

The Design and Implementation of Patent Revocation Proceedings: Innovation Issues

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Summary

Congressional recognition of the role patents play in promoting innovation and economic growth has resulted in the introduction of legislation proposing changes to the patent system. Among other goals, these changes would potentially decrease the cost of resolving disputes concerning patents, increase commercial certainty regarding the validity of particular patents, address potential abuses committed by speculators, and account for the particular needs of individual inventors, universities, and small firms with respect to the patent system.

In pursuit of these goals, several bills introduced in the 111th Congress would alter the current system of "patent revocation proceedings" administered by the U.S. Patent and Trademark Office (USPTO). The term "patent revocation proceeding" commonly refers to a legal procedure through which members of the public may challenge the validity of an issued patent.

Current law provides for two types of patent revocation proceedings: an *ex parte* reexamination and *inter partes* reexamination. Any individual may cite a patent or printed publication to the USPTO and request that an *ex parte* reexamination occur. If the USPTO determines that the request raises "a substantial new question of patentability," then it will commence the *ex parte* reexamination. The USPTO will then review the patent with special dispatch. The proceeding results in either a certificate upholding the claims in original or amended form, or a certificate of cancellation rejecting all of the claims of the patent. *Inter partes* reexamination operates similarly to an *ex parte* reexamination, but allows more significant participation by the individual requesting the proceeding.

Some observers believe that both types of reexamination have not been widely used and could be improved. As a result, previous legislative proposals have called for their elimination or modification. These bills would have also created a new, more expansive "post-grant review proceeding." This proposed procedure was intended to provide a predictable, cost-effective, and timely mechanism for resolving patent validity disputes and limit repetitive claims against the patent owner.

Patent revocation proceedings involve a number of design parameters that may be adjusted in order to meet certain policy goals. Among these parameters are the time at which the proceeding may begin, the patentability issues that may be addressed, the availability of discovery, and the extent to which participants may reassert unsuccessful arguments in subsequent administrative or judicial proceedings. These parameters may be modified in order to encourage certain policy goals, including timely use and resolution of the proceedings, limiting the possibility of harassment of the patent owner, and providing predictable, effective, and transparent decisions.

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Increased congressional interest in the patent system has reflected growing recognition of the role patents play in promoting innovation and economic growth. In recent years, a number of bills have proposed changes to the patent system designed to address perceived deficiencies. Several of these bills would have altered the current system of "patent revocation proceedings" administered by the U.S. Patent and Trademark Office (USPTO). These proposals built upon several earlier laws, including the American Inventors Protection Act of 1999,[1] that provided interested parties with a mechanism for challenging a patent outside of the federal court system.

The term "patent revocation proceeding" commonly refers to a legal procedure through which members of the public may challenge the validity of an issued patent. Patent revocation proceedings are administrative in nature and are conducted before the USPTO. Current law provides for two types of patent revocation proceedings: an *ex parte* reexamination[2] and *inter partes* reexamination.[3] The chief distinction between these two sorts of proceedings is the level of participation by the individual who requested the reexamination. Once the USPTO decides to pursue an *ex parte* reexamination, the requestor no longer participates in the proceedings.[4] In contrast, the requestor participates in an *inter partes* reexamination throughout the duration of the proceedings.

Reexamination proceedings were intended to serve several goals, including allowing firms to resolve patent disputes in a more timely and less costly manner than litigation in the federal courts,[5] harnessing the technological and legal expertise of the USPTO,[6] and improving public confidence in the patent system.[7] Some observers believe that these proceedings are underutilized due to shortcomings in their design. Among the expressed concerns over reexamination proceedings is that they are too slow, too susceptible to abuse by patent opponents, and not truly an effective substitute for litigation in the federal courts.[8]

Legislative proposals in the 111th Congress would address existing patent revocation proceedings and also establish a new, more expansive "post-grant review proceeding."[9] Proponents of reform assert that these changes would better fulfill the original purposes of reexamination, ultimately allowing more efficient resolution of patent disputes and improving patent quality. On the other

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[1] Intellectual Property and Communications Omnibus Reform Act of 1999, Title IV (American Inventors Protection Act of 1999), P.L. 106-113, 113 Stat. 1501 (1999).

[2] The term "ex parte" means "done or made at the instance and for the benefit of one party only." *Black's Law Dictionary* (8th ed. 2004). The provisions governing *ex parte* reexamination proceedings are codified at 35 U.S.C. §§ 302-307 (2006).

[3] The term "inter partes" means "between two or more parties." *Black's Law Dictionary* (8th ed. 2004). The provisions governing *inter partes* reexamination proceedings are codified at 35 U.S.C. §§ 311-318 (2006).

[4] One exception exists to this general rule. In an *ex parte* reexamination, the requestor may possess one opportunity to participate in the proceeding once the USPTO has granted the request. Once a reexamination is declared, the patent owner may optionally file a preliminary statement. If the patent owner does so, then the requestor may then file a reply to the patentee's statements. 35 U.S.C. § 304 (2006).

[5] *See* Amy J. Tindell, "Final Adjudication of Patent Validity in USPTO Reexamination and Article III Courts: Whose Job Is It Anyway?", 89 *Journal of the Patent and Trademark Office Society* (2007), 787.

[6] *See* William Barrow, "Creating a Viable Alternative: Reforming Patent Reexamination Procedure for the Small Business and Small Inventor," 59 *Administrative Law Review* (2007), 629.

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

[8] *Id.*

[9] *See* H.R. 1260; S. 515; S. 610 (each styled the "Patent Reform Act of 2009").

hand, concerned observers note that patent revocation proceedings may hold disdavantages. In their view, these procedures may increase uncertainty about patent rights in the marketplace, be used strategically to harass patent proprietors, and strain USPTO administrative capabilities.[10] Proponents maintain that the design features of the different patent revocation proceedings endeavor to realize their potential advantages while minimizing their possible drawbacks.

This report introduces issues with respect to the design and implementation of patent revocation proceedings. It begins by providing an overview of the basic workings and policy aspirations of the patent system. The report then provides a more detailed review of *ex parte* and *inter partes* reexamination proceedings currently administered by the USPTO. Next, the report reviews changes to patent revocation proceedings that were proposed in pending legislation. The report closes by identifying a number of congressional issues and options with respect to patent revocation proceedings.

