COMMENTARY

JUNE 2017

Supreme Court: Biosimilar Applicants May Provide Commercial Marketing Notice Before FDA Approval

IN SHORT

The Situation: Intended to provide a faster route to approval for generic biologics, the Biologics Price Competition and Innovation Act, was the basis for a decision rendered by the U.S. Supreme Court in *Sandoz Inc. v. Amgen Inc*.

The Action: The Court sided with Sandoz on matters relating to enforceability of a provision requiring applicants to provide license applications and manufacturing information to the sponsor of the referenced product, and on the timing of marketing notices relative to FDA approval.

Looking Ahead: The Court noted that policy issues relating to the BPCIA might more appropriately be considered by Congress.

On June 12, 2017, the U.S. Supreme Court decided two important questions under the Biologics Price Competition and Innovation Act ("BPCIA"), which provides an abbreviated pathway for the approval of generic biologics: (i) the BPCIA's requirement that an applicant provide its abbreviated biologics license application ("Application") and manufacturing information to the sponsor of the referenced product is not enforceable through an injunction under federal law (although it may be under state law); and (ii) an applicant's required 180-day "notice of commercial marketing" is effective even if given before the FDA has approved the application.

The Supreme Court held that §262(*l*)(2)(A) is not enforceable by injunction under federal law but remanded to the Federal Circuit to determine whether a state-law injunction is available.

As to the notice provision, the Court held that a biosimilar applicant may provide "notice of commercial marketing" prior to FDA approval.

The Federal Circuit Ruling

The underlying dispute stems from Sandoz's filing of an Application, seeking approval of a biosimilar to Amgen's Neupogen® product. The Federal Circuit held that Sandoz did not violate the relevant provisions of the BPCIA by refusing to provide Amgen with its Application and related manufacturing information, and that the BPCIA's Application and manufacturing exchange provisions were not enforceable by an injunction.

According to the Federal Circuit, even though §262(*l*)(2)(A) uses the language "shall provide," the statute expressly contemplates a situation where the biosimilar applicant might not participate in the information exchange and contains an exclusive remedy for the reference product sponsor: a declaratory judgment action of infringement, validity, or enforceability under §262(*l*)(9)(C) on "any patent that claims the biological product or a use of the biological product." The Federal Circuit stated that "35 U.S.C. §271(e)(4) provides 'the only remedies which may be granted by a court for an act of infringement described in paragraph 2.' … Under §271(e)(2)(C)(ii), filing a subsection (k) application and failing to provide the required information under paragraph (l)(2)(A) is such an act of infringement."

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Thus, the Federal Circuit concluded that 42 U.S.C. §262(*l*)(9)(C) and 35 U.S.C. §271(e) provide that a claim of patent infringement is the only remedy available when the biosimilar applicant fails to provide its Application and manufacturing information. In view of this holding, the Federal Circuit affirmed dismissal of Amgen's state law claims of unfair competition and conversion against Sandoz for noncompliance with the BPCIA.

On the second question, the Federal Circuit held that a biosimilar applicant may give effective notice of commercial marketing only after the FDA has approved a biosimilar product for commercial marketing.

The Supreme Court Decision

The Supreme Court agreed with the Federal Circuit's conclusion that requirements in §262(*l*)(2)(A)—that a biosimilar applicant provide the reference product sponsor with its Application and manufacturing information—is not enforceable by an injunction under federal law, but disagreed with its reasoning. In particular, the Court disagreed with the Federal Circuit's reliance on 35 U.S.C. §271(e)(4), which provides exclusive remedies for artificial acts of infringement—not for failing to disclose the Application and manufacturing information required by §262(*l*)(2)(A).

The Federal Circuit's Error—and a Remedy for Applicant's Failure to Disclose

According to the Court, the Federal Circuit's error arose out of its apparent conclusion that an applicant's noncompliance with §262(*l*)(2)(A) is an element of the act of artificial infringement (along with the submission of the Application) under §271(e)(4). The Court made clear that it was not.

This scheme, the Court found, shifts control of the scope and timing of the patent litigation from the biosimilar applicant to the reference product sponsor.

Instead, the Court found that another provision, §262(*l*)(9)(C), provides the remedy for an applicant's failure to turn over its Application and manufacturing information. The prescribed remedy authorizes the reference product sponsor to file an immediate declaratory judgment action for patent infringement. This scheme, the Court found, shifts control of the scope and timing of the patent litigation from the biosimilar applicant to the reference product sponsor. For this reason, the Court affirmed the Federal Circuit's ruling that the BPCIA did not provide for injunctive relief to compel a biosimilar applicant to disclose its Application and manufacturing information as required by §262(*l*)(2)(A).

The Court remanded to the Federal Circuit on the question of whether an injunction is available under state law to enforce §262(*l*)(2)(A). In particular, the case was remanded for the Federal Circuit to determine whether California law would treat noncompliance with §262(*l*)(2)(A) as "unlawful."

The Timing of Notice Question

The Court's analysis of the second, and more significant, question—timing of notice of commercial marketing under §262(*l*)(2)(A)—focused on reference to the "licensed" product in the following statutory language:

> [The applicant] shall provide *notice* to the reference product sponsor not later than 180 days before the date of the first **commercial marketing** of the biologic product **licensed** under subsection (k).

§262(*l*)(2)(A)(emphasis added).

In particular, the Court found that references to licensed (or FDA-approved) products in the statute related only to the products that would be commercially marketed. It did not, in the Court's Opinion, modify or otherwise relate to the timing of the required notice. Accordingly, the applicant may provide notice either before or after receiving FDA approval. The Court noted that while both sides raised policy arguments in support of their respective positions, those policy considerations "are appropriately addressed to Congress, not the courts."

THREE KEY TAKEAWAYS

1. The Supreme Court has ruled that a key BPCIA requirement—that an applicant provide its abbreviated biologics license application and manufacturing information to the sponsor of the referenced product—is not enforceable by federal injunction.
2. The Supreme Court remanded back to the Federal Circuit the question as to whether the injunction is possible under state law.
3. The Court also concluded that a biosimilar applicant may provide "notice of commercial marketing" prior to FDA approval.

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