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Fed. Circ. Case May Change Biosimilar IPR Strategy

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(April 12, 2018, 12:35 PM EDT)

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Biosimilar developers have been aggressive in filing petitions for inter partes reviews of biologics patents before the Patent Trial and Appeal Board, many of them preceding the filing of a marketing application. Such early IPRs are attractive to biosimilar makers, because they provide a chance to challenge innovator patents years before the biosimilar maker files a marketing application with the U.S. Food and Drug Administration. Since a petitioner need not have Article III case-or-controversy standing to bring an IPR, the remoteness and uncertainty of future infringement in such circumstances does not preclude these early IPRs. Under settled precedent, however, a biosimilar maker must have Article III standing to seek a Federal Circuit appeal if the PTAB issues a final decision upholding the challenged patent. A decision expected from the Federal Circuit this quarter in Momenta Pharmaceuticals Inc. v. Bristol-Myers Squibb Co.[1] will address how and when a biosimilar maker can establish that standing.

Momenta concerns a PTAB decision affirming the validity of a BMS patent covering a formulation of Orencia, a biologic used to treat rheumatoid arthritis. Momenta asserts that it has "invested millions" in a potential biosimilar of Orencia that has reached Phase I trials, and that it is at a "fork in the road" of its development plans as a result of the PTAB's decision below affirming patentability. Momenta does not dispute either that it is still years away from filing a potential biosimilar product application or that the formulation of its product if and when such an application were submitted to the FDA is currently unknown.

Current State of the Law on Standing to Appeal From Final PTAB Decisions

Under Sandoz v. Amgen,[2] a biosimilar developer that has not submitted a marketing application with FDA cannot meet the Article III justiciability requirements to bring a declaratory judgment action. The Federal Circuit stated in Sandoz that the court was "aware of no decision in which we have found a case or controversy when the only activity that would create exposure to potential infringement liability was a future activity requiring an FDA approval that had not yet been sought."

Under existing Federal Circuit precedent, moreover, parties that are "not engaged in any activity that would give rise to a possible infringement suit" lack the "particularized, concrete stake in the outcome

of the reexamination" required for Article III standing, and thus cannot appeal a PTAB decision affirming patentability.[3] The patent challenger in Consumer Watchdog, a nonprofit consumer advocacy organization, argued that its injury was the burden on taxpayer-funded research in California allegedly caused by the patent. The Federal Circuit rejected this argument, concluding that the organization failed to establish injury-in-fact, since it did not allege any involvement in researching, commercializing, or licensing the patented technology. The court further rejected the notion that the estoppel provisions of the inter partes re-examination statute — which prevented a patent challenger from asserting invalidity arguments that were raised or reasonably could have raised during the reexamination in future proceedings — constitute an injury in fact to Consumer Watchdog, since the organization was not engaged in activity that would give rise to a later infringement suit or another administrative challenge. The court left it "to future panels to decide whether, under other circumstances, the preclusive effect of the estoppel provisions could constitute an injury in fact."

Three years later, in Phigenix Inc. v. ImmunoGen Inc.,[4] the Federal Circuit addressed the standing of a for-profit biotech company that sought to appeal an IPR decision affirming patentability. Phigenix, relying on the U.S. Supreme Court's decision in Cuozzo Speed Technologies LLC v. Lee,[5] confirmed that an appellant must establish Article III standing to appeal from a PTAB final written decision. The court then held that Phigenix lacked such standing. Phigenix did not manufacture any products, but alleged that its own '534 patent covers activities relating to the breast cancer drug Kadcyla sold under a license to ImmunoGen's '856 patent, which Phigenix had unsuccessfully challenged through IPR. Phigenix argued that it brought an IPR "to further its commercialization efforts with respect to its patent portfolio" after ImmunoGen's licensee refused its offer to license the '534 patent. Phigenix argued that it had suffered an actual economic injury because the '856 patent increases competition between itself and ImmunoGen and takes away licensing revenue that Phigeneix would receive if the if the '856 patent were invalidated. The Federal Circuit rejected this theory, finding that this "hypothetical licensing injury" was not substantiated by any supporting facts. The Federal Circuit also reaffirmed its holding in Consumer Watchdog that the estoppel provision preventing Phigenix from raising in future proceedings invalidity arguments that were raised or could have been raised in the IPR "does not constitute an injury in fact" when the appellant "is not engaged in any activity that would give rise to a possible infringement suit."[6]

Most recently, in Personal Audio LLC v. Electronic Frontier Foundation,[7] decided last August, the Federal Circuit clarified that a petitioner who succeeds in invalidating a patent through an IPR need not establish Article III standing to participate as an appellee in a patent owner's appeal of the PTAB's decision. Rather, standing to appeal "is measured for "the party invoking judicial review." "On cancellation of its patent claims," a patent owner clearly "experienced an alteration of its "tangible legal rights that is sufficiently distinct and palpable to confer standing under Article III."

