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Challenged Patent Upheld in the First Post-Grant Review Decision Involving Pharmaceuticals

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Post-grant review (PGR) is a review proceeding under the America Invents Act (AIA), and has only been available for patents filed on or after March 16, 2013. Consequently, it was significant that on November 14, 2016, the Patent Trial and Appeal Board (the PTAB), in *Altaire Pharmaceuticals, Inc. v. Paragon BioTeck Inc.*, upheld an eye solution patent challenged in a PGR, marking the first time the PTAB has upheld a patent in such a proceeding.

To date, there have been less than 50 PRG petitions filed and four final decisions rendered by the PTAB. In contrast to the three earlier decisions in which the PTAB found each of the challenged patents invalid, the November decision is the first that upheld the validity of a challenged patent.

The patent at issue is owned by Paragon Bio Teck and is directed to methods and compositions of stabilizing eye solutions containing phenylephrine, an agent for dilation of the pupil. In May 2015, Altaire Pharmaceuticals, Inc. filed a petition for a PGR of 13 claims of the patent. Altaire argued that the patent claims were unpatentable as obvious over Altaire's two lots of phenylephrine hydrochloride ophthalmic solution products that had been on sale prior to the filing date of the patent application. However, the Board, in its November decision, was unpersuaded, concluding:

> After considering the complete record developed at trial, we determined that Petitioner has not shown in this proceeding, by a preponderance of the evidence, that [the challenged claims of the patent] would have been obvious over Altaire's Product.

In reaching its decision, the Board examined closely the evidence submitted by Altaire in its invalidity challenge, including the status of Altaire's witness and the testing data. The Board found that Altaire had failed to timely qualify its witness as an expert in the proceeding, and therefore accorded no weight to this *fact*-witness's opinion. In addition, the Board found that Altaire, through the very same witness, failed to explain how the test had been performed and how the data had been generated and, as a result, gave no weight to such data.

There are a few general and specific noteworthy points about the PGR proceeding and the *Altaire* decision:

- Altaire's use of certain evidence (including its own testing data obtained from its proprietary testing methods) in this case highlights the much wider scope of patentability challenges available in a PGR proceeding than in an IPR (Inter Partes Review) proceeding. A petitioner in a PGR may challenge a claim based on §101 (patentable subject matter), §102 (prior use, sales, public availability, and printed publications), §103 (obviousness), §112 (written description, enablement, indefiniteness, but not best mode), and §251 (new matter in reissue patents). By comparison, in an IPR proceeding, patentability challenge can only be raised on ground under §102 and §103, and only based on patents and printed publications.
- Parties in a PGR proceeding should adhere to the *Trial Practice and Procedure before the PTAB* as the Board can be stringent in applying the rules. In the case, the Board rejected Altaire's attempt to qualify its witness as an expert in its reply brief, in response to the patent owner's position that the witness was a fact witness based on certain statements in his declaration submitted along with the petition. The Board, citing 37 CFR §42.23(b) ("a reply may only respond to arguments raised in the corresponding patent owner response"), explained:

> As we previously explained, 'respond,' in the context of this Rule, does not permit Petitioner to depart from the positions originally taken in the Petition and embark in a new direction with a new approach. Here, Petitioner intends to revise the witness status…from a lay person to an expert. This change would affect what subjects on which [the witness] may testify competently…Because retroactively qualifying [the witness] as an expert at the time of the Reply would impact our treatment of the testimony he provided in support of the Petition, and because Patent Owner did not have the opportunity to consider and respond to [the witness's] prior testimony in that capacity, we decline to do so at this late stage.

- The tests and data submitted in a PGR must meet the requirements of 37 C.F.R. §42.65 (expert testimony; tests and data), which includes the following:

> If a party relies on a technical test or data from such a test, the party must provide an affidavit explaining: (1) why the test or data is being used; (2) how the test was performed and the data was generated; (3) how the data is used to determine a value; (4) how the test is regarded in the relevant art; and (5) any other information necessary for the Board to evaluate the test and data.

The Board's decision in *Altaire* demonstrates that in a PGR it will examine evidence very critically and the failure to comply with the requirements may have severe consequences. Counsel must keep in mind that in a PGR, "the burden of persuasion is on the petitioner to prove unpatentability, and that burden never shifts to the patentee."

If you have questions or would like additional information on this topic, please contact a member of our Intellectual Property Group.