By Kathryn S. Beard, J.D.

A manufacturer intending to market a biosimilar product—a drug that is similar to a biologic that has already been licensed by the FDA—does not have to wait until it obtains FDA approval for the biosimilar before providing notice to the biological product’s manufacturer, according to the Supreme Court. The decision partially resolved a dispute between Amgen Inc. and Sandoz Inc. over their filgastim products, and corrected the Federal Circuit’s reasoning in its lower decision—the requirement in the Biologics Price Competition and Innovation Act of 2009 (BPCIA) that applicants provide sponsor with application and manufacturing information is not enforceable with an injunction under federal law. Instead, the BPCIA’s remedy is the authorization for the sponsor to bring an immediate declaratory-judgment action for artificial infringement. The Court remanded the case to the Federal Circuit to determine whether state law provides an opportunity for injunctive relief (Sandoz Inc. v. Amgen Inc., June 12, 2017, Thomas, C.).

Justice Clarence Thomas authored the unanimous decision, and Justice Stephen Breyer wrote a short concurrence.

BPCIA. The dispute is rooted in the BPCIA, passed as sections 7001-7003 of the Patient Protection and Affordable Care Act (ACA) (P.L. 111-148). The BPCIA sought to streamline the FDA approval process for biosimilars—similar but not identical to biologics and must be individually approved by the FDA, unlike generic drugs which are identical to the brand-name drug—while also providing a process to address patent issues arising from biosimilar creation. The manufacturer of a new biologic, known as the "sponsor," receives a 12-year exclusivity period to market the biologic without competition. The BPCIA created the abbreviated biologics license application (aBLA) process, which streamlines the FDA application process and provides exclusivity incentives to the first approved biosimilar.

Patent dance. In addition to the exclusive ability to market a biologic, however, sponsors may hold multiple patents covering the biologic, its therapeutic uses, and the processes used to manufacture it; these patents may constrain the ability for another applicant to market a biosimilar even after the 12-year exclusivity period has expired. The BPCIA created a way for the biosimilar manufacturer to exchange information with the sponsor, and created a requirement for the biosimilar manufacturer to provide notice to the biologic manufacturer no later than 180 days (that is, six months) before the date of first commercial marketing for the biosimilar.

As part of the aBLA process under the BPCIA, biosimilar applicants seeking to enter the market prior to expiration are required to notify the sponsor and provide a detailed analysis as to why each challenged patent is invalid or will not be infringed. If the sponsor files suit within 45 days of the biosimilar applicant’s notice, the FDA is required to suspend review and approval of the abbreviated new drug application for 30 months unless shortened or lengthened by court order.

A biosimilar applicant can only discover the patents that protect the innovator biologic after providing the innovator manufacturer with access to the aBLA application and related manufacturing process. This is the first step in the "patent dance" (see Shall we dance? Biosimilars step toward new legal and regulatory future, March 31, 2016). The biosimilar applicant and sponsor then undertake a limited duration, complex exchange of patent information and collaborate to identify a list of patents that will be subject to an initial pre-launch litigation. Once the list has been compiled, the sponsor has 30 days to file suit concerning those patents to enjoin the biosimilar’s launch or forfeit all monies but royalties in subsequent litigation on those patents.
A second round of pre-launch litigation can begin once the biosimilar applicant provides the sponsor with its notice of commercial marketing, which must be given at least 180 days prior to the intended launch of the biosimilar. In this second step, disclosed patents that were not on the initial pre-launch litigation list are eligible for possible injunctive relief, and applicants can file declaratory judgments during this time regarding patents that the sponsor elected not to pursue.

As conceived by the BPCIA, the parties will have the opportunity to litigate all relevant patents before a biosimilar is marketed. The law also includes provisions to encourage parties to comply with each step of the process. Sponsors are permitted to bring declaratory judgment actions for infringement if the biosimilar applicant fails to provide the necessary information (see 262(l)(9)(B) and (C)). Another provision, 271(e)(2)(C)(ii), makes it an artificial act of infringement to submit a biosimilar application with respect to any patent that could have been included on the applicant’s lists of applicable patents.

