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Case Alerts

Supreme Court Rules That Biosimilars Makers Can Give Notice Of Commercial Marketing Before FDA Licensure

In a June 12, 2017 decision authored by Justice Clarence Thomas, the United States Supreme Court in *Sandoz v. Amgen* ruled that, under the Biologics Price Competition and Innovation Act (BPCIA), biosimilar makers can give notice of commercial marketing ***before*** the United States Food and Drug Administration (FDA) licenses their biosimilar products.

The *Sandoz* ruling resolves an ambiguity in the text of the BPCIA, which gave rise to a presumption by some (and a holding by the Federal Circuit at 794 F.3d 1347, 1358 (2015)) that biosimilar makers had to wait until 180 days after FDA licensure of their biosimilar products before providing notice of the commercial marketing of those products—thereby potentially extending by an additional six months the BPCIA's statutory 12-year exclusivity period for innovator biologics. The *Sandoz* ruling makes clear that an additional six-month period of exclusivity was not contemplated by the BPCIA.

Background

Congress passed the BPCIA in 2010 to speed market entry of biosimilars, while also promoting the development of new, or "reference," biologics. The BPCIA thus allows a biosimilar to piggy-back on safety and efficacy data for a previously FDA-licensed reference biologic, but also provides 12 years of marketing exclusivity to a reference biologic. Additionally, to facilitate the early resolution of patent disputes between a biosimilar applicant ("applicant") and a reference biologic maker ("sponsor"), the BPCIA sets forth processes for the parties to exchange information and to litigate patent infringement claims. Two parts of those processes are at issue here.

First, 42 U.S.C. §262(*l*)(2)(A) states that an applicant "shall provide" the sponsor with a copy of its biosimilar application and manufacturing information within 20 days of the date that the FDA notifies the applicant that it has accepted the application for review. This then triggers a series of information exchanges between the applicant and sponsor (commonly known as the "patent dance") leading to early litigation of key patent disputes. If an applicant fails to disclose its application and manufacturing information under §262(*l*)(2)(A), then 42 U.S.C. §262(*l*)(9)(C) provides that the sponsor—but not the applicant—may immediately bring an action "for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product."

Second, 42 U.S.C. §262(*l*)(8)(A) states that an applicant "shall provide notice to the reference product sponsor not later than180 days before the date of the first commercial marketing of the biological product licensed under subsection (k) [*i.e.* the biosimilar in question]". Upon receiving such notice, the sponsor may bring a declaratory judgment action based on any remaining patents not yet litigated.

Here, Sandoz submitted to the FDA an application for Zarxio®, a biosimilar of Amgen's Neupogen® (filgrastim). Sandoz's biosimilar application was accepted for review by the FDA on July 7, 2014. One day later, Sandoz notified Amgen of its application and of its intent to commercially market Zarxio® upon FDA licensure (which Sandoz expected in the first half of 2015). Sandoz, however, did not provide Amgen with its application or manufacturing information.

In October 2014, Amgen sued Sandoz in the Northern District of California for patent infringement, for state law unfair competition claims, and to obtain injunctions to enforce §262(*l*)(2)(A) and §262(*l*)(8)(A) against Sandoz. Sandoz counterclaimed for declaratory judgments that Amgen's asserted patents were invalid and that Sandoz had not violated the BPCIA. In the ensuing litigation, the District Court granted partial judgment on the pleadings to Sandoz on its BPCIA counterclaims, and dismissed with prejudice Amgen's unfair competition claims. Amgen appealed to the Federal Circuit.

On appeal, the Federal Circuit held that Sandoz did not violate the BPCIA by withholding its application and manufacturing information, and that Amgen had no injunctive remedy for Sandoz's failure to comply with §262(*l*)(2)(A). The Federal Circuit also held that §262(*l*)(8)(A) requires an applicant to wait to give notice of commercial marketing until after the FDA licenses the biosimilar, because §262(*l*)(8)(A) expressly refers—using the past tense—to "the biologic product licensed under subsection (k)." Accordingly, the Federal Circuit enjoined Sandoz from marketing Zarxio® for 180 days after FDA licensure. Sandoz and Amgen cross-petitioned the Supreme Court for *certiorari*.

The Supreme Court Decision

The Supreme Court's June 12, 2017 decision answers two questions. The first is whether the requirement in §262(*l*)(2)(A) that a biosimilar applicant provide its application and manufacturing information to a sponsor is enforceable by an injunction under federal or state law. As to this question, the Supreme Court agreed with the Federal Circuit's conclusion that an injunction under federal law is not available—but criticized the Federal Circuit's reasoning underlying that conclusion.

