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Supreme Court Clarifies Biosimilar Drug Notice and Disclosure Requirements

Biosimilar Manufacturers May Provide Notice of Commercial Marketing Before FDA Approval

SUMMARY

In *Sandoz Inc.* v. *Amgen Inc.*,[1] the U.S. Supreme Court held that, under the Biologics Price Competition and Innovation Act of 2009, a biosimilar manufacturer need not wait until FDA approval to provide patentees with notice of a plan to commercially market a biosimilar product. The Supreme Court also ruled that a patent owner's exclusive federal remedy for a biosimilar manufacturer's failure to provide its FDA application and manufacturing information is a suit for declaratory judgment of patent infringement.

BACKGROUND

The Biologics Price Competition and Innovation Act of 2009 ("BPCIA" or "Act")[2] governs the approval and marketing of biologics and biosimilar products, which are typically large molecule drugs produced using biotechnology techniques from human, animal or microorganism sources. Like the Hatch-Waxman Act, the BPCIA creates an abbreviated process for the approval of a biosimilar, *i.e.*, a biologic product that claims to be biologically and clinically similar to an already approved biologic.[3] The BPCIA creates a comprehensive statutory scheme by which companies seeking to market a biosimilar can apply for FDA approval and resolve patent disputes with companies that hold patents covering existing biologics.[4]

Under the Act, the filing of a biosimilar application constitutes an act of patent infringement that can serve as the basis for a declaratory judgment action provided other statutory conditions are met.[5] Specifically, the Act provides that within 20 days after the FDA notifies the biosimilar applicant that its "application has been accepted for review," the applicant "shall provide" to the existing biologic manufacturer (the "patentee") a copy of the biosimilar application and information about how the biosimilar is manufactured.[6] Thereafter, the parties must exchange other information, including the identity of relevant patents for

litigation.[7] Under § 262(l)(9)(C), if the applicant fails to provide the application and manufacturing information required under § 262(l)(2)(A), the patentee is authorized to bring a declaratory judgment action for infringement. Separately, § 262(l)(8)(A) requires the biosimilar applicant to provide notice of commercial marketing to the patentee at least 180 days before the first commercial marketing of the biosimilar. After notice is given, either the patentee or the biosimilar applicant may bring a declaratory judgment action on patents that were not subject to the original patent identification process.[8]

Plaintiff Amgen Inc. ("Amgen") markets a patented biologic (Neupogen) that stimulates the production of white blood cells. Defendant Sandoz Inc. ("Sandoz") in May 2014 filed an application to market a biosimilar drug called Zarxio.[9] Immediately upon receiving notification from the FDA that its application was accepted for review, Sandoz notified Amgen of the application and its intent to "begin marketing Zarxio immediately upon receiving FDA approval."[10] Sandoz did not provide its application and manufacturing information to Amgen, but informed Amgen that it could sue for infringement under § 262(l)(9)(C).[11]

In October 2014, Amgen sued Sandoz in federal District Court in California, asserting patent infringement and violations of California's unfair competition law. Amgen sought injunctive relief under state law against (i) Sandoz's failure to disclose the application and manufacturing information as required by § 262(l)(2)(A) and (ii) Sandoz providing notice of commercial marketing before FDA approval.[12] The District Court dismissed Amgen's state law claims with prejudice. On appeal, the Court of Appeals for the Federal Circuit affirmed the dismissal of Amgen's state law claims, holding that the BPCIA provided the exclusive remedy for a failure to comply with the disclosure requirements of § 262(l)(2)(A). The Federal Circuit also held that a notice of commercial marketing can be provided only after FDA approval of the biosimilar application.[13]

THE SUPREME COURT'S DECISION

In a unanimous decision authored by Justice Thomas, the Supreme Court first held that the only federal remedy available to patentees to compel an applicant to disclose its application and manufacturing information under § 262(l)(2)(A) is an action for declaratory judgment of "infringement, validity, or enforceability of any patent that claims the biological product or a use" thereof.[14] Relying on the text and statutory context of the BPCIA, the Court agreed with the Federal Circuit that, as a matter of federal law, injunctive relief is not available to compel disclosure. However, the Court took issue with the Federal Circuit's reasoning, noting that the Federal Circuit's conclusion incorrectly relied on a provision (35 U.S.C. § 271(e)(4)) that provided remedies for infringement when the failure to disclose the information specified in § 262(l)(2)(A) is not an act of infringement.[15] Instead, the only federal remedy for non-compliance with § 262(l)(2)(A) is provided in § 262(l)(9)(C), which, in the absence of disclosure, authorizes the patentee "to bring an immediate declaratory-judgment action for artificial infringement" and "excludes all other federal remedies, including injunctive relief."[16]

