Patent Prosecution Update

July 2012

Proposed Rules of Procedure for USPTO Contentious Proceedings

The America Invents Act (AIA) established new contentious proceedings at the soon-to-be-created Patent Trial and Appeal Board (Board). These proceedings include *inter partes* review (IPR), post-grant review (PGR), and derivation proceedings. More

How Does the New U.S. Post-Grant Review Stack Up to an EPO Opposition?

by Wesley B. Derrick, Ph.D.

The America Invents Act (AIA) provides a number of proceedings to challenge improvidently granted patents. Though one of these, post-grant review (PGR) before the Patent Trial and Appeal Board (Board), appears to be nearly identical to European Patent Office (EPO) opposition practice, there are significant differences. More

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Proposed Rules of Procedure for USPTO Contentious Proceedings

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In preparation for these new proceedings, the United States Patent and Trademark Office (USPTO) has proposed regulations that are intended to streamline the issues for decision in order to conduct proceedings in a timely, fair, and efficient manner.[1] This article summarizes a "Practice Guide for Proposed Trial Rules" published by the USPTO. 77 Fed. Reg. 27 (Feb. 9, 2012).

As currently proposed, the proceedings may be instituted with the filing of a petition that meets certain requirements unique to each proceeding. While claim charts are not required, the proposed regulations encourage petitioners to provide claim charts with their petitions. It is envisioned that claim charts will help to streamline the process of identifying key features of a claim and comparing those features with specific evidence in a clear, succinct manner. It is anticipated that the Board will streamline issues for final decision by only authorizing proceedings on those challenged claims where the petition is able to establish the necessary threshold requirements. If the Board decides to institute a particular proceeding, it will issue a decision to that effect and concurrently enter a Scheduling Order.

The proposed regulations then suggest that an initial conference call will be held approximately one month from the date of institution of a proceeding to discuss the motions that the parties intend to file and to determine if any adjustment needs to be made to the Scheduling Order. Further, the proposed regulations suggest that the Board may preliminarily require a list of proposed motions to be filed no later than two business days prior to the initial conference call so that the parties can plan for the call. The proposed regulations contemplate that the conference call will help the Board and counsel adjust the schedule for taking action, to permit the Board to determine whether the listed motions are necessary and sufficient to resolve the issues raised, and to reveal the possibility that there may be a dispositive issue that may aid in the settlement of the proceeding. In IPR and PGR, the patentee is likely to be given an opportunity to file a preliminary response to the petition within two months of the grant of the filing date. The patentee also may move to amend the patent, but regulations propose that only one such motion will be allowed, and the motion should be raised during a conference call with the Board.

As currently proposed, the discovery process at the Board is likely to be a sequenced discovery process. It is contemplated that each party will be provided a discovery period, with the patentee going first. The goal of this sequenced discovery process will be to allow the parties to conduct meaningful discovery before motions and oppositions are filed. Additionally, cross-examination of a declarant may be ordered to take place in the presence of an administrative patent judge, particularly where the Board considers the demeanor of a witness critical to assessing credibility. Credibility may be particularly important when derivation or inequitable conduct is at issue or when testimony is given through an interpreter.

Further, the proposed regulations indicate that each party, upon request, will be afforded an opportunity to present oral argument before at least three members of the Board. The proposed regulations suggest that parties are encouraged to avoid using elaborate demonstrative exhibits, but that a handout or binder containing demonstrative exhibits can be helpful. The Board will enter a final written decision not more

than one year from the date a proceeding is instituted, unless a good-cause extension of six months is made.

The Practice Guide provides not only a good summary of the contentious proceedings but also some tips on how to draft effective petitions, motions, oppositions, and replies. Since all of these writings are subject to page limits in a further effort to streamline the proceedings, the USPTO suggests that parties focus on simple, well-organized, easy-to-follow arguments supported by readily identifiable evidence of record. The USPTO also reminds parties that judges of the Board are familiar with the general legal principles of patent law, so extended discussions on this topic are not necessary.

Overall, the UPSTO's proposed rules give parties wide latitude in how they present their cases and include several measures that demonstrate an effort to streamline the proceedings. The USPTO's Practice Guide provides several interesting insights on how to best make use of the newly created contentious proceedings.

