Patent Prosecution Update

March 2012

Contentious Proceedings at the USPTO Under the America Invents Act

by Rebecca M. McNeill

The America Invents Act of 2011 (AIA) makes significant changes to contentious proceedings at the United States Patent and Trademark Office (USPTO). The AIA creates a new post-grant review procedure and revises preissuance submission and *inter partes* reexamination (which will be called *inter partes* review under the AIA). More

Understanding the New *Inter Partes* Reexamination Standard

by Abhay D. Watwe, Ph.D.

The America Invents Act of 2011 (AIA) ushered in many changes, including changes to reexamination of issued patents before the United States Patent and Trademark Office (USPTO). For example, while the AIA retained the standard for initiating *ex parte* reexamination, it changed the standard for initiating an *inter partes* reexamination for any request filed on or after September 16, 2011. More

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This article summarizes each procedure and reviews some of their advantages and disadvantages. The chart below outlines aspects of the procedures, which will be available on September 16, 2012.[1]

	Preissuance Submission	***Ex Parte* Reexam**	**Post-Grant Review**	***Inter Partes* Review**
When?	Limited time after filing	After grant	No more than 9 months after grant	After 9 months from grant
Threshold Showing	N/A	Substantial new question of patentability	More likely than not that a claim is unpatentable or raises an important legal question	Reasonable likelihood of success
Anonymity	Yes		No	
Estoppel	None		Issues raised or reasonably could have been raised by the petitioner: USPTO, district court, and ITC	
Before Whom?	Examiner	CRU	Board	
Discovery/Evidence?	N/A	Declaration	Declaration and discovery	
Speed Within USPTO	Case dependent	Many years	1 to 1½ years	
Appeal	Only applicant can appeal		Both parties can appeal	

Preissuance Submission

Preissuance submission provides a challenger with a low-cost opportunity to present prior art publications and comment on their relevance early in an application's examination. This proceeding does not require a statement identifying the real party-in-interest and therefore allows a challenger to remain anonymous.

A preissuance submission, however, has disadvantages. First, the challenger has only one opportunity to present its comments, with no further rights to participate in prosecution. Therefore, the applicant could argue against the reference or amend the claims, and patent claims could issue that still pose problems for the challenger. Second, once the examiner considers the documents submitted, it is more difficult to use the same or similar documents in a future challenge, such as district court litigation. On the other hand, the preissuance submission procedure does not create any estoppel. A challenger may consider preissuance submission if, for example, the prior art anticipates the embodiment it wishes to practice, but should be very cautious in using this procedure.

Post-Grant Review and *Inter Partes* Review

The AIA creates a new opportunity to challenge a competitor's patent immediately after grant. Challengers can file for post-grant review within nine months of a patent's issuance. Post-grant review allows for challenges to a patent based on any ground of invalidity, including anticipation, obviousness,

utility, patent eligibility, enablement, written description, and definiteness. To initiate post-grant review, a challenger must show that it is more likely than not that at least one claim is unpatentable.

Inter partes review will replace *inter partes* reexamination. A challenger may request *inter partes* review after the nine-month post-grant review period has expired and so long as no post-grant review proceeding is still pending. This procedure will offer fewer opportunities for challenge, specifically, only anticipation and obviousness on the basis of patents or printed publications. To initiate *inter partes* review, a challenger must show that there is a reasonable likelihood that the petitioner would prevail with respect to at least one claim challenged in the petition.

Post-grant review and *inter partes* review also present a number of disadvantages. The real party-in-interest must be indentified in each proceeding. Each proceeding creates an estoppel against that party. The estoppel covers any issue that was raised or could have been raised by the petitioner, and applies to future proceedings at the USPTO, district court, or the International Trade Commission. Also, there likely will be much more limited discovery in post-grant review or *inter partes* review than in litigation. Thus, the challenger could be prejudiced by both limited discovery and the estoppel. Nevertheless, post-grant review or *inter partes* review could be an effective tool in clearing poor-quality patents from a competitive space for a more reasonable cost than litigation.[2] If a challenger could not consider litigation due to the expenses involved, or if a challenger would be satisfied to take a license (if available) from the patentee if the USPTO challenge failed, post-grant review or *inter partes* review could be a useful option.

