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Client Alert

Intellectual Property Practice Group

June 13, 2017

The Age of Competition
The Supreme Court Decides the First BPCIA Case

In a landmark ruling for the biotech and pharmaceutical industries, a unanimous Supreme Court decided *Sandoz Inc. v. Amgen Inc.*, 582 U.S. ____, Nos. 15-1039, 15-1195 (June 12, 2017), its first biosimilar case governed by the Biologics Price Competition and Innovation Act ("BPCIA"). The case provides clarity regarding two main issues: (1) whether a court may enforce an injunction against a biosimilar applicant that "opts out" of the "patent dance" by refusing to provide its abbreviated biologics license application ("aBLA") and manufacturing information (collectively, the applicant's "confidential information") to the innovator, also known as the reference product sponsor ("RPS"), and (2) whether the biosimilar applicant must obtain a license (*i.e.*, FDA approval) before giving notice to the RPS that it plans to begin commercial marketing of its biosimilar product.

The Court answered both questions in the negative, reversing and remanding the case to the Federal Circuit for a determination of whether the RPS may rely on state law to force the applicant to comply with the confidential information exchange provision. The Court's decision provided some much-needed clarity around the application of the BPCIA, and it removed one obstacle for competition on biological products—the 180-day delay in biosimilar product launch after a biosimilar applicant obtains a license from FDA. The ruling, however, does not change the RPS's ability to litigate each of its patents before that commercial launch.

The "Patent Dance"

The BPCIA provides an abbreviated pathway for a biosimilar applicant to seek approval to sell a competing biological product where no such statutory regime existed previously. The Supreme Court walked through the patent provisions of the BPCIA. *See* slip op. at 4–7 (Section C). The BPCIA weaves together nine provisions governing the procedure for, and timing of, patent litigation relating to biosimilar products.[1] If the applicant complies with the requirement to provide its confidential information in Section 2A, a cascading series of events follows—known as the "patent dance." The steps include the RPS sharing a comprehensive list of patents that could "reasonably be asserted" against the applicant (Section 3A), the parties exchanging contentions about the validity, enforceability and infringement of those patents (Section 3B, 3C), and procedures for the parties to determine which patents to litigate first (Sections 4 & 5).[2] The patents on the comprehensive

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list that the parties agree to litigate in the first wave are the "listed" patents, while the rest are the "unlisted" patents. Once the parties identify the listed patents, under Section 6, the RPS must file suit on the listed patents within 30 days to preserve its full scope of remedies.[3] If, on the other hand, the applicant fails to provide its confidential information, the statute sends the parties immediately into patent litigation, where the RPS may assert any patent that covers its biological product.[4] *See* slip op. at 7–8 (Section D) (failing to provide confidential information "effectively pretermit[s] the entire two-phase litigation process" by authorizing the RPS to file a declaratory judgment action).

The Case and the Federal Circuit Decision Below

In 2014, Sandoz filed the first aBLA under the BPCIA seeking FDA approval to market Zarxio®, a biosimilar version of Amgen's Neupogen® (filgrastim), a biological product used to stimulate the production of white blood cells. *See* slip op. at 8. After the FDA accepted Sandoz's aBLA for substantive review, in July 2014, Sandoz informed Amgen of its application, and gave notice of its planned commercial marketing. Sandoz later confirmed that it would not provide its confidential information to Amgen. *See id.* Amgen sued Sandoz in the Northern District of California for patent infringement, seeking injunctive relief for Sandoz's alleged violations of the BPCIA (Sections 2A and 8A) and California laws relating to unfair competition. *See id.* While the case was pending, FDA approved Sandoz's Zarxio® product, and Sandoz provided another notice of commercial marketing. *See id.* at 9. The district court found for Sandoz, and Amgen appealed to the U.S. Court of Appeals for the Federal Circuit. *See id.*

