Supreme Court won't force fast-track litigation over biologic drug patents

By Michael Scott Leonard

Makers of name-brand biologic drugs cannot obtain federal injunctions forcing companies that develop copycat versions to initiate the informal prelitigation procedures available under a law aimed at expediting patent disputes over biologics, a unanimous U.S. Supreme Court has decided.

Sandoz Inc. v. Amgen Inc. et al., No. 15- 1039, 2017 WL 2507337 (U.S. June 12, 2017).

In a 9-0 ruling June 12, the high court rejected an attempt by drugmaker Amgen Inc. to shoehorn its dispute with rival Sandoz Inc. over a "biosimilar" version of Amgen's immune booster Neupogen (filgrastim) into the "complex statutory scheme" established by the Biologics Price Competition and Innovation Act, 42 U.S.C.A. § 262.

The Federal Circuit found that the only consequence for Sandoz's failure to trigger the expedited procedures was that the company could not take advantage of that process.

REUTERS/Brian Snyder

The litigation concerns drugmaker Amgen Inc.'s dispute with rival Sandoz Inc. over a "biosimilar" version of Amgen's immune booster Neupogen. Here, a researcher displays a sample of a bacterium used in making an antibiotic drug.

The BPCIA, enacted as part of the Affordable Care Act, is supposed to streamline patent disputes involving biosimilar versions of biologic drugs — medicines derived from living organisms, typically through advanced genetic engineering, rather than through traditional pharmaceutical chemistry.

The law established informal quasi-discovery mechanisms triggered when a biosimilar maker notifies the brand-name biologic maker that it has filed an application with the U.S. Food and Drug Administration. That notification is known as an act of "artificial infringement" because even though the BPCIA specifically authorizes it, it is supposed to culminate in a patent infringement suit.

After Sandoz tried to introduce a filgrastim biosimilar called Zarxio without going through that process, Amgen sought an injunction ordering its rival to comply with the BPCIA.

The U.S. Court of Appeals for the Federal Circuit, the country's top patent court, held for Sandoz in July 2015. *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347 (Fed. Cir. 2015). Sandoz launched the drug the following September.

The Supreme Court partly affirmed June 12.

Writing for the court, Justice Clarence Thomas said an injunction would be improper, given the comprehensive regulatory regime established by the BPCIA, which specifies exactly what happens if a biosimilar applicant opts out of the prelitigation procedures.

Those consequences include making it easier for a brand-name biologics maker to file a patent infringement suit, he noted.

"Where, as here, 'a statute expressly provides a remedy, courts must be especially reluctant to provide additional remedies'" such as an injunction, Justice Thomas wrote, quoting *Karahalios v. National Federation of Federal Employees*, 489 U.S. 527 (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,'" he added, citing *Great-West Life & Annuity Insurance Co. v. Knudson*, 534 U.S. 204 (2002).

'A STATE LAW QUESTION'

Although the high court affirmed that part of the Federal Circuit's ruling, the justices departed from the appellate court's reasoning.

The Federal Circuit found that the only consequence for Sandoz's failure to trigger the expedited procedures was that the company could not take advantage of that process.

Among other things, Sandoz forfeited the right to file a declaratory judgment suit that could clarify the legal landscape before it committed to a costly, risky drug launch, the appeals court noted. Instead, the biosimilar

maker had to await Amgen's patent infringement suit, giving up the potential advantage of litigating on its own terms.

The Supreme Court vacated that part of the decision, noting that in addition to alleging patent infringement, Amgen had accused Sandoz of unfair trade practices under California law, Cal. Bus. & Prof. Code Ann. § 17205.

Although the BPCIA expressly and comprehensively governs patent liability once a biosimilar maker has committed the acts of "artificial infringement" that initiate the law's streamlined procedures, Justice Thomas said, it is unsettled whether the statute preempts state law claims that could ultimately lead to an injunction.

Because the unfair-trade-practices law penalizes only "unlawful" business conduct, the Federal Circuit should decide on remand whether Sandoz's decision to forgo the BPCIA's prelitigation procedures qualifies as "unlawful" in California, he said.

"We decline to resolve this particular dispute definitively because it does not present a question of federal law," Justice Thomas wrote. "Whether Sandoz's conduct was 'unlawful' under the unfair-competition law is a state law question, and the court below erred in … referring to the BPCIA alone."

180-DAY WAITING PERIOD

The high court also reversed another part of the Federal Circuit's decision concerning a BPCIA section, 42 U.S.C.A. § 262(l)(8)(A), that requires biosimilar makers to wait 180 days before selling their products after notifying the brand-name company of their intent to enter the market.

The appeals court found that biosimilar makers must wait until after the FDA licenses their product to trigger that 180-day waiting period, effectively imposing an additional delay.

That was wrong, Justice Thomas said.

"Section 262(l)(8)(A) contains a single timing requirement: The applicant must provide notice at least 180 days prior to marketing its biosimilar," he wrote. "The Federal Circuit, however, interpreted the provision to impose two timing requirements: The applicant must provide notice after the FDA licenses the biosimilar and at least 180 days before the applicant markets the biosimilar.

"We disagree," Justice Thomas added.

Justice Stephen Breyer concurred separately, saying in a one-paragraph opinion that although he agreed with the ruling, the FDA retained the authority to adopt other reasonable interpretations of the BPCIA. WJ

Related Filings:
Supreme Court Opinion: 2017 WL 2507337
Federal Circuit opinion 794 F.3d 1347

See Document Section A (P. 19) for the Supreme Court opinion.

Supreme Court sets rules for copycat versions of biologic drugs

Intellectual property attorneys discuss the impact of the U.S. Supreme Court's holding in *Sandoz Inc. v. Amgen Inc.*, No. 15-1039, 2017 WL 2507337 (U.S. June 12, 2017).

Courtenay Brinckerhoff, Foley & Lardner, Washington

The court's decision on the premarketing notice issue will mean that biosimilar products can be marketed as soon as they are approved, as long as there are no preliminary injunctions stemming from any still-pending patent litigation. That possibility might encourage biosimilar applicants to participate in the "patent dance," to increase the likelihood that all patent disputes will be resolved by the time the product is approved.

Paul A. Calvo, Sterne, Kessler, Goldstein & Fox, Washington

While the timing of an effective notice of commercial marketing is settled, the question of whether an injunction might be available under California unfair-competition law to compel participation with the patent dance was left to the Federal Circuit to reconsider. As a backdrop to the decision is the work lawmakers are undertaking to overhaul the Affordable Care Act. The decision begs the question of whether lawmakers will attempt to amend portions of the Biologics Price Competition and Innovation Act to override one or both of the court's holdings.

Christopher Loh, Fitzpatrick, Cella, Harper & Scinto, New York

At oral argument, Justice Stephen Breyer noted that, under Sandoz's interpretation of the law, "everyone will be free … to start bringing declaratory judgment actions" following early notice of commercial marketing. While the Supreme Court's reasoning here relies in part on congressional intent, I'm not so sure that this result was what Congress intended. I think one of the functions of the "patent dance" was to get the parties talking about patents early, and potentially settling certain patent issues, before the start of any litigation. The *Sandoz* decision has the potential to circumvent that process.

Irena Royzman, Patterson Belknap Webb & Tyler, New York

The decision forces innovators to litigate blind in cases where biosimilar makers do not disclose their regulatory application and manufacturing information. But in the long term, biosimilar makers are likely to follow the patent dance in most cases given the significant benefits of following the statute. As for the notice of commercial marketing, biosimilar makers will undoubtedly provide it prior to approval.