

Differing Burdens of Proof in the PTAB and District Courts can Allow Patent Challengers a Second Bite at the Apple

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The different burdens of proof in the Patent Trial and Appeal Board (PTAB) and in district court means that the PTAB may find patent claims unpatentable even after the claims were held valid over the same evidence in litigation. *Novartis AG v. Noven Pharm. Inc.*, No. 2016-1678, 2016-1679 (April 4, 2017).

In two separate Inter Partes Review (IPR) proceedings, the PTAB found the asserted claims of Novartis's U.S. Patent Nos. 6,316,023 and 6,335,031 unpatentable for obviousness over various combinations of prior art references. *Novartis*, No. 2016-1678, 2016-1679 at 2, 4. However, those same claims had previously been litigated in the U.S. District Court for the District of Delaware. *Id.* at 6. Based on the "same" arguments and the "same" evidence considered by the PTAB, the Delaware District Court held the claims not obvious, and the Federal Circuit affirmed the court. *Id.*; *Novartis Pharm. Corp. v. Watson Labs., Inc.*, 611 F. App'x 988 (Fed. Cir. 2015); *Novartis Pharm. Corp. v. Noven Pharm., Inc.*, 125 F. Supp. 3d 474 (D. Del. 2015).

Novartis argued that *In re Baxter International, Inc.* required that the PTAB must reach the same conclusion as the Delaware District Court and the Federal Circuit in the earlier proceedings. *Id.* at 6, 8 (discussing *In re Baxter Int'l, Inc.*, 678 F.3d 1357, 1365 (Fed. Cir. 2012) ("When a party who has lost in a court proceeding challenging a patent, from which no additional appeal is possible, provokes a reexamination in the PTO, using the same presentations and arguments, even with a more lenient standard of proof, the PTO ideally should not arrive at a different conclusion.")).

The Federal Circuit disagreed with Novartis. First, the Federal Circuit explained, the record at the PTAB differed from the record in the earlier trial proceeding. *Id.* at 6. According to the Federal Circuit, the PTAB correctly found that the Federal Circuit and Delaware District Court opinions were not controlling because additional evidence was present before the PTAB. *Id.* at 6-7.

The Federal Circuit further explained that Novartis's argument would have been incorrect even if the trial record had been the same. *Id.* at 7. The PTAB determines unpatentability by a preponderance of the evidence, while litigation in the district court requires proof of invalidity by clear and convincing evidence. *Id.* With a lower burden of proof, the PTAB may properly find patent claims unpatentable even though a district court had considered the same evidence and reached the opposite conclusion. *Id.* at 7-8. The Federal Circuit found support for its decision in the Supreme Court's opinion in *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131 (2016):

A district court may find a patent claim to be valid, and the [USPTO] may later cancel that claim in its own review. ... This possibility, however, has long been present in our patent system, which provides different tracks — one in the [USPTO] and one in the courts — for the review and adjudication of patent claims. As we have explained ..., inter partes review imposes a different burden of proof on the challenger. These different evidentiary burdens mean that the possibility of inconsistent results is inherent to Congress'[s] regulatory design.

Cuozzo, 136 S. Ct. at 2146. Thus, the Federal Circuit concluded that the prior decisions were not controlling on the PTAB. *Novartis*, No. 2016-1678, 2016-1679 at 8.

The Federal Circuit also distinguished the *Baxter* opinion Novartis relied on. *Id.* Although *Baxter* stated that the USPTO “ideally should not arrive at a different conclusion” as a district court faced with the same evidence and argument, this is an aspiration, not a rule. *Id.* *Baxter* also recognized that the different standards in the USPTO and the district courts allow for potentially different results. *Id.* at 8-9; *Baxter*, 678 F.3d at 1365.

The Federal Circuit also reviewed the factual findings behind the PTAB’s obviousness determination. *Id.* at 9. The Federal Circuit found that the PTAB’s findings were supported by substantial evidence and declined to reweigh the evidence as Novartis requested. *Id.* at 10-12.

This case highlights the different burdens of proof used in PTAB proceedings versus those in district court litigation. The preponderance of the evidence standard at the PTAB may be seen as an advantage for an accused infringer challenging a patent, and in this case, it seems to have given the accused infringer a successful second bite at the apple.