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[1] Final rules are expected to be published by August 16, 2012.

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How Does the New U.S. Post-Grant Review Stack Up to an EPO Opposition?

by Wesley B. Derrick, Ph.D.

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Initiating PGR

Initiating PGR will be straightforward. The challenger petitions the Board to initiate a proceeding. Anyone other than the patent owner may challenge the patent, provided the challenger has not already filed a suit challenging the validity of the patent. The challenger must pay a fee and file a petition providing a basis for invalidity for failure to meet requirements of at least one of 35 U.S.C. § 101 (statutory subject matter), § 102 (novelty), § 103 (nonobviousness), or § 112 (written description and enablement). The challenger must file the petition within nine months of the patent grant.

While the post-grant bases for invalidity mirror those in the EPO, there are differences with respect to novelty and nonobviousness. Under the U.S. laws, an invention may be entitled to a patent despite an earlier disclosure of the invention, as long as the disclosure qualifies for the one-year grace period afforded to inventors. In contrast, the European requirement for absolute novelty means that any prefiling disclosure effectively bars patent claims. The U.S. procedure is less forgiving elsewhere, however, in that applications by another and unpublished at the time of filing are considered in determining patentability under § 103. Such unpublished applications are excluded from consideration in determining inventive step under the European Patent Convention (EPC).

The PGR petition also requires an identification of the real parties in interest, which is not a requirement in an EPO opposition. Anonymity is not allowed under the AIA because PGR can estop the petitioner, or its privy, from raising any defense in a later United States Patent and Trademark Office (USPTO), district court, or International Trade Commission proceeding that was, or could have been, raised in the PGR.

The USPTO decision to institute a PGR also differs from initiation of an EPO opposition. The USPTO will require information that, if not rebutted, demonstrates it is more likely than not at least one of the challenged claims is unpatentable or the petition raises a novel or unsettled legal question that is important to other patents or patent applications. In contrast, the EPO does not weigh the sufficiency of information. Still further, even if the USPTO Board finds all AIA requirements are met, it has the discretion to not institute review, and its decision is "final and non-appealable." For these reasons, initiating PGR likely will be more difficult than initiating an EPO opposition proceeding, and an adverse decision not to initiate proceedings may be impossible to remedy in the United States.

Conduct of PGR

PGR may be affected by other administrative and legal proceedings. For instance, the AIA allows the USPTO discretion in structuring multiple concurrent proceedings, including derivation, reissue, and *ex parte* reexamination proceedings. In addition, PGR may not be instituted or maintained if the petitioner challenges validity in federal district court. In contrast, parallel validity proceedings in the EPO and national courts of EPO member states are possible, although some states allow for stays.

Though the procedural rules for conduct of PGR are not yet finalized, the most important rules likely will pertain to evidence and to amending or submitting alternative claims. Limited discovery will be allowed and certainly more expansive than in the EPO, while amending claims will be more restricted. The AIA provides for patent owners to file a single motion to cancel or amend any challenged claim or propose a reasonable number of substitute claims as a matter of right. The EPO, however, allows claim amendments "occasioned by the grounds for opposition specified in [EPC] Art. 100," even if the particular ground relied on has not been invoked by an opponent. *See, e.g.*, Guidelines for Examination in the European Patent Office Part D. - Chapter IV-5.3 (Apr. 2010). Moreover, the EPO allows patent owners to submit multiple potential claim amendments as auxiliary requests.

PGR challenges must be proven by a preponderance of the evidence, a lower standard than required in U.S. district court, where clear and convincing proof of invalidity is required. It is difficult to determine how either U.S. standard compares to the EPO's "balance of probabilities" standard, which varies depending on the issue, from simply requiring that one set of facts is more likely to be true than another up to a degree of certainty which is beyond any reasonable doubt.

Settlement and Arbitration

The AIA provides for settlement of PGR proceedings or for arbitration of any issue. If settlement is reached before the Board reaches the issues and no petitioners remain, it appears likely that the PTO will terminate proceedings without issuing a final written decision. This would differ from EPO practice where, once instituted, an opposition is driven by the panel's understanding of what should issue as a patent, exhibiting a greater bias to examine and issue only valid claims without much regard to any potential third party.

