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High Court Boosts Biosimilars By Allowing Early Notice

By **Jeff Overley**

Law360, New York (June 12, 2017, 10:31 AM EDT) -- The U.S. Supreme Court on Monday ruled that biosimilar makers can give 180-day notice of sales before their products win approval, a major decision that will speed up access to the lower-cost medicines.

The ruling in a case involving Amgen Inc. and Sandoz Inc. said that 180-day notice required by the Biologics Price Competition and Innovation Act can be given prior to licensure by the U.S. Food and Drug Administration. Amgen had argued that notice must await approval, which could have effectively delayed less-expensive competition by six months, but the Supreme Court disagreed.

A biosimilar maker "may provide notice either before or after receiving FDA approval," Monday's ruling said.

The issue of notice is important because biosimilars are discounted versions of brand-name biologics that often earn billions of dollars annually. For consumers and sellers of such biologics, any delay in biosimilar competition carries big financial implications.

"This ruling should help expand access and lower prescription drug costs for employers, health plans, labor unions and Medicare," Express Scripts, a major negotiator of prescription drug prices, said in a statement.

Monday's ruling, authored by Justice Clarence Thomas, was unanimous — something of a surprise, given that multiple justices questioned the wisdom of pre-approval notice during oral arguments in April. The ruling partially reversed the Federal Circuit, which in 2015 barred Sandoz from selling its Zarxio biosimilar until 180 days after approval.

Amgen had warned that pre-approval notice might lead to courtroom chaos because a biosimilar's attributes — and therefore its relevance to unexpired patents — are not set in stone until the FDA grants approval. But the Supreme Court on Monday said that concerns about delaying biosimilars were also valid, and that in any event, the BPCIA's text is what matters most.

"Even if we were persuaded that Amgen had the better of the policy arguments, those arguments could not overcome the statute's plain language," the opinion stated.

A crucial factor in the court's opinion was a BPCIA section that says innovator companies like Amgen can file suit "after receiving notice ... and before ... the first commercial marketing." By contrast, the BPCIA section that discusses 180-day notice does not clearly say that notice should come before commercial marketing, and the different structure is telling, according to Monday's opinion.

Monday's decision also found that a federal injunction is not available to compel biosimilar makers to disclose their approval applications to rivals. But the decision told the Federal Circuit to examine whether a state-law injunction is available.

At issue is whether nondisclosure would be deemed unlawful under California law. If so, the Federal Circuit should examine whether the BPCIA preempts any remedy beyond a declaratory judgment action, which the BPCIA explicitly allows as a remedy for nondisclosure, Monday's opinion said.

Voluntarily disclosure triggers a BPCIA process called the "patent dance" — a back-and-forth exchange of intellectual property information meant to streamline patent litigation. If disclosure doesn't occur, then brand-name biologic makers — but not biosimilar makers — can immediately file declaratory judgment actions. Monday's opinion described the choice as a tradeoff.

Failure to disclose gives brand-name manufacturers "the control that the [biosimilar maker] would otherwise have exercised over the scope and timing of the patent litigation," according to Monday's opinion. "It also deprives the [biosimilar maker] of the certainty that it could have obtained by bringing a declaratory judgment action prior to marketing its product."

Although Monday's opinion was unanimous, Justice Stephen Breyer filed a concurring opinion. In it, Justice Breyer argued that "Congress implicitly delegated to the [FDA] authority to interpret" the disputed BPCIA language.

"That being so, if that agency, 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, though we need not now decide any such matter," Justice Breyer wrote.

In a statement on Monday, Sandoz said that "the justices' unanimous ruling on the notice of commercial marketing will help expedite patient access to life-enhancing treatments."

"We also appreciate the clarity provided on the patent dance, which will help the biosimilars industry move forward," Sandoz added.

In a separate statement, Amgen said that it is "disappointed in the court's decision on the notice of commercial marketing" but "will continue to seek to enforce our intellectual property against those parties that infringe upon our rights."

Sandoz is represented by Morrison & Foerster LLP.

Amgen is represented by WilmerHale, Paul Weiss Rifkind Wharton & Garrison LLP and in-house counsel.

The cases are Sandoz Inc. v. Amgen Inc. et al., case number 15-1039, and Amgen Inc. v. Sandoz Inc., case number 15-1195, in the Supreme Court of the United States.

--Editing by Rebecca Flanagan.

Update: This story has been updated with comment from Amgen, Sandoz and Express Scripts as well as additional detail from the court's ruling.