

Patent dance remains on point

Federal Circuit confirms patent dance is optional, but will biosimilar makers opt out? **Irena Royzman** and **Michael Fresco** explore

The Federal Circuit's recent decision in *Amgen v Sandoz*¹ provides a measure of clarity for innovator companies and biosimilar makers eyeing patent litigation. While the Supreme Court of the US held in June that initiating the pre-litigation information exchanges set out in the Biologics Price Competition and Innovation Act (BPCIA) – colloquially referred to as the “patent dance” – cannot be enforced under federal law, the Federal Circuit's decision goes a step further. It holds that initiation of the exchanges cannot be enforced under state law, either. As a result, innovators seeking to compel disclosures from biosimilar makers have no recourse other than to sue for infringement. For a number of reasons, however, the decision might not prove as impactful in the long run as it may seem.

The BPCIA provides an abbreviated regulatory pathway for approval of biosimilars. It also provides carefully calibrated procedures to tee up and resolve patent disputes. After the FDA accepts a biosimilar maker's abbreviated Biologics License Application (aBLA), the patent dance ensues: the biosimilar maker “shall” provide to the innovator its aBLA and manufacturing information, the innovator provides a list of patents that may be infringed, the biosimilar maker provides its contentions in response, and so on. The exchange allows the parties to determine which patents will be litigated immediately, and which will wait. If the biosimilar maker fails to provide its initial disclosures, the BPCIA authorises the innovator to sue immediately for infringement. Otherwise, the innovator must await the end of the dance to sue and can sue only on the patents selected for immediate litigation.

The *Amgen v Sandoz* litigation goes back to 2014, and it is a case of firsts. The dispute centres on Sandoz's Zarxio, a biosimilar version of Amgen's Neupogen and the first biosimilar to be approved in the US. After Sandoz refused to give Amgen its aBLA and manufacturing information, Amgen sued under federal and

California state law. Sandoz obtained victory on the disclosure requirements in the district court, and the Federal Circuit affirmed on that issue in its first interpretation of the BPCIA. When Amgen appealed that decision, the US Supreme Court had its own first shot at the statute. The court ruled in favour of Sandoz, finding, among other things, that initiation of the patent dance cannot be compelled under federal law. The court remanded the case to the Federal Circuit to determine whether noncompliance with the BPCIA's disclosure provisions is unlawful under California law and whether the BPCIA preempts any state law remedy.

Federal preemption doctrine emanates from the Supremacy Clause of the Constitution. Generally speaking, it provides that state laws are invalid if they conflict with federal law (conflict preemption) or exist within a field completely occupied by federal law (field preemption). The Federal Circuit took up the preemption question first, and found both types of preemption applicable.

As to field preemption, the Federal Circuit noted that patents are “inherently federal in character”: they originate in federal law, federal courts have exclusive jurisdiction over patent cases, and the FDA has exclusive authority to license biosimilars. The court also pointed to the BPCIA's complexity and its “carefully calibrated scheme for preparing to adjudicate, and then adjudicating” biosimilar infringement claims, concluding that “the federal government has fully occupied this field.”

As to conflict preemption, the court found that allowing Amgen to pursue an injunction and damages under state law would “clash” with the BPCIA, because Congress made a deliberate choice not to provide the type of relief Amgen sought. The court also expressed concern that casting the BPCIA's “detailed regulatory regime in the shadow of 50 States' tort regimes” would “dramatically increase the burdens on biosimilar applicants”. The court, accordingly, ruled that Amgen's state

law claims could not proceed.

Amgen v Sandoz confirms that innovators cannot compel biosimilar makers to participate in the patent dance. But the decision's ultimate impact may be limited. Given the substantial benefit biosimilar makers can derive from the BPCIA's dispute resolution procedures, many biosimilar makers will probably follow them out of self-interest. For example, the patent dance affords biosimilar makers certainty and informed decision-making; they learn which patents may be asserted and the patent owner's infringement and validity contentions.

Biosimilar makers also gain control; after the patent dance is complete, biosimilar makers have substantial control over which patents are litigated immediately and can limit the number of patents that the innovator can assert in early litigation. Many biosimilar makers are, moreover, innovators themselves, and maintain an interest in compliance with the provisions of the BPCIA. For these reasons and others, many biosimilar makers have chosen to participate in the patent dance so far. The Federal Circuit's decision is unlikely to substantially alter that trend.

Footnote

1. *Amgen Inc v Sandoz Inc*, No. 2015-1499, 2017 US App LEXIS 25227 (Fed Cir 14 Dec 2017).

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