TO: Janet A. Gongola, Patent Reform Coordinator, USPTO

FROM: John Jay Marshall, Drinker Biddle & Reath LLP, john.marshall@dbr.com

DATE: October 26, 2011

**RE:** Requests for Comments on Proposed Rulemaking to Implement the AIA

**Chapter 32- Post Grant Review** 

I am a registered practitioner, and offer my following comments on the rules of practice that will apply to proceedings under AIA Chapter 32 –Post Grant Review [35 U.S.C.§§ 321-329].

**OVERVIEW:** The policy underlying Chapter 32 Post grant review ("PGR") is to improve patent quality though an early challenge to patents containing claims that should not have been granted. To be successful in achieving this result, the USPTO rules of procedure and evidence for PGR should not discourage potential patent challengers from using the PGR process.

The statutory scheme of PGR offers potential challengers the incentives of (a) a lower standard of proof (preponderance of the evidence vs. clear and convincing evidence), (b) opportunity to resolve questionable patent claims before engaging in conduct that carries a risk of infringement, (c) reasoned decisions by Administrative Patent Judges skilled in the technical field, and (d) the prospect of lower legal expenses than would be incurred in civil litigation.

The trade-off for these advantages of PBR is the estoppel provisions of §325(e). The estoppel provisions make it imperative that the PTAB rules not preclude invalidity issues or inhibit discovery to the extent that a potential challenger will decline PGR in the belief that it will not be able to raise meritorious invalidity issues or to take adequate discovery, particularly of non-party witnesses. Otherwise, the challenger will refrain from PGR and wait for an opportunity to use full FRCP procedure and discovery in the belief that it will get a fairer hearing in district court.

The public ultimately benefits from a curative amendment to ambiguous and/or overly broad patent claims. Private settlement in civil litigation resolves only the dispute between

patent owner and accused infringer without change to the patent claims. Settlement by amendment under §326(d)(2) would improve the quality of the patent for all. For this reason, settlement by amendment should be the preferred outcome of all PGR instituted under §324. Forcing the PGR to final written decision of the PTAB should be the exception rather than the norm, and should only occur where close issues of material fact or law must be resolved.

Consequently, the procedural regulations promulgated under the mandate of § 326 must provide potential challengers the security of knowing that meritorious invalidity contentions will not be impaired by overly narrow issue identification or insufficient discovery. The rules should also encourage settlement by claim amendment.

My specific recommendations that follow are intended to achieve the goals stated above.

# 1. The standards for showing sufficient grounds for instituting PGR [§326(2)] should require all factual allegations to be supported by evidence that is admissible under the Federal Rules of Evidence ("FRE"), except for hearsay evidence.

§322 sets forth the minimum requirements of the petition, but does not establish rules for admissibility of the evidence. The FRE should be the starting point for admissibility, and the new PGR regulations should make only such changes to FRE as are required by the nature of the PGR procedure. The petition under §324 is not just a pleading, and certainly not a notice pleading. It is a combination of factual allegations and supporting evidence in proof of each allegation. The evidence submitted with the petition should therefore be in a form that is either admissible under FRE, or is capable of being made into admissible evidence. Affidavits of fact witnesses should be based upon personal knowledge [FRE 602] and competent lay opinion [FRE 701]. Affidavits of expert witnesses should conform to FRE 702-705. All witness affidavits should be made under oath. All documents relied upon as evidence should be authenticated or self-authenticating under FRE 901(a) or 902. The main exception to FRE under the new regulations should be that hearsay objections do not apply at the petition stage, and that hearsay may even be relied upon in the final written decision at the discretion of the PTAB panel. Hearsay concerns in the petition can potentially be remedied by direct testimony and cross-examination of the out of court declarant after PGR is authorized. Any un-remedied hearsay can

be either excluded or given whatever weight the panel decides to be appropriate, at the panel's discretion. This practice would be in accordance with U.S. International Trade Commission evidence rules.

2. The patent owner's preliminary response to the petition under §323 should be limited to pointing out inadmissible evidence, argument that the admissible evidence even if believed does not establish invalidity, and to any reasons why the petition fails to meet the procedural requirements.

