

GENZYME THERAPEUTIC PRODUCTS LIMITED PARTNERSHIP v. BIOMARTIN PHARMACEUTICALS, INC., Appeal Nos. 2015-1720, 1721 (Fed. Cir. June 14, 2016). Before Moore, Bryson, and Reyna. Appealed from Patent Trial and Appeal Board (Board).

Background:

Genzyme holds two patents drawn to methods for treating Pompe's Disease. The Board instituted an IPR for each patent in response to petitions by Biomartin. Biomartin sought review of various claims on several obviousness grounds. For each patent, the Board instituted review on fewer than all of these grounds, the references relied on all being drawn to *in vitro* experiments. In its patent owner's response, Genzyme argued that one of ordinary skill in the art would not have found such experiments predictive of *in vivo* effectiveness, and that Biomartin should not be permitted to use any prior art showing successful *in vivo* tests to demonstrate obviousness. Biomartin replied, citing such prior art, which the Board relied on as showing the state of the art as of the filing date of the patents, in ultimately holding that the claims were unpatentable as obvious.

Genzyme appealed, mainly on the ground that the Board violated the notice and opportunity to respond requirements of the Administrative Procedures Act (APA) by relying on facts and legal arguments that were not part of the institution decisions.

Issue/Holding:

Did the Board err in violating the notice and opportunity to respond requirements of the APA and if not, did the Board err in holding that Genzyme's claims were unpatentable? No and no, affirmed.

Discussion:

The Court stated that the introduction of new evidence in an IPR is to be expected as long as the opposing party is given notice and an opportunity to respond. The Court added that "Genzyme's argument that the institution decision must refer to every bit of evidence that is relied on by the Board in its final written decision reflects a misunderstanding of the role of the institution decision in inter partes review proceedings before the Board." The Court further stated that given the facts that the institution decision comes at the outset of the proceedings, and that a patentee is not obligated to respond before the Board makes its institution decision, "it is hardly surprising that the Board cannot predict all the legal or factual questions that the parties may raise during the litigation."

The Court affirmed the decisions of the Board based on the grounds in which the IPRs were instituted, finding that it was permissible for the Board to rely on the new evidence for the reasons that it did, i.e., to show the state of the art. The Court cited precedent for permitting the introduction of such evidence and for such reasons.

The Court ultimately found that Genzyme was not denied notice and opportunity to respond to the new evidence, because in its patent owner responses, Genzyme itself raised the issue of *in vivo* studies and particularly addressed the prior art later introduced by Biomartin, and had the opportunity during the proceedings to respond thereto.