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Expert Analysis

Guidance May Be Coming on Article III Standing to Appeal PTAB Decisions

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To sue in federal court, a plaintiff must meet the standing requirements of the Case or Controversy Clause of Article III of the Constitution. Foremost among these requirements is that the plaintiff must have suffered an injury in fact. This constitutional minimum requirement applies not only when one private party sues another but also when a private party seeks appellate-court review of a final administrative agency action, including, as relevant here, appeals from decisions of the Patent Trial and Appeal Board.

A challenger need not, however, suffer injury in fact in order to challenge the validity of a patent before the PTAB itself.

The question then arises of how, if at all, a non-injured party that challenges a patent before the PTAB and loses may then demonstrate Article III standing to appeal to the federal courts from the PTAB's decision upholding the patent's validity. We report here on two pending appeals—one at the Supreme Court and one at the Court of Appeals for the Federal Circuit—that may soon answer this question. See *RPX v. ChanBond*, No. 17-1686 (U.S.); *Momenta Pharm. v. Bristol-Myers Squibb Co.*, No. 2017-1694 (Fed. Cir.).

> In 'RPX', the Supreme Court may decide whether the statutes that created Inter Partes Review proceedings before the PTAB implicitly created standing to challenge IPR denials in the federal courts.

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The Article III Standing Requirement

The standing doctrine "limits the category of litigants empowered to maintain a lawsuit in federal court to seek redress for a legal wrong." *Spokeo v. Robins*, 136 S. Ct. 1540 (2016). The "'irreducible constitutional minimum' of standing consists of three elements. The plaintiff must have (1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." Id. at 1547 (citations omitted).

"First and foremost" is injury in fact, which requires the plaintiff to show "that he or she suffered 'an invasion of a legally protected interest' that is 'concrete and particularized' and 'actual or imminent, not conjectural or hypothetical.'" Id. at 1548.

Notably, where a party that was not required to demonstrate standing in an agency proceeding then seeks judicial review of a final agency action, that party may "submit additional

evidence" of standing "to the court of appeals by declaration or other evidence." *RPX*, No. 2017-2346, slip op. at 3 (Fed. Cir. Jan. 17, 2018) (non-precedential).

'RPX v. ChanBond'

In *RPX*, the Supreme Court may decide whether the statutes that created Inter Partes Review proceedings before the PTAB implicitly created standing to challenge IPR denials in the federal courts.

RPX describes its "core business" as "acquiring patent rights on the open market and in litigation to achieve peaceful resolution of patent disputes." Id. at 2. RPX then began a "new business initiative" to "challeng[e] weak patents through" Inter Partes Review, and petitioned for such review of a patent held by ChanBond. Id. After a trial, the PTAB held that RPX had not proven that ChanBond's patent was invalid. RPX appealed to the Federal Circuit.

The Federal Circuit granted ChanBond's motion to dismiss RPX's appeal, holding that RPX lacks Article III standing because ChanBond had not accused RPX of infringement and RPX had not established any alternative basis to find that "a concrete and particularized harm will occur." Id. at 6.

As may prove relevant in the Supreme Court, RPX offered three arguments for why it suffered sufficient injury in fact: (1) injury to its "statutory right to compel cancellation of claims on unpatentable inventions"; (2) injury to its "standing relative to competitors"; and (3) injury to its "reputation of successfully challenging wrongfully issued patent claims." Id. at 4-6.

The Federal Circuit rejected the first argument—that a patent challenger has a statutory right to invalidate inappropriately issued patents—based on a prior case, *Consumer Watchdog v. Wisconsin Alumni Research Foundation*, which held that a statute creating a different Patent Office procedure to challenge patents "did not guarantee a particular outcome favorable to the requestor." 753 F.3d 1258, 1262 (Fed. Cir. 2014). By extension, "RPX was 'permitted to request [review] and participate once the PTO granted its request. That is all the statute requires." Slip op. at 4 (quoting *Consumer Watchdog*, 753 F.3d at 1262 (alteration in original)). The Federal Circuit then found RPX's evidence insufficient to support its competition- and reputation-based standing arguments, holding that "RPX has not demonstrated that the Board's determination increased or aids the competition in the market of the nondefendant IPR petitioners" and that an RPX's senior executive "concede[d] that he is 'unable to quantify the reputational and economic harm' caused by the Board's decision." Slip op. at 5, 6.

