

INTELLECTUAL PROPERTY LITIGATION

Expert Analysis

## Federal Circuit May Decide Prior Art Estoppel Issue

In contemporary patent disputes after the passage of the America Invents Act, it is common for the same patent to be at issue in district-court litigation and in inter partes review (IPR) proceedings before the Patent Trial and Appeal Board at the same time. In principle, the PTAB and a judge or jury could reach opposite conclusions about the validity of the same patent, with the Federal Circuit resolving appeals from the litigation and the PTAB proceedings.

Anticipating this possibility, Congress enacted 35 U.S.C. §315(e)(2) as part of the AIA, estopping IPR petitioners from raising certain defenses in district court. The most common use of that estoppel provision has been to bar an unsuccessful IPR petitioner from later re-arguing in district court the same invalidity challenges that it lost before the PTAB.

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*Int'l Ltd. v. Amneal Pharm.*, No. 2019-1147 (Fed. Cir. 2018). Given the rate at which parallel proceedings move through the PTAB and the courts, a defendant might well find itself facing trial in court on a patent

that it successfully persuaded the PTAB to invalidate, as happened in *BTG*. Whether the defendant may assert at trial its previously successful arguments is an issue of importance to anyone considering commencing an IPR proceeding.

We report here on the pending appeal, providing guidance for practitioners.

### The Estoppel Provision

The AIA provides, in relevant part:

(e) Estoppel.—

...

(2) Civil actions and other proceedings.—The petitioner in an inter partes review of a claim in a patent under this chapter that results in a final written decision under section 318(a), or the real party in interest or privy of the petitioner, may not assert either in a civil action ... or in a proceeding before the International Trade Commission ... that the claim is invalid on any ground that the petitioner raised or reasonably

could have raised during that inter partes review.

35 U.S.C. §315(e)(2). Because IPR proceedings must be based on patents or printed prior art, the “ground[s]” that are covered by §315(e)(2) generally include prior-art-based defenses of anticipation and obviousness.

Section 315(e)(2) has most often been applied to bar prior-art-based defenses at trial where the defendant advanced those arguments in an IPR proceeding and lost. Some of the decisions addressing estoppel against a losing IPR challenger have described §315(e)(2) as applying to “unsuccessful” IPR petitions. See, e.g., *Milwaukee Elec. Tool v. Snap-On*, 271 F. Supp. 3d 990, 1027 (E.D. Wis. 2017) (“Section 315(e)(2) prohibits an unsuccessful IPR petitioner from asserting in the district court ‘that the claim is invalid on any ground that the petitioner raised or reasonably could have raised during that inter partes review.’”); *Depomed v. Purdue Pharma L.P.*, No. 13-571, 2014 WL 3729349 (D.N.J. July 25, 2014).

One district court case confronted the opposite situation, namely a trial against a defendant that had prevailed in its IPR challenge. See *SiOnyx v. Hamamatsu Photonics K.K.*, 330 F. Supp. 3d 574, 600 (D. Mass. 2018). By the time of the district court trial in *SiOnyx*, the PTAB had invalidated the patent but the Federal Circuit had not yet resolved the appeal from that decision. The trial court precluded the patent owner from raising at

the district court trial the prior-art-based defenses on which it had prevailed before the PTAB. The court reasoned that such estoppel would work no unfairness to the defendant, and indeed would have “no practical effect” at all, because “either (1) the Federal Circuit will affirm the PTAB’s decision, in which case the claims will remain unpatentable ... and there will be no reason for this court to address their validity” or “(2) it will reverse the PTAB’s decision, in which case the grounds defendants asserted will no longer be ‘successful’ grounds and defendants will be estopped from raising them in this lawsuit.” *Id.*

#### **‘BTG v. Amneal’ District Court And IPR Proceedings**

The court in the *BTG* case reached the opposite conclusion. There, Amneal and other generic-drug manufacturers commenced IPR proceedings challenging BTG’s patent on a method of treating prostate cancer with BTG’s Zytiga in combination with the steroid prednisone, and they prevailed. The PTAB held that the combination of those two therapies was obvious, and invalidated the patent. BTG requested rehearing of the PTAB’s decisions.

