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Sandoz *Decision Increases Importance of Post-Grant Proceedings to Biosimilar Developers*

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On December 5, 2014, the US Court of Appeals for the Federal Circuit rendered its decision in *Sandoz, Inc. v. Amgen*, *Inc*., No. 2014-1693, a case with major implications for the emerging US biosimilars industry. The decision addresses when and how a party seeking to launch a biosimilar product in the United States can initiate litigation to challenge the brand company's potential blocking patents. This is the first instance in which the Federal Circuit has addressed the scope and applicability of the Biologics Price Competition and Innovation Act (BPCIA), which established a formal pathway for biosimilar approval in the United States.

Background

At issue in *Sandoz* is a litigation Sandoz initiated against Amgen and Hoffman-La Roche Inc. on June 24, 2013, in federal district court for the Northern District of California. Sandoz's complaint sought a declaratory judgment (DJ) that two patents owned by Roche and exclusively licensed to Amgen are invalid, unenforceable, and would not be infringed by the commercial marketing of Sandoz's biosimilar version of Amgen's blockbuster biologic product Enbrel® (etanercept).

The patents at issue extend Amgen's protection around Enbrel® an additional 15 years past the original patents on the product. Sandoz filed its complaint against Amgen prior to filing any application with the Food and Drug Administration (FDA) for approval to market its biosimilar etanercept product, which is currently in Phase III clinical trials. Sandoz will not file with the FDA until the Phase III trial is complete, and of course will not be able to market its version of etanercept in the United States without FDA approval. At the time of suit, Amgen had not alleged Sandoz was currently doing anything that exposes it to liability for infringing Amgen's patents rights around Enbrel®.

The District Court Decision

Amgen moved to dismiss Sandoz's complaint, asserting that the court lacked jurisdiction to hear the case because no immediate and real controversy between the parties exists. In a brief order, the court granted Amgen's motion to dismiss on two separate grounds.[1] First, the court ruled that its discretion to enter a DJ in the case is subject to the provisions of the BPCIA, which sets specific limitations on the timing and conduct of any litigation arising from the filing of an application for approval to market a biosimilar.[2] Specifically, the court concluded that "neither a reference product sponsor, such as Amgen, nor [a biosimilar applicant] such as Sandoz, may file a lawsuit unless and until they have engaged in a series of statutorily–mandated exchanges of information" related to patents potentially in dispute.[3] In this case, Sandoz had not complied with the statutory exchanges because it had not yet filed its biosimilar application at the FDA, which is necessary to trigger the exchange provisions. The district court also rejected Sandoz's assertion that DJ jurisdiction existed because Sandoz had given Amgen

the "notice of commercial marketing" required under the BPCIA. The court ruled that Sandoz could not, as a matter of law, provide Amgen with notice of commercial marketing when Sandoz's biosimilar etanercept had not yet been licensed by the FDA.[4]

Second, the court found that Sandoz also had not established DJ jurisdiction on traditional grounds because it had not established a "real and immediate injury or threat of future injury" caused by Amgen.[5] The court noted that Amgen had never threatened Sandoz with suit, and that public statements by Amgen that it intended to defend its patent rights covering etanercept were insufficient alone to show an imminent threat.[6] Likewise, the mere allegation by Sandoz that it intended to file an application for FDA approval of its biosimilar product at some point in the future was not sufficient to create a case on controversy.

The Federal Circuit Decision

On appeal, Sandoz argued that the litigation provisions of the BPCIA only govern the *statutory* patent infringement litigation authorized by the act after a biosimilar application is filed with the FDA, and do not apply to DJ actions in general. Sandoz further argued that nothing in the BPCIA can be construed to bar or limit in any way the ability to bring DJ actions to resolve patent disputes *prior* to filing a biosimilar application. Finally, Sandoz argued that the district court erred in concluding that Sandoz had not adequately demonstrated a sufficient actual case or controversy sufficient to allow the DJ action to proceed.

