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JUNE 15, 2017

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Biopharma Patent Litigation Group Alert: United States Supreme Court Considers First Biosimilars Act Case (*Sandoz Inc. v. Amgen Inc.*)

On June 12, 2017, the United States Supreme Court issued its ruling in *Sandoz Inc. v. Amgen Inc.*, No. 15-1039 (June 12, 2017), the first case involving the Biologics Price Competition and Innovation Act of 2009 (BPCIA) to come before the Court since the BPCIA's enactment in 2010. The Court's unanimous opinion vacated in part, reversed in part, and remanded the consolidated cases back to the Federal Circuit for further proceedings consistent with its opinion. The Court held that:

1. The BPCIA's requirement that a biosimilar applicant provide the brand-name biologic with its application and manufacturing information is not enforceable by injunction under federal law. The Court remanded the case to the Federal Circuit to determine if an injunction was available under California Unfair Competition Law.

2. A biosimilar applicant need not wait until FDA approval to provide notice to the brand-name biologic of commercial marketing but may do so at any time as long as it is 180 days prior to the date of the first commercial marketing of the biosimilar product.

STATUTORY BACKGROUND

Congress enacted the BPCIA in 2010 to establish a regulatory pathway for the FDA to license a follow-on biological product (*i.e.*, a "biosimilar" product).[1] This abbreviated approval pathway permits an applicant to rely upon previously submitted safety, purity, and potency data from an already-approved reference product. The applicant must show that its biosimilar is highly similar to or interchangeable with the reference product, including showing that the biosimilar "can be expected to produce the same

[1] 42 U.S.C. § 262(k).

clinical result as the reference product in any given patient."[2] The biosimilar applicant may not submit an application for a biosimilar until four years after the reference product was licensed and the biosimilar application may not be approved until twelve years after the reference product was licensed.[3]

The BPCIA includes a detailed patent dispute-resolution process that delineates the steps and timing of certain information exchanges, including exchange of a copy of the biosimilar application and lists of patents for which a claim of patent infringement may be asserted, between the applicant and sponsor.[4] The BPCIA further provides that the applicant "shall give 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)," which then allows the sponsor to seek a preliminary injunction based on previously identified but not yet asserted patents or newly issued or licensed patents.[5]

THE DISTRICT COURT & FEDERAL CIRCUIT OPINIONS

Amgen Inc. and Amgen Manufacturing Limited (collectively, Amgen) originally filed a patent infringement suit in the U.S. District Court for the Northern District of California after Sandoz Inc. (Sandoz) informed Amgen that it had filed an abbreviated Biologics License Application for its generic version of filgrastim, which referenced Amgen's filgrastim product marketed as Neupogen®. At the same time, Sandoz also informed Amgen that it would be marketing its biosimilar upon FDA approval.[6] Sandoz said that it would not provide Amgen with a copy of its biosimilar application or manufacturing information. Amgen filed suit seeking an injunction under the BPCIA and California Unfair Competition Law.

The district court concluded that, under the BPCIA, Sandoz was not required to provide Amgen with a copy of its application and biosimilar manufacturing information and that notice of commercial marketing may be given prior to FDA approval of the biosimilar product. The district court also dismissed Amgen's state law unfair competition claims.

A divided Federal Circuit agreed with the district court that the BPCIA does not require an applicant to disclose its application or manufacturing information. The Federal

[2] 42 U.S.C. § 262(k)(2)(A)–(B); 42 U.S.C. § 262(k)(4).

[3] 42 U.S.C. § 262(k)(7).

[4] 42 U.S.C. § 262(*l*).

[5] 42 U.S.C. § 262(*l*)(8).

[6] Sandoz received FDA approval for its biosimilar, marketed as Zarxio®, during the pendency of the district court litigation and then provided further notice of commercial marketing to Amgen.

Circuit noted that "Sandoz took a path expressly contemplated by 42 U.S.C. § 262(*l*)(9)(C)[7] and 35 U.S.C. § 271(e)(2)(C)(ii)." 794 F.3d 1347, 1360 (Fed. Cir. 2015). Additionally, the court reasoned that 35 U.S.C. § 271(e)(4) expressly provides the only court remedies available to the brand-name biologic if the applicant does not comply with the disclosure requirements, which does not include injunctions. Therefore, the Federal Circuit held that Amgen may not seek an injunction for Sandoz's failure to provide the information under federal law. Following the reasoning of this analysis, because Sandoz did not violate the BCPIA, the Federal Circuit affirmed the district court's dismissal of the state law claims, which require that there be a violation of a law such as the BCPIA.

In addition, the Federal Circuit reversed the district court, finding that applicant's notice of commercial marketing required by § 262(*l*)(8)(A)[8] could not be given before FDA approval of the biosimilar product, reasoning that the term "the biological product licensed under subsection (k)" language indicated that notice would follow licensure. *Id*. at 1357–58.

