

High Court Interprets The Biosimilars Statute — What Now?

By Irena Royzman and Nathan Monroe-Yavneh

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On Monday, the U.S. Supreme Court issued its first interpretation of the biosimilars statute, the Biologics Price Competition and Innovation Act of 2009. The BPCIA, part of Obamacare, introduced an abbreviated pathway for regulatory approval of biosimilars, allowing biosimilars to piggyback on the regulatory data of innovator biologics for their approval. Biosimilars are biologic medicines, grown in living cells, that copy innovator biologics but, due to the complexity of biologic medicines, cannot precisely duplicate them. Along with the regulatory pathway, the BPCIA provides carefully calibrated patent dispute resolution procedures to allow innovator companies to protect their patent rights. The ruling addresses these patent dispute resolution procedures in the first patent action under the BPCIA, *Amgen Inc. v. Sandoz Inc.*, and involves the first U.S. biosimilar product, Sandoz's Zarxio.

Justice Clarence Thomas, writing for a unanimous court, addressed two issues fundamental to patent litigation under the BPCIA that will impact courts, innovator companies and biosimilar makers for years to come. First, the court held that the BPCIA's requirement that biosimilar applicants provide the innovator company with their regulatory application and manufacturing information, the first step of the so-called patent dance, is not enforceable under federal law.[1] Second, the court concluded that a biosimilar maker can provide its 180-days' notice of commercial marketing prior to approval, reversing the Federal Circuit's holding that the BPCIA creates a defined statutory window to litigate patent disputes.[2]

While the court resolved both issues in ways that make it more difficult for patent owners to protect their rights, the consequences of the ruling may be modest in the long run. Biosimilar makers obtain significant benefits by following the BPCIA's procedures. The court's ruling also provides key drafting lessons for Congress on how to ensure that statutes it intends to be enforceable are ultimately enforced.

Bypassing the Patent Dance

The court first held that the BPCIA's requirement that a biosimilar applicant disclose its biosimilar application and manufacturing information is not enforceable under federal law. Instead, the BPCIA itself provides the remedy: the innovator can bring a declaratory judgment action for artificial infringement against the biosimilar applicant. The court reached the same result as the Federal Circuit



Irena Royzman



Nathan Monroe-Yavneh

but based on different reasoning.[3]

Central to the court's holding were two provisions of the BPCIA. Section 262(l)(2)(A) of the BPCIA sets forth the first step of the patent dance: The biosimilar applicant "shall" provide its regulatory application and manufacturing information to the innovator. Another provision, §262(l)(9)(C), provides that if the applicant fails to provide its application and information, then the innovator can initiate a declaratory judgment action for patent infringement. Before the Supreme Court ruling, much of the debate focused on whether "shall" was used in a mandatory or permissive sense; in other words, does §262(l)(2)(A) require disclosure? The court, however, focused on whether the §262(l)(2)(A) was enforceable by an injunction. It held that the inclusion of §262(l)(9)(C) showed that Congress intended a declaratory judgment action to be the remedy.[4] The Federal Circuit had also pointed to §271(e)(2)(C)(ii), which allows for a suit for artificial patent infringement, as a remedy for not providing the required disclosures.[5] The Supreme Court disagreed, explaining that §271(e)(2)(C)(ii) was triggered by the submission of the regulatory application and that its reference to a biosimilar applicant's failure to make the required disclosures of §262(l)(2)(A) was not an element of the claim of infringement, but rather defined what patents may be asserted in the lawsuit.[6] The court held that §262(l)(9)(C) was the sole remedy for failure to comply with §262(l)(2)(A) under federal law.