Patents and Innovation Policy

The Mechanics of the Patent System

The U.S. Constitution grants Congress the power "To promote the Progress of Science and useful Arts, by securing for limited Times to ... Inventors the exclusive Right to their ... Discoveries...."[11] The Patent Act of 1952 allows inventors to request the grant of a patent by preparing and submitting an application to the USPTO.[12] USPTO officials known as examiners then determine whether the invention disclosed in the application merits the award of a patent.[13]

In deciding whether to approve a patent application, a USPTO examiner will consider whether the submitted application fully discloses and distinctly claims the invention.[14] In particular, the application must enable persons skilled in the art to make and use the invention without undue experimentation.[15] In addition, the application must disclose the "best mode," or preferred way, that the applicant knows to practice the invention.[16]

The examiner will also determine whether the invention itself fulfills certain substantive standards set by the patent statute. To be patentable, an invention must meet four primary requirements. First, the invention must fall within at least one category of patentable subject matter. An invention that qualifies as a "process, machine, manufacture, or composition of matter" is eligible for patenting.[17] Second, the invention must be useful, a requirement that is satisfied if the invention is operable and provides a tangible benefit.[18]

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[10] *See* Mark D. Janis, "Rethinking Reexamination: Toward a Viable Administrative Revocation System for U.S. Patent Law," 11 *Harvard Journal of Law and Technology* (1997), 1.

[11] U.S. Constitution, Article I, Section 8, Clause 8.

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

[13] 35 U.S.C. § 131 (2006).

[14] 35 U.S.C. § 112 (2006).

[15] *See* Invitrogen Corp. v. Clontech Labs., Inc., 429 F.3d 1052, 1070-71 (Fed. Cir. 2005).

[16] *See* High Concrete Structures, Inc. v. New Enterprise Stone and Lime Co., 377 F.3d 1379, 1382 (Fed. Cir. 2004).

[17] 35 U.S.C. § 101 (2006).

[18] *Id. See* In re Fischer, 421 F.3d 1365, 1371 (Fed. Cir. 2005).

Third, the invention must be new, or different, from subject matter disclosed by an earlier patent, publication, or other state-of-the-art knowledge.[19] Finally, an invention is not patentable if "the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains."[20] This requirement of "nonobviousness" prevents the issuance of patents claiming subject matter that a skilled artisan would have been able to implement in view of the knowledge of the state of the art.[21]

If the USPTO allows the patent to issue, its owner obtains the right to exclude others from making, using, selling, offering to sell, or importing into the United States the patented invention.[22] Those who engage in those acts without the permission of the patentee during the term of the patent can be held liable for infringement. The maximum term of patent protection is ordinarily set at 20 years from the date the application is filed.[23] At the end of that period, others may employ that invention without regard to the expired patent.

Patent proprietors who wish to compel others to respect their rights must commence enforcement proceedings, which most commonly consist of litigation in the federal courts. Adjudicated infringers may be enjoined from further infringing acts.[24] The patent statute also provides for an 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."[25]

Although issued patents are presumed to be valid, accused infringers may assert that a patent is invalid or unenforceable on a number of grounds.[26] If the court agrees that the patented invention would have been obvious in view of the state of the art, for example, then it will declare the patent invalid. Several empirical studies have attempted to track the percentage of litigated patents that the courts conclude the USPTO improvidently granted. One study conducted by John R. Allison, a member of the University of Texas business school faculty, and Mark A. Lemley, a member of the Stanford Law School faculty, concluded that courts hold 46% of patents litigated to a final judgment to be invalid.[27] Other studies have reported results broadly consistent with the Allison & Lemley research.[28]

[19] 35 U.S.C. § 102 (2006).

[20] 35 U.S.C. § 103(a) (2006).

[21] *See* KSR International Co. v. Teleflex Inc., 550 U.S. 398 (2007).

[22] 35 U.S.C. § 271(a) (2006).

[23] 35 U.S.C. § 154(a)(2) (2006). Although the patent term is based upon the filing date, the patentee obtains 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 for certain reasons, including examination delays at the USPTO and delays in obtaining marketing approval for the patented invention from other federal agencies.

[24] 35 U.S.C. § 283 (2006). *See* eBay Inc. v. MercExchange L.L.C., 547 U.S. 388 (2006).

[25] 35 U.S.C. § 284 (2006).

[26] 35 U.S.C. § 282 (2006).

[27] John R. Allison & Mark A. Lemley, "Empirical Evidence on the Validity of Litigated Patents," 26 *American Intellectual Property Law Association Quarterly Journal* (1998), 185.

[28] *See* Rebecca S. Eisenberg, "Pharma's Nonobvious Problem," 12 *Lewis & Clark Law Review* (2008), 375 (discussing several empirical studies pertaining to patent invalidity rates).

The Court of Appeals for the Federal Circuit (Federal Circuit) possesses nationwide jurisdiction over most patent appeals from the district courts.[29] The Supreme Court enjoys discretionary authority to review cases decided by the Federal Circuit.[30]

Policy Goals

The patent system is intended to promote innovation, which in turn leads to industry advancement and economic growth. The patent system in particular attempts to address "public goods problems" that may discourage individuals from innovating. Innovation commonly results in information that may be deemed a "public good," in that it is both non-rivalrous and non-excludable. Stated differently, consumption of a public good by one individual does not limit the amount of the good available for use by others, and no one can be prevented from using that good.[31]

The lack of excludability in particular is believed to result in an environment where too little innovation would occur. Absent a patent system, "free riders" could easily duplicate and exploit the inventions of others. Further, because they incurred no cost to develop and perfect the technology involved, copyists could undersell the original inventor. Aware that they would be unable to capitalize upon their inventions, individuals might be discouraged from innovating in the first instance. The patent system corrects this market failure problem by providing innovators with an exclusive interest in their inventions for a period of time, thereby allowing them to capture their marketplace value.[32]

The patent system potentially serves other goals as well. The patent law may promote the disclosure of new products and processes, as each issued patent must include a description sufficient to enable skilled artisans to practice the patented invention.[33] At the close of the patent's 20-year term,[34] others may employ the claimed invention without regard to the expired patent. In this manner the patent system ultimately contributes to the growth of information in the public domain.

Issued patents may encourage others to "invent around" the patentee's proprietary interest. A patent proprietor may point the way to new products, markets, economies of production, and even entire industries. Others can build upon the disclosure of a patent instrument to produce their own technologies that fall outside the exclusive rights associated with the patent.[35]

The patent system also has been identified as a facilitator of markets. If inventors lack patent rights, they may have scant assets to sell or license. In addition, an inventor might otherwise be unable to police the conduct of a contracting party. Any technology or know-how that has been

[29] 28 U.S.C. § 1295(a)(1) (2006).

