attorney-client and work product documents....[84]

The Federal Circuit has stated that "the habit of charging inequitable conduct in almost every major patent case has become an absolute plague."[85] Other observers believe that because inequitable conduct requires an analysis of the knowledge and intentions of the patent applicants, the doctrine may also be contributing disproportionately to the time and expense of patent litigation.[86]

Due to these perceived burdens upon patent litigation, some experts have proposed that the inequitable conduct defense be eliminated.[87] Others believe that inequitable conduct is necessary to ensure the proper functioning of the patent system. As the Advisory Commission on Patent Law Reform explained in its 1992 report:

> Some mechanism to ensure fair dealing between the patentee, public, and the Federal Government has been part of the patent system for over 200 years. In its modern form, the unenforceability defense provides a necessary incentive for patent applicants to engage in fair and open dealing with the [USPTO] during the ex parte prosecution of patent applications, by imposing the penalty of forfeiture of patent rights for failure to so deal. The

[81] Glaverbel Societe Anonyme v. Northlake Mktg. & Supply Inc., 45 F.3d 1550 (Fed. Cir. 1995).

[82] Heidelberger Druckmaschinen AG v. Hantscho Comm'l Prods., Inc., 21 F.3d 1068 (Fed. Cir. 1993).

[83] Jazz Photo Corp. v. U.S. Int'l Trade Comm'n, 264 F.3d 1094 (Fed. Cir. 2001).

[84] John F. Lynch, "An Argument for Eliminating the Defense of Patent Unenforceability Based on Inequitable Conduct," 16 *American Intellectual Property Law Association Quarterly Journal* (1988), 7.

[85] Burlington Indus., Inc. v. Dayco Corp., 849 F.2d 1418 (Fed. Cir. 1988).

[86] *See, e.g.,* Scott D. Anderson, "Inequitable Conduct: Persistent Problems and Recommended Resolutions," 82 *Marquette Law Review* (1999), 845.

[87] Lynch, *supra*, at 7.

> defense is also considered to be an essential safeguard against truly fraudulent conduct before the [USPTO]. Finally, the defense provides a means for encouraging complete disclosure of information relevant to a particular patent application.... Thus, from a policy perspective, the defense of unenforceability based upon inequitable conduct is desirable and should be retained.[88]

To limit the use of inequitable conduct in patent litigation, the America Invents Act permits patent owners to request a "supplemental examination" in order to "consider, reconsider, or correct information believed to be relevant to the patent." If the USPTO Director believes that this information raises a substantial new question of patentability, then a reexamination will be ordered. The America Invents Act provides that a "patent shall not be held unenforceable ... on the basis of conduct relating to information that had not been considered, was inadequately considered, or was incorrect in a prior examination of the patent if the information was considered, reconsidered, or corrected during a supplemental examination of the patent." The supplemental examination request and resulting reexamination must be concluded prior to the start of litigation for the patent to obtain this benefit. The statute stipulates that if there is evidence of "material fraud," the Director of the USPTO is authorized to notify the Attorney General for "such further action as the Attorney General may deem appropriate."

Tax Strategy Patents

In recent years, the USPTO has issued patents on financial, investment, and other methods that individuals might use in order to minimize their tax obligations.[89] Under the America Invents Act, for the purpose of evaluating whether an invention meets the requirements of novelty and nonobviousness, "any strategy for reducing, avoiding, or deferring tax liability, whether known or unknown at the time of the invention or application for patent, shall be deemed insufficient to differentiate a claimed invention from the prior art."[90] Under this rule, unless a tax strategy patent claimed an additional component that met the novelty and nonobviouness requirements—such as new computer hardware—then the invention could not be patented. The new law stipulates that this provision does not apply to that part of an invention "used solely for preparing a tax or information return or other tax filing...."

The America Invents Act stipulates that the tax strategy patent provision does not apply to "a method, apparatus, technology, computer program product, or system used solely for financial management, to the extent it is severable from any tax strategy or does not limit the use of any tax strategy by any taxpayer or tax adviser." The statute also states that "[n]othing in this section shall be construed to imply that other business methods are patentable or that other business method patents are valid."

[88] 1992 Advisory Commission, *supra*, at 114.

[89] *See* CRS Report RL34221, *Patents on Tax Strategies: Issues in Intellectual Property and Innovation*, by John R. Thomas.

[90] P.L. 112-29 at § 14.

