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Post-Grant Reviews at the Patent Office: How They Could Be Used to Challenge Biotech and Pharma Patents

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In 2011, enactment of the America Invents Act (AIA) significantly changed the way in which U.S. patents could be challenged, establishing three new proceedings for the United States Patent Office to reconsider the patentability of issued patents: Inter Partes Review, Covered Business Method, and Post-Grant Review. The first two proceedings, Inter Partes Review and Covered Business Method, have already been put to heavy use, with roughly 1,615 Inter Partes Review petitions and 201 Covered Business Method petitions having been filed with the new Patent Trial and Appeal Board. And these proceedings have changed the way parties litigate validity disputes, including validity disputes over drug and biotech patents. The Patent Trial and Appeal Board, however, has yet to institute a Post-Grant Review proceeding.[1] The reason for this disparity is straight forward: Post-Grant Review may only be instituted on patents with priority dates that post-date March 16, 2013. We anticipate a significant uptick in Post-Grant Review filings as more eligible patents issue.

This article will compare and contrast Post-Grant Review to other proceedings, and discuss the situations in which Post-Grant Review will likely be useful in the biotech and pharma space.

Former and Current Proceedings to Challenge Patents

Before the AIA, validity and patentability challenges were typically fought in *ex parte* reexamination, *inter partes* reexamination, or district court litigation. Each of these proceedings has inherent advantages and disadvantages.[2] For example, while *ex parte* reexaminations can be requested any time during the enforceable life of the patent, have no estoppel effects on later proceedings, and are relatively inexpensive, their disadvantages include no opportunity for discovery or settlement, requests limited to novelty and obviousness and only on the basis of printed publications and patents, and slow completion times (typically two years, not including any appeals). *Inter partes* reexaminations were available up to September 16, 2012 (when they were replaced by Inter Partes Reviews). Their advantages included no presumption of validity, broadest reasonable claim construction, and the involvement of technically trained decision makers at the Patent Office. Disadvantages of *inter partes* reexaminations included no opportunity for discovery or settlement, requests only based on novelty and obviousness issues and only on the basis of printed publications and patents, and long time to completion (typically three to four years, not including any appeals). Outside of the Patent Office, competitors can challenge patents in federal district court. District court litigation is advantageous in some cases as it provides an opportunity for discovery, and a patent may be challenged for any reason (not just on novelty and obviousness grounds). However, district court litigation is

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[1] A PGR petition was filed on August 5, 2014, challenging U.S. Patent No. 8,684,420 B2 to Choon's Design Inc. covering the Rainbow Loom toy for making colorful rubber band bracelets popular with grade-school age children. *LaRose Industries, LLC v. Choon's Design Inc.*, PGR2014-00008. As case numbers are assigned sequentially, at least seven other PGR petitions may have been filed, but not disclosed to the public.

[2] http://ptolitigationcenter.com/essentials/common-questions/.

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expensive, lengthy (often takes three to four years to complete), uses a ''clear and convincing evidence'' standard, and often cases are not heard by a technically trained judge.

How Do Post-Grant Reviews Differ From Inter Partes Reviews?

Post-Grant Review and Inter Partes Review both have a significantly lower burden of proving invalidity than district court proceedings (a ''preponderance of the evidence'' vs. a ''clear and convincing'' standard), allow for limited discovery, allow for settlement, and have a statutorily mandated time-to-completion of less than 12 months (an additional 6 months is possible but only for good cause). Post-Grant Review and Inter Partes Review decisions may be appealed to the U.S. Court of Appeals for the Federal Circuit. In contrast to Inter Partes Review, where invalidity is limited to novelty and obviousness and only on the basis of printed publications and patents, Post-Grant Reviews may be particularly attractive as they allow a challenger[3] to raise a ground of invalidity that could be presented in a district court action. Specifically, invalidity can be asserted on any ground related to patent invalidity under 35 U.S.C. § 101, § 102, § 103, and § 112, except best mode.[4] The Patent Trial and Appeal Board standard for granting the institution of a Post-Grant Review is relatively low—the proceeding may be instituted as long as it is ''more likely than not that at least one claim is unpatentable.'' Post-Grant Review has distinct advantages over district court litigation or *ex parte* reexamination, including the shorter length of the proceeding and the broader classes of validity challenges, respectively. Additionally, the Patent Trial and Appeal Board judges that conduct the proceedings often have significant technical expertise.