In petitioning for a writ of certiorari, RPX abandoned its claim of injury in fact based on patent-inflicted injuries, see 2018 WL 3778563, at *9, and argued instead that the Inter Partes Review statutory framework itself confers standing. RPX argues that "Congress has specified by statute *bases* for RPX's injury in fact by creating private rights, the invasions of which constitute injuries in fact," id. at *10, and that such injuries "are both concrete and particularized." Id. at *11. Further, RPX argues that in creating a right of appeal to the Federal Circuit, "Congress intended for any party dissatisfied with a final decision to be able to appeal." Id. at *15.

ChanBond opposed RPX's petition in part by arguing that RPX waived its "primary statutory argument" by failing to raise it in the Federal Circuit. 2018 WL 4043313, at *12.

On Oct. 1, 2018, the court called for the views of Solicitor General. RPX's petition remains pending.

'Momenta v. BMS'

In *Momenta*, the Federal Circuit may soon decide when a putative competitor has standing to appeal from a PTAB decision rejecting its Inter Partes Review challenge.

Momenta is—or, at a minimum, at relevant times has been—developing a biologic product that is purportedly biosimilar to BMS's rheumatoid arthritis drug Orencia, which is claimed in a BMS patent. Momenta challenged that patent in an IPR, and the PTAB upheld

the patent as valid. Momenta appealed to the Federal Circuit. BMS moved to dismiss Momenta's appeal, alleging that Momenta lacks Article III standing. The Federal Circuit denied that motion without prejudice, directing the parties to brief standing as part of the merits of the appeal.

In opposing BMS's motion to dismiss, Momenta argued that it "is an established biotechnology company" that has "invested substantial time and resources to develop a biosimilar to BMS's" Orencia product, 2017 WL 3007595, at *15, including preparing "test batches" of the biosimilar product for a Phase I clinical trial, id. at *16. Momenta advanced three injuries in fact that it claims are caused by the adverse PTAB ruling: (1) current economic harm from altering its development plans, including potentially changing the formulation of its proposed biosimilar; (2) future economic harm from a patent infringement suit by BMS; and (3) harm in competing against BMS, because changing the formulation "would decrease Momenta's ability to obtain fast regulatory approval and grant BMS more time to build a dominant market position." Id. at *53-57. Momenta sought to distinguish itself from parties previously found to lack Article III standing, such as the "public interest group with a policy interest in narrowing patent rights" in *Consumer Watchdog*, and the "non-practicing licensing entity" in *Phigenix v. Immunogen*, 845 F.3d 1173 (Fed. Cir. 2017). 2017 WL 3007595, at *57-58.

BMS argued that Momenta did not have standing because Momenta had not yet filed its Biologics License Application with the Food & Drug Administration, and the filing of that BLA is, according to BMS, a prerequisite for infringement under the Biologics Price Competition and Innovation Act. See 2017 WL 4239102, at *23. BMS argued that a finding of injury in fact before a BLA is filed would "threaten a flood of appeals from IPR decisions by third-parties seeking an early avenue to federal court through uncertain future interests." Id. at *37. BMS also argued that "Momenta alleges only generalized and attenuated economic injuries" that are "hypothetical, not concrete, and based on a series of contingent events that may not occur." Id. at *1, *31.

While we await decisions, would-be IPR filers concerned about preserving their ability to appeal an adverse PTAB decision may wish to consider the relationship between the timing of the IPR and the onset of potentially infringing conduct.

Notably, on Oct. 1, 2018 Momenta informed the Federal Circuit that it "has initiated discussions with its collaboration partner, Mylan, to exit its participation in the development of" its proposed Orencia biosimilar. No. 17-1694, D.I. 98. On Oct. 23, 2018, the Federal Circuit ordered Momenta to show cause within ten days "why the appeal should not be dismissed as moot" in view of Momenta's potential discontinuance of development of its proposed biosimilar. D.I. 100. On Nov. 2, 2018, Momenta responded that the appeal is not moot because Momenta has not yet discontinued development of its proposed biosimilar. D.I. 102 at 2. Further, according to Momenta, the appeal will not be mooted even if Momenta does discontinue its involvement in development, because Momenta will receive a reasonable royalty on sales of any Mylan-developed Orencia biosimilar. Id. at 3.

Guidance for Practitioners

While we await decisions, would-be IPR filers concerned about preserving their ability to appeal an adverse PTAB decision may wish to consider the relationship between the timing of the IPR and the onset of potentially infringing conduct, and would-be IPR filers intending to rely on economic and reputational harm to support Article III standing may wish to develop an evidentiary record establishing those harms through particularized testimony.