A panel of Federal Circuit judges affirmed the district court's dismissal of Sandoz's complaint, concluding that Sandoz had not alleged an injury of sufficient immediacy and reality to create subject matter jurisdiction.[7] The Federal Circuit noted that "a case of actual controversy" is a prerequisite to exercising declaratory judgment jurisdiction. The test for determining whether a case or controversy exists is whether "there is a substantial controversy … of sufficient immediacy and reality to warrant the issuance of a declaratory judgment."[8] The Federal Circuit, however, expressly declined to address the lower court's interpretation of the BPCIA as barring a lawsuit by either the reference product sponsor or the biosimilar applicant unless and until the parties have engaged in the statutorily mandated patent information exchanges and as requiring, as a matter of law, licensure of the biosimilar product before the biosimilar applicant can provide the "notice of commercial marketing" required under the statute.[9]

In concluding that Sandoz's complaint does not present a case or controversy, the Federal Circuit panel noted that there was no prior decision in which the Federal Circuit had found a case or controversy to exist when the only activity that would create exposure to potential infringement liability was a future activity requiring FDA approval that had not yet been sought.[10] The court found the immediacy requirement lacking when the conclusion of Sandoz's Phase III trial, which was a prerequisite for filing for FDA approval, was still several years away when Sandoz filed suit. The court refused to assume that the Phase III trial would be successful, and noted that the trial could in fact uncover issues with Sandoz's product that could push the application filing date back even further. Alternatively, the clinical trial could fail resulting in Sandoz never seeking FDA approval, or Sandoz could modify its proposed product and file for approval on the modified product. The court also noted that Sandoz's complaint lacked specificity as to how Amgen's patents read or don't read on Sandoz's product; and instead relies on prior general assertions by Amgen that the patents at issue cover Enbrel, that Amgen will assert the patents against products that compete with Enbrel, and that Sandoz intends to market a competing product at some point in the future. Ultimately, the court concluded that the events allegedly exposing Sandoz to infringement liability "may not occur as anticipated, or indeed may not occur at all."[11] The court found that Sandoz also had not shown that it would suffer any "immediate and substantial adverse impact" from not being able to seek or secure a patent adjudication before filing its application for FDA approval.[12]

Unanswered Questions

The Federal Circuit in *Sandoz* specifically stated that its decision was limited to the particular facts before it, and does not address whether Sandoz would be able to seek declaratory judgment jurisdiction once it files its FDA application, or whether the BPCIA forecloses declaratory judgment actions outside of the context of the statutorily mandated patent information exchange once the application is accepted by the FDA.[13] The decision also did not clarify the additional issue disputed by the parties concerning what constitutes sufficient "notice of commercial marketing," which the BPCIA requires the biosimilar applicant to provide to the reference product sponsor at least 180 days prior to the launch of the biosimilar product.

Increased Importance of Post-Grant Proceedings before the USPTO

Although the *Sandoz* court made a point to limit the scope of its decision to the facts before it, the decision casts

substantial doubt on the ability of any biosimilar developer to bring a district court action challenging the reference product sponsor's patents prior to filing a biosimilar application with the FDA and triggering the patent information exchange provisions of the BPCIA. At the same time, the decision elevates the importance to biosimilar developers of post-grant challenges before the US Patent and Trademark Office (USPTO), such as *inter partes* review (IPR) and post-grant review (PGR), as means for obtaining some degree of early patent certainty before initiating the FDA approval process. IPRs in particular have proven to be a potent weapon for generic drug manufacturers in the context of Abbreviated New Drug Application (ANDA) litigation. The lower standard of proof required to show invalidity, the expedited pace of the proceedings, and the decreased cost in comparison to district court litigation coupled with the extremely high rate in which patent claims are being invalidated provide generic manufacturers with tremendous leverage to obtain favorable settlements with brand companies. We expect that the *Sandoz* decision should only increase the speed with which post-grant proceedings are adopted in the biosimilar arena.

1. Sandoz Inc. v. Amgen Inc., No. C-13-2904 MMC (N.D. Cal. Nov. 12, 2013) (order granting defendants' motion to dismiss).
2. *Id.* at 3.
3. *Id.*
4. *Id.* at 3.
5. *Id.* at 3–4.
6. *Id.* at 4.
7. Sandoz, Inc. v. Amgen, Inc., No. 2014-1693, slip op. at 6 (Fed. Cir. December 5, 2014).
8. *Id.*, Slip op. at 6.
9. *Id.*, Slip op. at 2.
10. *Id.*, Slip op. at 10.
11. *Id.*, Slip op. at 12.
12. *Id.*, Slip op. at 14.
13. *Id.*, Slip op. at 15.