Best Mode

The U.S. patent statute requires inventors to "set forth the best mode contemplated by the inventor of carrying out his invention."[91] Failure to disclose the best mode known to the inventor is a ground for invalidating an issued patent. The courts have established a two-part standard for analyzing whether an inventor disclosed her best mode in a particular patent. The first inquiry was whether the inventor knew of a way of practicing the claimed invention that she considered superior to any other. If so, then the patent instrument must identify, and disclose sufficient information to enable persons of skill in the art to practice that best mode.[92]

The America Invents Act continues to apply the best mode requirement to all patents. However, violation of the best mode requirement would no longer form the basis for an accused infringer's defense to a charge of patent infringement during enforcement litigation or post-grant review proceedings.[93] Compliance with the best mode requirement would remain subject to review by USPTO examiners during the initial prosecution of a patent, although USPTO rejection of applications based upon failure to comply with the best mode requirement is reportedly a rare circumstance.[94]

Clarification of Jurisdiction

The America Invents Act confirms that state courts do not possess jurisdiction to hear claims for relief under the patent, plant variety protection, and copyright laws.[95] The statute further provides that the Federal Circuit possesses jurisdiction over appeals relating to patent and plant variety protection cases. In addition, cases are allowed to be removed from courts that do not possess jurisdiction and transferred to those that do.

Transitional Program for Covered Business Method Patents

The America Invents Act creates a transitional post-grant review proceeding for the review of the validity of certain business method patents.[96] This transitional proceeding would be limited to patents that claim "a method or corresponding apparatus for performing data processing operations utilized in the practice, administration, or management of a financial product or service, except that the term shall not include patents for technological inventions." Only individuals who have been either sued for infringement or charged with infringement of a business method patent may petition the USPTO to commence such a proceeding. The transitional program would apply to all business method patents issued before, on, or after the date of enactment of the legislation.

[91] 35 U.S.C. § 112.

[92] *See, e.g.*, Chemcast Corp. v. Arco Industries Corp. 913 F.2d 923 (Fed. Cir. 1990).

[93] P.L. 112-XX at § 15.

[94] Jerry R. Selinger, "In Defense of "Best Mode": Preserving the Benefit of the Bargain for the Public, 43 *Catholic University Law Review* (1994), 1099 ("Failure to comply with best mode ... is not something an examiner normally can evaluate when reviewing the application.... ").

[95] P.L. 112-29 at § 19.

[96] P.L. 112-29 at § 18.

The new law stipulates that a party may seek a stay of litigation related to the transitional proceeding, and that the district court's decision may be subject to an immediate interlocutory appeal to the Federal Circuit. This transitional program is subject to a sunset provision that would repeal the program after eight years. In addition, the statute provides that its business method patent provisions shall not be construed as amending or interpreting categories of patent-eligible subject matter.

USPTO Satellite Offices

The USPTO has long been required to maintain its principal office in the metropolitan Washington, D.C., area. The law further allows the USPTO to "establish satellite offices in such other places in the United States as it considers necessary and appropriate in the conduct of its business."[97] The USPTO recently announced it would open its first satellite office in Detroit, MI.[98]

The American Invents Act requires the USPTO to establish three or more additional satellite offices in the United States subject to available resources.[99] The satellite offices are intended to increase inventor outreach activities, enhance patent examiner retention, improve recruitment of patent examiners, decrease the number of unexamined patent applications, and improve the quality of patent examination. The USPTO is required to ensure the geographic diversity of its satellite offices. The act designate the Detroit satellite office as the "Elijah J. McCoy United States Patent and Trademark Office."[100]

Other USPTO Programs

The America Invents Act provides for other reforms relating to the USPTO. Among them is the creation of a patent ombudsman program for small business concerns, subject to available resources.[101] In addition, the legislation allows the USPTO to prioritize examination of patent applications relating to technologies that are "important to the national economy or national competitiveness."[102] The new law proposes that studies be undertaken in the following areas: patents on genetic testing; diversity of patent applicants; international patent protection for small businesses; consequences of litigation by non-practicing entities; and implementation of the legislation.

Prohibition of Patents on Humans

The USPTO has interpreted the Thirteenth Amendment, which bans human slavery, as barring patents claiming human beings.[103] The America Invents Act gives statutory footing to this policy

[97] 35 U.S.C. §1(b).

[98] U.S. Patent and Trademark Office, Press Release, *USPTO to Open First Ever Satellite Office in Detroit* (Dec. 16, 2010), available at http://www.uspto.gov/news/pr/2010/10_65.jsp.

[99] P.L. 112-29 at § 23.

[100] P.L. 112-29 at § 24.

[101] P.L. 112-29 at § 28.

[102] P.L. 112-29 at § 25.

