Patent Prosecution Update

April 2010

Patent Reform Continues to Focus on Post-Grant Challenges

Congress's long-running efforts toward a compromise on patent reform legislation took another turn last month. On March 4, the Senate Judiciary Committee released an amendment to that legislation. The amendment replaces the bill approved by the Committee on April 2, 2009, without requiring any further Committee action. **More**

EPO News

On February 19, 2010, an Enlarged Board of Appeals (Board) at the European Patent Office (EPO) concluded that Swiss-style claims will no longer be acceptable at the EPO. Prior to the Board's decision, two types of medical-use claims were accepted by the EPO. The first and broadest type—the first medical-use claim—typically took the following form: "compound [X] for use as a medicament." **More**

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Patent Reform Continues to Focus on Post-Grant Challenges

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The amendment largely retains many of the provisions that have been a part of reform since its inception. They include, for example, "first inventor to file" legislation aimed at harmonizing U.S. laws with the patent laws of all other countries. The amendment also continues to address major issues relating to litigation, including damages reform and venue limitations, and focus on significant changes to post-grant challenges. This article summarizes "supplemental examination," a new procedure first provided for in this amendment, and significant changes to the "post-grant review" provisions that have been a part of patent reform for quite some time.

Supplemental Examination

The supplemental examination procedure responds to calls for inequitable conduct reform. Under this procedure, a patentee can request examination of a patent "to consider, reconsider, or correct information believed to be relevant to the patent." Within three months of that request, the Director of the U.S. Patent and Trademark Office (USPTO) will issue a certificate indicating whether the information raises "a substantial new question of patentability." If so, the Director will order patent reexamination.

The effect of supplemental examination is that a patent will not be held unenforceable on the basis of conduct relating to the information considered during the examination. The proposed legislation provides exceptions to this inequitable conduct shield. For example, the shield will not apply to allegations of inequitable conduct pled prior to a supplemental examination request. The shield also will not apply to an inequitable conduct defense in a district court or ITC action unless the supplemental examination and any Director-ordered reexamination are concluded prior to the date the action is brought. To get the benefit of supplemental examination, therefore, a patentee should request supplemental examination and await its conclusion and any subsequent reexamination's conclusion, prior to filing an infringement action.

Supplemental examination practice would take effect one year after enactment of patent reform legislation and apply to any patent, including those issuing before enactment. Supplemental examination, therefore, may be an effective tool to bar an inequitable conduct allegation if the USPTO considers potentially material prior art and finds it does not raise a new question of patentability.

Changes to Post-Grant Review

Our February 2010 issue of "Full Disclosure" described a post-grant review procedure proposed in the April 2009 legislation. (For that article, **click here**.) That procedure provided for an administrative proceeding at the USPTO to challenge a patent's validity. The March 4, 2010, amendment includes several significant changes to the procedure.

For example, the proposed standard to institute a post-grant review has changed. Prior legislation required a grantable petition to raise *a substantial new question of patentability* of at least one claim, like the current reexamination proceedings. The current proposal appears to raise the post-grant review

standard, requiring the petition to demonstrate that it is *more likely than not that at least one claim is unpatentable*. Alternatively, the proposal permits post-grant review if the petition raises a novel or unsettled legal question important to other patents or applications.

The legislative amendment also alters the proposed estoppels caused by a post-grant review. For example, a post-grant review petitioner may not request or maintain another USPTO proceeding with respect to a patent claim on any ground the petitioner *raised or reasonably could have raised* during the post-grant review. This estoppel may significantly limit the ability of a petitioner to file later reexamination requests, for example. The amendment retains a less-stringent estoppel that would apply to a later civil action, specifically that post-grant review would bar a petitioner from raising in a later civil action any invalidity ground *raised* in the post-grant review. Since this estoppel does not apply to grounds that *could have been raised*, a petitioner may want to include only certain grounds of invalidity in the petition, preserving perhaps stronger validity challenges for a later civil action.

The proposed amendment also expounds on the effect of a post-grant review on other pending actions. For example, a post-grant review may not be instituted or maintained if (a) the petitioner filed a civil action challenging the patent's validity or (b) the post-grant review is requested more than three months after a petitioner is required to respond to an infringement action. In addition, a court may not stay a preliminary injunction motion based on a post-grant review request if the infringement action is filed within three months of a patent's issuance.

As proposed, the post-grant review provisions take effect one year after enactment of patent reform legislation and apply only to patents issued after enactment. In a change that will undoubtedly initially affect the amount of post-grant reviews, the proposed legislation provides authority to the Director to limit the number of post-grant reviews during the first four years after the provisions take effect. So, for the five years following patent reform's enactment, we may see a limited number of reviews as the USPTO prepares for post-grant review.

