Updates
December 15, 2017
Federal Circuit Rules Out State-Law Remedies for Failure to Participate in the Biosimilars "Patent Dance"

On December 14, the Federal Circuit issued a decision that further clarifies the ground rules for disclosures of product information by manufacturers of biosimilar pharmaceutical products. In particular, the Federal Circuit ruled in *Amgen Inc. v. Sandoz* Inc. that the original sponsors of biologics products cannot invoke state laws to compel applicants that are seeking to market biosimilar products to disclose information about those products under the Biologics Price Competition and Innovation Act (BPCIA). The ruling is significant because it leaves the original sponsors of biologics with no mechanism—state or federal—to compel producers of biosimilar products to comply with BPCIA provisions requiring early disclosure of their product manufacturing information and applications for Food and Drug Administration (FDA) approval.

Obtaining FDA approval for a new biologic drug requires filing a biologics license application (BLA) to establish the drug's safety and efficacy. Under the BPCIA, others may later submit an abbreviated biologics license application (aBLA) showing that their products are similar to or interchangeable with the previously approved reference product. But the reference product sponsor may treat the filing of an aBLA as an artificial act of patent infringement and file a patent infringement lawsuit before approval of the aBLA. Section 262(*l*)(2)(A) of the BPCIA provides that the biosimilar applicant "shall" provide access to its aBLA and product manufacturing information as part of a structured, stepwise process of pre-suit information exchange between the original reference product sponsor and the biosimilar applicant.

In *Amgen v. Sandoz,* aBLA applicant Sandoz declined to provide information that reference product sponsor Amgen requested under Section 262(*l*)(2)(A), and Amgen filed suit claiming violations of the BPCIA and California's Unfair Competition Law. Earlier in the case, the Supreme Court affirmed a Federal Circuit panel ruling that federal law does not provide an injunction remedy to force biosimilar applicants to comply with Section 262(*l*)(2)(A). But the Supreme Court left open the possibility of using state-law unfair competition claims to achieve the same result, and it remanded for the Federal Circuit to resolve that issue in the first instance. The Federal Circuit has now concluded that the BPCIA fully occupied the field of biosimilar patent litigation and that any state-law remedies would conflict with congressional intent in that area, resulting in

federal-law preemption of any state-law remedy for non-compliance with Section 262(*l*)(2)(A).

As an initial matter, the Federal Circuit reasoned that no presumption against preemption applied because biosimilar patent litigation is not a field that the States traditionally occupied. The court noted that patents are federal rights, federal courts have exclusive jurisdiction over patent infringement suits, and FDA has exclusive authority to license biosimilars. The court further reasoned that the BPCIA is a complex statutory scheme, indicating that Congress preempted the field, and it concluded that Amgen was seeking to apply state law to obtain remedies that the BPCIA does not provide. Analogizing to precedent involving preemption of State immigration-related statutes, the court concluded that letting states impose their own penalties for violation of federal biosimilars law would conflict with Congress's careful framework.

Amgen argued that its state-law claims were compatible with the BPCIA, as they required additional elements and provided separate relief. But the court concluded that complying with BPCIA's detailed regulatory regime in the shadow of fifty state tort regimes and unfair competition standards would be too burdensome for biosimilar applicants. The court assumed that Congress acted intentionally in not providing an injunctive remedy and concluded that state laws imposing additional requirements and remedies conflicted with the congressional design.

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