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Standing on Shaky Ground: Continued Uncertainties for Appellants of Failed IPR Challenges

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In *Momenta Pharmaceuticals, Inc. v. Bristol-Myers Squibb Co.*,[1] the Federal Circuit denied standing to the petitioner of a failed inter partes review ("IPR") challenge. Momenta had been developing a biosimilar to the Bristol-Myers Squibb ("BMS") brand name drug Orencia (abatacept) and challenged claims of a BMS patent.[2] After the Patent Trial and Appeal Board ("PTAB") sustained patentability, Momenta appealed to the Federal Circuit.[3] While waiting for the court to issue its order as to standing and possibly the merits of the appeal, Momenta terminated development of its Orencia biosimilar.[4] As a result, the court concluded that Momenta no longer had potential for injury and the inquiry was mooted.[5] The case law on standing when appealing an IPR decision continues to highlight legal imbalances and raises questions as to the interplay between standing and FDA filings for drug products.

This case involves U.S. Patent No. 8,476,239 ("the '239 patent"), titled "Stable protein formulations." More specifically, the '239 patent claims stable formulations of the CTLA4Ig protein for subcutaneous administration comprising sugar and other ingredients.[6] CTLA4Ig is a fusion protein comprising the extracellular portion of cytotoxic T-lymphocyte antigen 4 ("CTLA4") and an immunoglobulin ("Ig") constant region.[7] The CTLA4Ig fusion protein functions to block antigen-presenting cells from activating T cells.[8] This feature enables therapeutic use for immune disorders.[9] The CTLA4Ig fusion protein is the active component of BMS's commercial product, Orencia (abatacept),[10] which is approved to treat adult rheumatoid arthritis, juvenile idiopathic arthritis, and adult psoriatic arthritis.[11] The '239 patent covers the subcuta-

[1] 915 F.3d 764 (Fed. Cir. 2019).
[2] *Id.* at 766.
[3] *Id.*
[4] *Id.* at 767.
[5] *Id.* at 770.
[6] '239 patent claims at 55:16–56:37.
[7] '239 patent at 7:15–22; Behzad Rowshanravan et al., *CTLA-4: A Moving Target in Immunobiology*, 131 Blood 58–67, 58 (2018).
[8] '239 patent at 3:45–46, 56–60.
[9] '239 patent at 3:46–52; *see also Momenta*, 915 F.3d at 766.
[10] Bristol-Myers Squibb Co., Orencia Prescribing Information 6 (Jun. 2017) [hereinafter "Orencia Information"]; '239 patent at 7:56–57.
[11] Orencia Information at 1.

neous formulation of Orencia.[12] Momenta had partnered with a collaborator, Mylan, to develop a biosimilar to Orencia and clinical trials of the biosimilar had begun by 2017.[13]

In July 2015, Momenta petitioned for IPR of the '239 patent.[14] The PTAB instituted the IPR and ultimately sustained patentability.[15] Momenta challenged all fifteen of the claims of the '239 patent as being obvious over a combination of three pieces of art that were not the sources of rejections during prosecution of the '239 patent.[16] The PTAB determined that Momenta had not established by a preponderance of the evidence that an ordinary artisan "would have had a reasonable expectation of success in formulating CTLA4Ig as a stable liquid formulation as recited in the challenged claims."[17]

In February 2017, Momenta appealed the PTAB decision to the Federal Circuit under 35 U.S.C. § 319.[18] BMS argued that Momenta lacked standing to invoke federal court jurisdiction and moved to dismiss the appeal.[19] On November 1, 2017, Momenta announced that its Orencia biosimilar had not met its desired endpoints in a Phase I clinical trial.[20] The court heard arguments on standing and on the merits in December 2017. Months later, on October 1, 2018, Momenta informed the court that it was discussing termination of the biosimilar program.[21] On December 6, 2018, Momenta publicly announced the end of development for its Orencia biosimilar.[22]

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[12] *Momenta*, 915 F.3d at 766.

[13] Non-Confidential Appellant's Opposition to Motion to Dismiss for Lack of Jurisdiction at 2–3, *Momenta*, 915 F.3d 764 (No. 2017-1694).

[14] *Momenta*, 915 F.3d at 766.

[15] *Momenta*, 915 F.3d at 765.

[16] Momenta Pharm., Inc. v. Bristol-Myers Squibb Co., No. IPR2015-01537, 2016 WL 7987985, *2–3 (P.T.A.B. Dec. 22, 2016).

[17] *Momenta*, No. IPR2015-01537 at 1, 15, 2016 WL 7987985, at *1, *15.

[18] *Momenta*, 915 F.3d at 766; Petitioner's Notice of Appeal at 3, *Momenta*, 915 F.3d 764.

[19] *Momenta*, 915 F.3d at 766.

[20] Press Release, *Momenta Pharmaceuticals, Momenta and Mylan Report Initial Results from Phase 1 Clinical Trial for M834, a Proposed Biosimilar of ORENCIA® (abatacept)* (Nov. 1, 2017), available at http://ir.momentapharma.com/news-releases/news-release-details/momenta-and-mylan-report-initial-results-phase-1-clinical-trial (last accessed Mar. 11, 2019).

