



THINK FORWARD

New Evidence May Be Presented After Institution of an IPR Proceeding

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On September 26, 2016, the Federal Circuit declined to review *en banc* a panel decision that a party challenging a patent in an IPR proceeding can present additional evidence of invalidity after a review is instituted. *Genzyme Therapeutic Products Limited Partnership v. Biomarin Pharmaceutical Inc.*, Appeal Nos. 2015-1720 and 2015-1721 (Fed. Cir. September 26, 2016). A three-judge panel had earlier held that “the introduction of new evidence in the course of the trial is to be expected in *inter partes* review trial proceedings and, as long as the opposing party is given notice of the evidence and an opportunity to respond to it, the introduction of such evidence is perfectly permissible[.]” *Genzyme Therapeutic Products Limited Partnership v. Biomarin Pharmaceutical Inc.*, 825 F.3d 1360, 1366 (Fed. Cir. June 14, 2016). In declining to review the panel decision, the Federal Circuit confirmed that petitioners can introduce new evidence after a review begins, so long as the opposing party is given notice of the evidence and an opportunity to respond to it.

PTAB Proceedings

Genzyme owns the patents at issue, which are directed to treating Pompe’s disease with injections of recombinant acid-glucosidase. Biomarin filed *inter partes* review petitions asserting the Genzyme patents are unpatentable as obvious in view of several prior art publications. Genzyme argued that the claims were not obvious because a person of ordinary skill in the art would not find that the *in vitro* experiments described in the (combination of) references are predictive of results in human subjects. In response, Biomarin cited two *in vivo* studies of enzyme replacement therapy as further support that Genzyme’s claims were obvious over the prior art. In its final written decision, the Board relied on the publications cited in its decision to institute the proceedings and on the additional evidence presented after the proceedings had been instituted and found the challenged claims unpatentable as obvious.

Federal Circuit

On appeal, Genzyme argued that the Board’s final written decision relied on arguments not set forth in the institution decision, in violation of the APA’s procedural requirements. In particular, Genzyme argued that the Board’s reliance on the new references was improper because Genzyme did not receive notice that the references would be considered or an opportunity to respond to the Board’s reliance on the references. The panel disagreed.

According to the panel, introduction of new evidence in the course of trial is permissible under the APA “as long as the opposing party is given notice of the evidence and an opportunity to respond to it.” The court held that “[t]here is no requirement, either in the Board’s regulations, in the APA, or as a matter of due process, for the institution decision to anticipate and set forth every legal or factual issue that might arise in the course of the trial.” Rather, “the purpose of the trial in an *inter partes* review proceeding is to give the parties an opportunity to build a record by introducing evidence – not simply to weigh evidence of which the Board is already aware.” The court found that the APA due process requirements had been satisfied because Genzyme had actual notice of the references and an opportunity to respond to

them.

Implications

The Federal Circuit's disposition has strategic implications for both petitioners and patent owners when litigating at the PTAB. Specifically, the decision may benefit parties drafting IPR petitions by allowing the consideration of evidence beyond the four corners of the petition. Conversely, patent owners may be deemed to have received actual notice of prior art references introduced after the institution of a proceeding, and accordingly may need to take advantage of other procedural devices to exclude references not specifically cited in the institution decision.

Contact Us

If you have any questions or wish to discuss how this decision impacts your business, please contact one of our [Brinks Attorneys](#).