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White Paper

SANDOZ INC. V. AMGEN INC.

SUPREME COURT INTERPRETS BIOLOGICS PRICE COMPETITION AND INNOVATION ACT

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In a unanimous decision in *Sandoz Inc. v. Amgen Inc.*,[1] the U.S. Supreme Court held that injunctive relief was not available under federal law to enforce 42 U.S.C. § 262(l)(2)(A) of The Biologics Price Competition and Innovation Act of 2009 ("BPCIA"). The BPCIA was introduced in 2010 as part of the Patient Protection and Affordable Care Act to provide an abbreviated pathway for biological product manufacturers to obtain FDA licensing for products that were "biosimilar" to or almost identical to already licensed biological products ("reference product"). In addition to the ruling on available remedies, the Court also held that notice of commercial marketing of a biosimilar may be provided to the reference product manufacturer ("sponsor") prior to receiving FDA approval. In doing so, the Supreme Court overturned the Federal Circuit, which had previously held that effective notice of commercial marketing may be provided by an applicant only *after* the FDA had licensed the biosimilar.

Sandoz sought FDA approval to market a biosimilar filgrastim product under the brand-name Zarxio. Amgen, the marketer of the reference product, Neupogen, claimed to hold patents on methods of manufacturing and using filgrastim. In 2014, Amgen sued Sandoz for patent infringement and asserted two claims under California's unfair competition laws. Amgen alleged that Sandoz engaged in "unlawful" conduct when it "failed to provide its application and manufacturing information under Section 262(l)(2)(A), and when it provided notice of commercial marketing under Section 262(l)(8)(A) before, rather than after, the FDA licensed its biosimilar."[2]

The first issue in the case was "whether §262(l)(2)(A)'s requirement that an applicant provide the sponsor with its application and manufacturing information is enforceable by an injunction under either federal or state law."[3] The Supreme Court agreed with the Federal Circuit's conclusion that injunctive relief was not available under federal law, but disagreed with the reasoning. Section 262(l)(2)(A) states that no later than 20 days after the FDA notifies the applicant of the acceptance of the application for review, the applicant for licensure of a biological product "shall provide," a copy of the application and manufacturing information to the sponsor of the reference product. The Federal Circuit reasoned that Sandoz's failure to disclose its application and manufacturing information to Amgen, as part of the "patent dance," was an act of artificial infringement under §271(e)(2)(C)(i) and relied on §271(e)(4) to conclude that injunctive relief was not available for acts of artificial infringement. But, based on the structure and language of §271(e)(2)(C), the Supreme Court determined that although submitting an application is considered an act of artificial infringement under §271(e)(2)(C)(i), failing to disclose the application and manufacturing information under §262(l)(2)(A) itself was not an act of artificial infringement under this clause. Instead, the Court concluded that "[w]hen an applicant fails to comply with §262(l)(2)(A), §262(l)(9)(C) authorizes the sponsor, but not the applicant, to bring an immediate declaratory-judgment action for artificial infringement as defined in §271(e)(2)(C)(ii)." However, the remedy provided by §262(l)(9)(C) excludes all other federal remedies, including injunctive relief. Therefore, the Supreme Court concluded that Amgen did not have access to injunctive relief, at least as a matter of federal law, to enforce the disclosure requirements of §262(l)(2)(A).

The Supreme Court also remanded the issue of whether injunctive relief was available as a remedy to enforce § 262(l)(2)(A) under state law back to the Federal Circuit. The Supreme Court stated that on remand, the Federal Circuit should determine whether California law would treat noncompliance with §262(l)(2)(A) as "unlawful" and if so, whether the BPCIA would pre-empt any additional remedy available under state law for an applicant's non-compliance with §262(l)(2)(A).

The second issue in the case was "whether an applicant must provide notice after the FDA licenses its biosimilar, or if it may also provide effective notice before licensure." The Supreme Court held that an applicant may provide notice *before* the FDA licenses its biosimilar. Section 262(l)(8)(A) provides that the "applicant shall provide notice to the sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)" Based on the phrasing of the clause, the Supreme Court determined that "of the biological product licensed under subsection (k)" modifies "commercial marketing" rather than "notice." In addition, the Supreme Court reasoned that if Congress intended to inflict two timing requirements, it would have done so explicitly as it did in adjacent provisions. Therefore, the Supreme Court concluded that Sandoz fully complied with §262(l)(8)(A) when it first gave notice of commercial marketing to Amgen before licensure.

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[1] *Sandoz Inc. v. Amgen Inc.*, 582 U. S. _____ (2017).

[2] *Id.*

[3] *Id.*