[21] Rule 28(j) Letter regarding Momenta October 1, 2018 Press Release at 1, *Momenta*, 915 F.3d 764.

[22] *Momenta*, 915 F.3d at 767; Momenta Pharmaceuticals, Inc., Report of unscheduled material events or corporate event (Form 8-K), at 35 (Dec. 6, 2018).

Writing for a unanimous panel, Judge Newman concluded that Momenta did not have standing and that the appeal was mooted by Momenta's "discontinuance of any potentially infringing activity."[23] Citing Supreme Court and Federal Circuit precedent on Article III standing, the court stated that although statutory procedural rights from Congress may relax Article III requirements, injury in fact is a necessary showing even for juridical review of agency action.[24]

Analyzing whether it suffered an injury in fact, the court concluded that Momenta's financial investment in developing the Orencia biosimilar was not sufficient to maintain the action after terminating the program.[25] Likewise, the estoppel provision in 35 U.S.C. § 315(e) did not suffice as an injury in fact because Momenta was not engaged in an activity that would potentially give rise to an infringement suit.[26] Potential future royalty payments from a collaborator was too speculative to support standing.[27] And unlike the appellant in *E.I. DuPont de Nemours & Co. v. Synvina C.V.*,[28] to whom the court did grant standing, Momenta did not have "concrete plans" for activity that created substantial risk of future infringement.[29] Additionally, regardless of Momenta's admitted engagement in infringing activity at the time the proceedings began, the inquiry was now moot.[30] With the end of potential infringement by Momenta, it no longer had potential for injury.[31]

Under the statutes governing IPRs, "[a] party dissatisfied with the final written decision" of the PTAB may appeal to the Federal Circuit.[32] However, parties before federal courts must meet the Article III case or controversy requirement. Because any "person who is not the owner of the patent"[33] can petition to institute an IPR, the population of peti-

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[23] *Momenta*, 915 F.3d.at 770.

[24] *Momenta*, 915 F.3d at 767–68.

[25] *Id.* at 768.

[26] *Id.* at 768–69. Under 35 U.S.C. § 315(e)(2), if an IPR results in a final written decision, the petitioner cannot subsequently assert in a civil action an invalidity argument "on any ground that the petitioner raised or reasonably could have raised" during the IPR.

[27] *Id.* at 769.

[28] 904 F.3d 996 (Fed. Cir. 2018).

[29] *Id.* at 769–70.

[30] *Id.* at 770.

[31] *Id.*

[32] 35 U.S.C. § 319.

[33] 35 U.S.C. § 311(a).

tioners in front of the PTAB who could be dissatisfied is much broader than the population that could have standing to appeal to the Federal Circuit.[34] The law thus creates an asymmetry between the parties—a patent owner whose patent was successfully challenged by IPR has standing to appeal to the Federal Circuit, whereas a petition whose challenge was unsuccessful may not have standing to appeal.[35] Although there are factual situations that would grant a petitioner standing at the Federal Circuit, the court has not generated many categorical rules. One way to satisfy the injury-in-fact requirement for standing is for a party to show that it has concrete plans to engage in activity with substantial risk of infringing the patent at issue.[36] Outstanding questions remain as to lines that could be drawn to establish injury in fact by potential patent infringement.

First, it is unclear how much a party must commit to future, potentially infringing activity in order to support a finding of injury in fact. When assessing the case or controversy requirement in a declaratory judgment action, the Federal Circuit has eschewed a bright-line test and instead has analyzed "all the circumstances" to determine if the case was of sufficient immediacy and reality.[37] In *Sandoz Inc. v. Amgen Inc.*,[38] Sandoz was developing a biosimilar to Amgen's rheumatoid arthritis drug Enbrel (etanercept) and had filed for a declaratory judgment related to Amgen's patents before filing its biosimilar license application with the FDA.[39] Given the unpredictability of clinical trial results, the court was

[34] *Momenta*, 915 F.3d.at 768 (noting that the case or controversy restrictions do not apply to administrative agencies and that IPR petitioners may lack constitutional standing) (citing Ritchie v. Simpson, 170 F.3d 1092, 1094 (Fed. Cir. 1999) and Cuozzo Speed Technologies, LLC v. Lee, 136 S.Ct. 2131, 2143–44, (2016)); *see also* Stephanie Goldberg, Note, *Third Party Standing at the Federal Circuit: A Patent Challenge Disparity*, HARV. J.L. & TECH. DIG. (2019), jolt.law.harvard.edu/digest/third-party-standing-at-the-federal-circuit-a-patent-challenge-disparity (discussing the standing doctrine applied to appeals to the Federal Circuit from third-party PTAB petitioners).

