

Loss of Standing and Mootness Where the Appellant Discontinued Development of a Potentially Infringing Product

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Momenta Pharmaceuticals, Inc. v. Bristol-Myers Squibb Company, No. 2017-1694 (Fed. Cir. Feb. 7, 2019)

After the Patent Trial and Appeal Board (PTAB) sustained the patentability of the claims of a pharmaceutical patent, the petitioner appealed the decision to the Federal Circuit. The patent owner moved to dismiss the appeal, arguing that the appellant no longer had standing to invoke federal court jurisdiction under Article III of the Constitution. Specifically, the patent owner argued that although the petitioner was attempting to develop a biosimilar counterpart to the patent owner's product at the time the PTAB petition was filed, the petitioner had since discontinued development of the counterpart. It became clear from a filing with the Securities and Exchange Commission that the petitioner had terminated its development of the potentially infringing biosimilar product. The Federal Circuit held that this decision to terminate development deprived the appellant of standing and mooted the appeal.

The Federal Circuit held that although the statutory grant of judicial review from the PTAB may "relax" the Article III criteria, "judicial review of agency action remains subject to the constitutional foundation of injury-in-fact." Here, although the petitioner was previously developing a biosimilar counterpart, the appellant could no longer show an injury that was "actual or imminent, not conjectural or hypothetical" after the petitioner terminated all potentially infringing activity. The Federal Circuit rejected the appellant's contention that it may receive royalties in the future from its collaborating partner if the partner elected to develop a biosimilar counterpart because that contention was too speculative. Because the appellant no longer had the potential for injury, the Federal Circuit dismissed the appeal for absence of standing and for mootness.

[A copy of the opinion can be found here](#)

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