

UPDATE

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ONE SHOT AND YOU ARE OUT AT THE PTAB



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Most judicial determinations come with a right to appeal, and indeed, we expect a right to appeal when we receive an unfavorable decision in any aspect of our lives. Yet the new trial proceedings at the United States Patent and Trademark Office set up by the America Invents Act (AIA) leave certain dissatisfied patent challengers without any effective recourse to appeal. Parties such as public interest organizations and hedge-fund operators are particularly affected, because they have a less direct interest in invalidating a patent than a classic patent challenger in federal court proceedings.

The AIA permits almost any party, whether or not the party has any relationship to a patent, to challenge the patent before the U.S. Patent and Trademark Office’s Patent Trial and Appeal Board (PTAB). A challenger may employ procedures including post-grant reviews (PGR) and *inter partes* reviews (IPR). The AIA states that any party dissatisfied with the outcome of the PTAB trial can appeal to the U.S. Court of Appeals for the Federal Circuit. 35 U.S.C. § 319 and 35 U.S.C. § 329. These provisions are similar to those set up for pre-AIA *inter partes*

reexamination (IPRE). Pre-AIA 35 U.S.C. § 315(a), (b). Historically, appeals from the PTAB have been made to the Federal Circuit. However, the Federal Circuit cannot exercise its jurisdiction in an appeal of a PTAB decision 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. Thus, a third party may challenge a patent at the PTAB but may not necessarily be able to appeal an adverse decision at the Federal Circuit, despite the expansiveness of § 319 and § 329.

The Federal Circuit has already decided a handful of cases relating to permissible parties in appeals from the PTAB. It has heard oral arguments in other cases within the last few months that it will soon decide. These decisions will influence not only who will appeal PTAB decisions, but also who will bring the original actions in the PTAB, and when they will bring them.

DECIDED CASES

The handful of cases that the Federal Circuit has decided involve challengers who are not in direct competition with the patent holder.

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Such challengers have been non-profit organizations who do not themselves compete with the patent owner and a for-profit company that indirectly competed with the patent owner in the same business sector but did not compete over the same product.

NON-PRACTICING ENTITIES

Non-practicing entities are often termed “trolls” in the patent litigation context. These entities sue third parties for infringement of the non-practicing entities’ patent rights. Non-practicing entities have gotten a bad reputation because they do not commercially exploit their patent rights, but extract a royalty from parties that are commercially practicing. In the IPR context, non-practicing entities challenge others’ patents, either to clear commercial space for its members’ individual efforts, to manipulate stock prices, or to accomplish some political goal. So far, these reasons have been deemed too attenuated to permit appeal.

Consumer Watchdog v. Wisconsin Alumni Research Foundation

Consumer Watchdog tried to invalidate a patent of the Wisconsin Alumni Research Foundation using an *inter partes* reexamination. (753 F.3d 1258 (Fed. Cir. 2014)). Like the IPR statute, the reexamination statute “allowed” a third party requester to appeal adverse decisions. Nonetheless, the court found that Consumer Watchdog, a not-for-profit public charity, lacked a particularized, concrete stake in the outcome of the appeal, and thus had no Article III case or controversy with the patent owner. The court also found that the estoppel provision for *inter partes* reexaminations did not constitute injury in fact, as any injury that could result from estoppel was only conjectural or hypothetical for Consumer Watchdog as a non-practicing entity. However, the court

refrained from precluding future use of the estoppel provisions to show injury in an appropriate case.

Phigenix, Inc. v. Immunogen, Inc.

Phigenix, Inc. v. Immunogen, Inc. arose out of an IPR. (845 F.3d 1168 (Fed. Cir. 2017)). Phigenix was not a manufacturer of a product but a developer of an intellectual property portfolio. It argued that the PTAB’s failure to invalidate the patent-in-suit would increase Phigenix’s competition for licensing its own properties, constituting an actual economic injury. The appellate court held that Phigenix had not proved that it was subject to any actual or imminent injury. Moreover, it was not engaged in any activity that would give rise to a possible infringement suit, so the estoppel provision does not cause any foreseeable harm.

Personal Audio, LLC v. Electronic Frontier Foundation

The Federal Circuit in *Personal Audio, LLC v. Electronic Frontier Found.*, found that the non-practicing entity, Electronic Frontier Foundation (EFF), could participate in the appeal. (867 F.3d 1246 (Fed. Cir. 2017)). Even though EFF was a third party petitioner in an IPR, and a non-practicing entity, it was not the appellant but rather the appellee. Since the patent owner, Personal Audio, had appealed and had standing by virtue of the negative decision of the PTAB regarding its patent, Article III was satisfied. Once standing was satisfied for the party bringing the case to the court, the participation of EFF as the appellee did not offend Article III.

PRACTICING ENTITIES

Practicing entities are typically those that make, use, or sell a patented invention. If they do not own the patent at issue or have a license to it, then they are at risk of suit for

infringement. These are entities that could likely challenge a patent in district court; but because the PTAB provides a more economical and faster venue, they have chosen to use it as a venue. The questions around these parties seem to hang on just how close to qualifying as declaratory judgment plaintiffs these parties need to be.

