Post-Grant Reviews: The AIA's Lesser-Used Stepchild – How to Use Them Effectively to Clear the Way to Practice Your Life Sciences Inventions

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The Leahy-Smith America Invents Act (AIA) was signed into law in 2011 and brought several important changes to U.S. patent law, including moving the U.S. from a "first-to-invent" to a "first-inventor-to-file" system and establishing the Patent Trial and Appeals Board (PTAB) to handle challenges to issued patents including *inter partes* reviews (IPRs) and post-grant reviews (PGRs).

The AIA outlines procedures and timelines for IPRs and PGRs, but the timing for when patents may be challenged differs between IPRs and PGRs. A petition to institute an IPR on a first-to-invent patent (filed before March 16, 2013) can be filed any time after the grant of the patent or reissue, while an IPR petition on a first-inventor-to-file patent (filed on or after March 16, 2013) can be filed 9 months after the grant of the patent or reissue, or if a PGR has been instituted, after the termination of the PGR. In addition, an IPR can be filed within one year of the patent owner being served with a summons in a patent litigation suit. IPR challenges are limited to arguments under 35 U.S.C. 102 (novelty) and 103 (obviousness) based on publicly available printed publications. In contrast, a PGR can only be filed within 9 months of the issuance of the patent, but the challenge can be based on any of 35 U.S.C. 101 (utility, subject matter eligibility), 112 (written description, enablement and indefiniteness), 102, or 103.

Both IPRs and PGRs carry with them estoppel from asserting invalidity in district court for any ground that the petitioner raised or reasonably could have raised during that IPR or PGR. But because of the broader scope of possible challenges in PGRs compared to IPRs, the potential scope of estoppel following a PGR is broader. The PTAB has reported that only 3-4% of post-grant challenges are PGRs, and many attribute this low percentage to the PGR estoppel issue. Given that roughly 90% of all IPRs are filed in response to litigation, it is not surprising that IPRs have historically been the predominant choice rather than PGRs.

But what about the case where a potential challenger is looking to invalidate an issued patent in the context of freedom to operate rather than in response to litigation? Perhaps the challenger is considering a collaboration or a sale and due diligence or routine monitoring uncovers a recently issued patent that could pose a problem. A PGR provides an opportunity to challenge a patent under 101 and 112 in addition to the prior art statutes 102 and 103 in a less expensive forum than district court.

Moreover, the USPTO's recent recission of the June 2022 "*Fintiv* memo"[1] and subsequent memoranda from Chief Judge Boalick[2] and Acting Director Stewart[3] hint that discretionary denials of IPRs could now increase. In contrast, during a recent meeting at the USPTO, PTO officials indicated that PGR petitions would be much more favorably considered.

Given the apparent preference the USPTO would give to PGR petitions, along with the facts that: (1) section 112 arguments can be raised in PGRs but not IPRs; (2) that 112(a) written description rejections are increasingly prevalent in Tech Center 1600 where applicants attempt to obtain broad claims to nucleic acid and amino acid sequences; and (3) that 112(a) written description invalidity arguments in district court, particularly with respect to antibody claims (in a $100+ billion industry) are increasingly successful, utilizing PGRs to challenge life sciences patents should be considered as part of a freedom to operate strategy.

[1]https://www.uspto.gov/about-us/news-updates/uspto-rescinds-memorandum-addressing-discretionary-denial-procedures

[2]https://www.uspto.gov/sites/default/files/documents/guidance_memo_on_interim_procedure_recission_20250324.pdf

[3]https://www.uspto.gov/sites/default/files/documents/InterimProcesses-PTABWorkloadMgmt-20250326.pdf