Factual background. Amgen has marketed its biologic filgrastim under the brand name Neupogen® since 1991. In 2014, Sandoz filed an application for a biosimilar filgrastim product referenced to Neupogen, and the FDA accepted the application for review. Sandoz notified Amgen that it anticipated obtaining approval for its biosimilar and that it intended to launch the product immediately upon approval. Sandoz did not provide Amgen with product information required under the patent-dispute provisions of the BPCIA. Upon receiving FDA approval of its biosimilar, Sandoz notified Amgen that it intended to take its biosimilar to market, and Amgen filed suit. The parties disagreed upon whether the BPCIA requires a biosimilar manufacturer to exchange information with the sponsor, and on the timing of the required notice. Specifically, whether the notice could be given before receiving FDA approval, therefore allowing marketing of the biosimilar upon receipt of approval as long as 180 days had passed, or whether notice could only be provided after the FDA approved the biosimilar, requiring the biosimilar manufacturer to wait an additional 180 days to market, and thereby giving the sponsor an additional six months’ exclusivity.

The Federal Circuit’s decision held that the information exchange is optional despite statutory language saying “shall provide,” and that Amgen was entitled to an additional 180-day marketing exclusivity period based on Sandoz’s late notification (see Court interprets biosimilar ‘enigma’ in favor of abbreviated biologic license applicant, July 22, 2015; Biosimilar dispute headed to the Supreme Court, January 17, 2017). The consolidated action was somewhat rare for the Court; it consisted of a Sandoz petition appealing the Federal Circuit’s decision on two questions presented, and a conditional cross-petition from Amgen presenting a third question.

Decision. The unanimous Court held that the remedy provided by the BPCIA—permitting a sponsor to bring an immediate declaratory-judgment action for artificial infringement as defined under the BPCIA—is effective, because Sandoz failed to disclose requisite information to Amgen, and was accordingly subject to an action for artificial infringement. In so holding, the Court determined that the Federal Circuit misinterpreted the statute, and clarified that Sec. 271 specifically states that submitting an application for FDA approval of a biosimilar for a patent that could have been identified on the list required by the patent dance is an act of artificial infringement, not an element of artificial infringement. Statutory language offset by commas and reading, “if the applicant for the application fails to provide the application and information required,” according to the Court, “merely assists in identifying which patents will be the subject of the artificial infringement suit.” Therefore, the submission of an application with the FDA represents an act of artificial infringement with respect to any patent that could have been included on the required list for the patent dance. The exclusive remedy is the sponsor’s ability to bring an immediate declaratory-judgment action for artificial infringement. Therefore, injunctive relief is not available as a federal remedy. The Court remanded the case to the Federal Circuit to determine whether California’s state unfair competition statute provides the injunctive remedy precluded by the BPCIA and if so, whether the BPCIA preempts state remedies.

The Court also determined that notice of commercial marketing can be provided before FDA approval is obtained—brand-name biologic manufacturers are not entitled to an additional six months’ of exclusivity for their products. Thomas interpreted the statutory language to find that “licensed” merely means that on the date of the first commercial marketing, the biosimilar product must be licensed, not before the notice is provided.
Therefore, notice of intent to market a biosimilar may be provided to the biologic’s sponsor either before or after the biosimilar obtains FDA approval. Sandoz therefore "fully complied" with the statute when it gave its first notice to Amgen, and the Federal Circuit erred in issuing an injunction prohibiting Sandoz from marketing its biosimilar for 180 days after licensure.

**Concurrence.** In a one-paragraph concurrence, Breyer joined the opinion of the Court, but wrote separately to request FDA interpretation of the statute. He suggested that the Court’s interpretation of the BPCIA, while "a reasonable interpretation," may need to be departed from or altered if the agency, once it obtains "greater experience administering this statute," finds that a "different interpretation would better serve the statute’s objectives." The concurrence is not surprising; during oral arguments, Breyer repeatedly brought up agency rulemaking and suggested that FDA regulations would have made the case clearer (see SCOTUS, attempting to untangle biosimilar notice knot, suggests help from agency rulemaking, April 26, 2017).

**Impact.** Apotex, Inc., which had been in a similar dispute against Amgen for a pegfilgrastim biologic, failed in its suit when the Federal Circuit held that notice of intent to market must be given only after FDA approval is obtained (see Biosimilar applicant must give 180-day post-licensure notice to reference sponsor, July 6, 2016) participated in the suit as amicus curiae after the Court denied its petition for writ of certiorari (see SCOTUS denies cert in biosimilar licensing dispute, December 12, 2016). The Court’s decision makes it likely for Apotex to request that the Federal Circuit reopen or reconsider its earlier opinion.

Sandoz’s Global Head of Biopharmaceuticals, Carol Lynch, told Wolters Kluwer that the decision will "help expedite patient access to life-enhancing treatments." Lynch added that “the clarity provided on the patent dance . . . will help the biosimilars industry move forward." To date, the FDA has approved five biosimilars, with the most recent approval two months ago.

The cases are Nos. 15-1039 and 15-1195.

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Companies: Sandoz Inc.; Amgen Inc.

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