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EPO News

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These claims were generally used to cover a recently discovered medical use of a known compound. The second and more narrow type—the Swiss-style claim—typically took the following form: "the use of compound [X] for the manufacture of a medicament for treating of disease [Y]." These claims were generally used to cover a new therapeutic use of a known pharmaceutically active compound. After considering the changes brought about by the European Patent Convention of 2000 (EPC 2000), however, the Board announced that Swiss-style claims may no longer be used when "the subject matter of a claim is rendered novel only by a new therapeutic use of a medicament." *In re Abbott Respiratory*, G 0002/08 at 44 (EPO Enlarged Board of Appeals 2010). Instead, the Board found that EPC 2000 "unambiguously permits purpose-related product protection for each further new medical use of a substance or composition already known as a medicine [and] the protection is equivalent, as far as the further uses are concerned, to that offered by the 'Swiss type claim'." *Id.* The EPO's decision ends twenty-five years of acceptance by the EPO of Swiss-style claims.

Although the Board did not announce a definitive date for the EPO to begin rejecting Swiss-style claims, the Board stated that applicants must stop using Swiss-style claims no later than three months after its opinion is officially published, which has yet to happen. Further, the Board announced that its decision will not have any retroactive effects. Thus, patents granted with Swiss-style claims will not be impacted.

From the standpoint of EPO practice, the Board's decision did not affect the substantive question of what medical inventions may be patented—it merely modified the acceptable claim form. Additionally, applicants will be able to amend claims in an unacceptable form to comply with EPO guidelines. Finally, rather than using the Swiss-style claims in the future, applicants may use the alternative medical-use claim format, which is typically in the following form: "substance [X] for the treatment of disease." The EPO generally considers this claim form and Swiss-style claim format to be of similar scope. However, the precise scopes of these two claim types has yet to be established by the European courts.

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PTA Still Pestering USPTO

As reported in the February 2010 edition of "Full Disclosure," the Federal Circuit in *Wyeth v. Kappos* recently found fault with the USPTO's method of calculating patent term adjustment (PTA). In response, the USPTO established an interim procedure for requesting PTA recalculation in accordance with the framework set forth in that decision. Under the procedure, patentees can request recalculation of PTA for any patent issued before March 2, 2010, within 180 days of the patent's issuance. The interim procedure, however, is not without flaws, and the *Wyeth* decision continues to pester USPTO officials.

In one example, requesting PTA recalculation due to "*Wyeth* errors" under the interim procedure does not preserve the patentee's right to have the PTA calculation reviewed by a court. A statutory 180-day window for seeking judicial review continues to run from patent issuance. Thus, a patentee requesting PTA recalculation under the interim procedure may find that the USPTO does not respond within the 180-day period for seeking judicial review. Although not operating under the interim procedure, this is the position Arius Two, Inc. (Arius) found itself in. Arius's patent issued on August 25, 2009, and Arius requested PTA recalculation on September 8, 2009. But, as of early February 2010, Arius had not heard from the USPTO. Realizing that its 180-day window for seeking judicial review was going to expire on February 25, 2010, Arius commenced suit against Director Kappos in the U.S. District Court of the District of Columbia on February 16, 2010. *See Arius Two, Inc. v. Kappos*, No. 1:10-cv-00225-RMU (D.D.C. filed Feb. 16, 2010).

In another example, Idera Pharmaceuticals, Inc. (Idera) found that it was unable to request PTA recalculation for its patent that issued on April 14, 2009, because the 180-day window set by the USPTO's interim procedure had expired even before the USPTO announced the interim procedure. Similarly, judicial review of the USPTO's PTA calculations for the Idera patent was not available because the 180-day period for seeking such review had expired by the time the Federal Circuit announced its decision in *Wyeth*. Unwilling to accept these circumstances, Idera turned to the doctrine of "equitable tolling." According to the Federal Circuit, the doctrine of equitable tolling provides that "a statute of limitations does not run against a plaintiff who is unaware of his cause of action." *Serdarevic v. Advanced Med. Optics Inc.*, 532 F.3d 1352 (Fed. Cir. 2008). Idera then sued Director Kappos, alleging that the *Wyeth* decision "constituted a change in law sufficient to invoke the doctrine of equitable tolling . . . ." *See Idera Pharms. Inc. v. Kappos*, No. 1:10-cv-00166-EGS (D.D.C. filed Feb. 4, 2010).

Although the USPTO now calculates PTA in accordance with *Wyeth*, these two cases illustrate unsettled issues with the newly enacted interim procedure, which are likely to keep USPTO officials busy in the coming months.