The Arguments on Appeal in Momenta

Momenta argues that the Federal Circuit's Sandoz v. Amgen decision requiring a marketing application to establish injury-in-fact applies only to declaratory judgment suits. Momenta also argues that it has suffered an injury-in-fact due to the estoppel effect of 35 U.S.C. § 315(e). Although a similar argument was rejected in Phigenix, Momenta asserts that, unlike Phigenix, it is engaged in activity that would give rise to a possible future infringement suit. Momenta asks in the alternative that the Federal Circuit panel vacate the board's decision upholding the validity of BMS' patent if the panel finds that the appeal is not justiciable.

BMS counters that Momenta has suffered no injury-in-fact because its claims are based on a "general,

speculative, and contingent threat of infringement liability" and "hypothetical future economic injuries." Under Sandoz, BMS argues, Momenta cannot show a concrete injury until it files a biosimilar application with the FDA. BMS further argues that "[a]llowing a third-party like Momenta to proceed to federal court earlier by choosing to pursue an IPR would permit biosimilar litigants to circumvent the specific BPCIA [Biologics Price Competition and Innovation Act] regime through general AIA procedures." This would lead to "a flood of appeals from IPR decisions by third-parties seeking an early avenue to federal court through uncertain future interests that would be premature if brought to federal court in the first instance."

Import of the Forthcoming Momenta Decision

The Momenta decision promises to impact to what extent biosimilar makers challenge innovator patents years before filing marketing applications with the FDA and before they have standing. If the Federal Circuit holds that potential future FDA applicants like Momenta have standing to appeal final IPR decisions based on evidence of early product development expenditures and the possibility of infringement liability years in the future, the trend of early IPRs will continue.

At the Dec. 5, 2017, oral argument, however, a majority of the Momenta panel appeared poised to require the filing of a biosimilar application to confer Article III standing. Although Judge Timothy Dyk expressed an inclination to find for Momenta on the basis of standing cases from outside the patent context, Judge Raymond Chen commented that that Momenta was "years away from being a true competitor," and that the company's alleged injury was built on a "chain of contingencies." And Judge Pauline Newman, who may prove to be the deciding vote, focused on the fact that Momenta would be unable to bring a declaratory judgment action on the current facts.

If the panel requires a biosimilar marketing application for standing on appeal, as many expect based on the court's precedent, Momenta will confirm a "win or go home" system for biosimilar developers who wager on early IPRs. That is, under a "win or go home" system, a biosimilar developer may choose to challenge innovator patents long before filing a biosimilar marketing application, but risks an unappealable loss. If successful before the PTAB, the developer could participate in the patent owner's appeal under Personal Audio. But if unsuccessful, the early challenger would be unable to appeal the PTAB decision affirming patentability.

That risk of a nonappealable PTAB decision affirming patentability may provide an incentive for many biosimilar makers to save their patent challenges until a year and a half (the time for a final written decision) prior to submission of a marketing application so as to be able to rely on the filing of a regulatory application at the time of an appeal. However, given the high affirmance rate of PTAB decisions at the appellate level, among other reasons, other biosimilar makers may simply take their chances with early IPRs even if a loss is nonappealable. The same may be the case of biosimilar makers that have noninfringement or invalidity arguments that cannot be raised in IPR proceedings and thus can be presented in court even after a final written decision by the PTAB upholding the challenged patent.

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[1] No. 17-1694 (Fed. Cir. argued Dec. 5, 2017).

[2] 773 F.3d 1274 (Fed. Cir. 2014).

[3] Consumer Watchdog v. Wisc. Alumni Research Found., 753 F.3d 1258, 1262 (Fed. Cir. 2014), cert denied 135 S. Ct. 1401 (2015).

[4] 845 F.3d 1168 (Fed. Cir. 2017).

[5] 136 S. Ct. 2131, 2143-44 (2016).

[6] See 35 U.S.C. § 315(e).

[7] 867 F.3d 1246 (Fed. Cir. 2017).