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Sometimes the Patent Office Has the Last and Only Word

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The Federal Circuit just issued a decision that confirms its stance on Article III standing for appeals from *inter partes* reviews (IPRs), making it tougher for unsuccessful IPR petitioners to obtain judicial review of U.S. Patent and Trademark Office (USPTO) decisions. In *Momenta Pharmaceuticals, Inc. v. Bristol-Myers Squibb Co.* (available at: http://www.cafc.uscourts.gov/sites/default/files/opinions-orders/17-1694.Opinion.2-7-2019.pdf) (BMS), the Federal Circuit held that Momenta lacked Article III case or controversy standing to appeal the USPTO decision confirming BMS's patent relating to ORENCIA® (abatacept).[1]

Momenta was developing a biosimilar, but withdrew its application when the proposed biosimilar failed Phase I clinical trials. BMS moved to dismiss the appeal on Article III grounds due to the withdrawal. Momenta argued that it had not abandoned the project, and that the BMS patent was still an obstacle and the resulting estoppel would cause an

injury to Momenta. The Federal Circuit, however, was not persuaded and dismissed the appeal. The court stated that Momenta's withdrawal of the biosimilar terminated potentially infringing activity, and that the possibility of estoppel was now irrelevant.

This decision:

- confirms that unsuccessful IPR petitioners need to establish an actual injury to appeal a USPTO decision
- confirms that a statutory right to appeal is not sufficient on its own to provide Article III standing
- should not impact IPR petitioners who are engaged in patent litigation.

Congress created IPRs to provide an administrative proceeding in the USPTO to allow petitioners to contest the validity of U.S. patents before the Patent Trial and Appeal Board.[2] Any person can petition to institute an IPR as long as they are not the owner of the patent in question.[3]

An IPR petitioner who is unsuccessful can face an estoppel in the USPTO, International Trade Commission and the courts that prevents them from pursuing a "claim on any ground that the petitioner raised or reasonably could have raised" during the IPR.[4] The unsuccessful IPR petitioner, however, does have a statutory right of appeal to the Federal Circuit.[5] Thus, Congress sought to create a balance between estoppel and the availability of judicial review.[6]

In 2017, in *Phigenix, Inc. v. ImmunoGen, Inc.*, the Federal Circuit[7] held that, although an unsuccessful IPR petitioner has a statutory right to appeal, it might not possess the requisite "injury in fact" to have standing to appeal under Article III of the U.S. Constitution. The Federal Circuit explained that an injury in fact that is sufficient for standing must be concrete and particularized" and not "conjectural or hypothetical."[8] In that case, Phigenix argued that the ImmunoGen patent interfered with licensing efforts and could result in an estoppel, but the Federal Circuit found that these concerns did not amount to an injury in fact, and thus the Phigenix appeal was dismissed. The court has now altered the aforementioned balance.

It remains to be determined how the unavailability of judicial review under Article III will impact the application of the estoppel provisions against an unsuccessful IPR petitioner.

Endnotes

1 *Momenta Pharmaceuticals, Inc. v. Bristol-Myers Squibb Co.*, No. 2017-1694 (February 7, 2019).

2 The Board is required to conduct the IPR to secure a "just, speedy, and inexpensive resolution." 37 C.F.R. § 42.1(b).

3 35 U.S.C. § 311(a).

4 35 U.S.C. §315(e).

5 35 U.S.C. §§ 141(c), 319. This procedure stands in contrast to the ex parte reexamination statue, which has no estoppel against a third-party requester and no right of judicial review for the third-party requester. *Greenwood v. Seiko Instruments*, 8 USPQ2d 1455 (D.D.C. 1988).

6 In the previous and analogous *inter partes* reexamination proceeding, the Federal Circuit held that estoppel "applies only after all appeal rights are exhausted." *Bettcher Indus., Inc. v. Bunzl USA, Inc.*, 661 F.3d 629, 648 (Fed. Cir. 2011).

7 *Phigenix, Inc. v. ImmunoGen, Inc.,* 845 F.3d 1168 (Fed. Cir. 2017).

8 *Id.* at 1171.