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BPCIA Preempts State Law Remedies for Biosimilar Applicant's Refusal to Disclose Abbreviated Biologics License Application

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The Federal Circuit has issued its decision on remand from the Supreme Court in *Amgen Inc. v. Sandoz Inc.*, No. 15-1499 (Fed. Cir. Dec. 14, 2017), holding that the Biologics Price Control and Innovation Act ("BPCIA") preempts state law remedies when an applicant seeking licensure of a biosimilar drug product chooses not to disclose its licensure application to the sponsor of the reference biologic product pursuant to 42 U.S.C. § 262(l)(2)(A). Under the Federal Circuit's ruling, injunctive relief is not available under federal or state law, and the reference product sponsor's sole remedy is to file a declaratory judgment action under § 262(l)(9)(C).

The dispute between Amgen and Sandoz has been watched closely by the pharmaceutical industry for over three years. In May 2014, Sandoz filed an abbreviated biologics license application ("aBLA") seeking FDA approval for Zarxio®, a biosimilar version of Amgen's Neupogen® (filgastrim) product. Under the BPCIA, an applicant seeking licensure of a biosimilar drug product "shall provide to the reference product sponsor a copy of the [aBLA]" within 20 days of receiving notice that the FDA has accepted its application for review. 42 U.S.C. § 262(l)(2)(A). Sandoz did not disclose its aBLA to Amgen in accordance with § 262(l)(2)(A).

In October 2014, Amgen sued Sandoz for infringing a patent directed to a method of using filgrastim and for unfair competition and conversion under California state law. Amgen's state law claims were based on its allegation that Sandoz violated the BPCIA by failing to disclose its aBLA under § 262(l)(2)(A). Sandoz counterclaimed for a declaratory judgment that its decision not to disclose its aBLA was permissible under the BPCIA. The district court granted partial judgment on the pleadings to Sandoz, holding that the BPCIA permits a biosimilar applicant not to disclose its aBLA and dismissing Amgen's state law claims. The Federal Circuit affirmed in part.

The Supreme Court granted certiorari and held that § 262(l)(9)(C) provides a remedy for a biosimilar applicant's failure to disclose its aBLA – the filing of a declaratory judgment action by the reference product sponsor – and excludes all other federal remedies, including injunctive relief. The Supreme Court remanded the case and directed the Federal Circuit to determine (1) whether California law would treat noncompliance with § 262(l)(2)(A) as "unlawful;" and (2) whether the BPCIA preempts any additional remedy available under state law for an applicant's failure to comply with § 262(l)(2)(A).

On remand, the Federal Circuit assumed *arguendo* that state law remedies exist and proceeded directly to the question of whether the BPCIA preempts such remedies. The court concluded that it does. In finding field preemption, the court noted that the BPCIA statutory scheme "is 'comprehensive' and 'provide[s] a full set of standards governing' the exchange of information in biosimilar patent litigation, 'including the punishment for noncompliance.'" The court also noted the Supreme Court's holding that "the remedy provided by § 262(l)(9)(C) excludes all other federal remedies, including injunctive relief,"

for failure to comply with § 262(l)(2)(A). Against this backdrop, the Federal Circuit held that the scheme established by the BPCIA "[i]s so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it."

The Federal Circuit also found that conflict preemption barred Amgen's state law claims. The court noted that Amgen was seeking to impose penalties "through state law" that are "unavailable under the BPCIA for failure to comply with § 262(l)(2)(A)'s disclosure requirements" and that this "conflict in the method of enforcement" creates "an obstacle to the regulatory system Congress chose." The court also noted that "compliance with the BPCIA's 'detailed regulatory regime in the shadow of 50 States' tort regimes,' and unfair competition standards, could 'dramatically increase the burdens' on biosimilar applicants beyond those contemplated by Congress in enacting the BPCIA."

The Federal Circuit's decision limits the remedies available to a reference product sponsor, and the potential consequences to a biosimilar applicant, for the applicant's noncompliance with § 262(l)(2)(A)'s disclosure requirements.

The full opinion is available at: http://www.cafc.uscourts.gov/sites/default/files/opinions-orders/15-1499.Opinion.12-13-2017.1.PDF

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