Federal Circuit's Sandoz v. Amgen Decision Forecloses Early Declaratory Judgment Suits by Biosimilars Applicants

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On December 5, in the closely watched *Sandoz v. Amgen* case, the Federal Circuit held that a biosimilars applicant cannot use the Declaratory Judgment Act to challenge a reference product sponsor's patent prior to filing a biosimilars application under the Biologics Price Competition and Innovation Act (BPCIA). The 3-judge panel's decision affirmed the district court's ruling that it lacked jurisdiction to hear Sandoz's complaint, based on the constitutional requirement that there be a "case of actual controversy" to permit relief under the Declaratory Judgment Act.

Had Sandoz's complaint been allowed to proceed, biotechnology companies developing biosimilars products would have had a clear pathway to avoid the complex and expensive patent challenge procedures specified by the BPCIA, including the requirement that a biosimilars applicant share the content of its application with the reference product sponsor. Sandoz had argued, among other things, that the Declaratory Judgment Act provided an alternative means to challenge patents prior to the filing of a biosimilars application, because until then the BPCIA limitations on declaratory judgments could not apply. That argument is foreclosed by the Federal Circuit's holding that the actual filing of an application seeking FDA approval of a specific product is a necessary predicate of declaratory judgment jurisdiction.

Sandoz had filed its complaint in district court the same day that it began a Phase III clinical trial of its etanercept biosimilar. Sandoz argued that it had been engaged in discussions with the FDA to plan for its biosimilars application since 2010, that it had invested many millions of dollars to develop its product, and that its large-scale Phase III trial was merely "confirmation" of earlier study results. The district court held that it lacked jurisdiction because there was no immediate, real controversy between the parties. The court further held that the BPCIA's establishment of procedures to define and narrow disputes between biosimilars applicants and the reference product sponsors precluded Sandoz's separate DJ action. Following its precedent in the Hatch-Waxman context concerning generic drug products, the Federal Circuit held that Sandoz's facts did not meet the "immediacy and reality" requirements for a declaratory judgment because the biosimilars product may be altered as a result of the Phase III trial and, consequently, the focus of the patent dispute could change or the dispute could be eliminated altogether.

This case raised many questions about the patent challenge procedures available to biosimilars applicants. The Court did not decide whether declaratory judgment jurisdiction exists once the biosimilars application is filed and accepted by the FDA, nor did it decide whether the BPCIA's special patent challenge provisions may preempt such an action, even if the jurisdictional requirements are met.

Sandoz argued that either party is free to file a declaratory judgment action once the biosimilars applicant has given notice of its intention to market its product. The district court rejected this, holding that neither the reference product sponsor nor the biosimilars applicant can sue until they have engaged in the BPCIA pre-litigation patent exchange process, which begins only after the biosimilars application is filed. The Court also left open the question of what constitutes "notice of commercial marketing" under the BPCIA, which requires such notice "not later than 180 days before the first commercial marketing" of the biosimilars product. Sandoz argued that it had provided such notice. The district court disagreed, relying on language in the BPCIA suggesting that such notice can only be given only after the product has been licensed (approved) by the FDA. According to Sandoz, this would result in a 6-month delay in the launch of a biosimilars product, contrary to Congress' intent in limiting the reference product's exclusivity period to 12 years.

While many questions remain, it is clear under the Federal Circuit's ruling that a biosimilars applicant hoping to determine the validity and scope of a potentially blocking patent in advance of submitting its complete data package and application to the FDA cannot use a

declaratory judgment action as the mechanism to do so. Instead, the likely best alternative for such an applicant will be to challenge the patent's validity in a USPTO *inter partes* review proceeding authorized under the America Invents Act. Such a proceeding may not provide clarity as to the patent's scope, however, as long as the USPTO continues to apply its "Broadest Reasonable Interpretation" rule to claim construction in these proceedings.

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