Reexaminations

Finally, *ex parte* reexamination will continue without change. Like preissuance submission, it will not create an estoppel, but the opportunities to participate in the challenge are limited. *Inter partes* reexamination is still currently available, although the legal standard for initiating the proceeding has changed to a reasonable likelihood of success.

By creating new opportunities for challenge, the AIA will require even more thoughtfulness when assessing the competitive landscape. Each procedure has disadvantages and advantages that we recommend weighing carefully before choosing how to respond to a competitor's patent.

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[1] Initially, only business method patents will be subject to post-grant review. For all other patents, only patents with an effective filing date of March 16, 2013, or later will be subject to post-grant review.

[2] The proposed USPTO fees for post-grant review and *inter partes* review, however, are not insubstantial. The proposed fee for a post-grant review of 20 claims is $35,800. The proposed fee increases up to, for example, $44,750 for 21-30 claims. The proposed fees for *inter partes* review are also substantial. For example, the proposed fee for *inter partes* review for 20 claims is $27,200. The proposed fee increases up to, for example, $34,000 for 21-30 claims.

Rebecca M. McNeill practices client counseling and patent prosecution. She has a special interest in counseling clients on patent application filing and developing worldwide prosecution strategies. Ms. McNeill provides a full range of patent prosecution and counseling services to her clients and develops patent strategies in concert with clients' business goals. Ms. McNeill has worked with biotech start-ups, research foundations, and larger, established pharmaceutical companies. She has considerable experience managing patent portfolios.

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Understanding the New *Inter Partes* Reexamination Standard

by Naveen Modi and Abhay D. Watwe, Ph.D.

(cont'd)

Prior to enactment of the AIA, the USPTO determined whether or not to initiate an *ex parte* or *inter partes* reexamination proceeding based on the so-called "substantial new question of patentability" (SNQ) standard. Under this standard, a prior art patent or printed publication "raises a substantial question of patentability where there is a substantial likelihood that a reasonable examiner would consider the prior art patent or printed publication important in deciding whether or not the claim is patentable." MPEP § 2242(I) (8th ed. Rev. 7, July 2008). The USPTO requires that a request for reexamination "must point out how any questions of patentability raised are substantially different from those raised in the previous examination of the patent before the Office." *Id*. § 2616. The request must also demonstrate "that a patent or printed publication that is relied upon in a proposed rejection presents a new, non-cumulative technological teaching that was not previously considered and discussed on the record," either during the prosecution of the patent or in any subsequent proceeding. *Id.* Historically, using this standard, the USPTO has granted over 90% of the requests it has received.

With the AIA, Congress changed the standard for initiating an *inter partes* reexamination. Now, an *inter partes* requester must demonstrate that there is a reasonable likelihood that the requester will prevail with respect to at least one challenged claim. The House report accompanying the bill stated: "The threshold for initiating an inter partes review is *elevated* from 'significant new question of patentability'—a standard that currently allows 95% of all requests to be granted—to a standard requiring petitioners to present information showing that their challenge has a reasonable likelihood of success." H.R. Rep. No. 112-98 (Part 1), at 47 (2011) (emphasis added). This new standard, therefore, presumably requires a higher showing than the SNQ standard.

How the USPTO will apply this new standard, however, remains unclear. The few recent USPTO decisions on *inter partes* reexaminations filed after September 16, 2011, suggest that the USPTO equates "reasonable likelihood that the requester will prevail" with a prima facie showing of unpatentability, which is not required under the SNQ standard. Thus, whether a request will be granted under this new standard may turn on whether the examiner agrees or disagrees with the requester's assertions regarding unpatentability of the challenged claims. For example, in an *inter partes* reexamination filed immediately after September 16, 2011, the USPTO granted the reexamination request because the examiner concluded that the prior art references asserted by the third-party requester anticipated or rendered obvious at least one challenged claim. More recently, however, the USPTO denied an *inter partes* reexamination request when the examiner concluded, based on the prosecution history of the challenged patent, that the prior art reference did not teach one or more features of a challenged claim. In this case, the examiner evaluated the prior art asserted by the requester in light of the prosecution history of the patent and the USPTO's own analysis from a prior reexamination of the patent. Thus, unlike its application of the SNQ standard, the USPTO appears to be performing a more detailed analysis of the rejections proposed by third-party requesters to evaluate the reasonable likelihood that the requester will prevail with respect to at least one claim.