Specifically, the Supreme Court asserted that the Federal Circuit erred in relying on 35 U.S.C. §271(e)(4), which provides the sole remedies "which may be granted by a court for an act of artificial infringement," and which does not include a provision that authorizes a court to compel compliance with §262(*l*)(2)(A). The flaw in that reasoning, according to the Supreme Court, is that "Sandoz's failure to disclose its application and manufacturing information was not an act of artificial infringement" giving to a remedy under 35 U.S.C. §271(e)(4). Rather, it is the submission

of the biosimilar application that constitutes the relevant act of "artificial infringement" for that statute.

Leaving aside the Federal Circuit's erroneous reliance on 35 U.S.C. §271(e)(4), the Supreme Court ruled that a separate statutory provision of the BPCIA— 42 U.S.C. §262(*l*)(9)(C), which, as noted above, allows the sponsor (but not the applicant) to file early for declaratory judgment—provided the "exclusive" remedy under federal law for a failure to comply with §262(*l*)(2)(A). In reaching that conclusion, the Supreme Court noted that:

Where, as here, 'a statute expressly provides a remedy, courts must be especially reluctant to provide additional remedies.' *Karahalios* v. *Federal Employees*, 489 U. S. 527, 533 (1989). The BPCIA's "carefully crafted and detailed enforcement scheme provides strong evidence that Congress did *not* intend to authorize other remedies that it simply forgot to incorporate expressly." *Great-West Life & Annuity Ins. Co.* v. *Knudson*, 534 U. S. 204, 209 (2002) (internal quotation marks omitted). The presence of §262(*l*)(9)(C), coupled with the absence of any other textually specified remedies, indicates that Congress did not intend sponsors to have access to injunctive relief, at least as a matter of federal law, to enforce the disclosure requirement.

The Supreme Court declined to resolve the subsidiary issues of whether the disclosure of a biosimilar application and manufacturing information under §262(*l*)(2)(A) is "mandatory or conditional," and whether an applicant who withholds such information has committed an "unlawful" act amenable to relief under California law. The Supreme Court instead remanded those issues, and instructed that, "[o]n remand, the Federal Circuit should determine whether California law would treat noncompliance with §262(*l*)(2)(A) as 'unlawful.' If the answer is yes, then the court should proceed to determine whether the BPCIA pre-empts any additional remedy available under state law for an applicant's failure to comply with §262(*l*)(2)(A) . . . and whether Sandoz has forfeited any pre-emption defense." The Court likewise took "no view on whether a district court could take into account an applicant's violation of §262(*l*)(2)(A) (or any other BPCIA procedural requirement) in deciding whether to grant a preliminary injunction" against marketing the biosimilar.

Turning to the second question—whether §262(*l*)(8)(A) requires a biosimilar applicant to wait to give notice of commercial marketing until after the FDA licenses the biosimilar—the Supreme Court answered that question in the negative. The Supreme Court rejected the Federal Circuit's attempt to read a timing requirement into the term "licensed" in §262(*l*)(8)(A), and instead held that "[t]he statute's use of the word 'licensed' merely reflects the fact that, on the 'date of the first commercial marketing,' the product must be 'licensed.' . . . Accordingly, the applicant may provide notice either before or after receiving FDA approval." In reaching that conclusion, the Supreme Court reasoned that Congress already had included in §262(*l*)(8)(A) an express timing requirement—that the applicant provide 180 days' notice—and that, had Congress intended to impose a second timing requirement, it would have done so expressly as well.

The Supreme Court rejected Amgen's argument that the past-tense phrasing of the term "licensed" in §262(*l*)(8)(A) should be accorded weight in view of other BPCIA provisions that refer to biologic products in the present tense. The Supreme Court observed that those present-tense references concerned the evaluation of biosimilar applications prior to licensure, and that, "[i]n contrast, nothing in §262(*l*)(8)(A) turns on the precise status or characteristics of the biosimilar application."

Last, the Supreme Court dismissed the parties' competing policy arguments concerning the effects of prelicensure notice of commercial marketing, asserting that "[t]he plausibility of the contentions on both sides illustrates why such disputes are appropriately addressed to Congress, not the courts."

In a concurring opinion, Justice Breyer noted that, if the FDA, "after greater experience administering this statute, determines that a different interpretation would better serve the statute's

objectives, it may well have authority to depart from, or to modify, today's interpretation."

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