

U.S. Supreme Court Rules on Patent Provisions of Biosimilars Law

DECISION PROVIDES FLEXIBILITY TO APPLICANTS, NOT SPONSORS

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In a case watched carefully by manufacturers of innovator therapies and biosimilars alike, the U.S. Supreme Court has clarified important aspects of the process for addressing patent disputes *before* a biosimilar hits the market. In *Sandoz Inc. v. Amgen Inc.*,¹ the Court took up the complex procedure for identifying, negotiating, and resolving patent infringement issues set forth in the Biologics Price Competition and Innovation Act of 2009 (BPCIA).² With respect to disclosure of application materials and manufacturing information, as well as notice of commercial marketing—both key components of the BPCIA “patent dance”—the Court concluded that flexibility lies with the manufacturer of the biosimilar, not with the innovator company. Like the BPCIA itself, the decision reflects a preference for accelerating biosimilar entry into the marketplace—a trend worth noting despite the fact that the U.S. Food and Drug Administration (FDA) has not yet developed a pathway for approval of bioequivalent plasma protein therapies.

THE BPCIA PROCESS

Like the Hatch-Waxman Act before it, which was intended to accelerate market entry by generic equivalents of traditional chemical pharmaceuticals, the BPCIA is intended to reduce the economic burden on patients and health systems by increasing competition from lower-cost biosimilar products. The provisions of the Act that provide for (it is hoped) expedited resolution of potential patent issues are central to this effort. In order to encourage innovation, the BPCIA prohibits the FDA from licensing a biosimilar until 12 years

after a new biologic product is first approved.³ But the BPCIA also includes patent provisions so that the 12-year exclusivity period is not effectively extended by subsequent years of infringement litigation. The patent provisions promote disclosure by the biosimilar manufacturer (the “applicant”) and provide a detailed framework for upfront negotiations with the innovator company (the “sponsor”), long before a biosimilar product enters the market.

To facilitate these upfront discussions and negotiations, the BPCIA creates an artificial act of infringement—the filing of an abbreviated Biologics License Application (aBLA). Ordinarily, a patent infringement action cannot be filed until an infringing act—making, using, offering to sell, or selling a patented invention in the U.S.—takes place, which typically does not occur until commercial marketing commences.

The filing of an applicant’s aBLA triggers the BPCIA’s “patent dance,” which consists of a disclosure phase followed by two potential phases of litigation:

- Disclosure Phase – Once the FDA notifies the applicant that its aBLA has been accepted, the BPCIA provides that, within 20 days, the applicant “shall provide” the sponsor with a copy of the aBLA and information about how the biosimilar is manufactured.⁴ This information enables the sponsor to determine if any of the patents it holds on the innovator product will potentially be infringed. This initial disclosure by the applicant triggers further rounds of disclosure by both sides, the purpose of which is to assemble a list of patents that both sides



agree are in play and must either be litigated or licensed. Finally, the applicant must provide the sponsor with at least 180 days advance notice before marketing the biosimilar commercially.⁵

- **Litigation Phase 1** – In the first phase, the parties decide, either by negotiating or through simultaneous exchange of lists, which (if any) patents should be litigated immediately. The applicant has substantial control over the scope of this first phase because the number of patents on the sponsor’s list cannot exceed the number on the applicant’s list, although the sponsor always has the right to list at least one.
- **Litigation Phase 2** – The second phase is triggered when the applicant provides the mandatory 180-day advance notice of commercial marketing. At this point, either the applicant or the sponsor may bring an infringement action based on any patent not addressed in Phase 1. In addition, the sponsor may seek a preliminary injunction barring the applicant from engaging in commercial marketing or sale.

THE SUPREME COURT’S DECISION

Against this backdrop, the Supreme Court addressed the specific claims of Amgen against Sandoz. Amgen manufactures the biologic filgrastim—a form of a protein that stimulates the growth of white blood cells. It is used to treat neutropenia—a lack of certain white bloods—which can be caused by cancer, a bone marrow transplant, chemotherapy

treatments, or other conditions. Amgen obtained an FDA license for its filgrastim product, which it marketed under the brand name Neupogen, and began marketing the product commercially in 1991. In 2014, Sandoz filed an aBLA seeking approval to market a filgrastim biosimilar, under the brand name Zarxio, and named Neupogen as the reference product. The filing of the aBLA triggered the “patent dance.” As the procedure played out, however, Sandoz adopted controversial interpretations of two of the BPCIA’s patent provisions that ultimately brought the case to the Court’s attention.

