Patent Law Alert:
SUPREME COURT CLARIFIES THE RULES FOR BIOSIMILARS

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(June 12, 2017) In *Sandoz v. Amgen*, 582 U. S. ___ (2017), the Supreme Court addressed the "plain language" of a "carefully crafted and detailed enforcement scheme" relating to "biologic" drugs. Under this complex statute that was enacted as part of ObamaCare as an effort to get generic biosimilar and interchangeable biologic drugs on the market quicker if the patent hurdle can be overcome. On a bottom line basis, the Court adopted a view that will likely encourage more biosimilar and interchangeable biologic drugs to come to market quicker despite the existence of issued patents covering the original biologic drugs.

Sandoz addressed two important questions regarding the processes for both obtaining FDA approval of a biosimilar and resolving a patent dispute between the manufacturer of a biosimilar ("applicant") and the manufacturer of a licensed reference biologic ("sponsor"):

1. Whether the requirement of the Biologics Price Competition and Innovation Act of 2009 ("BPCIA") that an applicant seeking a license to manufacture a biosimilar under the FDA's abbreviated review process set forth in 42 U.S.C. § 262(k) must provide its application and manufacturing information to the sponsor is enforceable by an injunction under either federal or state law.

The Court held that an injunction was not available under Federal Law, although it left open the possibility on remand or otherwise as to whether an injunction may be available under state law (in particular California law) or a preliminary injunction based on other parts of the patent statute. (Slip op. at 10 & n.2).

2. Whether an applicant must provide notice of the commercial marketing of a biosimilar to the sponsor of the reference biologic under the BPCIA only after the licensing of the biosimilar, or if it may provide notice before the biosimilar has been licensed.

The Court held that the applicant need not wait for a license to meet the notice requirement, thus accelerating the speed to which an applicant can get a proposed biosimilar to market. (Slip op. at 15).

The Court agreed with the U.S. Court of Appeals for the Federal Circuit ("Federal Circuit") that an injunction under federal law is not available to enforce the BPCIA's requirement that the applicant must provide its application and manufacturing information to the sponsor. (Slip op.

at 10). However, the Court relied on a different rationale than the Federal Circuit. (Slip op. at 12). In reaching its conclusion, the Court (per Thomas, J.) held that, under the language and context of the BPCIA, an injunction is not available under 35 U.S.C. § 271(e)(4) if an applicant fails to provide its application and manufacturing information to the sponsor because such failure does not constitute patent infringement under 35 U.S.C. § 271(e)(2)(C). (Slip op. at 11–12). The Court further held that the sole remedy provided in the BPCIA for such failure by the applicant is that the sponsor can immediately file a declaratory judgment action for infringement under 35 U.S.C. § 271(e)(2)(C)(ii). (Slip op. at 12).

Interestingly, the Court "express[ed] no view" as to whether a US District Court could take into account an applicant's failure to provide its application and manufacturing information to the sponsor when it decides whether to grant a preliminary injunction against the applicant's marketing of the biosimilar. (Slip op. at 13 n.2). The answer to this question will no doubt be left unresolved by the Court for many more years.

The Court declined to resolve the issue of whether an injunction is available under California's unfair competition law, since "it does not present a question of federal law." (Slip op. at 14). The Federal Circuit had concluded that an injunction was unavailable under California law, but the Court stated that the Federal Circuit's holding was based on its incorrect interpretation that an applicant's failure to provide its application and manufacturing information to a sponsor constitutes patent infringement under the BPCIA. (Slip op. at 14). The Court remanded this issue to the Federal Circuit, and also instructed the Federal Circuit to consider whether federal law preempts an injunction under California's unfair competition law if such an injunction were to be available. (Slip op. at 15).

The Court also held that an applicant may provide notice of commercial marketing of a biosimilar to the sponsor "either before or after receiving FDA approval." (Slip op. at 16). The Court reasoned that the plain language and context of the BPCIA require only that a biosimilar be licensed on the date it is first marketed commercially. (Slip op. at 16–18). This holding favors earlier disclosure and will likely accelerate the speed to which an applicant can get a proposed biosimilar to market.

Justice Breyer issued a short concurring opinion, in which he concurred in the Court's "reasonable interpretation" of the terms of the statute, but he presented his view that the FDA may have the authority to substitute its own interpretation of the statutory terms if "a different interpretation would better serve the statute's objectives." (Breyer, J. slip op. at 1). This concurring opinion foreshadows a battle looming over the continued viability of the *Chevron* doctrine at the Supreme Court. It is anticipated that this battle will be the centerpiece of the Court's resolution of *SAS Institute Inc. v. Lee and ComplementSoft, LLC* next term.

We will continue to monitor developments in the law on biosimilars. In the meantime, please feel free to contact one our attorneys regarding issues raised by this case.

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