This is essentially a Judgment on the Pleadings standard. All factual allegations made in the petition and properly supported by admissible evidence must be taken as true until proven otherwise. For example, the preliminary response may point out reasons why an affiant's testimony is inadmissible under FRE, but should not allege that the affiant is biased. Credibility of the witness can be challenged after PGR is authorized. All evidence used by the patent owner to rebut allegations in the petition should be reserved until after the Director's decision to authorize PBR. The patent owner's rebuttal evidence will be contained in a written submission, supported by evidence, at a time and in a form prescribed by the new regulations under §326(a)(8).

3. The sufficiency of the evidence standard for authorizing PGR is defined by the statute and therefore must be adhered to in the new regulations. Under §324(a), the Director must consider the invalidity allegations and evidence submitted with the petition to determine whether such information, if "not rebutted, would demonstrate that it is more likely than not" that a claim or claims is unpatentable.

Two things about this standard should be made clear in the regulations. First, the phrase "more likely than not" is the traditional plain language formulation of the preponderance of evidence standard when it is used in a jury instruction. Second, the phrase "if not rebutted" implies that the claim is presumed to be invalid based upon the evidence in the petition. This presumption creates a shift in the order of evidence. As soon as the Director makes a determination to institute PGR, the burden lies with the patent owner to come forward with

evidence to rebut or meet the evidence of invalidity. The presumption does not, however, shift the ultimate burden of proof. This is consistent with FRE 301 for all similar civil presumptions.

#### 4. The patent owner's factual response after PBR has been authorized should only come after a period of limited discovery.

§326(a)(8) mandates that the Director establish the requirements for the patent owner's factual response<sup>1</sup>. It does not set a time for such response except that it be after a PGR is authorized. In fairness, the patent owner should have a limited time to take discovery in pursuit of evidence to rebut the presumption of invalidity before filing its factual response. The discovery process, however, should not be structured such that one party goes forward before the other. Discovery by all parties should proceed simultaneously.

# 5. The model for the new regulations on PGR discovery should follow the example of the TTAB rules for Inter Partes proceedings<sup>2</sup> by incorporating Federal Rules of Civil Procedure ("FRCP") as the default rules.

FRCP rules have the advantage of being taught in the law schools and widely understood by lawyers across the nation. The PTAB should not deviate from FRCP unless the nature of the PTAB proceedings provide a compelling reason to do so. The Director should not accept wholesale re-writing of procedural rules for PGR and other PTAB proceedings that will require a specialized practice, and which may cause loss of a valid invalidity issue through a procedural error rather than on the merits. There may be certain situations where it is proper to deviate from FRCP, a few of which are described in this comment, but the norm should be FRCP.

<sup>&</sup>lt;sup>1</sup> Note that the statute refers to a §323 response. That section refers to the preliminary response, not the factual response . The remaining text of §326(a)(8), however, makes clear that it means the response due after authorization of PGR.

<sup>&</sup>lt;sup>2</sup> 37 CFR § 2.120 Discovery

<sup>(</sup>a) In general. Wherever appropriate, the provisions of the Federal Rules of Civil Procedure relating to discovery shall apply in opposition, cancellation, interference and concurrent use registration proceedings except as otherwise provided in this section.

6. FRCP Rules of Discovery should be adopted, except for the standard of relevance set forth in §326(5) - evidence directly related to factual assertions advanced by either party.

The statute is clear that discovery be "limited to evidence directly related to factual assertions advanced by either party". This standard is more limited than the FRCP discovery standard of "reasonably calculated to lead to the discovery of admissible evidence", but it is still a relatively broad standard that can expand or contract depending upon the extent of the factual assertions of the parties. This flexible scope of discovery is entirely appropriate since the parties' assertions may be narrow in some proceedings and broad in others. The FRCP standard is intended to allow parties to discover evidence to support claims or defenses that the party may not have previously known about; whereas the PGR standard limits the discovery to invalidity issues that are already known enough to be alleged in the petition and patent owner's response.

7. PGR regulations should not change the standard FRCP limits on discovery, such as the Rule 30 limits on the maximum number and duration of depositions and the Rule 33 limit on interrogatories.

Departure from FRCP on such matters is a trivial and meaningless exercise that should not be part of the rulemaking for PGR. The FRCP limits are not inflexible and contemplate that a "one-size-fits all" approach to discovery may be too restrictive in some cases. See, FRCP 26(b)(2) and 26(f)(3)(E). Instead, the Director should adopt the current FRCP discovery rules, and require by regulation that the parties meet and confer on the topics listed in FRCP 26(f), which include agreement to modify the discovery limits, reduce the number of issues, and discuss the possibility of settlement; and to propose a joint pre-trial schedule that includes agreed upon discovery deadlines. The PGR rules may establish outside time limits, but allow the parties to budget their time within those limits as they wish.