After finding that injunctive relief was not available under federal law, the Court declined to resolve the issue of whether injunctive relief might be available under state law and instead directed the Federal Circuit on remand to consider the remedies, if any, available under California law and whether "the BPCIA pre-empts any additional remedy available under state law."[17]

On the question of when an applicant can provide notice of commercial marketing, the Court reversed the Federal Circuit, holding that § 262(l)(8)(A) allows the applicant to provide notice "either before or after receiving FDA approval."[18] Section 262(l)(8)(A) provides that the applicant "shall provide notice to the [patentee] not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." The Federal Circuit had interpreted this text to mean that "an applicant's biosimilar must already be 'licensed' at the time the applicant gives notice."[19] The Supreme Court disagreed, noting the phrase "of the biological product licensed under subsection (k)" modified "commercial marketing" rather than the required "notice," and, therefore, it is at the time of commercial marketing "by which the biosimilar must be 'licensed,'" not the time of notice.[20] As such, "the applicant may provide notice either before or after receiving FDA approval."[21]

Justice Breyer filed a separate concurrence to note that "Congress implicitly delegated to the Food and Drug Administration authority to interpret" the statute at issue, and should the agency decide to interpret the statute differently, they may have authority to do so.[22]

IMPLICATIONS

The Supreme Court's decision generally promotes the early resolution of patent disputes for biosimilars, and allows biosimilar manufacturers to access the market more quickly. Under the Court's interpretation of the commercial marketing notice requirement, biosimilar applicants may provide notice far in advance of FDA approval, and thus may begin marketing their biosimilar products immediately after approval is granted.

The Court's decision also assures biosimilar applicants that they may not be compelled as a matter of federal law to disclose their application and manufacturing information, although a decision not to disclose carries with it the risk of substantial loss of control and certainty over the patent litigation process. An applicant understandably may not want to disclose confidential information on its biosimilar product and manufacturing process to a competitor, or undergo the complex patent identification steps laid out in § 262(l)(3)-(5), however, that allows the patentee to bring an infringement action based on patents of its own choosing. The Court's decision arguably brings the patent litigation process under the BPCIA closer to that under the Hatch-Waxman Act.

The decision also leaves open the possibility that injunctive relief (or other remedies) may be available through state law against applicants who choose not to disclose their application and manufacturing

information. This could lead to an increase in state law claims in BPCIA cases where either side chooses not to comply with certain provisions of the Act.

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ENDNOTES

1 582 U.S. ___, Nos. 15-1039 and 15-1195 (June 12, 2017) (slip op.).

2 124 Stat. 808.

3 42 U.S.C. § 262; slip op. at 2-3. However, unlike the Hatch-Waxman Act, the BPCIA does not provide an automatic stay of approval of a biosimilar application upon initiation of related patent litigation.

4 As opposed to new biologic applications whereby the manufacturer must demonstrate that the biologic is "safe, pure, and potent," 42 U.S.C. § 262(a)(2)(C)(i)(I), biosimilar applicants need only show that the biosimilar product is "highly similar" to the reference biologic product and that there are no "clinically meaningful differences" between the two in terms of "safety, purity, and potency," § 262(i)(2)(A), (B).

5 35 U.S.C. § 271(e)(2)(C)(i)-(ii); slip op. at 3-4.

6 42 U.S.C. § 262(l)(2)(A).

7 *Id.* § 262(l)(3)-(6).

8 *Id.* § 262(l)(9)(A).

9 Slip op. at 8.

10 *Id.*

11 *Id.*

12 *Id.* at 9. While the case was pending in the District Court, the FDA approved Zarxio and Sandoz provided a second notice of commercial marketing to Amgen. *Id.*

13 *Id.*

14 42 U.S.C. § 262(l)(9)(C); slip op. at 12.

15 Slip op. at 10-11.

16 *Id.* at 12.

17 *Id*. at 14-15.

18 *Id.* at 16.

19 *Id.* (quoting 794 F.3d at 1358).

20 *Id.*

21 *Id.*

22 Slip op. at 1 (Breyer, J., concurring).

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