[30] 28 U.S.C. § 1254(1) (2006).

[31] *See* Dotan Oliar, "Making Sense of the Intellectual Property Clause: Promotion of Progress as a Limitation on Congress's Intellectual Property Power," 94 *Georgetown Law Journal* (2006), 1771.

[32] *See* Dan L. Burk & Mark A. Lemley, "Is Patent Law Technology-Specific?," 17 *Berkeley Technology Law Journal* (2002), 1155.

[33] 35 U.S.C. § 112 (2006).

[34] 35 U.S.C. § 154 (2006).

[35] *See* Rebecca Eisenberg, "Patents and the Progress of Science: Exclusive Rights and Experimental Use," 56 *University of Chicago Law Review* (1989), 1017.

disclosed to a prospective licensee might be appropriated without compensation to the inventor. The availability of patent protection decreases the ability of contracting parties to engage in opportunistic behavior. By lowering such transaction costs, the patent system may make transactions concerning information goods more feasible.[36]

Through these mechanisms, the patent system may act in a more socially desirable way than its chief legal alternative, trade secret protection. Trade secrecy guards against the improper appropriation of valuable, commercially useful, and secret information. In contrast to patenting, trade secret protection does not result in the disclosure of publicly available information. That is because an enterprise must take reasonable measures to keep secret the information for which trade secret protection is sought. Taking the steps necessary to maintain secrecy, such as implementing physical security measures, also imposes costs that may ultimately be unproductive for society.[37]

The patent system has long been subject to criticism, however. Some observers have asserted that the patent system is unnecessary due to market forces that already suffice to create an optimal level of innovation. The desire to obtain a lead time advantage over competitors may itself provide sufficient inducement to invent without the need for further incentives.[38] Other commentators believe that the patent system encourages industry concentration and presents a barrier to entry in some markets.[39]

Each of these arguments for and against the patent system has some measure of intuitive appeal. However, they remain difficult to analyze on an empirical level. We lack rigorous analytical methods for studying the impact of the patent system upon the economy as a whole. As a result, current economic and policy tools do not allow us to calibrate the patent system precisely in order to produce an optimal level of investment in innovation.

An Introduction to Patent Revocation Proceedings

Once the USPTO formally issues a patent, the agency's involvement with that legal instrument ordinarily comes to a close.[40] However, the USPTO may be called upon to reconsider its initial decision to approve a patent application through several "post-grant proceedings" that apply to issued patents. Two of these proceedings, *ex parte* reexamination and *inter partes* reexamination, are revocation proceedings—that is to say, they are primarily used by individuals who wish to challenge the validity of an issued patent.

Both types of reexamination proceedings address a perceived shortcoming in the patent system. Absent such proceedings, interested individuals would be unable to challenge the validity of a patent unless they became involved in a "substantial controversy" with the patent's proprietor.[41]

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[36] Robert P . Merges, "Intellectual Property and the Costs of Commercial Exchange: A Review Essay," 93 *Michigan Law Review* (1995), 1570.

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

[38] *See* Frederic M. Sherer, *Industrial Market Structure and Economic Performance* (1970), 384-87.

[39] *See* John R. Thomas, "Collusion and Collective Action in the Patent System: A Proposal for Patent Bounties," *University of Illinois Law Review* (2001), 305.

[40] The USPTO does accept maintenance fees, which are due 3½, 7½, and 11½ years after the grant of the patent. The patent will expire if the maintenance fee is not paid. *See* 35 U.S.C. § 41(b) (2006).

[41] *See* MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118 (2007).

This requirement that an immediate, concrete dispute between the patent owner and another individual arises because the Constitution vests the federal courts with jurisdiction only where a "case or controversy" exists.[42] A charge of patent infringement typically satisfies the "case or controversy" requirement.[43]

The "case or controversy" requirement significantly limits the ability of members of the public to challenge the USPTO's decision to grant a patent. Unless the patent proprietor becomes involved in an actual, continuing controversy with another person, that person cannot successfully request that a court determine whether the patent is valid or not. Reticent patent proprietors may therefore potentially create uncertainty in the marketplace. Manufacturers, researchers, investors, and others who question the validity of a patent, but possess no forum to address their concerns, may be unable to make informed decisions regarding the subject matter of that patent.[44]

Patent revocation proceedings address this perceived gap by allowing any interested person to challenge any U.S. patent at the USPTO. Because these proceedings are administrative in nature, the constitutional "case or controversy" requirement does not apply to them.[45] As a result, the USPTO may be called upon to review the validity of an issued patent at any time during its term.

Ex Parte Reexamination

Congress introduced reexamination proceedings into the patent law in 1980.[46] The American Inventors Protection Act of 1999 renamed the traditional sort of reexamination as an "*ex parte* reexamination" and also provided for the possibility of an "*inter partes* reexamination."[47]

Under the *ex parte* reexamination regime, any individual, including the patentee, a licensee, and even the USPTO Director himself, may cite a patent or printed publication to the USPTO and request that a reexamination occur.[48] The reexamination request must be in writing and explain the relevance of the cited reference to every claim for which reexamination is requested. The request must also be accompanied by the appropriate fee, which as of January 1, 2010, was $2,520. Although the USPTO does not maintain the identity of the requester in confidence, individuals desiring anonymity may authorize a patent agent or attorney to file the request in the agent's own name.

A USPTO examiner then must determine whether the patents or printed publications cited in the request raise "a substantial new question of patentability."[49] This standard is met when there is a significant likelihood that a reasonable examiner would consider the reference important in deciding whether the claim is patentable. If the USPTO determines that the cited reference does

[42] U.S. Const., Art. III, sec. 2, cl. 1.

[43] *See* Prasco, LLC v. Medicis Pharm. Corp., 537 F.3d 1329 (Fed. Cir. 2008).

[44] *See* Cat Tech LLC v. TubeMaster, Inc., 528 F.3d 871 (Fed. Cir. 2008).

[45] *See* Amy J. Tindell, "Final Adjudication of Patent Validity in PTO Reexamination and Article III Courts: Whose Job Is It Anyway?," 89 *Journal of the Patent and Trademark Office Society* (2007), 787.

[46] 35 U.S.C. §§ 301, 302 (2006).

[47] P.L. 106-113.

[48] *See* 35 U.S.C. § 302 (2006).