[35] In a similar case, petitioner JTEKT was denied standing to appeal an IPR at the Federal Circuit and recently filed a petition for writ of certiorari. The question presented by JTEKT is whether the Federal Circuit can refuse to hear appeal from the petitioner of an adverse IPR decision for lack of injury in fact, in light of the statutorily created right to appeal. Petition for Writ of Certiorari at i, JTEKT Corp. v. GKN Automotive Ltd., No. 18-750 (Dec. 7, 2018).

[36] JTEKT Corp. v. GKN Auto. LTD., 898 F.3d 1217, 1220 (Fed. Cir. 2018).

[37] Sandoz Inc. v. Amgen Inc., 773 F.3d 1274, 1277 (Fed. Cir. 2014) ("The inquiry, focused on the combination of immediacy and reality, involves no bright-line test.") (citing MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118, 127 (2007)).

[38] 773 F.3d 1274 (Fed. Cir. 2014).

[39] *Id.* at 1276. Sandoz filed for declaratory judgment of non-infringement of two Amgen patents and that both patents were unenforceable and invalid. *Id.*

hesitant to grant standing in the absence of an FDA filing.[40] The court's concern in *Sandoz*—that any dispute about patent infringement was at the time "subject to significant uncertainties"[41]—came to fruition in *Momenta*. Would a declared intent to file with the FDA be sufficient to show injury in fact? Under *Sandoz* in a declaratory judgment context, one would expect not. However, in *Altaire Pharm., Inc. v. Paragon Bioteck, Inc.*,[42] which involved a failed post grant review challenge, the court found that Altaire had demonstrated injury in fact by showing a declared intent to file a drug application, a concurrent action seeking declaratory judgment of invalidity, and the patent owner's refusal to stipulate that it would not sue for infringement.[43] Although in *Momenta* the Federal Circuit did not decide that an FDA filing would be necessary for standing in an appeal of an IPR, its conclusion points in that direction.

Second, it is also not clear how detailed a party would have to describe their potentially infringing activity in order to demonstrate injury in fact. In *DuPont*, DuPont provided details on how its activity could support a claim of infringement of Synvina's patent, laying out specifics as to its activity related to the patent claims to show injury in fact.[44] How much particularity would be required to show a "substantial risk" of future infringement? Perhaps for drug products the potential infringement bar would be lower than for the chemical technology in *DuPont*.[45] Potential infringers developing drug products would necessarily file with the FDA before products entered the market, and filing with the FDA is statutorily defined as an act of infringement in the context of biosimilars or generic drugs.[46] Outside the drug and medical device context, a petitioner on appeal may need to lay out how closely their activities align with a competitor's patent claims, another requirement that is not included in 35 U.S.C. § 319.

The *Momenta* decision did not clarify when to file IPRs in conjunction with product development and FDA filings, as had been expected

[40] *See id.* at 1281 and cases cited therein.

[41] *Id.* at 1280.

[42] 889 F.3d 1274, 1283 (Fed. Cir. 2018), *remand order modified by stipulation*, 738 F. App'x 1017 (Fed. Cir. 2018).

[43] *Altaire*, 889 F.3d at 1282–83.

[44] *DuPont*, 904 F.3d at 1004.

[45] The patent at issue in *DuPont* relates to methods of generating a chemical useful for "green" chemistry. *DuPont*, 904 F.3d at 999.

[46] 35 U.S.C. § 271(e)(2).

by practitioners.[47] Instead, the decision has left uncertainty in demonstrating injury in fact as an unsuccessful IPR petitioner and continued party asymmetry for IPR appeals. Also of note is that Momenta's termination of the biosimilar development occurred ten months after oral arguments related to standing and to the merits. Given how heavily the decision rested on Momenta's subsequent activities, if the court had issued its opinion earlier, the result may have been different. Meanwhile, BMS reported revenue of $2.7 billion from Orencia in 2018, about $1.9 billion of which was from the U.S.[48] The U.S. composition of matter patent covering Orencia expires in 2019,[49] the method of use patents expire in 2021,[50] and there are no known credible biosimilars in the clinical stages of development. ■

[47] Lewis R. Clayton & Eric Alan Stone, *Supreme Court and Federal Circuit May Soon Provide Further Guidance on Article III Standing to Appeal PTAB Decisions*, N.Y. L.J. (Nov. 13, 2018), https://www.law.com/newyorklawjournal/2018/11/13/supreme-court-and-federal-circuit-may-soon-provide-further-guidance-on-article-iii-standing-to-appeal-ptab-decisions/; Scott McKeown, *BPCIA & FDA Steps as Article III Standing from the PTAB?*, Patents Post Grant (Feb. 7, 2019), https://www.patentspostgrant.com/bpcia-fda-steps-article-iii-standing-ptab/.

[48] Bristol-Myers Squibb Co., Annual Report (Form 10-K), at 35 (Feb. 25, 2019).

[49] Bristol-Myers Squibb Co., Annual Report (Form 10-K), at 7 (Feb. 13, 2018).

[50] Bristol-Myers Squibb Co., Annual Report (Form 10-K), at 5 (Feb. 25, 2019).