
By Bryant Storm, J.D.

The U.S. Court of Appeals for the Federal Circuit affirmed the dismissal of Amgen, Inc. claims challenging Sandoz, Inc.’s behavior regarding approval of a biologic product that is biosimilar to Amgen’s Neupogen®. Although the court reasoned that Sandoz did not violate the federal law or regulations regarding disclosure obligations under the biosimilar approval process, the court did hold that Amgen was entitled to an additional 180-day marketing exclusivity period because of Sandoz’s late notification of its intention to market its biosimilar. The court also remanded the case to the district court for further proceedings on the merits of the parties’ patent infringement claims (Amgen, Inc. v Sandoz, Inc., July 21, 2015, Lourie, A.).

Biosimilars. The Biologics Price Competition and Innovation Act (BPCIA), which was passed in 2010 as sections 7001-7003 of the Patient Protection and Affordable Care Act (ACA) (P.L. 111-148), created an abbreviated pathway for FDA approval of “biosimilar,” biologic products. Traditionally, the FDA approves biologics through acceptance of a biologics license application (BLA) containing clinical data demonstrating the safety and effectiveness of a product. The BPCIA allows streamlined approval for drugs that are “biosimilar” to or “interchangeable” with a previously approved reference product. The application process for these biosimilar products is known as an abbreviated BLA (aBLA).

Patents. To maintain a balance of innovation, the statute provides four years of exclusivity before a competitor can submit a biosimilar application and 12 years of exclusivity before the FDA will approve a competing biosimilar. The BPCIA also includes a patent-dispute procedure which, under 35 U.S.C. § 271(e)(2)(C), allows infringement suits based on a biosimilar application prior to FDA approval and prior to marketing of the biological product. As part of the patent-dispute resolution procedure, under 42 U.S.C. § 262(l), biosimilar applicants provide the sponsor of the reference drug with manufacturing information regarding the biosimilar product no later than 20 days after the FDA accepts its application for review. This is designed to facilitate an exchange of patents at issue so that infringement suits can proceed. The law also requires aBLA applicants to provide reference product sponsors with a notice of commercial marketing (see The challenge of the FDA’s biosimilars regulation, August 20, 2014). To illustrate the overall complexity of the statute, quoting Winston Churchill, the court called the law “a riddle wrapped in a mystery inside an enigma.”

Application. Amgen has marketed filgrastim under the brand name Neupogen since its approval in 1991. In 2014, Sandoz filed an aBLA for a biosimilar filgrastim product referenced to Neupogen. 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. On March 6, 2015, the FDA approved Sandoz’s aBLA for all approved uses of Amgen’s Neupogen. Sandoz notified Amgen a second time, following approval of the product, indicating that Sandoz intended to take its biosimilar to market. Sandoz intended to launch the filgrastim product under the name Zarxio (see FDA enters new era with approval of first biosimilar, March 11, 2015).

Lawsuit. Amgen brought suit against Sandoz in federal court asserting violations of California’s unfair competition law, conversion, wrongful use of Amgen’s approved license on Neupogen, and infringement of Amgen’s patent for a particular method of using filgrastim. Amgen also alleged that Sandoz violated the BPCIA by not providing Amgen with information required under Section 262(l) and by providing premature and ineffective notice of commercial marketing of Zarxio because the notice was given prior to FDA approval of the product. Sandoz filed a counterclaim alleging that it complied with the BPCIA and that Amgen’s filgrastim patent was invalid and therefore could not have been infringed.
District court. The district court granted partial judgment for Sandoz reasoning: (1) the BPCIA allows an aBLA applicant not to disclose its aBLA and manufacturing information to a reference product sponsor, subject only to a lawsuit on the infringement, validity, or enforceability of a patent; (2) a decision not to disclose that information does not authorize a reference product sponsor to obtain injunctive relief, restitution, or damages against the applicant; and (3) an applicant can give valid commercial marketing notice prior to FDA approval. As a result, the court dismissed Amgen’s unfair competition and conversion claims. The court also denied Amgen’s state law request for an injunction to bar Sandoz from marketing Zarxio. The patent claims remain pending in the district court (see Drug company’s request for preemptive non-infringement judgment of biosimilar drug in development fails, November 14, 2013)