[49] 35 U.S.C. § 303(a) (2006).

not raise "a substantial new question of patentability," then it will refund a large portion of the requestor's fee. The USPTO's denial of a reexamination request may not be appealed.[50]

On the other hand, if the USPTO determines that the cited reference does present a substantial new patentability question, then it will issue an order for reexamination.[51] The patentee is then afforded the opportunity to file a preliminary statement for consideration in the reexamination. If the patentee does so, then the requestor may then file a reply to the patentee's statements.[52] As a practical matter, because most patentees do not wish to encourage further participation by the requestor, few preliminary statements are filed.[53]

Following this preliminary period, the USPTO will essentially reinitiate examination of the patent. Prosecution then continues following the usual rules for examination of applications.[54] However, several special rules apply to reexaminations. First, the USPTO conducts reexaminations with special dispatch.[55] Examiners must give priority to patents under reexamination, and will set aside their work on other patent applications in favor of the reexamination proceeding. To further ensure their timely resolution, patentees may not file a continuation application in connection with a reexamination.[56] Second, the patent owner may not update the patent with additional information not originally found within the patent during reexamination.[57]

If the reexamined claims are upheld in original or amended form, the USPTO will issue a reexamination certificate. Once this certificate has issued, the reexamined patent once more enjoys the statutory presumption of validity.[58] If the USPTO finds the claims to be unpatentable over the cited reference, then it will issue a certificate of cancellation.[59] Patentees adversely affected by a reexamination may appeal the USPTO's decisions to the Federal Circuit.[60]

Frequently, a defendant accused of infringement before a court files a reexamination request at the USPTO. If the USPTO accepts the request, the USPTO and a court will find themselves in the awkward situation of simultaneously considering the validity of the same patent. In *Ethicon, Inc. v. Quigg*,[61] the Federal Circuit concluded that because the Patent Act required reexaminations to be conducted with "special dispatch," the USPTO may not stay reexamination proceedings due to ongoing litigation. Whether a court will stay litigation in favor of the reexamination lies within the discretion of the judge. Such factors as the technical complexity of the invention, the overall

[50] 35 U.S.C. § 303(c) (2006).

[51] 35 U.S.C. § 304 (2006).

[52] *Id.*

[53] *See* Paul Morgan, "Reexamination vs. Litigation—Making Intelligent Decisions in Challenging Patent Validity," 86 *Journal of the Patent and Trademark Office Society* (2004), 441.

[54] 35 U.S.C. § 305 (2006).

[55] *Id.*

[56] *Id.*

[57] *Id.*

[58] 35 U.S.C. § 307(a) (2006).

[59] *Id.*

[60] *See* 35 U.S.C. § 306 (2006).

[61] 849 F.2d 1422 (Fed. Cir. 1988).

workload of the court, and whether the reexamination request was filed early or late in the litigation typically influence this determination.[62]

Congress recognized that third parties may have made commercial decisions based upon the precise wording of the claims of an issued patent. If that patent is reexamined and survives with different claims, this reliance interest could be frustrated. In order to protect individuals who may have relied upon the scope of the claims of the original patent, the Patent Act allows for so-called intervening rights.[63] Intervening rights allow third parties to sell off existing inventory free of the patent right. In addition, courts may allow continued practice of an invention claimed in a reexamined patent to the extent they deem equitable "for the protection of investments made or business commenced" before the grant of the reexamination certificate.[64]

Inter Partes Reexamination

As the title "*ex parte* reexamination" suggests, the role of the reexamination requestor is very limited in these proceedings. Only the patentee may participate in the dialogue with the examiner, and only the patentee may appeal the matter to the courts if the USPTO reaches an unsatisfactory conclusion. Some potential patent challengers did not believe the limited role provided for them offered a viable alternative to validity challenges in court.[65] As a result, some observers believed that the ability of *ex parte* reexamination to provide an expert forum as a faster, less expensive alternative to litigation of patent validity was compromised. In particular, far fewer *ex parte* reexaminations were requested than some observers had originally anticipated.[66]

The Optional Inter Partes Reexamination Procedure Act of 1999 responded to these concerns by providing patent challengers with an additional option.[67] They may employ the traditional reexamination system, which was renamed an *ex parte* reexamination. Or, they may opt for a considerable degree of participation in a new procedure known as *inter partes* reexamination.[68] Under this legislation, third party requesters may choose to submit written comments to accompany patentee responses to the USPTO.[69] The requester also may appeal USPTO determinations that a reexamined patent is not invalid to the courts.[70] The filing fee for *inter partes* reexaminations is $8,800 as of January 1, 2010.

Congress was concerned that competitors of the patent proprietor might attempt to litigate a patent validity issue in the courts following an unsuccessful *inter partes* reexamination at the

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[62] *See* Soverain Software LLC v. Amazon.com, Inc., 356 F.Supp.2d 660 (E.D. Tex. 2005).

[63] 35 U.S.C. § 252 (2006).

[64] *Id.*

[65] *See* J. Steven Baughman, "Reexamining Reexaminations: A Fresh Look at the *Ex Parte* and *Inter Partes* Mechanisms for Reviewing Issued Patents," 89 *Journal of the Patent and Trademark Office Society* (2007), 349.

[66] Katherine M. Zandy, "Too Much, Too Little, or Just Right? A Goldilocks Approach to Patent Reexamination Reform," 61 *New York University Annual Survey of American Law* (2006), 865.

[67] Enacted in the 106th Congress, this legislation formed Subtitle F of the American Inventors Protection Act of 1999, which in turn was Title IV of the Intellectual Property and Communications Omnibus Reform Act of 1999, P.L. 106-113, 113 Stat. 1501 (1999).

[68] *See generally* Tun-Jen Chiang, "The Advantages of *Inter Partes* Reexamination," 90 *Journal of the Patent and Trademark Office Society* (2008), 579.

[69] 35 U.S.C. § 314 (2006).

[70] 35 U.S.C. § 315 (2006).

USPTO, or the reverse, requesting *inter partes* reexamination based upon the same validity issue they had unsuccessfully raised in court.[71] The potential need for repetitive defensive efforts was deemed to be abusive to patent proprietors. As a result, the *inter partes* reexamination statute provides that third party participants may not raise issues that they raised or could have raised during the *inter partes* reexamination during subsequent litigation.[72] Similarly, an individual who loses a validity challenge in federal court may not later initiate an *inter partes* reexamination proceeding on any grounds it raised or could have raised in federal court.[73] These provisions are termed "estoppel" provisions because they stop, or bar, individuals from making repetitive arguments in later proceedings.