Effect of Appeal and Decision

If PGR is initiated and not dismissed prior to a written decision, the Board will determine the patentability of all challenged, and any added, claims. As noted earlier, final written decisions have significant estoppel effects, while EPO oppositions give rise to no estoppels. Parties opposing a patent before the EPO can even use the same arguments and evidence in later national litigation or revocation proceedings.

The AIA provides for appellate relief to those dissatisfied with the Board's decision, by way of appeal to the Federal Circuit. In contrast, the EPO allows appeal to an administrative body, the Boards of Appeal, but there is no avenue to appeal outside the EPO.

Conclusion

Despite apparent similarities between PGR and EPO oppositions, critical differences in their conduct and effects warrant careful review of applicable law and practice. Understanding both the similarities and differences should allow practitioners to better develop a global opposition strategy utilizing the new patent regime in the United States.

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Rule Review—Rule 1.116(b) and the USPTO's After Final Consideration Pilot

Rule 1.116(b) provides a mechanism for patent applicants to amend claims after a final rejection and prior to appeal. Specifically, it allows for (1) amendments canceling claims or complying with a requirement of form set forth in a previous Office action; (2) amendments presenting rejected claims in better form for appeal; or (3) amendments touching the merits, when presented with reasons why the amendment is necessary and was not earlier presented.

On March 25, 2012, the United States Patent and Trademark Office (USPTO) launched a pilot program to further its goal of compact prosecution and cut down on the number of unnecessary Requests for Continued Examination (RCEs). The After Final Consideration Pilot (AFCP), ending September 30, 2012, affords examiners extra time to consider responses after final rejections. The program allows applicants and examiners to work together in after-final situations to move applications towards allowance by authorizing three hours of nonproduction time for examiners to consider after-final responses for utility applications.

During the pilot program, after an applicant files a response to a final Office action under Rule 1.116, the examiner determines whether he should take advantage of the extra time allowed by the program. The examiner should determine how long it will take to fully consider the response, including conducting the additional searches required to determine whether the amendments distinguish over the prior art. If the examiner does not think the response can be fully considered even in the extra time provided under the AFCP program, he should treat the response according to current, non-AFCP practice.

The preliminary results of the AFCP show an increase in allowance rates for applications after final rejection. Although the AFCP does not provide for an applicant to request participation in the program, an applicant may want to suggest participation informally through a phone call to the examiner, especially if the applicant believes that the amendments are of a nature to be examined in the AFCP-prescribed time periods. Regardless, it may be useful for an applicant to file a response under 37 C.F.R. § 1.116 after a final rejection during the pilot program, if the applicant believes such a response may lead to allowance of the application with only limited further search and consideration by the examiner.

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The Federal Circuit Says

An inventor's subjective belief that a reference is immaterial to patentability may not defeat a finding of intent to deceive. *Aventis Pharma S.A. v. Hospira, Inc.*, 675 F.3d 1324, 1333–34 (Fed. Cir. 2012). In *Aventis*, the Federal Circuit affirmed the district court's finding that Aventis's patents were unenforceable for inequitable conduct because references withheld by the inventor were necessarily but-for material to the patentability of the claimed inventions. Moreover, the Federal Circuit held that an inventor's incredible testimony relating to his belief of a reference's relevance to patentability may support a finding of an intent to deceive.

The Aventis patents relate to the administration of docetaxel, a chemotherapy drug, which belongs to a class of compounds known as taxanes. Because taxanes have low solubility in water, they are often mixed with additives for stabilization. Previous taxane preparations caused serious side effects, including anaphylactic shock and ethanol intoxication. Two of Aventis's patents describe (1) taxane compounds, including a perfusion that avoids anaphylactic and alcohol intoxication manifestations; and (2) taxane compounds with reduced ethanol.