[103] See Commissioner of Patents and Trademarks, Policy Statement on Patentability of Animals, 1077 Off. Gaz. Pat. (continued...)

by stipulating that "no patent may issue on a claim directed to or encompassing a human organism."[104]

Patent Term Extension Filings

The Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, provides holders of patents on pharmaceuticals and other regulated products with an extended term of protection to compensate for delays experienced in obtaining marketing approval. Under prior law, a petition to receive such a term extension "may only be submitted [to the USPTO] within the sixty-day period beginning on the date the product received permission under the provision of law under which the applicable regulatory review period occurred...."[105] The America Invents Act stipulates that if regulatory approval is transmitted after 4:30 PM Eastern time on a business day, or is transmitted on a day that is not a business day, then the product shall be deemed to have received such permission on the next business day.[106]

Further Considerations

Although the America Invents Act is the product of years of discussion and debate, some observers believe that Congress did not address certain issues of pressing concern to the patent system. One of these issues involves the propriety of current judicial assessments of damages in patent infringement cases. Some observers believe that judges and juries have tended to overcompensate patent holders when they make damages awards, particularly in cases where the accused infringement includes additional features not covered by the patent.[107] Other commentators found the level of compensation to be appropriate and expressed concerns that legislative reforms might reduce damages awards to such a degree as to diminish the value of patent ownership.[108] A number of recent judicial opinions, including *Lucent Technologies, Inc. v. Gateway, Inc.*,[109] appear to have recognized expressed concerns about damages awards in patent cases and the Federal Circuit has issued rulings designed to increase their fairness and predictability. Perhaps because of these judicial developments, the America Invents Act ultimately did not address the award of damages in patent cases. For some, however, concerns linger concerning the damages issues.[110]

Some observers believe that Congress should have required the USPTO to publish all patent applications during their pendency. When enacting the American Inventors Protection Act of

(...continued)

Office 24 (April 7, 1987).

[104] P.L. 112-29 at § 33.

[105] 35 U.S.C. § 156(d)(1).

[106] P.L. 112-29 at § 37.

[107] *See, e.g.,* Elizabeth M. Bailey et al., "Making Sense of 'Apportionment' in Patent Damages," *12 Columbia Science and Technology Law Review* 255 (2011) (noting these concerms).

[108] *See, e.g.,* Martha K. Gooding & William C. Rooklidge, "The Real Problem with Patent Infringement Damages," 91 *Journal of the Patent and Trademark Office Society* 484 (2009).

[109] 580 F.3d 1301 (Fed. Cir. 2009).

[110] *See, e.g.,* Brad Smith, "In a Competitive Economy, The Country's Prosperity Depends More Than Ever on a Healthy Patent System," *Inside Counsel* 8 (May 1, 2010).

1999, Congress for the first time introduced the concept of pre-grant publication into U.S. law. Since November 29, 2000, U.S. patent applications have been published 18 months from the date of filing, with some exceptions. The most significant of these exceptions applies where the inventor represents that he will not seek patent protection abroad. In particular, if an applicant certifies that the invention disclosed in the U.S. application will not be the subject of a patent application in another country that requires publication of applications 18 months after filing, then the USPTO will not publish the application.[111] As a result, inventors who do not wish to seek foreign patent rights retain the possibility of avoiding pre-grant publication. Congress had previously considered eliminating this exception, and some observers continue to believe this was the preferable option. On the other hand, many commentators believe that this exception is more fair to individuals, small firms, and other innovators that may be especially vulnerable to piracy of their products.

Another concern that some observers argue has not been sufficiently addressed is that of patent fee "diversion." Under that practice, the USPTO is not provided the budget authority through the appropriations process to spend all fees collected within a fiscal year. Beginning in 1990, appropriations measures have, at times, limited the ability of the agency to use the full amount of fees collected in each fiscal year. Some observers believe that "fee diversion" has limited the ability of the USPTO to discharge its statutory duties effectively. On the other hand, others believe that the agency obtains sufficient financial support and point to the need to support other governmental programs.[112] The approach embodied in the America Invents Act keeps USPTO use of fees within the appropriations process, but mandates that any excess fees be used only to fund USPTO activities. It remains to be seen if this provides the USPTO with the necessary resources.

The Leahy-Smith America Invents Act is by any reasonable measure a watershed event in the field of intellectual property law. The numerous reforms introduced by the legislation, intended to improve, update, and adopt global best practices, will undoubtedly bring immediate changes to patent practice by the USPTO, the private bar, and innovative firms. Experience will inform us whether the legislation meets its intended goals of increasing patent quality, making patent dispute resolution more fair and efficient, improving the environment for innovation, and enhancing the economic growth of the United States.

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[111] 35 U.S.C. § 122(b).

[112] See CRS Report RS20906, *U.S. Patent and Trademark Office Appropriations Process: A Brief Explanation*, by Wendy H. Schacht.