The Current State of Post-Grant Review

The USPTO regularly releases to the public current data concerning both sorts of reexamination proceedings. This data supplies considerable information concerning the practical workings of these proceedings. With respect to *ex parte* reexamination, a total of 10,066 requests had been filed from the July 1, 1981, conception date of these proceedings through June 30, 2009. Approximately 36% of these requests were filed by the patent owner,[74] 2% by the USPTO Director, with the remaining 62% filed by third parties. The USPTO granted 9,675, or approximately 92%, of these requests. *Ex parte* reexamination proceedings had an average pendency of 25.1 months and a median pendency of 19.5 months. *Ex parte* reexamination proceedings resulted in a certificate cancelling all the claims 11% of the time, a certificate confirming all the claims 25% of the time, and a certificate amending at least one claim 64% of the time.[75]

A total of 671 *inter partes* reexamination requests had been filed from the November 29, 1999, conception date of the proceedings through June 30, 2009.[76] The USPTO granted 583, or approximately 95%, of these requests. *Inter partes* reexamination proceedings had an average pendency of 36.1 months and a median pendency of 33.0 months. *Inter partes* reexamination proceedings resulted in a certificate cancelling all the claims 60% of the time, a certificate confirming all the claims 5% of the time, and a certificate amending at least one claim 35% of the time.[77]

In combination with commentary from members of the patent community, this data supports a number of observations. First, the number of both types of reexamination requests is fewer than

[71] Janis, *supra* note 8, at 481.

[72] 35 U.S.C. § 315(c) (2006).

[73] *Id.*

[74] The notion that a rights holder would wish to oppose its own patent may at first seem anomalous. However, a patent proprietor may request a reexamination against its own patent so that it may amend the patent's claims. Amended claims may be more likely to withstand validity challenges by third parties, present a stronger case for infringement against a competitor's products or processes, or provide other advantages. *See* Jeffrey G. Sheldon, "Strengthening and Weakening the Patent Through Reexamination and Reissue," 492 *Practising Law Institute/PAT* (Sept. 25, 2007), 119.

[75] USPTO, *Ex Parte* Reexamination Filing Data—June 30, 2009 (available at http://www.fr.com/news/articledetail.cfm?articleid=771).

[76] USPTO, *Inter Partes* Reexamination Filing Data—June 30, 2009 (available at http://www.fr.com/news/articledetail.cfm?articleid=772).

[77] *Id.*

some observers had anticipated.[78] Although some commentators expected that thousands of reexamination requests would be filed each year, the actual number has been considerably less.[79] Both forms of reexamination appear to be growing in popularity in recent years, however.[80] In 2007, for example, 643 *ex parte* reexamination requests were filed, as compared to 375 in 1997 and 240 in 1987. The small but growing number of *inter partes* reexamination requests may in part be explained because this proceeding is only available to challenge patents that issued from applications filed after November 29, 1999.[81] As a result, no *inter partes* reexamination requests were filed at all in 1999, and only one such request was made in 2001. In 2007, 126 *inter partes* requests were filed, and 128 requests were filed between January 1, 2008, and June 30, 2008.[82]

Second, *ex parte* reexamination requests result in the cancellation of all of a patent's claims only 11% of the time. This data supports the view of some observers that *ex parte* reexamination requests favor the patent proprietor in practice.[83] One explanation for this perceived tendency is that *ex parte* reexamination proceedings are seen as restrictive in nature, with limited grounds for challenging a patent and minimal participation by the patent challenger.[84] On the other hand, 64% of reexamination certificates result in amendments to the claims of the challenged patents. These amendments may narrow the scope of patent protection in such a way to allow competitors more readily to design around the patent, thereby providing a satisfactory result to the reexamination requestor. Indeed, another way to perceive these statistics is that 75% of the time, the USPTO finds the patent subject to *ex parte* reexamination at least partially invalid.[85] These critiques also do not apply to *inter partes* reexamination proceedings, where all the claims of the patent are cancelled 60% of the time.

Third, both sorts of reexamination requests take over two years on average to complete. The length of this proceeding is explained in part by the demands of the workload of the USPTO and complexity of some of the technologies involved. Some commentators believe that these proceedings take too much time to complete. During the pendency of the reexamination, litigation or licensing of the patent may prove difficult due to the pending USPTO decision.[86]

Other concerns have arisen with respect to reexamination. The estoppel provisions associated with *inter partes* reexaminations are among those that have attracted criticism.[87] The *inter*

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[78] *See* William Barrow, "Creating a Viable Alternative: Reforming Patent Reexamination Procedure for the Small Business and Small Inventor," 59 *Administrative Law Review* (2007), 629.

[79] *See* Shannon M. Casey, "The Patent Reexamination Reform Act of 1994: A New Era of Third Party Participation," 2 *Journal of Intellectual Property Law* (1995), 559.

[80] *See* James W. Hill & M. Todd Hales, "Patent Reexamination After *KSR*," 50 *Orange County Lawyer* (Aug. 2008), 30.

[81] *See* Betsy Johnson, "Plugging the Holes in the *Ex parte* Reexamination Statute: Preventing a Second Bite at the Apple for a Patent Infringer," 55 *Catholic University Law Review* (2005), 305.

[82] USPTO, "*Inter Partes* Reexamination Filing Data—June 30, 2007" (available at http://www.fr.com/news/articledetail.cfm?articleid=772).

[83] *See* Roger Shang & Yar Chaikovsky, "*Inter Partes* Reexamination of Patents: An Empirical Evaluation," 15 *Texas Intellectual Property Law Journal* (2006), 1.

[84] *See* Kristen Jakobsen Osenga, "Rethinking Reexamination Reform: Is It Time for Corrective Surgery, or Is It Time to Amputate?," 14 *Fordham Intellectual Property, Media & Entertainment Law Journal* (2003), 217.

[85] Johnson, *supra*, at 305.

[86] *Id.* at 330.