8. PGR regulations should adopt the mandatory initial disclosure of FRCP 26(a), but with different guidelines on what materials must be disclosed without a formal request.

The statute already requires the petition to set forth sufficient admissible evidence to establish the presumption that one or more claims are invalid under the preponderance of evidence, so most of the challenger's relevant evidence is disclosed at the petition stage. An initial mandatory disclosure rule after PGR authorization should at minimum require identification of persons likely to have knowledge of the facts alleged, and the location of documents likely to be related to the facts alleged.

9. The discovery rules must be adequate to provide relevant information for all of the 35 U.S.C. 282(b) defenses, including on-sale and public use, and "otherwise available to the public" bars where the most relevant evidence may lie with a non-party seller or buyer, or a recipient of the information.

The scope of PGR discovery is conceptually much broader than the discovery that might be required in single-issue proceedings such as an interference to determine the first to invent, where the relevant information is almost entirely in the possession of the parties. This broader scope requires liberal use of 35 USC 24 subpoena power.

10. The right to take non-party discovery using the subpoena powers of 35 U.S.C. §24 should attach at an early point after authorization of the PBR, and permit a scope of discovery commensurate with the standard stated in the statute – "directly related to factual assertions advanced by either party", regardless of whether the factual assertion applies to claims other than the §324(a) threshold claim or claims for which the post-grant review is instituted.

The following is hypothetical example of how this would be applied.

EXAMPLE: A patent is granted with independent claim 1 directed to a composition. Dependant claims narrow the elements in the composition to specific species and concentration limits. The petition filed under 35 USC 322(a) is accompanied by product labels that are conclusive evidence that a non-party sold a composition that is an anticipation under new §102 as to claim 1, and the petition further alleges that upon information and belief the same prior art composition would anticipate or render obvious some dependent claims if the details of the actual composition were known in greater detail than is apparent from the labels. In this situation, the Director would presumably institute the review based upon claim 1 being more

likely than not to be invalid unless the evidence contained in the labels is rebutted. The authorization of the PGR should not, however, limit discovery so as to exclude the dependant claims. A 35 U.S.C. §24 subpoena to the non-party seller must be of sufficient scope to seek evidence of the exact composition in the prior art sales, which may invalidate some or all of the dependant claims.

### 11. The Patent Law Judges of the PTAB should not be directly supervising discovery. It is a time consuming task that is better left to the parties and to any district courts from which a §24 subpoena issues.

District courts can easily apply the statutory standard that the scope of discovery "be limited to evidence directly related to factual assertions advanced by either party", which merely requires the party seeking such discovery show the direct relationship to such assertions. The parties should not have to seek leave of the PTAB to conduct discovery that is in their joint discovery plan or that they later conclude to be necessary. The rules should allow the parties to deviate from the discovery plan by stipulation, rather than require a motion that will be uncontested. The PTAB should only intervene when the parties do not agree.

12. The PTAB should be tasked with proscribing sanctions for discovery abuse [§326(6)] on a case-by-case basis where the sanction is commensurate with the degree of abuse. The regulations should provide that the PTAB retains jurisdiction to impose such sanctions after the final written decision, even if the sanctions descision falls later than the one year or 18 month time limit for final written decision.

It will often be difficult to determine whether a particular discovery event was abusive or was necessary until a final written decision reveals the prevailing party and the importance of the discovery to the invalidity determination.

#### 13. The new regulations should encourage settlement by amendment as the preferred resolution of a PGR proceeding.

The PGR rules should require a statement in the joint discovery plan, analogous to a FRCP 26(f) report, that the parties have met and conferred in good faith on amendments that could resolve one or more invalidity contentions. The rules should further require a similar

periodic statement (e.g., every three months) that the parties have discussed settlement by amendment. The rules may even provide that the parties are encouraged or required to engage in mediation with a neutral mediator on the possibility of settlement by amendment.

To encourage open discussion and protect settlement discussions from being used against a party, the regulations should also provide a specific evidence limitation, similar to FRE 408, that statements made in settlement discussions can not be used as evidence for invalidity.