CLIENT ALERT

Biosimilars: If You Don't Dance the Patent Dance, You Have to Wait Until the FDA Approves Your Moves

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On July 21, the Federal Circuit issued a landmark ruling in *Amgen, Inc. v. Sandoz, Inc.* on the first biosimilar product approved by the U.S. Food and Drug Administration (FDA) to enter the market. The three-judge panel granted a partial victory to Sandoz in its fight with Amgen by holding that Sandoz did not violate the Biologics Price Competition and Innovation Act (BPCIA) by not disclosing its abbreviated biologics license application (aBLA) and the manufacturing information by the statutory deadline. The court also held that a biosimilar applicant is required to give the reference sponsor 180-day notice of the first commercial marketing of the biosimilar only *after* the biosimilar is approved by the FDA. This will not affect Sandoz, who already received FDA approval to market its Zarxio (Novartis' generic version of Amgen's cancer drug Neupogen®). But pegging the notice provision to FDA approval, rather than submission, essentially extends the exclusivity for brand-name biologics by six months. While describing the BPCIA as "a riddle wrapped in a mystery inside an enigma," the Federal Circuit panel itself was fractured and the decision held something for both sides. The decision in *Amgen, Inc. v. Sandoz, Inc.,* was the Court's attempt to "unravel the riddle, solve the mystery, and comprehend the enigma."

As background, the district court below had held that (i) disclosure of a biosimilar applicant's Biologic License Application (BLA) and proprietary manufacturing information to the reference product sponsor is permissive; and (2) that a biosimilar applicant is required to give the reference sponsor 180-day notice of the first commercial marketing of the biosimilar only **after** the biosimilar is approved by the FDA. *See* our previous Client Alert: "District Court's Decision Paves the Way for the First U.S. Biosimilar."

The Disclosure and Negotiation Procedures of 42 U.S.C. § 262 Are Permissive

On appeal, the Federal Circuit held that 42 U.S.C. § 262(l)(9)(C) provides that if a biosimilar applicant "fails to provide the application and information required under paragraph (2)(A), then the [reference product holder] … may bring a declaratory judgment action on any patent that claims the biological product or a use of the biological product." *Amegen v. Sandoz,* Slip Op. at 13. But as a consequence of failing to disclose this information, the biosimilar applicant cannot bring "a declaratory judgment action on patents that claim the biological product or its use." *Id*. In so doing, the court reasoned that to hold otherwise would "render paragraph (l)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii) superfluous." *Id.* at 14.

Failing to provide the aBLA and the required manufacturing information has its own consequences. In that instance, a biosimilar applicant makes the 180-day advance-notice provision mandatory. *Id.* at 21. This leaves open the question of whether providing such information would allow a biosimilar applicant to provide notice to the reference product holder in advance of receiving FDA approval.

The 180-Day Notice Provision Must Occur After FDA Approval

In proceedings below, the district court had held that the 180-day notice could be given in advance of FDA approval. *See* the district court ruling. The Federal Circuit overturned that portion of the decision, holding that notice can only be given for "licensed products" – *i.e*. those licensed for marketing by the FDA. *Amgen v. Sandoz*, Slip Op. at 16-17. Writing for the majority, Judge Lourie noted that the statute discusses only "licensed products," not "the biological product that is the subject of " the application, as that term is used elsewhere in the statute. Judge Lourie furhter noted that by so holding, the Court would not be tacking on an "extra" 180 days of exclusivity for future reference product holders because "[t]hat extra 180 days will not likely be the usual case, as aBLAs will often be filed during the 12-year exclusivity period for other products." *Id.* at 18. In dissent, Judge Chen, however, pointed out that the, "practical consequence of the majority's interpretation is that (*l*)(8)(A) provides an inherent right to an automatic 180-day injunction," without providing a supporting basis in the statutory language. Instead, Judge Chen would have dissolved the injunction pending appeal.

This decision clarifies two related issues of first impression related to the BPCIA, namely the consequences of a biosimilar applicant's failing to disclose its aBLA and what effect that failure will have on the 180-day notice provision. But it leaves open what, if any, effect disclosing that information would have on the notice provision. Stay tuned.

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