Amgen had argued that the ability to seek a declaratory judgment was hardly a remedy, since it conferred little to no benefit to the innovator. The court disagreed, interpreting the BPCIA to vest control of the litigation in either the biosimilar applicant or innovator, depending on whether the patent dance is followed.[7] The court noted that an applicant that follows all the steps of the BPCIA leading up to the filing of a patent infringement action has substantial control over which of the innovator's patents are litigated and when. By contrast, when the applicant fails to follow the BPCIA's provisions, the innovator can bring a declaratory judgment action for infringement of any patent immediately. Therefore, the court held, §262(l)(9)(C) "vests the sponsor the control that the applicant would otherwise have exercised over the scope and timing of the patent litigation" and "also deprives the applicant of the certainty that it could have obtained by bringing a declaratory-judgment action prior to marketing its product." [8]

In holding that the disclosures initiating the patent dance are not enforceable under federal law, the court did not reach the question of whether "shall" in §262(l)(2)(A) means "shall," explaining that it was not necessary to its decision.[9] The language of the opinion, however, is consistent with an understanding of "shall" in its ordinary, mandatory sense: the opinion refers to the disclosures as "required"[10] and nondisclosure is described as a "violation" of §262(l)(2)(A).[11] Indeed, the court raised on its own, though it expressed no view, that "an applicant's violation of §262(l)(2)(A)" may be a factor that is taken into account in deciding whether to grant a preliminary injunction. [12]

The court also addressed Amgen's request for injunctive relief under California state law, which the Federal Circuit rejected. The Supreme Court declined to rule on the question of whether Sandoz's failure to provide its aBLA and manufacturing information would be considered "unlawful" under California's unfair competition law, instead remanding that question to the Federal Circuit. The Court signaled, however, that the BPCIA may preempt any such remedy, noting that the Federal Circuit "is also of course free to address the pre-emption question first by assuming that a remedy under state law exists." [13]

In a brief concurrence, Justice Stephen Breyer echoed his sentiments from the April oral argument that the U.S. Food and Drug Administration has authority to interpret the statute and may be in a better position to than the court. While agreeing with his colleagues' "reasonable interpretation" of the BPCIA,

he suggested 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” the court’s interpretation.[14]

Notice of Commercial Marketing Before Approval

The court also held that a biosimilar applicant can provide notice of commercial marketing at any time. Under Section 262(l)(8)(A), the applicant “shall provide notice to the reference product sponsor not later than 180 days before the date of first commercial marketing of the marketing of the biological product licensed under” the BPCIA’s regulatory pathway. Amgen had argued that the use of the word “licensed” meant that notice could only come after the FDA approved the biosimilar; the Federal Circuit had agreed.[15] The Supreme Court, however, reasoned that “licensed” modifies “commercial marketing.”[16] In other words, “licensed” merely refers to the status of the biosimilar at the time of marketing.

The Federal Circuit had held that “[r]equiring that a product be licensed before notice of commercial marketing ensures the existence of a fully crystallized controversy regarding the need for injunctive relief. It provides a defined statutory window during which the court and the parties can fairly assess the parties’ rights prior to the launch of the biosimilar product.”[17] Amgen echoed these policy views in its arguments. But the court declined to reach the question of the policy and purpose of the notice of commercial marketing, noting that such arguments “could not overcome the statute’s plain language.”[18]

The court’s holding provides a benefit to biosimilar makers. Previously, biosimilar makers had to wait until FDA licensure to give their notice, and then wait an additional six months before selling the product. Following the court’s decision, notice can be given at any time, and sales can begin as soon as the FDA approves the biosimilar.

The Long-Term Impact

The court’s decision is a win for biosimilar makers, but may ultimately have a limited impact in most cases. It is now clear that innovators have no recourse in federal court to enforce the BPCIA’s disclosure requirements and that the subsequent steps of the patent dance can therefore also be bypassed. But, in the long term, it is likely that biosimilar makers will follow the patent dance. As the court noted, the patent dance provides significant benefits to biosimilar applicants: They have substantial control over the scope and timing of patent litigation. For example, in the AbbVie v. Amgen litigation over Amgen’s biosimilar of AbbVie’s Humira, Amgen completed the patent dance. This enabled Amgen to limit the first phase of patent litigation to 10 patents — far fewer than the large patent estate that AbbVie wanted to litigate immediately.[19] Indeed, in the almost two years since the Federal Circuit’s Amgen v. Sandoz decision in 2015, a number of biosimilar applicants have followed the patent dance.