Given that only about six months have elapsed since enactment of the AIA, it is still too early to tell whether the new standard will indeed prove to be more stringent. Given the uncertainty and to ensure that an *inter partes* request gets granted under the new standard, a requester should do a detailed analysis showing how the claims it is challenging are unpatentable. For instance, a requester should consider submitting detailed claim charts mapping the claim language to the prior art and show how the claims are unpatentable under 35 U.S.C. § 102 and/or § 103.

Naveen Modi practices all aspects of patent-related work, including litigation (U.S. district court, U.S. International Trade Commission (ITC), and appellate), client counseling, interferences, patent prosecution, and opinions. He has conducted all types of discovery, drafted briefs, prepared and examined witnesses, and argued in court. He has been involved in over 50 reexamination proceedings, including advising clients on concurrent litigation. His practice encompasses a range of technical areas, including medical devices, software, networking, business methods, semiconductor devices, and electronics.

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Rule Review—Rule 1.105's Requirements for Information

Rule 1.105 provides the United States Patent and Trademark Office (USPTO) with a mechanism for requesting additional information from the applicant. Specifically, during examination, the USPTO may request "information as may be reasonably necessary to properly examine" the application. The Rule also provides examples of the types of information that the examiner may request. They include the existence of relevant commercial databases; whether a prior art search was made and, if so, what was searched; literature that relates to the claimed invention or was used to draft the application or in the invention process; the improvement and use of the claimed invention; and technical information known to the applicant.

Recently, the USPTO has used Rule 1.105 to request applicants to identify all related patents and copending applications and their specific claims that may present double patenting issues with the claims being examined. The examiner bases the request on the requirement that the USPTO analyze patentability under 35 U.S.C. § 101. The request, however, may not be proper under Rule 1.105, at least as it relates to specific claims that may present double patenting issues.

According to the Manual of Patent Examining Procedure (MPEP), "requirements under 37 C.F.R. 1.105 are not requesting opinions that may be held or would be required to be formulated by applicant." MPEP § 704.11 (8th ed. Rev. 6, Sept. 2007). Moreover, the *examiner* must determine whether a proper basis exists to enter a double patenting rejection under 35 U.S.C. § 101. See MPEP § 804 II (8th ed. Rev. 5, Aug. 2006). Subpart (a)(3) of Rule 1.105 further indicates that requests for information are for *factual* information. For at least these reasons, a request that an applicant provide information on double patenting issues, especially specific claims, may go beyond the scope of Rule 1.105.

While the USPTO may use Rule 1.105 to request a variety of information, the Rule is not without limits. In responding to a request, an applicant should first determine whether the request is consistent with the language of the Rule and the guidance provided in the MPEP, including whether the information requested is nonfactual and/or an opinion that the USPTO, not the applicant, has the burden of providing.

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The Federal Circuit Says

The patentability of subject matter that is facially within the classes set forth under 35 U.S.C. § 101 is most reliably resolved in accordance with the conditions of 35 U.S.C. §§ 102, 103, and 112. *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057 (Fed. Cir. Aug. 2011). In *Classen*, the Federal Circuit reviewed the district court's finding that Classen's patent claims are ineligible subject matter under § 101 in light of the Supreme Court's decision in *Bilski v. Kappos*, 130 S. Ct. 3218, 177 L. Ed. 2d 792, 95 U.S.P.Q.2d 1001 (2010), finding that § 101 should be used only as a threshold test, considering all of the specific facts of each individual case.