Meanwhile, while the rehearing request was pending, trial in New Jersey approached. BTG moved in limine to preclude the defendants from asserting at trial the prior-art-based defenses on which they had succeeded before the PTAB. The court denied the motion, holding

that §315(e)(2) estoppel does not apply to the defenses that had been successful before the PTAB, because that would compel the “absurd and unintended result” of “applying estoppel against the *victor* in an IPR.” Amneal Br. at 12 (emphasis in original).

After trial, the district court found *de novo* that the patent was obvious, essentially for the same reasons the PTAB had done so. On post-trial motions, the district court confirmed its in limine ruling, asserting that estoppel against a successful IPR challenger would “require a party to stand mute in court because it previously prevailed on the same issue before the PTAB” and “would be a decision reached without consideration of legally relevant facts and issues” such that the court “could find itself in the position of being required to enter an injunction against infringement based on a patent already found invalid.” *BTG Int’l Ltd. v. Amneal Pharm.*, No. 15-cv-5909, 2018 WL 5734626, at \*15 n.13 (D.N.J. Oct. 31, 2018).

#### **The Pending Appeal**

In the Federal Circuit, BTG argues that the district court should have precluded the defendants from asserting the obviousness of the patent under §315(e). BTG notes that the language of §315 does not say anything about the estoppel being limited to an unsuccessful challenger, whereas the pre-AIA estoppel for inter partes reexamination had expressly applied to

only unsuccessful challengers. See pre-AIA 35 U.S.C. §315(c). And BTG responded to the district court's concern about a successful challenger being required to "stand mute" in court as a defendant, by noting that the defendant would not have to stand mute; it could contest infringement and argue the invalidity of the patent for lack of written description, lack of enablement, anticipation by non-printed prior art such as a prototype, or any other invalidity defense that could not have been raised before the PTAB.

Amneal, for its part, argued that the word "estoppel" is generally understood to mean preclusion of an unsuccessful argument, and that §315(e) is entitled "Estoppel," and responded to BTG's assertions about pre-AIA provisions and legislative history. Amneal urged that §315(e)(2) "should be construed consistent with traditional collateral-estoppel principles," and that collateral estoppel "is a consequence of losing," not winning. Amneal Br. at 18. They argued that "No legislative history suggests that Congress intended to turn those traditional principles on their head and produce absurd results such as automatic injunctions against generic launch despite PTAB unpatentability findings." *Id.*

The Federal Circuit invited the United States Patent and Trademark Office to file an amicus brief addressing these issues, along with questions about when a PTAB decision becomes final where a reconsideration motion is pending.

Regarding the effect of §315(e)(2) on parties who prevail in an IPR challenge, the Patent Office agreed with BTG that "the plain language [of §315(e)(2)] makes no distinction between successful and unsuccessful petitioners" and "requires estoppel to attach when the proceedings result in a final written decision, regardless of whether a rehearing request remains outstanding." PTO Br. at 1–2. Thus, according to the PTO, "[i]f the petitioner has pursued an

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While the 'BTG' case remains pending and, if the Federal Circuit agrees with the Patent Office, thereafter, potential challengers will need to consider the possibility that they could face trial in court on a patent on which they have already prevailed before the PTAB, and would not be able to assert in that trial the printed-prior-art-based defenses on which they had prevailed.

inter partes review that resulted in a final written decision, the petitioner may not assert in district court ... any invalidity ground that was or reasonably could have been raised during the inter partes review, regardless of the *actual* outcome of that decision." *Id.* at 4 (emphasis in original). The Patent Office acknowledged that this reading of the statute "leads to the counterintuitive result that a district court would not be able to

consider invalidity arguments that the Board found persuasive," and suggested that the defendant could seek to stay the district court proceedings while the Federal Circuit resolved an appeal from the PTAB's IPR decision.

Oral argument is scheduled for March 14, 2019.

### Guidance for Practitioners

The decision to commence an IPR proceeding implicates not only the likelihood of success on the challenge but also the consequences for district court litigation. While the *BTG* case remains pending and, if the Federal Circuit agrees with the Patent Office, thereafter, potential challengers will need to consider the possibility that they could face trial in court on a patent on which they have already prevailed before the PTAB, and would not be able to assert in that trial the printed-prior-art-based defenses on which they had prevailed. They would, of course, be able to assert other defenses, and to contest infringement. And if their prior-art-based defenses were sufficiently central, or simply because of the efficiencies involved, they could ask the district court to stay proceedings while the appeal from the PTAB decision played out. The Patent Office's amicus brief provides support for that approach.