Clarity from chaos

THE CASE:
Sandoz Inc v Amgen Inc
Supreme Court of the US
12 June 2017

There are two strategies to consider following the Supreme Court's first Biologics Price Competition and Innovation Act case, explain **Margaret Bolce Brivanlou** and **Abby Parsons**

In a landmark ruling for the biotech and pharmaceutical industries, a unanimous US Supreme Court decided *Sandoz Inc v Amgen Inc*,[1] its first biosimilar case governed by the Biologics Price Competition and Innovation Act ("BPCIA"). 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 licence from FDA. While the industry largely views the decision as a victory for biosimilar applicants, it does not hinder the ability of the innovator company, also known as the Reference Product Sponsor ("RPS"), to litigate each of its patents before a biosimilar commercial launch. Still, many open questions remain regarding best practices for navigating patent cases under the BPCIA in a quickly changing area of law. In the wake of the Supreme Court's decision, litigants should understand the ruling and consider two strategies.

The case below and SCOTUS' ruling

The *Sandoz* case arose from Sandoz filing an abbreviated biologic licence application ("aBLA") to market Zarxio, a biosimilar product of Amgen's Neupogen product for stimulating the production of white blood cells. The district court found for Sandoz, and Amgen appealed to the US Court of Appeals for the Federal Circuit. The Federal Circuit panel split; it held that Sandoz did not violate the BPCIA by refusing to provide its confidential information under 42 USC § 262(l)(2)(A) in light of two provisions in the BPCIA that expressly contemplate an applicant's failure to comply,[2] but the panel decided that Sandoz's notice of commercial marketing was not effective under Section 262(l)(8)(A) because Sandoz had not first obtained a licence from FDA.[3] The Federal Circuit maintained the injunction against Sandoz through appeal.[4]

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In a much-anticipated opinion authored by Justice Thomas, the Supreme Court vacated in part, reversed in part, and remanded the case back to the Federal Circuit. The Supreme Court held that no federal injunction can force an applicant to provide its confidential information under Section 2A, but an applicant need not obtain a licence from FDA to give an effective notice of commercial marketing under Section 8A.

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[.]"[5] 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.[6] 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. The Supreme Court remanded the case for the application of California law, leaving for the Federal Circuit the question of whether the BPCIA preempts State law.[7]

The Supreme Court reversed the Federal Circuit's interpretation of the notice of commercial marketing provision, explaining its reasoning in a single paragraph.[8] 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 20 words to determine whether an applicant must wait until it has a licence 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 because Section 8A only contained one timing requirement ("before") where Section 8B had two ("before" and "after").[9] Finally, and although the injunction against Sandoz expired on 2 September 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."[10]

Strategy 1: Avoid the side-show about state law

The state-law injunction issue is a side-show because it likely is preempted by federal law and will trigger early motion practice. This could delay action on the patent issues, and time is of the essence. Accordingly, both parties may be better off to avoid it. For an RPS, it likely is unwise to put too much hope in the possibility of obtaining injunctive relief under state law for a biosimilar's refusal to provide its confidential information under Section 2A. It is tempting to explore because this issue may be around for some time: the Federal Circuit may not decide preemption on remand because Sandoz may have waived its preemption defence below,[11] and only one case is presently postured to tee up the issue again on appeal.[12] Accordingly, an RPS should consider including a state-law claim for unfair competition seeking injunctive relief, but expect an uphill battle. 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."[13]

Biosimilar applicants also may be well served by avoiding the state-law injunction issue. This may seem counterintuitive because, at least in the short term, applicants have one good reason to get out of the patent dance[14] as soon as possible: there is nothing stopping FDA from approving a biosimilar product where the 12-year exclusivity on the RPS product has run. That fact is true for every aBLA on file at FDA to date. Until an RPS product has life on its 12-year clock, a biosimilar applicant might short-circuit the patent dance in a different way: by providing its confidential information, but failing to complete the whole process. On those facts, the RPS could bring an immediate action for declaratory judgment under Section 9B – effectively terminating the patent dance – and no court has determined whether Section 9(B) of the BPCIA is enforceable with an injunction (either state or federal). There is always the chance of coming out of the frying pan and into the fire.

Strategy 2: Prepare for expedited patent litigation, and consider challenging the application of the notice of commercial marketing provision in certain instances

As described above, and at least in the short term, the Supreme Court's decision permitting an applicant to provide its notice of commercial marketing before obtaining a licence from FDA may gut Congress's intent in creating the patent dispute resolution provisions of the BPCIA. Both sides of a BPCIA case should prepare for the possibility of expedited patent litigation, even well in advance of a biosimilar applicant filing an aBLA. 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, on motions for preliminary injunction. That means for both sides, having your ducks in a row, so to speak, may be more important than ever. For example, an RPS should evaluate its portfolio early, ensure that it has clean title to each patent, and anticipate potential challenges. A biosimilar applicant may want to consider conducting freedom to operate and invalidity searches to prepare its positions early. The Supreme Court's ruling may expedite the launch of at least a handful of biosimilar products, but it also may expedite the pace of BPCIA litigation.

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Despite its obvious intent to provide clarity, the Supreme Court's opinion did not address all the BPCIA's possible scenarios. For example, in an expedited patent case described above, the parties would not complete the detailed steps of the patent dance. Specifically, the RPS would not provide a comprehensive list of patents covering its biological product to the applicant under Section 3A, the parties would not decide which of those patents to assert in the first wave of patent litigation (ie, the "listed patents"), and by default, the parties could not identify "unlisted" patents, or those patents that were on the RPS's comprehensive list but are not asserted in the first wave. Yet, if the applicant still must give a notice of commercial marketing, Section 8B is triggered, authorising the RPS to seek a preliminary injunction, but only with respect to the unlisted or new patents. Requiring the applicant to give notice of commercial marketing in this situation renders the BPCIA both nonsensical and redundant. After all, what good is the ability to sue the applicant for infringing certain patents already in litigation? Accordingly, litigants may want to challenge the application of the notice of commercial marketing with motion practice in certain scenarios to relieve this statutory tension.

Footnotes

1. 582 US _, Nos. 15-1039, 15-1195, 2017 WL 2507337, at *10, *16 (12 June 2017).
2. *See Amgen Inc v Sandoz Inc,* 794 F.3d 1347, 1355–56 (Fed Cir 2015) (explaining 42 USC § 262(l)(9)(C) and 35 USC § 271(e)(2)(C)(ii)).
3. *See* 794 F.3d at 1357.
4. Id at 1360–61.
5. 2017 WL 2507337, at *10.
6. *See* Id at *11.
7. Id at *14.
8. *See* Id at *15.
9. *See* Id at *16.
10. Id.
11. *See* Id at *14 (suggesting that "Sandoz has forfeited any pre-emption defence").
12. *See Janssen Biotech, Inc v Samsung Bioepis Co, Ltd,* No 17-3524 (D Del filed 17 May 2017) (defendant did not provide its confidential information and gave immediate notice of commercial marketing).
13. Transcript of Oral Argument at 27, *Sandoz Inc v Amgen Inc* (US argued 26 April 2017) (No 15-1039, 15-1195).
14. The "patent dance" generally refers to the exchange provisions in the BPCIA found in 42 USC §§ 262(l)(2)-(5).

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