THE FEDERAL CIRCUIT DISMISSES BIOSIMILAR PETITIONER'S IPR APPEAL FOR LACK OF STANDING DUE TO MOOTNESS

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In *Momenta Pharmaceuticals, Inc. v. Bristol-Myers Squibb Company*,[1] the Federal Circuit dismissed a biosimilar petitioner's appeal of an adverse inter partes review ("IPR") decision for lack of standing. In dismissing the appeal, the Federal Circuit relied on the doctrine of mootness, holding that Momenta Pharmaceuticals, Inc. ("Momenta") lost its standing to sue when it had, during the pendency of the IPR, abandoned development of its biosimilar.

BACKGROUND

Momenta centers on Bristol-Myers Squibb Company's ("BMS") patent on specific fluid formulations of the active immunosuppressive agent in BMS's rheumatoid arthritis medication ORENCIA®. In July 2015, while developing a biosimilar to ORENCIA®, Momenta petitioned the U.S. Patent and Trademark Office for *inter partes* review of BMS's patent under the post-grant review provisions of the America Invents Act (the "AIA").[2] The Patent Trial and Appeal Board ("PTAB") instituted review and ultimately sustained patentability of BMS's patent.[3] Thereafter, Momenta filed an appeal to the Federal Circuit.

BMS moved to dismiss the appeal for lack of standing because Momenta had withdrawn its proposed biosimilar product after failed Phase 1 clinical trials.[4] Specifically, BMS pointed to:

1. a press release in which Momenta had announced its initiation of "discussions with its collaboration partner, Mylan, to exit its participation in the development of . . . [its] proposed biosimilar to ORENCIA®" in favor of refocusing on the development of other products;[5] and
2. a subsequent Preliminary Prospectus Supplement and Form 9-K filed by Momenta with the Securities Exchange Commission stating that it had "elected to terminate [its] collaboration with Mylan with respect to the development of . . . [its] proposed biosimilar to ORENCIA®."[6]

In opposition to BMS's motion to dismiss the appeal, Momenta argued that it had not abandoned its intent to produce a biosimilar to ORENCIA®, that BMS's patent was an obstacle to Momenta, and that the AIA's estoppel provision would preclude Momenta from asserting invalidity of BMS's patent in future litigation. Combined with its continued interest in potential future royalties should Mylan decide to produce an ORENCIA® biosimilar, Momenta argued that these facts constituted an injury-in-fact sufficient to establish standing.[7]

THE FEDERAL CIRCUIT'S STANDING ANALYSIS

The Federal Circuit panel unanimously sided with BMS, dismissing Momenta's appeal for lack of standing under the doctrine of mootness.[8] The panel relied on several Federal Circuit cases applying principles of standing to appeals from PTAB decisions. The court cited *Consumer Watchdog* and *Phigenix* for the proposition that a "possible future economic interest," as opposed to a "particularized or personal interest," is insufficient to establish standing.[9] The court contrasted such situations with instances where a petitioner has "concrete plans" for "future activity that create[] a substantial risk of future infringement," such as in the *DuPont v. Synvina* case.[10]

But because those cited cases focus on standing in general and not whether standing can be lost during proceedings for mootness, the court emphasized that "mootness is the doctrine of standing set in a time frame; that is, the requisite personal interest that must exist at the time of commencement of the litigation (standing) must continue throughout its existence (mootness)."[11] Thus, the court concluded, "the cessation of potential infringement mean[t] that that Momenta no longer ha[d] the potential for injury, thereby mooting the inquiry."[12]

Specifically, the court highlighted that Momenta had "no concrete plans" and estoppel was "irrelevant now that Momenta ha[d] 'exited' its development of the ORENCIA® product."[13] In addition, "Momenta's argument that it might at some future time receive a royalty from Mylan, if Mylan should produce an ORENCIA® biosimilar, ha[d] no support in precedent."[14]

COMPARING *MOMENTA V. BMS* WITH *AMERIGEN V. UCB*

Momenta v. BMS came on the heels of *Amerigen*,[15] a case decided one month earlier, in which the Federal Circuit held that a Hatch-Waxman petitioner, Amerigen Pharmaceuticals Limited ("Amerigen"), possessed standing to maintain an appeal of an adverse *inter partes* review decision. Although *Amerigen* does not implicate mootness, comparing *Momenta* with *Amerigen* sheds some light on how Momenta "lost" standing.