The Federal Circuit panel split. The Federal Circuit affirmed the district court's interpretation of Section 2A, finding that Sandoz did not violate the BPCIA by refusing to provide its confidential information in light of two provisions in the BPCIA that expressly contemplate an applicant's failure to comply. *See Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1355–56 (Fed. Cir. 2015) (explaining 42 U.S.C. § 262(*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii)). However, the panel reversed the district court's interpretation of Section 8A, the notice of commercial marketing provision, because it determined that a biosimilar applicant must obtain a license from FDA *before* its notice is legally effective. *See* 794 F.3d at 1357. As to injunctive relief, the court dismissed as moot Amgen's appeal of the district court's denial of the injunction for failing to comply with section 8A of the BPCIA under California law because the Federal Circuit enjoined Sandoz from marketing its product until 180 days from its second notice of commercial marketing, which Sandoz provided after it obtained a license from FDA. *See id.* at 1360–61. The Federal Circuit affirmed the dismissal of Amgen's state-law claims because Sandoz's failure to comply with section 2A of the BPCIA was not "unlawful." *Id.* at 1361. The panel majority reconciled its decision to maintain the injunction because the case purportedly was unique: the reference product had been licensed since 1991, so its 12 years of exclusivity was long expired.[5]

In a much anticipated opinion authored by Justice Thomas,[6] the U.S. Supreme Court vacated in part, reversed in part, and remanded the case back to the Federal Circuit.

No Federal Injunction Can Force an Applicant to Provide its Confidential Information

The Supreme Court "agree[d] with the Federal Circuit that an injunction under federal law is not available to enforce § 262(*l*)(2)(A), though for slightly different reasons[.]" Slip op. at 10. The Supreme Court clarified that the artificial act of infringement contemplated in the BPCIA is the act of filing an aBLA under section (k), *regardless* of whether the applicant provides its confidential information or not. *See id.* at 10–11. The Federal Circuit's reliance on the exclusive remedy provided in Section 271(e)(4) was misplaced because failure to provide its confidential information is not part of the artificial act of infringement itself. *See id.* at 12 ("In neither instance [§§ 271(e)(2)(C)(i) or (ii)] is the applicant's failure to provide its application and manufacturing information an element of the act of artificial infringement, and in neither instance does § 271(e)(4) provide a remedy for that failure." (citation omitted)). Like the Federal Circuit, the Supreme Court looked to Section 262(*l*)(9)(C) to provide the remedy where an applicant fails to provide its confidential information—authorizing the RPS to bring an immediate declaratory judgment action for patent infringement.

"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." *Id.* at 13.

One interesting aspect of the opinion—at least for now—relates to the potential availability of a state-law cause of action (and corresponding injunction) in cases where the applicant fails to comply with Section 2A of the BPCIA. The Federal Circuit held that the Amgen's attempt to enjoin Sandoz under California unfair competition laws failed because Sandoz's refusal to provide its confidential information under the BPCIA was not "unlawful." *See id.* at 14.[7] The Supreme Court "decline[d] to resolve this particular dispute definitively because it does not present a question of federal law." *Id.* at 14. Furthermore, "[w]hether Sandoz's conduct was 'unlawful' under the unfair competition law is a state-law question, and the court below erred in attempting to answer that question by referring to the BPCIA alone." *Id.* at 15. The Supreme Court remanded the case for the application of California law, leaving for the Federal Circuit the question of whether the BPCIA pre-empts State law. *Id.*

Applicant Need Not Obtain FDA License to Give Effective Notice of Commercial Marketing

The Supreme Court reversed the Federal Circuit's interpretation of the notice of commercial marketing provision, explaining its reasoning in a single paragraph. *See* slip op. at 16. Section 8A requires an applicant to give notice to the RPS "not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." The primary debate in the briefs and at oral argument focused on the statutory interpretation of those twenty words to determine whether an applicant has to wait until it has a license from FDA *before* it can give the notice. The Supreme Court made short shrift of that debate, stating that the "statute's plain language" commanded its result. *See* slip op. at 18. The Court reasoned that because the phrase "[c]ommercial marketing" modifies "the biological product licensed under subsection (k)," and not "notice"—"'[c]ommercial marketing is the point in time by which the biosimilar must be 'licensed.'" *Id.* at 16. The Court further contrasted the text of the very next provision of the BPCIA (Section 8B), where Congress imposed two timing requirements using "before" and "after," with Section 8A, where Congress elected only one timing requirement of "before." *Id.* at 18–19. The Court dismissed the lengthy policy arguments of the parties and amici because the "plausibility of the contentions on both sides illustrates why such disputes are appropriately addressed to Congress, not the courts." *Id.* at 18. Finally, and although the injunction against Sandoz expired on September 2, 2015, the Supreme Court held that "the Federal Circuit erred in issuing a federal injunction prohibiting Sandoz from marketing Zarxio until 180 days after licensure." *Id.*

