Patent For Pupil Dilation Using Claimed Composition Survives Post Grant Review

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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 by a preponderance of the evidence that patent claims were obvious in view of the petitioner's prior art compositions. 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 petitioner's prior art compositions.

PGR2015-00011 – *Altaire Pharmaceuticals, Inc. v. Paragon Bioteck, 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, the witness will not be treated as an expert. While an expert may testify on certain topics, such as prior art teachings of the level of ordinary skill in the art, a lay witness may not do so. The PTAB will not allow a petitioner to retroactively qualify a fact witness as an expert at the time of the petitioner's reply because doing so would deprive the patent owner the opportunity to consider and respond to the witness's prior testimony in that capacity.

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 on November 14, 2013, and thus the '623 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 filed within nine months of the patent grant on October 14, 2014. The petitioner filed the PGR petition on May 11, 2015, and 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 and asserted that it rendered obvious the claimed purity limitations and was 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, based on the full record including the patent owner's response to the petition, and the petitioner's reply, 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 declaration in support of the petition, he testified "based on [his] personal knowledge of the facts stated [t]herein." Nowhere in that declaration, however, did he explain his "knowledge, skill, experience, training, or education" that would provide the basis for his qualification as an expert. Thus, the PTAB found it appropriate to consider him as a fact witness in the proceeding, and not as an expert. His later declaration filed with the petitioner's reply, accompanied by his curriculum vitae, and detailing his experience in the pharmaceutical industry was too little, too late to qualify him as an expert in this PGR proceeding.

The PTAB found that, based on the full record, it could not verify that the test data of the petitioner's product that the petitioner relied on was generated using the petitioner's own proprietary method, and not the United States Pharmacopeia (USP) standard method. Even accepting the petitioner's assertion that it used its proprietary method, the PTAB stated that it was

not persuaded to rule in the petitioner's favor. This is because, as the patent owner correctly pointed out, the tests and data submitted with the petition did not meet the requirements of 37 C.F.R. § 42.65(b). The only declaration filed with the petition failed to explain, among others, how the test 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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