[87] *See* David L. Steward, "*Inter Partes* Reexam—On Steroids," 85 *Journal of the Patent and Trademark Office Society* (2003), 656.

partes reexamination statute provides that third party participants may not raise during subsequent litigation issues that they raised or could have raised during the *inter partes* reexamination.[88] Similarly, an individual who loses a validity challenge in federal court may not later provoke an *inter partes* reexamination proceeding on any grounds it raised or could have raised in federal court.[89] Some experts believe that these provisions weigh too heavily against patent challengers and therefore discourage use of *inter partes* reexaminations.[90] However, other commentators observe that an infringer who fails to convince a court that the asserted patent is invalid stands in the same position as the party that loses in an *inter partes* reexamination—in either setting, the law provides a single opportunity to argue that the patent was invalid.[91] Further, Congress intended that these provisions would limit possibilities for harassing patent owners through repetitive litigation and reexaminations proceedings.[92]

Other observers have criticized a tactic sometimes employed once a court concludes that an individual infringes a patent. The adjudicated infringer may employ reexamination proceedings in an effort to convince the USPTO to invalidate a patent that a court had previously upheld. Some observers believe that it is inappropriate for the USPTO to strike down a patent that a court had recently confirmed.[93] These tactics may also raise concerns over separation of powers between the executive and judicial branches.[94] On the other hand, differences between judicial and USPTO proceedings may contribute to divergent outcomes between these fora. For example, although patents enjoy a presumption of validity in the courts,[95] they are not entitled to this presumption during reexamination proceedings.[96]

In sum, divergent views exist with respect to *ex parte* and *inter partes* reexamination proceedings. Although individual commentators vary in their assessments of the effectiveness and fairness of these patent revocation proceedings, persistent discussion has occurred within the patent community concerning their potential modification. In addition, many observers have proposed the creation of additional mechanisms for allowing members of the public to challenge the USPTO's patentability determination without subjecting patent proprietors to harassment.[97] As this report next discusses, some features of these proposals have become the subject of congressional legislative proposals.

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[88] 35 U.S.C. § 315(c) (2006).

[89] *Id.*

[90] *See* Joseph D. Cohen, "What's Really Happening in *Inter Partes* Reexamination," 87 *Journal of the Patent and Trademark Office Society* (2005), 207; Susan Perng Pan, "Considerations for Modifying *Inter-Partes* Reexam and Implementing Other Post-Grant Review," 45 *IDEA: The Journal of Law and Technology* (2004), 1.

[91] Chiang, *supra*, at 580.

[92] Qin Shi, "Reexamination, Opposition, or Litigation? Legislative Efforts to Create a Post-Grant Patent Quality Control System," 31 *American Intellectual Property Law Association Quarterly Journal* (2003), 433.

[93] *See* Tremesha S. Willis, "Patent Reexamination Post Litigation: It's Time to Set the Rules Straight," 12 *Journal of Intellectual Property Law* (Spring 2005), 597.

[94] Tindell, *supra*.

[95] 35 U.S.C. § 282 (2006).

[96] *See In re* Swanson, 540 F.3d 1368, 1377 (Fed. Cir. 2008).

[97] *See, e.g.,* Eric Williams, "Remembering the Public's Interest in the Patent System—A Post-Grant Opposition Designed to Benefit the Public," 2006 *Boston College Intellectual Property and Technology Forum* (Nov. 7, 2006), 110702.

Proposals for Reform in the 111th Congress

Legislative interest in improving upon current patent revocation proceedings in part motivated the introduction of three bills in the 111th Congress. These bills were H.R. 1260 (introduced by Congressman Conyers on March 3, 2009), S. 515 (introduced by Senator Leahy on March 3, 2009, and reported by Senator Leahy with amendments on April 2, 2009), and S. 610 (introduced by Senator Kyl on March 17, 2009). Each of these bills was styled as the "Patent Reform Act of 2009."

With respect to existing patent revocation proceedings, S. 610 would entirely eliminate *inter partes* reeexamination. In contrast, H.R. 1260 and S. 515 would retain these proceedings. Each of the three bills would retain *ex parte* reexamination proceedings.

Each of the bills would also introduce a new administrative procedure termed a "post-grant review proceeding" or "post-grant review procedures." The post-grant proceeding proposed by the three bills shares certain common features. First, the maximum length of the proceeding was set to one year, with an extension by six months possible for good cause shown. Second, each post-grant proceeding would be administered by a newly established "Patent Trial and Appeal Board." Third, any participant dissatisfied with the outcome would be able to bring an appeal to the Federal Circuit. Finally, with the exception of confidential material that has been sealed by the USPTO, the file of this procedure would be made available to the public. The following table identifies selected features with respect to each of these bills.

Table 1. Selected Features of Proposed Patent Revocation Proceedings

Selected Issues	H.R. 1260	S. 515	S. 610
Individuals who may request the USPTO to conduct the post-grant proceeding.	A "person who is not the patent owner."	A "person who is not the patent owner."	A "person who has a substantial economic interest adverse to the patent."
The time period during which an individual may request that the USPTO conduct the post-grant proceeding.	12 months after the patent issues; or any time if the patent owner consents in writing.	12 months after the patent issues; or any time if the patent owner consents in writing.	9 months after the patent issues (termed a "first-period proceeding") or any time, so long as a first-period proceeding is not pending (termed a "second-period proceeding").
The range of patent validity issues that the USPTO may consider during the post-grant proceeding.	Any relevant validity issue except for best mode.	Any relevant validity issue except for best mode.	In a first-period proceeding, any relevant validity issue. In a second-period proceeding, validity issues are limited to novelty and nonobviousness based upon patents and printed publications.
The required showing in order for the USPTO to grant a request to conduct a post-grant proceeding.	The petition must establish a substantial question of patentability for at least one claim in the patent.	The petition must establish a substantial question of patentability for at least one claim in the patent.	The petition must present information that, if not rebutted, would provide a sufficient basis to conclude that at least one claim is invalid.
The ability of the patent owner to amend the patent's claims during the post-grant proceeding.	One amendment may be filed as a matter of right, with additional amendments permitted only for good cause shown. The scope of the claims may not be enlarged.	One amendment may be filed as a matter of right, with additional amendments permitted only for good cause shown. The scope of the claims may not be enlarged.	One amendment may be filed as a matter of right, with additional amendments permitted only for good cause shown or upon the joint request of the parties in order materially to advance settlement. The scope of the claims may not be enlarged.
The presumption of validity enjoyed by the patent subject to the post-grant proceeding.	The patent is not presumed to be valid. The petitioner shall have the burden of proving invalidity by a preponderance of the evidence.	The patent is not presumed to be valid. The petitioner shall have the burden of proving invalidity by a preponderance of the evidence.	The patent is presumed to be valid. The petitioner shall have the burden of proving invalidity by a preponderance of the evidence in a first-period proceeding and by clear and convincing evidence in a second-period proceeding.
The ability of the individual requesting the post-grant proceeding to raise validity issues with respect to that patent in later proceedings.	The requestor is prevented from raising validity issues in later proceedings based on an issue raised in the post-grant proceeding.	The requestor is prevented from raising validity issues in later proceedings based on an issue raised in the post-grant proceeding.	The requestor is prevented from raising validity issues in later proceedings based on an issue raised or that could have been raised in the post-grant proceeding.
The availability of discovery in the post-grant proceeding.	Discovery is available to the participants in the post-grant proceeding.	Discovery is available to the participants in the post-grant proceeding.	Discovery is available to the participants in the post-grant proceeding. In a second-period proceeding, such discovery is limited to depositions of witnesses who submit affidavits or

