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Biosimilars in Post-Grant Proceedings at the USPTO PTAB

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Patents Covering Biosimilars

- Most biosimilars are covered by a substantial number of patents
- Patents continue to be issued during the life of a patent
- How best to challenge multiple patents?
  - Post-grant proceedings vs. district court litigation
    - Cost
    - Likelihood of success

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IPRs/PGRs can be an effective tool for biosimilar manufacturers to challenge U.S. patents

- Currently, a biosimilar manufacturer can use two different procedures to attack a U.S. Patent
  - Biologics Price Competition and Innovation Act (BPCIA)
  - Post-grant trial proceedings at the Patent Trial and Appeal Board (PTAB)

Inter Partes Review (IPR)

- Trial conducted at the PTAB to review the patentability of one or more claims of a patent based on lack of novelty (35 USC § 102) or obviousness (35 USC § 103) in view of prior art patents and/or printed publications
- Petitioner must file petition
  - The later of either: (1) 9 months after the grant of the patent or issuance of a reissue patent; or (2) if a post grant review is instituted, the termination of the post grant review; and
  - Up to one year after petitioner has been sued by patent owner

Inter Partes Review (IPR)

- Standard for instituting – more likely than not the claims are unpatentable, or novel or unsettled legal question important to other patents/applications
- Estoppel applies to arguments raised or that could have been raised
- Procedure took effect on September 16, 2012, and applies to any patent issued before, on, or after September 16, 2012

Post Grant Review (PGR)

- Trial conducted at the PTAB to review the patentability of one or more claims of a patent based on lack of subject matter eligibility (35 USC § 101), lack of novelty (35 USC § 102) or obviousness (35 USC § 103) in view of prior art patents and/or printed publications, lack of written description, enablement or definiteness (35 USC § 112), double patenting (NOT BEST MODE OR INEQUITABLE CONDUCT)
- Petitioner must file petition within 9 months after the grant of the patent or issuance of a reissue patent

Post Grant Review (PGR)

- Standard for instituting – reasonably likely that the claims are unpatentable
- Estoppel applies to arguments raised or that could have been raised
- Procedure applies to any patent with an effective filing date on or after March 16, 2013

Issues to Consider When Filing Petition

- How are claims construed in post-grant proceedings?
- Have other Petitions been filed on the same patent?
  - Can the deficiencies in prior petitions be overcome?
- How are follow-on petitions by the same Petitioner treated?
- How are follow-on petitions by different Petitioners treated?

How are claims construed in post-grant proceedings?

- Previously – broadest reasonable interpretation (BRI)
- PTAB recently issued a final rule changing the claim construction standard applied during IPR, PGR, and the transitional program for covered business method patents (CBM) proceedings before the PTAB
  - Final rule replaces BRI with federal court claim construction standard articulated in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (*en banc*), and its progeny
  - PTAB will take into consideration any prior claim construction determination in a civil action, or a proceeding before the International Trade Commission (ITC)

Hatch-Waxman Integrity Act

- Senator Orrin Hatch of Utah introduced a bill to amend the Hatch-Waxman Act on June 14, 2018
- “to prevent the *inter partes* review process for challenging patents from diminishing competition in the pharmaceutical industry and with respect to drug innovation.”
- Having two separate pathways for attacking patents on branded drugs puts added litigation pressure on innovators – “second bite at the apple”
- Would require ANDA or biosimilar applicant to choose between the ANDA/biosimilar approval pathway or challenge in an IPR or PGR

Rothwell Figg Biosimilars IPR Dashboard

https://www.biosimilarsip.com/wp-content/uploads/2018/08/IPR-Dashboard.pdf

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Follow-on Petitions by a New Petitioner

- **Example -** Rituxan® (rituximab) **-** Monoclonal antibody marketed by Genentech and Biogen Pharmaceuticals
- Biogen U.S. Patent No. 9,296,821 – methods of treating low-grade or follicular non-Hodgkins lymphoma along with a chemotherapeutic regimen
  - PTAB instituted a first IPR on certain claims after petition by Celltrion (IPR2017-01095)
  - PTAB instituted a second IPR on certain claims after petition by Pfizer (IPR2018-00186)

Pfizer IPR2018-00186 on Rituxan® (rituximab)

- PTAB applied Supreme Court precedent in *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1360-61 (2018) to this “follow-on petition” in which a new petitioner (Pfizer) challenged the same patent at issue in a prior IPR by a previous petitioner (Celltrion)
- “when considering whether to exercise our discretion to deny institution under 35 U.S.C. § 325(d), we must consider not simply whether to deny institution regarding certain claims or certain challenges, but whether to do so regarding the petition, as a whole.”
- Pfizer’s new argument that the recitation in Claim 4 of providing a “beneficial synergistic effect” was non-limiting
    - persuaded the Board that Pfizer’s challenge was not ”substantially the same” as Celltrion’s, and thus chose not to exercise its discretion to deny the Petition

Follow-on Petitions by the Same Petitioner

- **Example -** Biogen U.S. Patent No. 8,329,172 relating to Rituxan® – methods of treating low-grade B-cell non-Hodgkins lymphoma after chemotherapy
  - PTAB denied petition by Boehringer Ingelheim (IPR2015-00418)
  - PTAB denied petition by Celltrion and Teva (IPR2017-01093)
  - PTAB denied a first petition by Pfizer, finding that a Rituxan® label was not a prior art printed publication because there was insufficient evidence of its having been made available prior to the critical date (IPR2018-01166)
  - PTAB instituted an IPR where Pfizer substituted the Rituxan® label with a journal article containing the same information and available prior to the critical date (IPR2018-00285)

Follow-on Petitions by the Same Petitioner

- PTAB's decision to institute noted that although § 325(d) grants discretion to decline institution based on the presentation of the same or substantially the same art, the statute does not require the result, and the Board's discretion may take into account the facts of each case

- Dissent focused on seven factors in *General Plastics* case, stating that Pfizer: (1) previously filed a petition directed to the same claim; (2) knew of the newly asserted references at the time of the original petition; (3) had access to the prior Preliminary Response and institution decision; and (4) did not provide adequate explanation for its previous failure to demonstrate that the Rituxan® label qualified as a printed publication, and for these reasons, denial of institution was warranted.

Serial IPR Challenges to the Same Patents by the Same Petitioner

- Considerations from Precedential Board Decision in *General Plastic Industrial Co., Ltd. V. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19 (P.T.A.B. Sept. 6, 2017)
  - 1. whether the same petitioner previously filed a petition directed to the same claims of the same patent;
  - 2. whether at the time of filing of the first petition the petitioner knew of the prior art asserted in the second petition or should have known of it;
  - 3. whether at the time of filing of the second petition the petitioner already received the patent owner's preliminary response to the first petition or received the Board's decision on whether to institute review in the first petition;
  - 4. the length of time that elapsed between the time the petitioner learned of the prior art asserted in the second petition and the filing of the second petition;
  - 5. whether the petitioner provides adequate explanation for the time elapsed between the filings of multiple petitions directed to the same claims of the same patent;
  - 6. the finite resources of the Board; and
  - 7. the requirement under 35 U.S.C. § 316(a)(11) to issue a final determination not later than 1 year after the date on which the Director notices institution of review.

Thank you!

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