THE SUPREME COURT DECISION

The Supreme Court first addressed whether the requirement that an applicant provide the brand-name biologic with its application and manufacturing information is enforceable by an injunction under either federal or state law. As noted above, the Court held that an injunction is not available under federal law but remanded to the Federal Circuit to determine whether an injunction would be available under state law, rejecting the Federal Circuit's previous analysis. Relying on strict statutory construction, the Supreme Court noted that the BPCIA itself provides that the applicant's failure to comply with disclosure of its application and manufacturing information authorizes the sponsor to bring an immediate declaratory-judgment action for infringement and "excludes all other federal remedies, including injunctive relief." Slip op. at 12. The Court declined to address the issue of whether § 262(*l*)(2)(A) mandates that an applicant disclose its application and manufacturing information. The Court reasoned that no question of federal law was raised because the BPCIA "does not require a court to decide whether §262(*l*)(2)(A) is mandatory or conditional; the

[7] 42 U.S.C. § 262(*l*)(9)(C): **(C) Subsection (k) application not provided.** If a subsection (k) applicant fails to provide the application and information required under paragraph (2)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product.

[8] 42 U.S.C. § 262(*l*)(8)(A): **(A) Notice of commercial marketing.** The subsection (k) applicant shall 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).

court need only determine whether the applicant supplied the sponsor with the information required under §262(*l*)(2)(A)." *Id*. at 14–15.

The Court remanded the issue of whether Sandoz's act of failing to provide its application and manufacturing information was unlawful under California unfair competition law. The Court directed the Federal Circuit to determine whether California law would treat Sandoz's non-compliance as unlawful and if so, whether the BPCIA preempts this state law remedy.

The Court next addressed the second question, whether an applicant must provide notice of commercial marketing after the FDA licenses its biosimilar, or if it may also provide effective notice before licensure. Again, applying strict statutory construction, the Court reversed the Federal Circuit, holding that an applicant may provide notice of commercial marketing either before or after receiving FDA approval of its application. The Court analyzed the language of § 262(*l*)(8)(A), which requires that the applicant give notice to the sponsor at least 180 days prior to commercial marketing of its biosimilar product. The Court held that "of the biological product licensed under subsection (k)" modified "commercial marketing," and thus, "'commercial marketing' is the point in time by which the biosimilar must be 'licensed.'" *Id*. at 16. Thus, the notice itself could be provided to the sponsor either before or after FDA approval. Moreover, comparing the notice section with an adjacent provision that contained a dual timing requirement shows that, unlike the conclusion reached by the Federal Circuit, the 180-day notice provision "contains a single timing provision" based only on commercial marketing and not FDA approval. *Id*.

Justice Breyer's concurring opinion invites the FDA to "depart from, or to modify, [the Court's] interpretation" if it "determines that a different interpretation would better serve the statute's objectives." *Id*. (Breyer, J., concurring).

KEY TAKEAWAYS AND PRACTICE NOTES

1. Under Federal law, an applicant's failure to follow the statutory steps gives the sponsor the right to bring a declaratory judgment action for patent infringement but not for an injunction.

    a. If an applicant fails to provide its application and manufacturing information, which effectively negates the entire two-phase litigation process, a sponsor may immediately bring action based on any patent that "could" have been included in the patent lists.

    b. If an applicant provides its application and manufacturing information but fails to complete subsequent steps required by the BPCIA, a sponsor may bring a declaratory judgment suit for infringement based on any patent included on

the sponsor's list of patents (as well as later-acquired patents that have been added to the list).

2. Failure by an applicant to follow the statutory steps vests in the sponsor the control that an applicant would otherwise have to impact the scope and timing of the patent litigation and deprives the applicant of the certainty it could have obtained by bringing action prior to marketing its product.

3. A sponsor's state unfair competition claims may provide relief from an applicant's failure to comply with BPCIA disclosure requirements. But, it remains to be seen whether these claims will survive federal preemption challenges.

    a. The threat of a state law injunction may induce applicants to provide the required application and manufacturing information.

    b. The strength of this potential state law remedy could be determined by the Federal Circuit on remand, but is more likely to be determined by district courts in the various states. A diversity of decisions amongst the states could lead to forum shopping.

4. An applicant must give notice at least 180 days before the date of first commercial marketing, and this timing of the notice is not tied to the date the FDA issues its biosimilar license.

    a. Because applicants may provide notice of first commercial marketing at any time, it is possible that the sponsor's period of marketing exclusivity under the BPCIA of brand-name biologics will be limited to the 12 years provided by the statute.

    b. Applicants are incentivized to give notice prior to the time they believe approval is forthcoming within 180 days. This would be sufficient to prevent the notice from being an obstacle to entry into the market.

    c. A sponsor's control over the timing of a lawsuit, when an applicant does not follow the statutory steps for disclosure, is as a practical matter diminished by the Court's reversal regarding the 180-day notice provision.

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