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The Federal Circuit Says

Inequitable conduct may be found where a patentee knowingly failed to disclose to a USPTO examiner contradictory representations made in another forum with respect to prior art. In *Therasense, Inc. v. Becton, Dickinson & Co.*, Nos. 08-1511, -1512, -1513, -1514, -1595 (Fed. Cir. Jan. 25, 2010), the Federal Circuit found U.S. Patent No. 5,820,551 ("the '551 patent"), owned by Abbott Diabetes Care, Inc. (Abbott), Therasense, Inc.'s (Therasense) successor, to be unenforceable due to inequitable conduct during prosecution. The '551 patent related to disposable glucose test strips utilizing electrochemical sensors, and its claims were particularly directed to electrochemical sensors lacking a protective membrane.

During examination, the USPTO rejected the claims of the '551 patent over U.S. Patent No. 4,545,382 ("the '382 patent"), which was also owned by Abbott. In response, Abbott represented to the USPTO that the claims of the '551 patent were specifically directed to a new glucose sensor that did not require a protective membrane when testing blood samples. In particular, Abbott argued that the teachings of the '382 patent relating to sensors for use with blood samples required a protective membrane over the sensors. Slip op. at 20. Moreover, Abbott submitted a declaration to the USPTO stating that, at the time of the '382 patent's invention, such protective membranes were considered to be essential when testing blood samples, and that one skilled in the art would read the '382 patent's "optionally, but preferably" language relating to protective membranes not as a technical teaching but rather as "patent phraseology" that did not have a clear meaning. *Id*. at 20-22. Shortly thereafter, the USPTO allowed the claims of the '551 patent.

During a revocation proceeding before the EPO of EP Patent No. 0 078 636 ("the '636 patent"), a counterpart to the '382 patent with a virtually identical specification, an Abbott predecessor represented to the EPO that the '636 patent "is unequivocally clear. The protective member is optional, however, it is preferred when used [with samples of] blood." *Id*. at 22 (emphasis omitted). The Federal Circuit therefore agreed with the district court's conclusions that the representations made to the EPO contradicted the representations made to the USPTO because the EPO documents clearly explained that a protective membrane was not necessary when testing blood samples. *Id*. at 22-23.

Further, the Court found that the district court's holdings that the representations made to the EPO were material to the prosecution of the '551 patent, that Abbott was aware of those representations, and that Abbott intentionally withheld them from the USPTO, were supported by the record and were either not clearly erroneous or undisputed. Based on these findings, the Court concluded that to deprive a USPTO examiner of the EPO statements—statements directly contrary to the representations made to the USPTO—on the grounds that they were not material would be to eviscerate the duty of disclosure. Moreover, if this could be regarded as a close case, which the Court found it was not, the Court reminded the bar that "the duty of disclosure requires that the material in question be submitted to the examiner rather than withheld by the applicant." *Id*. at 26. The Federal Circuit ultimately affirmed the district court's decision finding the '551 patent unenforceable due to inequitable conduct.

The *Therasense* decision highlights the importance of coordinating the prosecution of cases within a family or related families. In addition to minimizing the risk of taking inconsistent positions, a single counsel overseeing the prosecution of related cases in multiple forums may be also able to better comply with the duties of disclosure, if any, required by those forums.

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Did You Know?

The USPTO implemented a new examiner "count system" in February. The USPTO's count system in some respects drives the examination process. It determines the amount of time an examiner spends examining a patent application, allocates the credit the examiner receives at each stage of examination, and is used to evaluate an examiner's productivity and performance. Previously, an examiner received one count for a first action on the merits and another count for final disposition of an application, which included allowances and abandonments, for a total of two counts per application. In addition, the filing of a Request for Continued Examination (RCE) under the previous system renewed the number of counts available to the examiner. Stated differently, an RCE would provide the examiner with an abandonment count and an opportunity to earn two additional counts, as described above. Some believed that the prior system may have incentivized examiners inappropriately, for example, causing some examiners to short shrift amendments after final action in the hopes of baiting an RCE.

The new count system retains the overall number of counts available per application (i.e., two), but skews the count distribution to favor more thorough initial examination. The new system also incentivizes examiners to work with applicants to identify patentable subject matter. The new system awards 1.25 counts for a first office action on the merits, 0.25 counts for a final rejection, and 0.5 counts for disposal. Notably, after a first action, an examiner may earn the remaining 0.75 disposal counts by allowing the application instead of issuing a final action. The new system also decreases the value of RCEs to an examiner. Unlike the old system, the first filed RCE provides the examiner with an opportunity to earn only 1.75 additional counts, and each additional RCE provides the examiner with an opportunity to earn only 1.5 additional counts. This decreases the appeal of forcing continued RCE practice. The new system also provides examiners with up to one hour of nonexamination time to initiate interviews.

The USPTO expects this new system, with its emphasis on improved initial examination, to lead to earlier identification of patentable subject matter, greater overall quality, and compact prosecution. To take advantage of the new system, applicants should consider greater use of interviews early in the examination process.

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