PPG Industries, Inc. v. Valspar Sourcing, Inc. *PPG Industries, Inc. v. Valspar Sourcing, Inc.*, like *Consumer Watchdog*, arose out of an *inter partes* reexamination. (679 Fed.Appx. 1002 (Fed. Cir. 2017)). The Federal Circuit found that the third party reexamination petitioner fulfilled the Article III requirements to appeal, based on two types of evidence. First, PPG had launched a commercial enterprise (which arguably infringed the challenged patents). Second, a customer of PPG's informed it that Valspar intended to sue PPG for infringement based on that commercial enterprise. These two types of evidence provided a particularized, concrete stake in the outcome of the reexamination. The court also held that the stake was "enhanced" by the potential estoppel.¹

Altaire Pharmaceuticals, Inc. v. Paragon Biotech, Inc.

Altaire Pharmaceuticals, Inc. v. Paragon Biotech, Inc., arose as an appeal from a post grant review (PGR) decision of the PTAB. (889 F.3d 1274 (Fed. Cir. 2018)).

Altaire manufactures a phenylephrine ophthalmic solution, which Paragon exclusively markets and distributes under contract. The patent under review in the PGR, U.S. 8,859,623 ('623), issued from a patent application that was filed by Paragon. It claims a method of administering an ophthalmic composition having a certain initial chiral purity and stability, in which the ophthalmic composition is stored within a certain temperature range and has a certain chiral

purity when administered after storage. The PTAB found that Altaire had not sustained its burden to show that Paragon's patent was not patentable.

Altaire was not under immediate threat of suit by Paragon for infringement because it only sells to Paragon under the exclusive marketing and distribution contract. However, on appeal Altaire asserted that it had Article III standing based on four sources of harm: (1) its contract with Paragon expires in 2021, and may terminate even sooner if Paragon is successful in a separate district court suit, threatening Altaire's ongoing business; (2) it has concrete plans to submit an Abbreviated New Drug Application (ANDA) to the U.S. Food and Drug Administration (FDA), in response to which it expects Paragon to file suit against it for infringement; (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.

The Federal Circuit found Altaire had demonstrated injury based on reasons (1) and (2). The court found that the injury was imminent and not merely contingent on future possible events. It further found that estoppel (reason (3)) compounds the injury, even though estoppel on its own is not sufficient to create injury sufficient for standing.

CASE TO BE DECIDED

Momenta Pharmaceuticals, Inc. v. Bristol-Myers Squibb Co.

The Federal Circuit heard arguments on December 5 in *Momenta Pharmaceuticals, Inc. v. Bristol-Myers Squibb Co.* (No. 17-1694).

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Momenta used the IPR procedure to challenge Bristol-Myers Squibb's patent covering a formulation of ORIENCIA® (abatacept) for treating rheumatoid arthritis. Momenta failed to persuade the PTAB that Bristol-Myers Squibb's claims were obvious. Momenta appealed the decision to the Federal Circuit under 35 U.S.C. § 319.

In its Federal Circuit appeal, Momenta asserts that it suffers individualized, concrete harm sufficient to establish Article III injury in fact. It bases its position on costs incurred in developing its current drug candidate, costs it would incur should it need to alter its business plan to use a non-infringing alternative, and the estoppel provision (35 U.S.C. § 315(e)) for IPRs. Momenta urges that prior appeals from rulings of other administrative agencies found injury when an economic harm was reasonably probable or highly likely. It also cites cases where business competitors are presumed to be harmed if their competitors are benefited.

Bristol-Myers Squibb asserts that Momenta, like Consumer Watchdog and Phigenix, has not suffered a concrete and particularized injury from the PTAB's decision not to revoke the Bristol-Myers Squibb patent. Momenta has no product on the market, no product approved for the market by the FDA, and no product that has passed the three phases of clinical testing. Momenta is merely requesting an advisory opinion, Bristol-Myers Squibb asserts.

CONCLUSION

The issue of standing to appeal from a PTAB final written decision creates interesting procedural issues for the Federal Circuit. Usually the Federal Circuit functions solely as an appellate body, reviewing decisions of courts and agencies that have already weighed and sifted the evidence to determine the facts. However, appeals from the PTAB may raise issues of Article III standing that were not relevant below, and for which the record contains no evidence. The Federal Circuit must decide when the evidence will be submitted. It must also decide how and when it will consider the evidence. So far, the court has requested that challenges to standing be raised in the main brief of the party raising it, rather than holding a preliminary hearing or separate briefing.

Substantively, the court has decided two cases in which non-practicing entities failed to demonstrate standing to appeal. In two other cases, involving practicing entities, standing was found where the appellant submitted evidence of threat of suit. The case currently under consideration by the Federal Circuit will likely define whether the court will adopt a standard for PTAB appeals similar to that required for filing a declaratory judgment or perhaps some relaxed standard. ■

¹ Ultimately, the appeal was dismissed as moot, and the PTAB decisions were vacated, because the patentee, Valspar, unilaterally gave PPG a Covenant Not to Sue.