Classen's patents are based on a theory that the schedule of infant immunization for infectious diseases can affect the later occurrence of certain chronic disorders, and that immunization should be conducted on the schedule that presents the lowest risk with respect to such disorders. Two of Classen's patents, U.S. Patent Nos. 6,420,139 ("the '139 patent") and 6,638,739 ("the '739 patent"), claim a method of (1) screening and comparing information on immunization schedules and the occurrence of chronic disease to identify the lower risk schedule, and then (2) immunizing by administering the vaccine on that schedule. The claims of a third patent, U.S. Patent No. 5,723,283 ("the '283 patent"), do not include the later immunization step.

Section 101 states: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title." Based upon its interpretation of § 101, the district court found all three Classen patents ineligible for patenting as directed to the "abstract idea" that there is a relationship between the infant immunization schedule for infectious diseases and the later occurrence of chronic disorders.

On appeal, the *Classen* court looked to the Supreme Court's *Bilski* decision for guidance. The Federal Circuit focused on *Bilski*'s reiteration of the concern for "barr[ing] at the threshold." The Federal Circuit noted that *Bilski* encouraged the preservation of the distinctions between the threshold inquiry of patent eligibility and the substantive conditions of patentability, recognizing that even if an invention meets the requirements of § 101, it still must satisfy the remaining conditions of Title 35 by being novel, nonobvious, and fully and particularly described.

Thus, the *Classen* court found that the presence of a mental step is not itself fatal to § 101 eligibility, and that the infinite variety of mental and physical activity negates application of a rigid rule of ineligibility. Instead of applying a rigid rule, *Classen* found that each case must be determined on its own facts, considering all of the surrounding circumstances to determine if patent-eligible subject matter is present. The *Classen* court held that even though it had serious doubts about the substantive patentability of the claims, the '139 and '739 patents contain patent eligible subject matter because they include the physical step of immunization on a determined schedule. The Federal Circuit held this specific, tangible application sufficient to meet the § 101 bar, finding that questions of substantive patentability are most reliably resolved in accordance with the conditions of §§ 102, 103, and 112.

The *Classen* court, however, did draw a line on patent eligibility. The Federal Circuit held that because the '283 patent claim is limited to the *idea* of comparing known immunization results that are found in scientific literature, it does not qualify as patent eligible subject matter. The claim does not apply any physical step, but merely claims the idea of collecting and comparing known information. The Court found that merely disclosing an abstract idea is insufficient to cross the § 101 threshold.

Classen demonstrates the Federal Circuit's continued struggle with the application of § 101, still avoiding the creation of a bright-line rule for patent drafters to follow. In the absence of a bright-line rule, patent drafters should present for examination claims having a wide variety of scope, and keep in mind that even if a claim passes the § 101 threshold, it still must pass all of the other patentability requirements.

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Did You Know?

As reported in the November 2011 edition of "Did You Know?," the United States Patent and Trademark Office (USPTO) introduced new provisions for a patent applicant to expedite the examination of its application. To be eligible for expedited processing, a nonprovisional application filed after September 26, 2011, and via the USPTO's electronic filing system must not include any multiple dependent claims, and must be limited to four independent claims and thirty total claims. In addition, the application filing must include all application parts, the regularly required filing fees, a $4,800 ($2,400 for small entities) prioritized examination fee, a $130 processing fee, a $300 publication fee, and a request for prioritized examination.

Currently, expedited processing is available for only 10,000 applications per USPTO fiscal year. As of February 24, 2012, the USPTO granted expedited status to 854 applications, and another 638 prioritized examination requests were pending USPTO review for the current fiscal year. These numbers are significantly short of the 10,000 application maximum.

Anticipating that the number of applications accorded expedited status will not reach 10,000, the USPTO recently expanded eligibility for expedited processing to any application in which a Request for Continued Examination (RCE) is filed. Now, an applicant is permitted to request expedited processing for an application after the filing of an RCE, so long as the USPTO has not mailed a first office action after the RCE filing. However, such an "after-RCE" request for expedited processing may be granted only once in an application, regardless of whether the application was previously accorded expedited status at filing.

Applicants with commercially relevant applications pending before the USPTO may want to consider filing a request for expedited processing in applications where the filing of an RCE is necessary or has recently occurred. This may help to secure patent grants quickly where doing so is likely to have an effect on a company's business.

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