Disclosure. The appellate court started its review by considering whether the BPCIA did indeed allow an aBLA applicant to choose not disclose its aBLA or provide manufacturing information to the sponsor of the reference product. Amgen asserted that language stating that the applicant “shall provide” the information to the reference product sponsor rendered the information disclosure mandatory and not permissible. Sandoz disagreed and argued that it was permissive and that the result of not disclosing the information was to give Amgen, as the reference product sponsor, the right to file an infringement suit and obtain the undisclosed information in discovery—a right that Amgen acted on. The court agreed with Sandoz and held that the statute expressly contemplated the actions that Sandoz took. Specifically, the court noted that while the statute sought to promote the information disclosure, it did not mandate it, which was made apparent by the statutory consequence of a patent infringement lawsuit—the very consequence that Amgen pursued.

Notice. Amgen argued that Sandoz violated the commercial marketing provision of the BPCIA, requiring an aBLA applicant to provide “notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k).” Amgen asserted that the notice was insufficient because it was given prior to the point where Sandoz’s product was licensed. Sandoz countered that the plain language of the requirement permitted notice prior to FDA approval and that Amgen’s reading would create an automatic 180-day bar on marketing of any aBLA-approved product following approval. The court agreed with Amgen on the notice issue and held that the statutory language compelled a finding that “notice, to be effective under this statute, must be given only after the product is licensed by the FDA.” The court reached its conclusion by taking note of other provisions that referred to the status of a product not as licensed but as the biological product that is the subject of an application. The court recognized that its holding established an additional 180 days of market exclusivity for Amgen; however, the court reasoned that such a period of exclusivity was consistent with the four- and 12-year exclusivity periods contemplated elsewhere in the statute. As a result, the court held that Sandoz’s first notice of commercial marketing was ineffective and its second notice, the one given the day of the FDA’s approval of Zarxio, March 6, 2015, was the operative notice date. The court held that Sandoz was permitted to begin marketing Zarxio 180 days after that later notice date: September 2, 2015.

Unfair competition. The appellate court also affirmed the lower court’s dismissal of Amgen’s unfair competition claim on the grounds that it could not proceed due to the fact that Sandoz did not violate the BPCIA. The court held that the only violation of the BPCIA was Sandoz’s initial failure to comply with the marketing notice provision. However, because Sandoz later provided sufficient notice and because Sandoz could not market Zarxio prior to September 2, 2015, the claims were moot.

Conversion. The court agreed with Sandoz that Amgen failed to establish the necessary elements of a conversion claim because Amgen could not show a wrongful act. Because Sandoz developed its aBLA from publically available information and was lawfully permitted to refrain from disclosing manufacturing information, the court reasoned that Sandoz did not engage in any wrongful conduct.

Injunction. Amgen also challenged the denial of its motion for preliminary injunction. However, the issue was moot because Amgen sought an injunction only until the district court decided the parties’ cross-motions for judgment on the pleadings. The court reasoned that, because that decision already occurred, the injunction issue was resolved. However, the appellate court previously granted an emergency motion in favor of Amgen for an
injunction pending appeal. The court ordered that, in light of its holdings regarding the BPCIA, the injunction was to be extended through September 2, 2015. The court also remanded the case to the district court for further consideration of the patent infringement claims.

**Concurrence and dissent.** Judge Newman concurred with the court regarding the mandatory nature of the commercial marketing notice and the existence of the subsequent 180-day exclusivity period. However, she dissented with respect to the court’s holding on the permissive nature of the aBLA and manufacturing information disclosure. In dissent, Judge Newman explained that by making the information disclosure less than mandatory, the court undermined the BPCIA’s focus on “efficient resolution of patent issues.” The dissent explained that the mandatory nature of the disclosure was designed to avert and expedite patent litigation—a design that was made ineffective by the majority’s reading of the disclosure requirement as a permissive one.

**Dissent.** Judge Chen dissented on different grounds, rejecting the court’s interpretation of the notice requirement and the ensuing 180-day exclusivity period. He reasoned that when an aBLA applicant refuses to comply with the aBLA and manufacturing information disclosure, the subsequent provisions, including the ones related to marketing notice, “cease to matter.” In other words, by electing not to disclose its aBLA and manufacturing information, Sandoz should have been relieved of its marketing notice obligation. As a result, Judge Chen reasoned that the court’s interpretation of the disclosure and notice requirements were inconsistent and inappropriately provided Amgen with a 180-day exclusivity windfall.

The case is No. 2015-1499.

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