Of course, when biosimilar makers do not follow the patent dance and refuse to provide their application and manufacturing information, innovators are likely to have no choice but to litigate blind in an effort to protect their patent rights. In such circumstances, innovators are likely to assert any patents that may be infringed, whether it is a few or dozens of patents. This burdens the court and parties with potentially unnecessary litigation; innovators may not know when to sue, who to sue, or which patents are infringed. The notice of commercial marketing does not help in determining the timing of the lawsuit, as biosimilar makers can now provide it at any point, as Sandoz did with its initial notice. Under the court’s decision, the notice does not need to have any relationship to the impending

market launch of the biosimilar.

One current BPCIA action, *Amgen v. Hospira*, illustrates why innovators may be forced to litigate blind when the biosimilar applicant refuses to provide its disclosures. In that action, Hospira did not provide Amgen with manufacturing information for its biosimilar of Amgen's Epogen.^[20] Amgen sued, asserting some of its patents, but held off on asserting a number of manufacturing patents until it obtained discovery in the litigation. Hospira refused to provide discovery for any nonasserted patents. The district court agreed with Hospira, holding that there is no independent basis for discovery under the BPCIA or under the Federal's Circuit decision in *Amgen v. Sandoz*.^[21] The issue — with Amgen arguing that it should not have to litigate blind or not be able to enforce its patent rights — is now before the Federal Circuit.

Lessons for Congress

In concluding that §262(l)(9)(C) provides the remedy for an applicant's failure to provide the requisite information, the court reasoned that the "presence of this remedy, 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."^[22] Indeed, the Supreme Court reasoned that "[t]he 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."^[23]

Amgen had argued that specifying a particular consequence did not mean that there were no other consequences. But the court's analysis suggests that when Congress specifies any consequences for a particular violation (whether of the BPCIA or otherwise), it should state that other remedies may be available under federal law, including injunctive relief, to ensure that its statutory provisions are enforceable. The result for this case and this statute would have been entirely different if Congress had included such a throwaway sentence — one that many believe Congress could not fathom was needed.

Irena Royzman, Ph.D., is a partner at Patterson Belknap Webb & Tyler LLP in New York and co-chairs the firm's biotechnology practice.

Nathan Monroe-Yavneh is an associate in the firm's New York office.

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[1] *Sandoz, Inc. v. Amgen, Inc.*, 582 U.S. ___ (June 12, 2017), No. 15-1039, slip op. at 10.

[2] *Id.* at 16.

[3] *Id.* at 10-13.

[4] *Id.* at 12.

[5] *Amgen, Inc. v. Sandoz, Inc.*, 794 F.3d 1347, 1354 (Fed. Cir. 2015).

[6] *Sandoz, slip op. at 11-12.*

[7] *Id. at 12.*

[8] *Id.*

[9] *Id. at 14-15.*

[10] *Id. at 15.*

[11] *Id. at 13 n.2.*

[12] *Id.*

[13] *Id. at 13-15*

[14] *Id. at 1 (Breyer, J., concurring).*

[15] *Amgen, 794 F.3d at 1357.*

[16] *Sandoz, slip op. at 16.*

[17] *Amgen, 794 F.3d at 1358.*

[18] *Sandoz, slip op. at 18.*

[19] *See Complaint at 6, AbbVie, Inc. v. Amgen, Inc., No., 16-cv-666 (D. Del. Aug. 4, 2016), ECF No. 1.*

[20] *Amgen Inc. v. Hospira Inc., No. 16-2179, slip op. at 2 (Fed. Cir. Aug. 12, 2016).*

[21] *Id.*

[22] *Sandoz, slip op. at 13.*

[23] *Id. at 12 (emphasis in original).*