Impact of the Decision

Because there are fewer than ten BPCIA litigations pending, the Supreme Court's holding has limited reach. Going forward, however, all biosimilar litigants must comply with its ruling, and the decision provides added clarity around the application of the BPCIA—something that both sides of any BPCIA case will appreciate.

On remand, the Federal Circuit may decide the Supreme Court's open question about the availability of a state-law injunction. For example, at oral argument before the Supreme Court, the Department of Justice attorney stated: "I think there are strong arguments that this would be preempted. This is a highly detailed scheme. And if States were to start to interject different means of enforcing it on a State-by-State basis, that might wreak some havoc, but we've not taken a position on that." Transcript of Oral Argument at 27, *Sandoz Inc. v. Amgen Inc.* (U.S. argued Apr. 26, 2017) (No. 15-1039, 15-1195). That said, the answer on whether the BPCIA pre-empts state law may have to wait for another day; as the Supreme Court noted, Sandoz may have waived its pre-emption defense below. *See* slip op. at 15 (suggesting that "Sandoz has forfeited any pre-emption defense"). If that is the case—and until the next case arguing pre-emption is properly before the Federal Circuit—RPS holders going forward may look to the strength of a State's unfair competition laws in deciding where to file new BPCIA cases.[8]

The Supreme Court's decision may gut Congress's intent in creating the patent dispute resolution provisions of the BPCIA, at least in the short term.[9] As a practical matter, as soon as FDA accepts a new aBLA for review, an applicant may refuse to provide its confidential information and immediately give notice of commercial marketing. BPCIA cases therefore may come as declaratory judgment suits, and to a certain extent,[10] on motions for preliminary injunction. As a result, the Supreme Court's ruling may expedite the launch of at least a handful of biosimilar products. At least with respect to the questions of pre-emption and the notice of commercial marketing provision, the Supreme Court may have further opportunity to reconsider its interpretation after district courts begin to hear more challenges under the BPCIA.

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[1] *See* 42 U.S.C. §§ 262(*l*)(1)-(9).

[2] *See id.* §§ 262(*l*)(3)-(5).

[3] *Id*. at § 262(*l*)(6).

[4] 35 U.S.C. § 271(e)(2)(C)(ii); 42 U.S.C. § 262(*l*)(9)(C).

[5] *See* 42 U.S.C. § 262(k)(7); *see also* 794 F.3d at 1358 ("A statute must be interpreted as it is enacted, not especially in light of particular, untypical facts of a given case.").

[6] Justice Breyer wrote separately to concur in the judgment and to encourage the FDA to weigh in. *See* slip op. at 1.

[7] The Court also noted that the "state-law holding rests on an incorrect interpretation of federal law[,]" because the Federal Circuit purportedly considered the applicant's failure to comply with the information exchange as an element of the artificial act of infringement. *Id.* at 14.

[8] This is, of course, constrained by the Supreme Court's holding last month on patent venue. *See TC Heartland*, --- S.Ct. ----, 2017 WL 2216934, at *3.

[9] Today, every aBLA pending at FDA refers to a reference product approved more than 12 years ago and thus, is not subject to any period of regulatory exclusivity. Where a portion of the 12-year exclusivity remains for the RPS's product at issue, the biosimilar applicant still may consider participating in the patent dance, as it provides increased certainty without the need for emergency intervention by the courts. As a practical matter, we may not see those cases for a decade or more.

[10] Note that the Court's ruling creates statutory tension where an applicant refuses to provide its confidential information, then also immediately provides a notice of commercial marketing, because the latter triggers the availability of a motion for a preliminary injunction by the RPS, but only with respect to the "unlisted" or new patents acquired by the RPS. *See* 42 U.S.C. § 262(*l*)(8)(B); *see also Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1369–70 (Chen, J., dissenting).