Selected Issues	H.R. 1260	S. 515	S. 610
			otherwise necessary in the interest of justice.
The relationship of the post-grant proceeding to other proceedings before the USPTO.	An individual may not file more than one petition with respect to the same patent. The Director may determine the manner in which other proceedings are stayed, transferred, consolidated, or terminated.	An individual may not file more than one petition with respect to the same patent. The Director may determine the manner in which other proceedings are stayed, transferred, consolidated, or terminated.	Multiple first-period proceedings will be consolidated. In a second-period proceeding ordered by the Director, the Director may join other petitioners to that proceeding in his discretion. The Director may determine the manner in which other proceedings are stayed, transferred, consolidated, or terminated.
The relationship of the post-grant proceeding to litigation in the courts.	The Director may stay a post-grant review proceeding if a pending civil action for infringement addresses the same or substantially the same questions of patentability.	The Director may stay a post-grant review proceeding if a pending civil action for infringement addresses the same or substantially the same questions of patentability.	The Director may stay a first-period proceeding until after infringement litigation is complete if the infringement action were filed within 3 months after grant of a patent, the patent owner requests a stay, the litigation and post-grant proceeding concern the same or substantially the same issues of patentability, and such a stay would not be contrary to the interests of justice. A post-grant review proceeding may not be maintained if the petitioner has filed a civil action challenging the patent's validity. A second-period proceeding may not be instituted if the petition is filed more than 3 months after the petitioner must respond to a charge of patent infringement in the courts.

As this table demonstrates, patent revocation proceedings involve a number of parameters. The particular choices made in selecting these parameters may reflect the following policy goals:

Timely Challenges

Many observers believe that interested members of the public should be encouraged to bring patent challenges as soon as possible after the patent issues.[98] Balanced against this goal was the desire to provide members of the public access to USPTO review throughout the term of the patent.[99] The three bills endeavor to balance these goals by setting varying time limits for commencing a post-grant proceeding. S. 610 also appears to encourage timely challenges by augmenting the presumption of validity and limiting the scope of the challenge for proceedings not brought within nine months of the date the patent issues.

Timely USPTO Decision-Making

The three bills each would require the USPTO to complete the post-grant proceeding within one year, with the possibility of a single extension of up to six months. In addition, the bills would provide the USPTO with the ability to merge different proceedings that involve the same or similar issues. These features may increase the possibility that the USPTO will expeditiously administer post-grant proceedings.[100] However, these time limits may be difficult for the USPTO to meet and may require the USPTO to devote considerable resources to post-grant proceedings.

Predictable Decisions

Each of the three bills would create a Patent Trial and Appeal Board with exclusive responsibility for administering the post-grant proceeding. Such concentrated authority may potentially increase the uniformity of decisions reached by the USPTO in post-grant proceedings.[101]

Effective Decisions

In comparison with existing reexamination proceedings, the proposed post-grant proceedings would provide for a broader range of patentability issues that the USPTO must consider.[102] Unlike reexaminations, the post-grant proceedings also would allow the participants to engage in discovery. Discovery potentially allows one party to the proceeding to obtain information about the case from the other party in order to assist in trial preparation. These substantive and procedural rules potentially allow the USPTO to resolve a broad range of patentability issues in a lower-cost, more expedient procedure than federal litigation. The breadth of potential

[98] *See* Eric E. Williams, "Patent Reform: The Pharmaceutical Industry Prescription for Post-Grant Opposition and Remedies," 90 *Journal of the Patent and Trademark Office Society* (2008), 354.

[99] *See* D. Ward Hobson Jr., "Reforming the Patent System: A Closer Look at Proposed Legislation," 3 *Oklahoma Journal of Law and Technology* (2006), 29.

[100] Kunin & Fetting, *supra*.

[101] *Id.*

[102] *See* Kevin R. Davidson, "Retooling Patents: Current Problems, Proposed Solutions, and Economic Implications for Patent Reform," 8 *Houston Business and Tax Law Journal* (2008), 425.

patentability issues may make post-grant proceedings more difficult for the USPTO to resolve, however.

Transparent Decisions

Each of the bills calls for the record of the proceedings to be made available to the public.

Minimizing Repetitive Charges Against the Patent Owner

The bills also incorporate features that may decrease the possibility that post-grant proceedings may be used against a patent owner in an arguably abusive manner.[103] Among them is the requirement that the USPTO must assess whether the petitioner has raised legitimate patentability arguments prior to commencing the post-grant proceeding. The patent owner is also afforded at least one opportunity to amend the claims in view of prior art references that are cited by the petitioner. Finally, each of the bills would bar an unsuccessful petitioner in a post-grant proceeding from raising the same issues in other proceedings. Although these provisions were intended to shield the patent owner from repetitive arguments, they may also make the proceedings less attractive to potential challengers.

Patent Revocation Proceedings and Innovation Policy

Patents derive their value from the rights they confer to exploit proprietary technologies. The increased focus on intellectual property in our information-based, knowledge-driven economy has arguably caused industry to raise its expectations with respect to the quality, timeliness, and efficiency of the granting of patents.[104] As the USPTO currently employs approximately 6,000 patent examiners with varying degrees of experience, legal training, and technical education,[105] maintaining consistency in patent grant determinations presents a challenging task for USPTO management.[106]

By recruiting members of the public to act as "private patent examiners,"[107] post-grant proceedings allow the USPTO to confirm its earlier determinations regarding that subset of patents that prove to be of marketplace significance.[108] In this respect, it should be appreciated

[103] *See* Matthew Sag & Kurt Rohde, Patent Reform and Differential Impact," 8 *Minnesota Journal of Law, Science & Technology* (2007), 1.

[104] *See* Chris J. Katopis, "Perfect Happiness?: Game Theory as a Tool for Enhancing Patent Quality," 10 *Yale Journal of Law and Technology* (2007-08), 360.

[105] *See* Government Accountability Office, *U.S. Patent and Trademark Office: Hiring Efforts Are Not Sufficient to Reduce the Patent Application Backlog* (Sept. 2007).

[106] Stephen G. Kunin & Anton W. Fetting, "The Metamorphosis of *Inter Partes* Reexamination," 19 *Berkeley Technology Law Journal* (2004), 971.

