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Intellectual Property Pharmaceutical Practice
June 13, 2017

Sandoz Inc. v. Amgen Inc. clears the way for potential earlier launch of biosimilars

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In *Sandoz Inc. v. Amgen Inc.*, No. 15-1039 (U.S. June 12, 2017) the Supreme Court held (i) that biosimilar applicants may provide the requisite 180-days' notice of commercial marketing to the reference product sponsor even before receiving a license (approval) from FDA and (ii) that a biosimilar applicant's nondisclosure of its application and manufacturing information cannot be remedied by an injunction under federal law.

In 2014, Sandoz filed a biosimilar application for filgrastim, relying on Amgen's Neupogen® as the reference product. After receiving notice that FDA accepted the application for review but before receiving a license from FDA to market the product, Sandoz notified Amgen under 42 U.S.C. §262(l)(8(A) that it intended to begin marketing its filgrastim product immediately upon receipt of an FDA license. At that time, Sandoz did not provide a copy of its application and manufacturing information to Amgen, as required by 42 U.S.C. §262(l)(2)(A). Sandoz instead invited Amgen to bring an infringement action, citing to §262(l)(9)(C), which gives the reference product sponsor standing to bring suit against an applicant that does not comply with §262(l)(2)(A). Amgen filed suit asserting patent infringement and that Sandoz violated the Biologics Price Competition and Innovation Act of 2009 (BPCIA) as well as California's unfair competition law for failing to provide its application and manufacturing information.

The district court granted partial summary judgment on the pleadings: the court held that Sandoz had not violated the federal statute, and it dismissed with prejudice Amgen's claims arising under the state statute. The Federal Circuit agreed that Sandoz did not violate the federal statute in failing to disclose its application and manufacturing information, but enjoined Sandoz from marketing its biosimilar product until 180 days after it provided notice after receiving a licence from FDA.

The question presented to the Supreme Court was whether the statute requires that the biosimilar applicant receive a license from FDA before providing its 180-day notice of commercial marketing to the reference product sponsor under §262(l)(8)(A).

The Supreme Court also addressed whether the disclosure requirement of §262(l)(2)(A) is enforceable by injunction under either federal or state law.

The Supreme Court held that:

(1) an injunction requiring the disclosures of 42 U.S.C. §262(l)(2)(A) is not appropriate under federal law because §262(l)(9)(C) provides the sole remedy contemplated by the statute;

(2) the Federal Circuit misinterpreted 35 U.S.C. §271(e) in finding that the federal statute precluded state law claims regarding the disclosures required by 42 U.S.C. §262(l)(2)(A), and remanded for the Federal Circuit to address whether state law provided a basis for an injunction and/or are pre-empted by federal statute; and

(3) an applicant is not required to wait for a license from FDA before providing its 180-day notice of marketing under 42 U.S.C. §262(l)(8)(A).

The Court's ruling effectively could speed up market entry of biosimilar products, permitting the biosimilar applicant to launch immediately upon receiving a license from FDA, without having to wait 180 days after license to launch. Even with FDA license, however, a biosimilar applicant may be wary of launching its product early given the risk of a finding of patent infringement and damages.

Subject to the Federal Circuit's ruling on remand regarding the pre-emption question and applicability of California unfair competition statute, the Supreme Court's ruling may also give biosimilar applicants a way out of the lengthy patent dance and quicker route to litigation, forcing sponsors to file suit without seeing the application's confidential information, thereby melding the lengthy first and second phases of the BPCIA litigations into one. Avoiding the patent dance, however, could cause the litigation to become more uncertain at least with respect to which patents the sponsor may assert and the cost of the litigation, as the sponsor might decide to over assert the patents in its portfolio.

KEY TAKE-HOMES:

1. 42 U.S.C. §262(l)(8)(A) does not require the applicant to wait for license (approval) from FDA before submitting their 180-day notice of marketing to the reference product sponsor.
2. It may be possible for a reference product sponsor to enforce the disclosure requirements of 42 U.S.C. §262(l)(2)(A) under state laws, but not under federal statute.

For more information on the matters discussed in this *Locke Lord QuickStudy*, please contact the authors.

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