



Intellectual Property Alert: Can a Potential Infringer Use an IPR to Gain Access to Article III Courts?

By Sarah A. Kagan

January 9, 2018 — The U.S. Court of Appeals for the Federal Circuit heard arguments in a case that will clarify an important aspect of the *inter partes* review (IPR) process: who has standing to appeal an adverse decision? On December 5, Momenta and Bristol-Myers Squibb sparred and parried with a judicial panel consisting of Judges Newman, Dyk, and Chen. *Momenta Pharmaceuticals, Inc. v. Bristol-Myers Squibb Co.* (No. 17-1694).

Momenta used the IPR procedure to challenge Bristol-Myers Squibb’s patent covering a formulation of ORIENCIA® (abatacept) for treating rheumatoid arthritis. Momenta failed to persuade the U.S. Patent and Trademark Office’s Patent Trial and Appeal Board (PTAB) that Bristol-Myers Squibb’s claims were obvious. Momenta appealed the decision to the Federal Circuit under 35 U.S.C. 319 (“A party dissatisfied with the final written decision of the Patent Trial and Appeal Board under section 318(a) may appeal the decision pursuant to sections 141 through 144. Any party to the inter partes review shall have the right to be a party to the appeal.”). Despite the broad language of §319 (“a party dissatisfied” and “any party to the IPR”), Momenta’s appeal may not be considered on the merits due to a possible lack of Article III standing.

Ordinarily, a party does not have standing to challenge a U.S. patent in an Article III court unless the party is sued for infringement or is threatened with such a suit. Momenta does not have standing based on infringement or threatened litigation. Rather, it is trying to obtain standing to challenge validity in an Article III court by appealing from an IPR.

In its Federal Circuit appeal, Momenta asserts that it suffers individualized, concrete harm sufficient to establish Article III injury in fact. It bases its position on costs incurred in developing its current drug candidate, costs it would incur should it need to alter its business plan to use a non-infringing alternative, as well as on the estoppel provision (35 U.S.C. 315(e)) for IPRs. Momenta urges that prior appeals from administrative agency rulings found injury when an economic harm was reasonably probable or highly likely. It also cites cases where business competitors are presumed to be harmed if their competitors are benefited.

Momenta’s legal arguments rely on analogizing its situation to that of parties in cases involving other administrative agencies. It distinguishes its facts from the two cases in which appeals from decisions of the PTAB were dismissed for lack of standing. In particular, Momenta distinguishes

over *Consumer Watchdog v. Wis. Alumni Research Found.*, 753 F.3d 1258 (Fed. Cir. 2014) (involving a public interest group) and *Phigenix, Inc. v. Immunogen*, 845 F.3d 1168 (Fed. Cir. 2017) (involving a non-practicing, licensing entity).

Consumer Watchdog arose out of a failed invalidation attempt using an *inter partes* reexamination. Like the IPR statute, the reexamination statute allowed a third party requester to appeal decisions. Nonetheless, the court found that *Consumer Watchdog* lacked a particularized, concrete stake in the outcome of the appeal. The court also found that the estoppel provision did not constitute injury in fact, as that injury was only conjectural or hypothetical. *Phigenix* arose out of an IPR. *Phigenix* was not a manufacturer but a developer of an intellectual property portfolio. It argued that the PTAB's failure to invalidate the patent-in-suit would increase its competition for licensing its own properties, constituting an actual economic injury. The court held that *Phigenix* was not engaged in any activity that would give rise to a possible infringement suit, so the estoppel provision does not cause harm. *Momenta* argues that these two cases are distinct from its case, because the IPR petitioners in those cases failed to provide evidence of particularized harm.

Bristol-Myers Squibb asserts that *Momenta*, like *Consumer Watchdog* and *Phigenix*, has not suffered a concrete and particularized injury from the PTAB's decision not to revoke the *Bristol-Myers Squibb* patent. *Momenta* has no product on the market, no product approved for the market by the U.S. Food and Drug Administration, and no product that has passed the three phases of clinical testing. *Momenta* is merely requesting an advisory opinion, *Bristol-Myers Squibb* asserts.

Bristol-Myers Squibb notes that the PTAB decision did not deny *Momenta* anything to which it was entitled. The patent belongs to *Bristol-Myers Squibb*, and *Momenta* is not particularly affected by the PTAB's decision. Neither *Momenta*'s expenditures for research and development nor potential estoppel against *Momenta* using the same arguments or other available arguments in later proceedings convert the decision of the PTAB into a present harm, *Bristol-Myers Squibb* urges. *Bristol-Myers Squibb* argues that Article III standing will first arise only when *Momenta* (a third party) has filed a biosimilar application under the Biological Price Competition and Innovation Act.

Like *Bristol-Myers Squibb*, *Momenta* points to the Biological Price Competition and Innovation Act as providing a means for pre-market patent challenge. But *Momenta* urges that the remedy provided by that act is not an exclusive remedy.

The judges in the oral arguments appeared to signal their positions. At a few junctures, one judge answered the question of a second judge. Each judge seemed to have one aspect of the case that weighed heavily. Judge Chen repeatedly noted that *Momenta*'s commercial product was not certain at this point. The current proposed product might fail clinical tests, *Momenta* might redesign the product to be non-infringing (as hinted in a public statement by the company), and the FDA might not approve the product for market. If the court found that *Momenta* had standing, the court's opinion on patentability might be nothing more than an advisory opinion. Judge Dyk indicated that

Momenta might have no opportunity to challenge the patentability of the Bristol-Myers Squibb patent prior to making substantial expenditures, if standing to appeal were not found. Judge Newman noted that Momenta's current drug development and clinical testing are protected by the safe harbor of 35 U.S.C. 271(e)(1), so that Momenta was not currently infringing.

The parties, while recognizing that 35 U.S.C. 319 was not sufficient to provide standing to Momenta, disagreed on the standard that should be applied. Should Momenta's involvement in an administrative process with an adverse outcome, coupled with plans to develop an infringing product, be sufficient to achieve standing? Or must Momenta wait until it meets the requirements for a declaratory judgment plaintiff to challenge the validity in an Article III court? The issue in this case could, of course, be moot if the Supreme Court's decides that IPRs are unconstitutional in *Oil States Energy Services, LLC v. Green's Energy Group, LLC* (No. 16-712).

Click [here](#) to listen to the arguments in *Momenta Pharmaceuticals, Inc. v. Bristol-Myers Squibb Co.*

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