As compared to Inter Partes Review, the disadvantages of Post-Grant Review that may discourage some companies from utilizing this proceeding include the limited timeframe to bring an action (within nine months from patent grant), the cost, and the potential estoppel of later proceedings. In addition, legal arguments that could be persuasive to a district court judge will not carry the same weight with an administrative patent judge on the Patent Trial and Appeal Board. For example, the Patent Trial and Appeal Board is likely to give less weight to policy arguments than a district court. Regarding the potential estoppel of later proceedings, if a Post-Grant Review results in an adverse final written decision to the challenger, the challenger may not request or maintain a proceeding before the Patent Office, the International Trade Commission, or a federal district court, on any ground that the challenger raised or reasonably could have raised during the proceeding.[5] However, as estoppel does not attach in the absence of a final written opinion from the Patent Trial and Appeal Board, the challenger could avoid estoppel by negotiating a settlement with the patent owner.

Post-Grant Reviews Appear Similar to European Oppositions

In some respects, Post-Grant Reviews are similar to oppositions at the European Patent Office (EPO), which have been a popular way to litigate certain patent disputes. Post-Grant Reviews and EPO oppositions have the same time to file, similar bases for institution of the proceedings, and both permit the amendment of claims and appeal of the final decision. Table I below compares and contrasts some of their main features.

[3] The challenger cannot be the patent owner.
[4] 35 U.S.C. §§ 321(a)-(c).
[5] 35 U.S.C. § 325(e).

Table I. Comparison of Post-Grant Review to EPO Opposition[6]

	Post-Grant Review	EPO Opposition
Timing of Filing	9 months from patent grant	9 months from publication of patent grant
Filing fee	$30,000 for up to 20 claims	EUR 775
Identity	Requires identification of the real-party-in-interest[7]	Any third party; can remain anonymous
Possible Bases for Request	patent-eligible subject matter (§ 101), anticipation (§ 102), obviousness (§ 103), and requirements of § 112, other than best mode (not limited to patents and printed publications)	Novelty, inventive step or industrial applicability, non-patentable subject matter or matter offensive to public interest or morality, insufficient disclosure
Adjudicating Group	Patent Trial and Appeal Board composed of administrative law judges	3 patent examiners, at least two of which did not take part in the examination of the original patent
Right to amend	Limited; Patent owner has right to file claim amendments once	More liberal; Patent owner has right to file multiple claim amendments (main and auxiliary requests)
Discovery	Limited discovery available	Not available
Time to Completion	Decision must be reached within one year	Average time to completion is about 3-5 years (without appeals)
Right to Appeal	Either party can appeal. Appeal goes directly to the U.S. Court of Appeals for the Federal Circuit	Either party can appeal. Appeal goes to the EPO Board of Appeals. No judicial recourse to an adverse EPO Board of Appeal decision.
Ability to Settle	Parties retain ability to settle	Parties retain ability to settle

[6] http://www.epo.org/applying/european/oppositions.html.
[7] 35 U.S.C. § 322(a)(2).

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	Post-Grant Review	EPO Opposition
Estoppel Effect	Precludes challenger from raising in the PTO, district court, or USITC any issue that was ''raised or reasonably could have been raised''	Challenger not estopped from raising same issues in subsequent litigation

Future Contexts in Which Post-Grant Review May Be Used

While to date no Post-Grant Review has been instituted, there are some instances where Post-Grant Review may be the preferred forum to challenge biotech and pharma patents. One instance is where two parties are in litigation and a new patent related to that litigation issues. The challenger may utilize Post-Grant Review to challenge validity of the new patent to prevent the addition of the patent to the suit thereby slowing down the litigation. For example, during Hatch-Waxman litigation, often additional patents grant, which are listed in the Food and Drug Administration's Orange Book. Another example is method of making or process patents that present infringement issues.

