IP Alert: Which Patent Trial and Appeal Board Trial Decisions Cannot be Appealed?

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By Sarah A. Kagan

The U.S. Court of Appeals for the Federal Circuit heard oral arguments on March 6, 2018, in the appeal of Altaire Pharmaceuticals, Inc. v. Paragon Bioteck, Inc., 2017-1487, from the post grant review (PGR) decision of the U.S. Patent and Trademark Office (USPTO) Patent Trial and Appeal Board (PTAB). The panel was sympathetic to Altaire's position regarding the facts of the case ("The facts are on your side") and unsympathetic to Paragon Bioteck ("You got a patent on their product," "Your client's position…is at best predatory 'gotcha,'" "Paragon relied on the data of Altaire," and "The facts of the case cut your throat"). However, the judges also voiced concerns that they may not have the authority to decide the appeal due to Altaire's possible lack of standing.

The America Invents Act (AIA) set up new trial procedures within the USPTO, including PGR and inter partes reviews (IPR). The AIA permits almost any party to challenge a patent, whether or not the party has any relationship to the patent. The AIA also states that any party dissatisfied with the outcome of the PTAB trial can appeal to the Federal Circuit. 35 U.S.C. § 319 and 35 U.S.C. § 329. However,

the Federal Circuit cannot exercise its jurisdiction in an appeal if the appellant does not have standing, i.e., if no case or controversy exists between the parties, according to Article III of the U.S. Constitution. The case or controversy must be actual or imminent, not conjectural or hypothetical.

Altaire and Paragon have a frayed business relationship. Altaire manufactures a phenylephrine ophthalmic solution, which Paragon exclusively markets and distributes. Although Altaire had been manufacturing and selling the phenylephrine ophthalmic solution since 2000, it did so under an exemption from Food and Drug Administration (FDA) approval for grandfathered drugs. In 2011, Altaire decided to come under the FDA regulatory system and teamed up with Paragon to file a New Drug Application (NDA). Altaire supplied the technical information, and Paragon filed the NDA, which was granted.

The patent under review in the PGR, U.S. 8,859,623 ('623), issued from a patent application that was filed by Paragon alone. It claims a method of administering an ophthalmic composition having a certain initial chiral purity and stability, in which the ophthalmic composition is stored at a temperature of -10 °C to +10 °C and has a certain chiral purity when administered after storage. The only independent claim reads:

> 1. A method of using an ophthalmic composition for pupil dilation, the composition comprising R-phenylephrine hydrochloride having an initial chiral purity of at least 95% and an aqueous buffer, wherein the chiral purity of R-phenylephrine hydrochloride is at least 95% of the initial chiral purity after 6 months, the method comprising:
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> administering the composition into an eye of an individual in need thereof, wherein the composition is stored between -10 to 10 degree Celsius prior to administration, and wherein the composition comprises R-phenylephrine hydrochloride having a chiral purity of at least 95% when administered after storage.

Altaire filed, in addition to the petition for PGR of the '623 patent, two district court suits. In one suit, it seeks a declaratory judgment of invalidity and unenforceability of the '623 patent. In the other, it

alleges misappropriation of confidential information used in the ’623 patent. Paragon, in counterclaims, seeks to terminate the contract it has with Altaire.

What imminent injury to Altaire would give it standing and permit the Federal Circuit to decide the appeal? Altaire asserts four sources of harm in its brief: (1) it has concrete plans to submit an Abbreviated New Drug Application (ANDA) to the FDA, in response to which it expects Paragon to file suit against it for infringement; (2) its contract with Paragon expires in 2021, and may terminate even sooner if Paragon is successful in its counterclaim at the district court; (3) if the PTAB decision is not reversed, Altaire will face potential estoppel from pursuing any claim against the ’623 patent that it raised or could have raised in the PGR (under 35 USC 325(e)); and (4) it suffers reputational harm because it (or one of its employees) is not named as an inventor on the ’623 patent.

Paragon counters in its brief that Altaire’s fear of future harm is based on harm that is speculative and contingent. Such attenuated harm is insufficient to confer standing, Paragon urges. Paragon further argues that the alleged reputational harm is irrelevant because a PGR cannot remedy inventorship.

Altaire’s reply brief rebuts Paragon’s contention of only speculative and contingent harm to Altaire by pointing out that Altaire currently manufactures and sells an infringing product and has done so for years, even prior to the ’623 patent. This demonstrates concrete plans to commercialize even though it has not yet filed an ANDA. Altaire urges that the patent is a current impediment to its manufacture and sales to third parties, because it does not have a license from Paragon to the ’623 patent. Thus, the invalidation of the patent in the PGR would remove one obstacle to its broader commercialization. Altaire additionally argues that the existence of the patent changed the contractual relationship of the parties, because Paragon now has a cudgel with which to keep Altaire in the relationship. If Altaire breaches the contract by selling to third parties, it would face an infringement suit in addition to contract damages. Additionally, Altaire asserts that the harm of estoppel is more than merely speculative because Paragon has already sought dismissal of one of the two district

court cases based on PGR estoppel. Finally, Altaire urges that correcting the inventorship is not the only remedy for the reputational harm. Cancellation of all patent claims in the PGR would address the reputational harm.

During oral arguments at the Federal Circuit, Judge Schall repeatedly suggested that the court might wait to see how summary judgment motions are decided in the related district court litigation regarding contract termination. Judge O'Malley asked Altaire what would be left of its case for standing if the court did not believe its theory of reputational harm. The implications of this questioning are that Altaire's case for standing might be stronger if the contract were terminated and that its reputational harm theory may not have traction with the Court.

In response to questioning from Judge Schall, Altaire admitted that use of its product would contribute to or induce infringement of the '623 patent claims by the ultimate users. Not permitting its appeal from the PGR decision seems unfair to Altaire, as the judges seemed to express, because the same admittedly infringing product was allegedly sold by Altaire prior to the patent effective filing date. The court would need to find standing to remedy any unfairness.

The issue of standing to appeal from an IPR, like appeal from a PGR, has been raised in a number of cases.[1] So far, the Federal Circuit has decided two cases in which the outer bounds were set. The court in Consumer Watchdog v. Wisconsin Alumni Research Foundation, 753 F.3d 1258 (Fed. Cir. 2014) did not find standing for a public interest group that did not infringe or plan to infringe the challenged patent. The court in Phigenix, Inc., v. Immunogen, Inc., 845 F.3d 1168 (Fed. Cir. 2017), also did not find standing for a patent challenger that had no plans to take any action that would infringe the patent. Rather, the patent challenger asserted that the patent created business competition for its licensing business.

These cases do not suggest where the Federal Circuit might draw the line on imminent harm sufficient to provide standing. Similarly, the court has not decided whether estoppel will apply to a losing challenger in an IPR or PGR that tried to appeal but was found to lack standing to appeal.[2]

The court may use Altaire's appeal to help define the contours of standing to appeal from AIA trial decisions.

Click here to hear the oral arguments in Altaire Pharmaceuticals, Inc. v. Paragon Bioteck, Inc.

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[1] See, e.g., Momenta Pharmaceuticals, Inc. v. Bristol Myers Squibb Co. (Fed Cir. 17-1694) and our report of it here.

[2]The court may reach the estoppel issue in the Altaire appeal because Altaire asserted that the potential estoppel was an imminent harm.

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