

Collateral Estoppel Does Not Attach To PTAB Invalidity Determination Pending Appeal

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Recently, in [Sanofi-Aventis v. Mylan](#), 2:17-cv-09105-SRC-CLW, Judge Stanley Chesler of the United States District Court, District of New Jersey, denied a motion by defendant Mylan for summary judgment of invalidity of asserted patent claims that were found to be obvious by the Patent Trial and Appeal Board (“PTAB”). With the appeal of those decisions pending, Judge Chesler reasoned that the difference in the burdens of proof applicable at the PTAB and in instant case barred the application of issue preclusion under Supreme Court guidance in [B&B Hardware, Inc. v. Hargis Indus.](#), 135 S. Ct. 1293, 1303 (2015).

The case arose on October 24, 2017, when Sanofi-Aventis U.S. LLC, Sanofi-Aventis Deutschland GmbH, and Sanofi Winthrop Industrie (collectively, “Sanofi”), filed suit for patent infringement against Mylan N.V., Mylan GmbH, Mylan Inc., and Mylan Pharmaceuticals Inc. (collectively, “Mylan”), after Mylan filed a New Drug Application with the United States Food and Drug Administration (“FDA”) seeking approval to sell its proposed copies of Sanofi’s Lantus® and Lantus® SoloSTAR® drug products prior to the expiration of eighteen patents, including U.S. Patent Nos. 7,476,652 (“the ‘652 patent”) and 7,713,930 (“the ‘930 patent”) (together, the “formulation patents”). The formulation patents relate to pharmaceutical formulation of acidic insulin having improved stability.

Prior to the filing of Sanofi’s complaint, Mylan had already petitioned for *inter partes* review (“IPR”) of the formulation patents in IPR2017-01526 (the ‘652 patent) and IPR2017-01528 (the ‘930 patent). On December 13, 2017, the PTAB granted the petition and *inter partes* reviews were instituted for both patents. One year later, in Final Written Decisions, the PTAB found all challenged claims of Sanofi’s formulation patents unpatentable as obvious.

Based on the rulings of the PTAB, Mylan moved for summary judgment of invalidity of the formulation patents, arguing that collateral estoppel barred Sanofi from relitigating that issue. Sanofi countered by arguing that collateral estoppel cannot apply in instances where the first and second proceedings have differing standards of proof. Based on *B&B Hardware*, which states that “issues are not identical if the second action involves application of a different legal standard, even though the factual

setting of both suits may be the same,” the District Court held that differences in the legal standard, unlike procedural differences, do bar issue preclusion, before denying Mylan’s motion for summary judgment. Specifically, the Court observed that patent owners in district court enjoy a presumption of patent validity that does not apply in post-grant proceedings where the burden to demonstrate obviousness is by a preponderance of the evidence, rather than by clear and convincing evidence. The ruling by Judge Chesler also highlights the differences in legal effect for final PTAB decisions pending appeal at the Federal Circuit. While Sanofi lived to fight another day, had Mylan been the unsuccessful party before the Board, it would have been statutorily estopped from renewing its obviousness arguments and any other invalidity position that it “raised or reasonably could have raised during that inter partes review” pursuant to 35 U.S.C. § 315(e)(2).

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