Another situation in which a company may want to use Post-Grant Review is to force narrowing of the claims of a newly issued patent. By arguing that the claims are invalid over the prior art, a challenger may be able to use this procedure to force the patent owner to narrow the scope of the patent claims. If the claims are removed or amended to exclude the prior art, the competitor can design a non-infringing product or practice the prior art. Further, because the narrowed claims are still in place, they may prove useful in keeping other competitors off the market.

A third instance where a Post-Grant Review may be filed is similar to ''pocket reexams'' or ''pocket Inter Partes Reviews.'' In this case, a challenger may prepare a Post-Grant Review request but not file it with the Patent Office. Instead, the challenger presents the petition to the patent owner (or make the patent owner aware of its existence) as a tactic for negotiating more favorable licensing terms.[8]

Another instance where a Post-Grant Review may be filed is exemplified in the first ever publicly disclosed Post-Grant Review proceeding.[9] The petitioners, LaRose Industries, LLC and Toys ''R'' Us, allege that the Choon patent is subject to Post-Grant Review because the claims are not supported by the original disclosure and have an effective filing date of July 26, 2013. The effective filing date provisions of the first-inventor-to-file sections of the AIA indicate that any one claim amendment in a ''pre-AIA'' application can turn that application or patent into an application or patent subject to the AIA provisions if the claim is not supported by the original disclosure.[10] If the Choon patent claims are not supported by earlier filed applications, the patent would be subject to the AIA [first-inventor-to-file] provisions and Post-Grant Review. This lack of support argument allowed LaRose to assert invalidity based on indefiniteness, lack of written description and lack of enablement. Using this strategy, the validity of a patent could be challenged that would not otherwise be eligible for Post-Grant Review.

Post-Grant Review could also be particularly useful to challenge patents in view of recent developments in the law dealing with patent-eligible subject matter under 35 U.S.C. § 101. In particular, the Patent Office's recent guidelines[11] indicate that isolated natural products such as naturally occurring plasmids, chemicals, and bacterial strains, as well as non-naturally occurring products that are not markedly different from what exists in nature, are not patent-eligible. In addition, diagnostic or assay claims reciting steps that are well-understood, purely conventional or routine in the relevant field are likely not patent eligible. Although the Patent Office is examining applications filed on or after March 16, 2013, under the new guidelines, patents may still issue with claims that do not pass § 101 muster, and are thus susceptible to invalidity attacks under Post-Grant Review.

A final situation in which Post-Grant Review could be useful is in the context of a so-called 35 U.S.C. § 112/35 U.S.C. § 103 wedge. 35 U.S.C. § 112 dictates the content of the specification and includes the written description, enablement, and best mode requirements. 35 U.S.C. § 103 provides that an invention must not have been obvious to a person having ordinary skill in the art in view of the appropriate prior art. This wedge strategy is a two-part patent invalidation tactic in which a challenger makes both § 112 and § 103 arguments. By providing certain arguments to enable the invention, thereby defending against the § 112 attack, the patent owner may inadvertently strengthen a competitor's § 103 argument where the changes render the invention obvious.

In summary, Post-Grant Review has a number of features that make it an attractive option to challenge biotech and pharma patents. Advantages such as short trial duration, broad classes of validity challenges, the ability to settle and/or force claim amendments may make Post-Grant Review an attractive option in certain situations. As more eligible patents issue, it should soon become clear in which contexts Post-Grant Review will become the preferred forum.

The opinions expressed are those of the authors and do not necessarily reflect the views of the firm or its clients. This article is for general information purposes and is not intended to be and should not be taken as legal advice.

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[8] https://www.ipo.org/wp-content/uploads/2013/03/leveragingpatentreexam.pdf.

[9] *LaRose Industries, LLC v. Choon's Design Inc.*, PGR2014-00008.

[10] 35 U.S.C. § 100(i); AIA § 3(n)(1).

[11] The United States Patent and Trademark Office published a memorandum in March 2014 titled *Guidance for Determining Subject Matter Eligibility of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products* to implement a new procedure to address changes in the law relating to subject matter eligibility under 35 U.S.C. § 101 in view of recent court decisions including *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S.__, 133 S. Ct. 2107, 2116, 106 USPQ2d 1972 (2013), and *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S.__, 132 S. Ct. 1289, 101 USPQ2d 1961 (2012).