In *Aventis*, the inventor did not disclose two references to the United States Patent and Trademark Office (USPTO): (1) *Guéritte-Voeglein*, which stated "[m]oreover Taxotere (13a) showed a better solubility in excipient system (polysorbate 80/ethanol, 1:1) . . . ."; and (2) *Dictionnaire Vidal*, which disclosed using polysorbate 80 as a surfactant with the cancer drug etoposide. The inventor testified, however, that he had reviewed an early draft of the *Guéritte-Voeglein* reference, which did not include the statement describing the polysorbate 80/ethanol excipient system, and concluded that the reference was not relevant to patentability. He also testified that the etoposide-type experiments his team attempted with doxcetaxel failed to demonstrate certain stabilities, and, thus, it was unnecessary to disclose the *Dictionnaire Vidal* reference to the USPTO. Upon finding that the inventor's testimony was incredible, the district court held that the inventor intentionally withheld material references from the USPTO.

On appeal, the *Aventis* court deferred to the district court's credibility determinations. The Federal Circuit noted, however, that the district court had not relied solely on its credibility determination, but rather had viewed the inventor's testimony in light of other evidence, including the fact that the inventor himself approved the *Guéritte-Voeglein* reference for publication and had testified that he reviewed the article with "some care" before publication. Considering the evidence that supported a finding of specific intent to deceive, combined with its deference to the district court, the Federal Circuit upheld the district court's decision that the two Aventis patents were unenforceable for inequitable conduct.

The Federal Circuit focused on its decision in *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276 (Fed. Cir. 2011), as the standard for proving inequitable conduct. Under *Therasense*, a defendant must establish both but-for materiality of the withheld reference and an intent to deceive. But-for materiality is established if the USPTO would not have allowed the claim if it had been aware of the reference. To establish intent to deceive, the accused infringer must demonstrate that the applicant knew of the reference, knew it was material, and made a deliberate decision to withhold it. The court noted that

Therasense marked a change in inequitable-conduct jurisprudence, rejecting the "sliding-scale" approach, where inequitable conduct could be proved with a weak showing of intent and a strong showing of materiality, or vice versa. Although the district court did not have the benefit of the *Therasense* opinion, it found the withheld references constituted but-for material prior art and made distinct intent and materiality findings, rather than using the pre-*Therasense* sliding-scale approach.

Aventis therefore may indicate that the materiality of a reference inevitably informs a court's analysis of intent and, in some cases, may be more important than the stated intent of a party. Based upon the *Aventis* decision, patent attorneys should carefully review and submit all relevant prior art to the USPTO during the patent-application process, refraining from relying solely on inventors to self-select prior art for the USPTO. As shown in *Aventis*, an inventor's subjective belief that a reference is immaterial may not preclude a finding of inequitable conduct.

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Did You Know?

Under the new Quick Path Information Disclosure Statement (QPIDS) pilot program, the United States Patent and Trademark Office (USPTO) will allow applicants to submit an Information Disclosure Statement (IDS) after issue-fee payment. The program is intended to reduce the number of Requests for Continued Examination (RCEs) filed solely for the consideration of an IDS after the issue fee is paid.

Under the program, applicants may file an electronic petition in a case where the issue fee has already been paid to request the consideration of references in an IDS. Such references may include, e.g., intervening references published after a notice of allowance is received by an applicant, or references cited in a corresponding foreign application. The QPIDS pilot program will be available from May 16, 2012, to September 30, 2012, with an option to extend if successful.

QPIDS submissions must be made electronically, and will require an RCE, an IDS, and their required fees. The submission will be placed on an examiner's "expedited docket," requiring the examiner to review the submission in relatively short order. More particularly, QPIDS "submissions will be considered by the examiner before determining whether prosecution should be reopened. Prosecution will only be reopened where the examiner determines that reopening prosecution is necessary to address an item of information in the IDS. When the items of information in the IDS do not require prosecution to be reopened, the application will return to issue [and the RCE fee will be refunded], thereby eliminating the delays and costs associated with RCE practice." Press Release, U.S. Patent & Trademark Office, USPTO to Test New Option for Information Disclosure Statements (IDS) (May 10, 2012), *available at* http://www.uspto.gov/news/pr/2012/12-32.jsp. If, however, the examiner determines that any item of information in the IDS necessitates reopening prosecution, the IDS fee will be refunded, and the examiner will proceed to consider the item(s).

Thus, rather than having to file an RCE to ensure the USPTO considers newly discovered references in an already allowed application, applicants can now submit those references via a QPIDS submission. This may avoid the delays associated with current RCE practice, while affording applicants the security of having the references considered by the USPTO.

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