

## Post-Grant Review May Impact Biosimilars Litigation

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Post-grant review, created by the America Invents Act, is likely to have an impact on biosimilars litigation. PGR may prove to be an important forum for companies that do not want to wait until after filing their biosimilar applications to challenge the validity of relevant patents. PGRs are particularly attractive as challengers can raise almost any ground of invalidity that could be raised in a district court action, a broader claim construction is applied, the standard of proving invalidity is lower for a PGR than in district court ("preponderance of the evidence" vs. "clear and convincing"), settlement is possible, and a final decision is reached faster. Additionally, the costs associated with a PGR trial are considerably lower than the costs associated with a district court litigation.

However, disadvantages such as the limited timeframe to bring an action and the potential estoppel of later proceedings could deter some biosimilar applicants from utilizing this forum. To date, only two PGRs have been filed,[1] so it remains to be seen how often this forum will be used.



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### Background on Biosimilars

Biologic products are medical products manufactured in or extracted from biological sources. In comparison to small molecule drug products, biologics are large, complex molecules that are generally more difficult to synthesize, replicate, and bring to market.

The Biologics Price Competition and Innovation Act (BPCI Act) created an abbreviated approval pathway for biosimilar products. The BPCI Act was passed under the Patient Protection and Affordable Care Act and signed into law in 2010. In parallel with the U.S. Food and Drug Administration approval process, the statute requires the biologic reference product sponsor and the biosimilar applicant participate in a complex negotiation process to determine which patents will be litigated in district court. Depending on the product, the district court litigation could involve a number of patents directed to differing subject matter, such as to the molecule itself, methods of treatment, formulations, and methods of purifying the molecule. Such a variety of issues could result in a complicated, long, and expensive challenge for a biosimilar applicant.

Because of the potential time to patent finality and costs associated with the statutorily mandated negotiation process, biosimilar applicants may wish to pursue a different strategy to challenge the validity of a patent. One possible strategy to challenge the validity of a patent would be to file a declaratory judgment action.

To date, at least three different declaratory judgment actions have been filed by a biosimilar applicant prior to the biosimilar application being filed. However, one of those suits was dismissed for lack of jurisdiction. The district court held that the biosimilar applicant had no jurisdiction to challenge the potentially relevant patents prior to filings its abbreviated biologics licensing application.[2] Therefore, depending upon the circumstances, it may be difficult for a biosimilar applicant to establish declaratory judgment jurisdiction prior to filing its biosimilar application.

### **Will PGR Petitions Be a Popular Strategy for Biosimilar Applicants?**

An alternative to participating in the statutorily mandated negotiation process or filing a declaratory judgment action, a biosimilar applicant could challenge the validity of a patent prior to filing its biosimilar application by filing a PGR petition. However, the biosimilar applicant must file the petition within nine months of issuance of the patent and cannot have previously filed a declaratory judgment action challenging the validity of the patent.

Additionally, a PGR petition can only be filed on patents having at least one claim with a priority date after March 16, 2013. If a patent issued from an application filed after March 16, 2013, but claiming priority to an application filed prior to March 16, 2013, a biosimilar applicant may still be able to file a PGR petition if it can show that at least one claim is not entitled to the earlier filing date. LaRose Industries LLC and Toys "R" Us-Delaware Inc. used this strategy to assert the patent at issue in PGR2014-00008 is PGR-eligible. To date, the Patent Trial and Appeal Board has not issued a decision on institution, so it is unclear whether the PTAB will allow a PGR filer to use this strategy.

Therefore, a biosimilar applicant will be limited as to which patents it can challenge in a PGR — patents having a claim with a priority date after March 16, 2013, and issued within nine months of filing the petition. Because of product development timing, it is unlikely a biosimilar applicant will file a PGR on a patent directed to the drug molecule itself. Instead, depending on the biologic approval holder's life cycle management strategy, a biosimilar applicant may challenge secondary patent filings, such as formulation, methods of use, or methods of manufacturing the biologic product.

A PGR petitioner can assert one or more claims of a patent is invalid under one or more of 35 U.S.C. §§ 101, 102, 103 and 112, except best mode. The legal standard for institution by the PTAB is low. The proceeding will be instituted if it is "more likely than not that at least one claim is unpatentable." Because this standard is low, it is likely a well-drafted request for institution will be granted.

Further, depending upon the circumstances, a biosimilar applicant may want finality quickly. A PGR trial must be conducted by the PTAB within 12 months from institution (six months extension for good cause is allowed). The speed of the PGR trial may promote an earlier settlement agreement than would be reached if the validity challenge was taking place in the slower paced district court litigation.

A biosimilar applicant must carefully consider whether to challenge the validity of a patent by filing a petition for PGR. First, if a final decision adverse to the biosimilar applicant is entered, the biosimilar applicant is estopped from raising a defense that it raised or could have raised in a later proceeding before the PTAB, district court, or U.S. International Trade Commission. Second, certain defenses may be

more persuasive to a district court judge than to a PTAB judge.

Because no biosimilar applicant has filed a PGR petition, it is unclear how often a company will use this pathway to challenge the validity of a patent. However, generic pharmaceutical companies have frequently utilized the inter partes review proceedings before the PTAB. In fact, one of the two PGR petitions was filed by a generic pharmaceutical company. Therefore, it is likely that a biosimilar applicant will eventually take advantage of this post-issuance route to challenge the validity of a patent.

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[1] PGR2014-00008 was filed Aug. 5, 2014, by LaRose Industries LLC and Toys "R" Us-Delaware Inc. challenging the validity of claims 1-7 and 9-16 of U.S. Patent No.8,684,420 owned by Choon's Design Inc. PGR2014-00010 was filed Sept. 2, 2014, by Accord Healthcare Inc. challenging the validity of claims 1-5 and 8 of U.S. Patent No.8,598,219 assigned to Helsinn Healthcare SA and Roche Palo Alto LLC.

[2] Sandoz Inc. v. Amgen Inc., Case No. 3:13-cv-02904-MMC (N.D. Cal.)