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PTAB HIGHLIGHTS

New developments in post-issuance proceedings

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PTAB Review of Pupil Dilation Patent a Real Eye Opener on PTAB Case Witnesses and Tests

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December 7, 2016 — The Patent Trial and Appeal Board recently held in a post grant review (PGR) that a petitioner failed to prove that patent claims were obvious. The PTAB reached this holding after finding that the petitioner's declarant (its president) was a fact witness and not qualified as an expert, and that he failed to explain how tests were performed and data was generated on the petitioner's prior art compositions.

[PGR2015-00011 – *Altaire Pharmaceuticals, Inc. v. Paragon Biotech, Inc.* \(Paper 48\)](#)

A key takeaway from this case is that a petitioner will not prevail in a post-issuance review if it relies on tests or data in its petition, but does not meet the requirements of 37 C.F.R. § 42.65(b). The rule requires that:

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.

A second takeaway is that the PTAB will not consider testing protocols submitted with the petitioner's reply because doing so would deprive the patent owner of an opportunity to respond to the protocols.

A third takeaway is that it is important for a petitioner in a post-issuance review proceeding (PGR, *inter partes* review, or covered business method) to not rely on a fact witness as an expert without properly qualifying that witness as an expert when filing the petition. Otherwise, and even if the witness is later proven to be an expert, the witness will not be treated as an expert. While an expert may testify on certain topics, such as prior art teachings and the level of ordinary skill in the art, a lay witness may not do so. The PTAB will not allow a petitioner's reply to retroactively qualify a fact witness as an expert, because doing so would deprive the patent owner of the opportunity to consider and respond to the witness's prior testimony in a capacity as an expert.

The challenged patent, U.S. 8,859,623 (the '623 patent), discloses a way to maintain high purity pupil dilation compositions. The patent application was filed in late 2013, and thus the patent is an America Invents Act patent (i.e., an effective filing date on or after March 16, 2013). As an AIA patent, the '623 patent was subject to a petition for a PGR. The petitioner asserted that the claims of the '623 patent were obvious under 35 U.S.C. § 102(a)(1). Specifically, the petition presented two lots of petitioner's product with purity test data and asserted that they rendered obvious the claimed purity limitations and were publically available before the '623 patent application. The patent owner did not dispute that these lots qualified as prior art, and the PTAB instituted the PGR after finding that the petitioner had demonstrated in its petition that it was "more likely than not" that at least one challenged claim was unpatentable.

On final written decision, however, the PTAB held that the petitioner had not proven obviousness by a preponderance of the evidence. The PTAB held that the petitioner's declarant (its president) was a fact witness, and that the petitioner did not timely qualify him as an expert. In his original declaration presented in the petition, he testified "based on [his] personal knowledge of the facts." Nowhere in that declaration, however, did he explain his "knowledge, skill, experience, training, or education" that would provide basis for qualification as an expert. Thus, the PTAB found it appropriate to consider him a fact witness, and not an expert. A later declaration filed with the petitioner's reply was accompanied by his curriculum vitae, and detailed his experience in the pharmaceutical industry. However, the PTAB effectively deemed this later declaration as too little, too late to qualify him as an expert in the PGR proceeding.

The PTAB also found that the tests and data submitted with the petition did not meet the requirements of 37 C.F.R. § 42.65(b). The declaration filed with the petition failed to explain how the testing was performed and how the data was generated. Without this necessary information, the PTAB stated that it could not determine whether the evidence relied on by the petitioner was credible. The PTAB refused to consider documents about test protocols that were submitted with the petitioner's reply because the patent owner did not have an opportunity to respond.

The Leahy-Smith America Invents Act established new patent post-issuance proceedings, including the inter partes review, post grant review and transitional program for covered business method patents, that offer a less costly,

streamlined alternative to district court litigation. With the U.S. Patent and Trademark Office's Patent Trial and Appeal Board conducting a large and increasing number of these proceedings, and with the law developing rapidly, Banner & Witcoff will offer weekly summaries of the board's significant decisions and subsequent appeals at the U.S. Court of Appeals for the Federal Circuit.



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