First, 20 days after receiving notice that the FDA had accepted its application, Sandoz declined to provide Amgen with either a copy of the aBLA or any information about how the biosimilar was manufactured, despite the fact that the BPCIA states that an applicant “shall” provide this information. Amgen asserted that it, without this information, could not properly assess the infringement risk and sought an injunction to compel Amgen to comply with this provision of the BPCIA.

Despite the seemingly compulsory (“shall”) language in the Act, the Court concluded that this initial disclosure requirement was not enforceable by injunction. The Court reasoned that, where a statute expressly provides a remedy, courts should be “especially reluctant to provide additional remedies.”⁶ Looking to the text of the BCPIA, the Court pointed to an existing remedy – the sponsor’s right to bring an immediate infringement action when disclosure by the applicant is not forthcoming. As the Court explained, an injunction is not needed in this situation, as this remedy, which shifts to the

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sponsor control over the scope and timing of the litigation that otherwise would be exercised by applicant, already provides substantial leverage.

Second, rather than waiting until after the FDA had licensed the product, Sandoz gave notice of its intent to begin commercially marketing Zarxio immediately after FDA acceptance of its aBLA. In Amgen’s view, this substantially shortened the time that it would have to assess the relevant patents and potentially to seek a preliminary injunction barring Sandoz’s marketing of the biosimilar on grounds of infringement. Amgen expected that it would have at least six months (180 days) after the FDA licensed the product to consider such action, as the text of the BPCIA seemed to require it and had been the practice in prior cases.

Again, the Court sided with Sandoz, holding that notice of intent to commence commercial marketing may be given at any time. Looking to the relevant provision of the BPCIA, the Court observed that it “contains a single timing requirement: The applicant must provide notice at least 180 days prior to marketing its biosimilar.”⁷ Therefore, the lower court that imposed two requirements—by concluding that notice must be given after the FDA licenses the biosimilar and at least 180 days before marketing begins—had erred.

IMPLICATIONS OF THE DECISION

Both of the Court’s holdings are highly technical and of interest primarily to lawyers and those responsible for managing company patent portfolios. Of the two, the Court’s conclusion that an applicant need not disclose its aBLA or relevant manufacturing information, despite the BPCIA’s “shall” language, is the less surprising. The potential negative impact of this nondisclosure, as the Court notes, is felt mostly by the applicant itself, as it surrenders control over the scope and timing of any Phase 1 litigation. In light of the clarity here, it is puzzling that the Court left open the issue of whether state law could be used to compel an applicant to comply with BPCIA disclosure.⁸ It would certainly be unusual for a federal statute

like the BPCIA to be applied differently depending on whether a claim arises in, say, California, as opposed to New Jersey or Massachusetts.

The Court’s conclusion that 180-day advance notice of commercial marketing can be given at any time is more surprising. This interpretation does seem to render the requirement meaningless. If the notice can be given whenever an applicant wishes, why did the Congressional drafters of the BPCIA specify a precise lead time like 180 days? What did they envision that the sponsor, now on notice of the applicant’s intent to market commercially, would do with those six months? A fair reading suggests that this provision was intended to give the sponsor 180 days after a biosimilar is licensed—the first point at which an actual product launch becomes a possibility—to seek an injunction.

The larger takeaway from the decision, however, is the Court’s general willingness to interpret the BPCIA favorably to applicants and consistent with faster product launches. At the time of the BPCIA’s passage, most observers regarded the legislation as at least attempting to balance the interests of biosimilar manufacturers and innovator companies. The Amgen decision, in contrast, seems to move away from this even-handed approach, and move closer to acceptance of faster market entry by biosimilars as the Act’s overriding priority. Industry decision-makers should bear this shift in mind as the concept of biosimilarity gains greater acceptance. ●

References:

1. 582 U.S. ___ (June 12, 2017), No. 15-1039, slip op.
2. Pub. L. No. 111-148, §7001, 124 Stat. 119, 804 (2010).
3. 42 U.S.C. §§262(k)(7)(A), (B).
4. *Id.* at §262(l)(2)(A).
5. *Id.* at §262(l)(8)(A).
6. *Sandoz*, slip op. at 12 (quoting *Karahalios v. Federal Employees*, 489 U.S. 527, 533 (1989)).
7. *Id.* at 16.
8. *Id.* at 15 (noting that, on remand, the Federal Circuit should determine whether noncompliance with the BPCIA’s disclosure provisions is “unlawful” under California’s unfair competition law).