[107] *See* John R. Thomas, "Collusion and Collective Action in the Patent System: A Proposal for Patent Bounties," 2001 *University of Illinois Law Review* (2001), 305.

[108] *See* Mark A. Lemley, "Rational Ignorance at the Patent Office," 95 *Northwestern University Law Review* (2001), 1495.

that the validity of only a small subset of issued patents is ever called into question.[109] For example, one commentator estimated that only about five percent of issued patents are litigated or licensed.[110] Post-grant proceedings may therefore direct the attention of the USPTO to those patents that industry believes to be of particular significance and arguable validity.

In addition, an administrative process for reassessing patentability determinations in a reliable, cost-effective, and timely manner could potentially allow members of the public to make commercial decisions with more certainty over the impact of patent rights.[111] By reducing costs to patent owners, it could also channel resources that innovative firms currently spend on defending their patent rights in the courts into further research and development.[112]

The designers of a patent revocation proceeding may need to take into account a number of potentially conflicting policy goals. A sufficiently robust, efficient, and predictable proceeding may attract individuals with a valid adverse interest to a patent. In this respect, it should be recognized that patent validity adjudications potentially benefit the public even though they take place between the patent owner and the petitioner. Because such determinations may either confirm that the award of a patent was appropriate, or dedicate the previously patented subject matter to the public domain, members of the public may benefit when the validity of a patent is upheld or denied.[113]

On the other hand, baseless or repetitive challenges potentially reduce the value of intellectual property ownership. They may ultimately reduce the value of the innovation that results from the grant of the patent as well.[114] Unmeritorious challenges may also strain USPTO capabilities and divert administrative resources from more worthwhile tasks.[115]

In view of these and other innovation policy concerns, Congress possesses a range of options with respect to patent revocation proceedings. If the current *ex parte* and *inter partes* reexamination proceedings are deemed satisfactory, then no action need be taken. If reform is believed to be desirable, making limited changes to the existing reexamination proceedings presents another option. Legislation might, for example, alter the estoppel provisions associated with *inter partes* reexamination, expand the range of substantive patent law issues that could form the basis for the patent challenge, or provide for some form of discovery in these proceedings.

A third option, taken in part by H.R. 1260, S. 515, and S. 610, is to establish a new revocation proceeding more robust than the two types of reexamination available under current law. Such a proceeding is adversarial in nature and may include discovery, estoppel effects, a broad range of patentability issues subject to review, and other features found in litigation in the federal courts. This sort of proceeding may potentially form a more desired substitute for litigation in the federal courts. However, as more litigation features are incorporated into patent revocation proceedings,

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[109] In 2007, the USPTO granted 183,901 patents and received 484,955 applications. *See* USPTO, *U.S. Patent Statistics Chart Calendar Years 1963-2007* (available at http://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm).

[110] *See* Lemley, *supra*, at 1507.

[111] *See* Osenga, *supra*, at 254.

[112] Kunin & Fetting, *supra*, at 973.

[113] Thomas, *supra*.

[114] *See* Zandy, *supra*, at 890-91.

[115] Doug Harvey, "Reinventing the U.S. Patent System: A Discussion of Patent Reform Through An Analysis of the Proposed Patent Reform Act of 2005," 38 *Texas Tech Law Review* (2006), 1133.

they potentially grow more costly for the participants and more difficult for the USPTO to administer.[116]

As discussed earlier in this report, patent revocation proceedings are defined through a number of parameters. In the event that reform is considered desirable, these features may be adjusted in view of particular policy goals. For example, to avoid prolonged uncertainty over a patent's validity, H.R. 1260, S. 515, and S. 610 each establish a one-year time period, potentially extendable to 18 months, for the USPTO to complete the proceeding. Other legislative strategies for achieving this goal exist. Legislation might set no fixed time limit upon the proceeding, for example, but rather provide for extension of the term of any patent involved in a revocation proceeding that exceed a certain time limit on a day-per-day basis.

Arguably one of the more controversial features of the various patent revocation proceeding proposals is the determination of when such a proceeding could be brought. Some observers believe that revocation proceedings should be conducted as soon as possible during a patent's term. They observe that patent owners commonly expend greater resources in developing and marketing an invention as the term of a patent progresses. Earlier resolution of validity challenges may decrease uncertainty and allow for better investment decisions.

Prompt determinations may also benefit the public by increasing clarity over the precise scope of the patent right. Uncertainty over patent title may adversely affect the ability of start-up firms, as well as other enterprises that rely significantly upon their intellectual property rights, to obtain funding from investors.[117] These observers support a brief time limit on bringing a revocation proceeding.[118]

On the other hand, some commentators believe that the value of many patents is not realized until later in their terms. In particular, the developers of new pharmaceuticals, medical devices, and other regulated products often do not receive government permission to market these products until several years after they have procured a patent.[119] Because many products fail to achieve government marketing approval,[120] discerning which patents will be of marketplace significance in the future may be a difficult inquiry. Significant temporal restrictions may in effect remove certain patents on regulated products from post-grant proceedings altogether.

These observers further note that post-grant proceedings at the USPTO have traditionally been available at any time during the term of the patent. In addition, the validity of a patent may be challenged any time the patent is asserted during litigation. These commentators do not favor any sort of time limit on bringing a patent revocation proceeding.[121] By establishing different time frames for initiating a patent revocation proceeding, the three bills in the 111th Congress balance these competing views in distinct ways.

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[116] *See* Zandy, *supra*, at 880.

[117] *See generally* CRS Report RL33367, *Patent Reform: Issues in the Biomedical and Software Industries*, by Wendy H. Schacht (discussing role of patents in process of procuring venture capital).

[118] *See* Williams, *supra*, at 360-61 (discussing these views).

[119] *See* Rebecca S. Eisenberg, "The Role of the FDA in Innovation Policy," 13 *Michigan Telecommunications and Technology Law Review* (2007), 345.

[120] *See generally* Carl Tobias, "FDA Regulatory Compliance Reconsidered," 93 *Cornell Law Review* (2008), 1003.

[121] *Id.*

Patent revocation proceedings were among the notable intellectual property issues discussed in recent hearings before Congress. Much of this discussion focused upon the experience of innovative industry with existing reexamination proceedings. Legislation proposing more expansive patent revocation proceedings may be viewed as attempting to achieve the goals of the earlier reexamination statutes: The creation of a predictable, cost-effective, and timely mechanism for resolving patent validity disputes while limiting harassment of the patent owner.

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