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Termination Of Product Development Precludes Standing To Appeal PTAB IPR Decision Upholding Patent

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In *Momenta Pharmaceuticals, Inc. v. Bristol-Meyers Squibb Co.*, the Federal Circuit issued another decision analyzing the contours of a petitioner's Article III standing to appeal PTAB decisions upholding a patent. In contrast to *Amerigen*, where the court found standing for a would-be generic competitor whose ANDA was subject to a Paragraph III certification against the challenged patent, in *Momenta* the court found that the challenger's termination of product development precluded standing.

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The Patent At Issue

The Patent at issue was BMS's U.S. Patent No. 8,476,239, directed to "fluid formulations of the protein molecule CTLA4Ig … an immunosuppressive agent used in treatment of immune system disorders such as rheumatoid arthritis." As noted in the court decision, the patent pertains to BMS's Orencia® (abatacept) biologic product.

In 2015, Momenta petitioned for *Inter Partes* Review (IPR) of the '239 patent. The PTAB instituted review, but upheld the patent against Momenta's challenge. When Momenta appealed to the Federal Circuit, BMS challenged Momenta's Article III standing to do so.

Momenta's Product Development

According to the Federal Circuit decision, "Momenta was reportedly attempting to develop a biosimilar counterpart of Orencia®" when it petitioned for IPR of the '239 patent. In its motion to dismiss the Federal Circuit appeal, BMS asserted that "Momenta's proposed product had failed its Phase 1 clinical trials and had been withdrawn." Before the Federal Circuit, "Momenta responded that it had not abandoned its intent to produce a counterpart of the Orencia® product, that the '239 Patent is an obstacle to these activities, and that it is injured by the estoppel provision," of the IPR statute, such that it does have Article III standing to appeal.

Subsequently, Momenta advised the court of "discussions with its collaboration partner, Mylan, to exit its participation in the development of … M834, a proposed biosimilar to ORENCIA®." According to BMS, that "confirm[ed] Momenta's lack of standing to appeal."

In response to the court's order to show cause, Momenta argued that, "because of BMS's patent and the Board's decision upholding it, Momenta and its partner Mylan still face the same fork in the road about the commercial formulation for their biosimilar product—they must decide whether to proceed with the current formulation or switch to a more expensive and potentially less commercially viable option. That decision and the costs associated with it still turn on the outcome of this appeal." Momenta also submitted declaration evidence of its "economic interest in any Orencia® biosimilar that might be developed by Mylan, and Momenta's potential right to royalties from Mylan should this product be developed by Mylan."

Subsequently, ***BMS*** filed copies of documents Momenta had filed with the SEC stating:

We have elected to terminate our collaboration agreement with Mylan with respect to the development of . . . M834, a proposed biosimilar to ORENCIA® . . . . On November 19, 2018, we delivered a formal notice of this partial termination to Mylan, as provided in the collaboration agreement.

As noted by the court, after that submission Momenta neither responded nor withdrew its appeal.

The Federal Circuit Decision

The Federal Circuit decision was authored by Judge Newman and joined by Judges Dyk and Chen.

In reaching its decision, the court cited Supreme Court precedent for the principal that, although the standing requirements of "immediacy" and "redressability" may be relaxed by statute, "the requirement of injury in fact is a hard floor of Article III jurisdiction that cannot be removed by statute." According to the court:

> [T]he appellant must always have a "concrete and particularized" interest in the outcome – an interest, to the extent one existed, that has now been eliminated by Momenta.

With regard to Momenta's argument that estoppel arising from the IPR proceeding created an injury-in-fact, the court responded that "Estoppel cannot constitute an injury-in-fact when Momenta is not engaged in any activity that would give rise to a possible infringement suit."

With regard to Momenta's arguments regarding potential future royalty payments if Mylan produces an Orencia® biosimilar product, the court noted that speculative future events do not confer standing.

Dispensing with Momenta's other arguments, the court concluded:

> Momenta does not have standing to invoke federal appellant jurisdiction, and the appeal is mooted by Momenta's discontinuance of any potentially infringing activity.

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