Amerigen involved a patent owned by UCB Pharma GMBH ("UCB") covering a compound used to treat urinary incontinence marketed as TOVIAZ®. Petitioner Amerigen had filed an Abbreviated New Drug Application and received tentative approval from the Food and Drug Administration ("FDA"). But notably, because Amerigen had a Paragraph III certification for UCB's patent,[16] the FDA could not finally approve Amerigen's generic to TOVIAZ® for launch until UCB's patent had expired.[17] Thus, it was not possible for Amerigen's generic to infringe UCB's patent.

Despite the fact that Amerigen could not infringe UCB's patent, which could be likened to Momenta's inability to infringe BMS's patent due to withdrawal of its ORENCIA® biosimilar, the Federal Circuit nonetheless held that Amerigen "ha[d] a concrete, economic interest in the sales of its tentatively approved drug" sufficient for standing.[18] The court focused on the fact that "the launch of [Amerigen's] tentatively approved drug [was] blocked by [UCB's] patent, and invalidation of the patent would advance the drug's launch."[19] Therefore, the relevant distinction is that Amerigen continued to have a concrete economic interest that could be advanced by

the appeal, and Momenta did not — the Federal Circuit deemed Momenta's potential royalty from Mylan not concrete enough.

CONCLUSION

In *Momenta*, the Federal Circuit applied the doctrine of mootness to a petitioner's appeal of an adverse *inter partes* review for the first time. Based on this decision, drug developers should keep in mind that standing must be maintained to appeal a final decision from an inter partes review when considering whether, and to what extent, to withdraw from developing a biosimilar or generic product. Terminating ongoing development efforts could have the unintended consequence of eliminating Article III standing, and creating estoppel from making invalidity arguments if an economic interest were to arise in the future.

Notes

[1] Momenta Pharm., Inc. v. Bristol-Myers Squibb Co., Opinion No. 17-1694 (Fed. Cir. Feb. 7, 2019).
[2] *Id.* at 3.
[3] *Id.*
[4] *Id.*
[5] *Id.* at 3–4.
[6] *Id.* at 5.
[7] *Id.* at 3, 8.
[8] *Id.* at 6–11.
[9] *Id.* at 9 (citing Consumer Watchdog v. Wis. Alumni Res. Found., 753 F.3d 1258, 1262–63 (Fed. Cir. 2014) and Phigenix, Inc. v. Immunogen, Inc., 845 F.3d 1168, 1173–76 (Fed. Cir. 2017)).
[10] *Id.* at 9–10 (citing E.I. DuPont de Nemours & Co. v. Synvina C.V., 904 F.3d 996, 1005 (Fed. Cir. 2018)).
[11] *Id.* at 11 (internal quotation omitted).
[12] *Id.*
[13] *Id.* at 8.
[14] *Id.*
[15] Amerigen Pharmaceuticals Ltd. v. UCB Pharma GMBH, Opinion No. 17-2596 (Jan. 11, 2019).
[16] Amerigen had initially filed a Paragraph IV certification. However, in district court litigation against a licensee of UCB's patent, Amerigen stipulated to infringement, the court held the patent not invalid, and Amerigen waived its right to appeal. That court's holding that UCB's patent was not invalid and was infringed had the effect of converting Amerigen's Paragraph IV certification to a Paragraph III certification. *Id.* at n.13.
[17] *Id.* at 11–12 n.13.
[18] *Id.* at 13.
[19] *Id.* at 11.

