PTAB Holds Claims Invalid That Were Held To Be Not Invalid In Litigation Appeal

By Robert H. Resis

November 17, 2015 — The Patent Trial and Appeal Board recently held claims in two separate patents to be invalid that were previously held to be not invalid in a litigation appeal. In separate *inter partes* review proceedings, the PTAB held that the district court decision, affirmed by the Federal Circuit, upholding the validity of the claims did not control because the petitioner in the IPR presented additional prior art and declaratory evidence that was not before the court in the litigation. The IPR cases involved U.S. 6,316,023 and 6,335,031, which describe pharmaceutical compositions useful for treatment of Alzheimer's disease. The IPR cases are identified below.

IPR2014-00549 – *Noven Pharmaceuticals, Inc. et al. v. Novartis AG et al.* (Paper 69)(PTAB, September 28, 2015) — held: claims 1, 2, 4, 5, 7, and 8 of U.S. 6,316,023 have been shown by a preponderance of the evidence to be unpatentable (obvious in view of a primary reference (Enz) and other prior publications). IPR2015-00265 filed by petitioner Mylan was joined with IPR2014-00549.

IPR2014-00550 – *Noven Pharmaceuticals, Inc. et al. v. Novartis AG et al.* (Paper 69)(PTAB, September 28, 2015) — held: claims 1, 2, 4, 5, 7, and 8 of U.S. 6,335,031 have been shown by a preponderance of the evidence to be unpatentable (obvious in view of Enz and other prior publications). IPR2015-00268 filed by petitioner Mylan was joined with IPR2014-00550.

In the '549 IPR, the Board noted that in another case involving patent owner Novartis, but not the petitioners Noven and Mylan, the district court held that claims 2 and 7 of the '023 patent and claims 3, 7, 13, 16 and 18 of the '031 patent are not invalid as obvious. *Novartis Pharm.*

Corp. v. Par Pharm., Inc., 48 F. Supp. 3d 733 (D. Del. 2014), *aff'd*, *Novartis Pharm. Corp. v. Watson Labs, Inc.*, _ F. App'x _, Nos. 2014-1799 et al., 2015 WL 2403308 at *5-8 (Fed. Cir. May 21, 2015) (*Watson*). The Board stated that the Federal Circuit's *Watson* decision does not control here because Noven has presented additional prior art and declaratory evidence that was not before the Court in *Watson*. The Board also noted the petitioner's preponderance of the evidence burden in the IPR being different than the clear and convincing evidence burden of proving unpatentability required in the district court litigation. "Thus, while we have considered the Federal Circuit's decision, we have independently analyzed patentability of the challenged claims based on the evidence and standards that are applicable to this proceeding."

The Board held that the petitioner had shown a reasonable likelihood that independent claims 1 and 7 of the '023 patent were unpatentable over Enz in view of a secondary reference (Saski). The petitioner asserted that Enz taught a composition that met every limitation claims 1 and 7, except for the addition of an antioxidant. The petitioner relied on the declaration testimony of Dr. Kydonieus, which asserted that Saski provided a person of ordinary skill in the art (POSITA) a reasonable expectation that the rivastigmine transdermal patch taught by Enz would be unstable during long-term storage of two to three years. The petitioner asserted that using Enz serves as a starting point for formulating a rivastigmine transdermal patch and that a POSITA would have strived to develop stable pharmaceutical products with a commercially viable shelf life. In furtherance of that goal, the petitioner and Dr. Kydonieus asserted that one of the first steps a POSITA would have taken when formulating a drug product is to investigate the stability of the active component, and that Saski informs of that investigation. In particular, petitioner asserted that Saski teaches that compounds having an amino group can undergo oxidative decomposition over the shelf life of the product when the product comprises an acrylic adhesive. According to the petitioner and Dr. Kydonieus, based on that teaching of Saski, a POSITA would have expected Enz's transdermal patch to be unstable during long-term storage because it comprised a drug having an amino group, i.e., rivastigmine, and was formulated with an acrylic polymer adhesive. The petitioner further asserted that a POSITA would have been motivated to add an antioxidant, particularly tocopherol, as recited in claim 2 of the '023 patent, to Enz's rivastigmine transdermal composition with a reasonable expectation of maintaining the stability of the patch during long-term storage, as this is the precise solution disclosed in Saski.

The patent owner argued that Saski did not teach or suggest any oxidative degradation problem for rivastigmine, and therefore a POSITA would not have been motivated to include an antioxidant in the rivastigmine transdermal formulation disclosed in Enz. After considering the record as a whole, the Board sided with the petitioner. The Board stated that the patent owner and its declarant have mistakenly disregarded the suggestion provided by the combined prior art that a compound having an amine group and formulated with an acrylic plaster is susceptible to oxidative degradation. "It is this susceptibility, i.e., a predicted potential for oxidative degradation, that provides the skilled artisan with a reasonable expectation that the formulation

will oxidatively degrade and the motivation to address that problem by employing a means known to avoid that problem, such as adding an antioxidant, as taught by Saski."

In the '550 IPR, the Board made similar holdings in connection with claims of the '031 patent.

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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