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U.S. Appeals Court Renders First Interpretations Of Biosimilars Law

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In *Amgen v. Sandoz*, Fed. Cir., No. 15-1499 (July 21, 2015), a divided panel of the U.S. Court of Appeals for the Federal Circuit issued its first decision interpreting the Biologics Price Competition and Innovation Act (BPCIA), and did so in a manner that favors biosimilar applicants in one respect while favoring reference product sponsors (*e.g.*, owners of original biologic products) in another. The result for Amgen and Sandoz is that Sandoz can start selling Zarxio™, its biosimilar version of Amgen's Neupogen® (filgrastim) product, on September 2, 2015. The result for other biosimilar applicants is less clear, since the court's decision leaves open more questions than it answers.

The Biosimilar Framework

Similar to the Hatch-Waxman Act that governs the approval of traditional generic drugs in the U.S., the BPCIA allows a biosimilar applicant to rely on the FDA's previous approval of the reference product (*e.g.*, the original biologic product) and file an "abbreviated" application for approval of a product that is "biosimilar" to or, in the alternative, "interchangeable" with, the reference product. As noted by the Federal Circuit, the BPCIA seeks to balance the innovator's investment in developing the reference product with the price competition a generic will bring to the market by providing that the a biosimilar application cannot be filed until the reference product has been approved for at least 4 years, and that approval of a biosimilar application cannot be effective until the reference product has been approved for at least 12 years. (Since Amgen's Neupogen® product had been approved for more than 12 years before the BPCIA was enacted, these time periods were not relevant in this case.) The statute also requires biosimilar applicants to give at least 180 days' prior notice of commercial marketing to the owner of the original biologic product (the "reference product sponsor").

The Biosimilar Patent Dance

Also like the Hatch-Waxman Act, the BPCIA includes patent dispute resolution procedures, but the similarity ends there. The BPCIA lays out what the Federal Circuit referred to as a "unique and elaborate" process that commences when the biosimilar applicant shares its biosimilar application with the reference product sponsor, continues with exchanges of lists of patents and validity/infringement contentions and negotiations of the patents to be litigated, requires the reference product sponsor to assert the negotiated patents right away to avoid limitations on remedies, and culminates with a last-chance opportunity to assert additional patents after the

biosimilar applicant provides the 180 days' premarketing notice.

The Neupogen® // Zarxio™ Biosimilar Dispute

Amgen has marketed filgrastim, a recombinantly produced human granulocyte colony-stimulating factor protein (C-CSF), since 1991 under the brand name Neupogen®. Neupogen® is used to reduce the chance of infection in certain cancer patients undergoing chemotherapy. In May of 2014, Sandoz sought FDA approval of a biosimilar of Neupogen® (filgrastim-sndz or Zarxio™) under the BPCIA. Sandoz notified Amgen of its biosimilar application, but did not provide a copy to Amgen and did not follow any of the other patent dispute resolution procedures of the statute. As to premarketing notice, Sandoz first notified Amgen of its intent to commercially market Zarxio™ in July of 2014, before it was approved, and gave notice again when it became the first approved biosimilar product on March 6, 2015.

Amgen sued Sandoz in the United States District Court for the Northern District of California alleging, among other things, violation of California's unfair competition laws and conversion based on Sandoz' alleged failure to comply with the BPCIA. The district court found no violation of the BPCIA to support Amgen's state law claims. The Federal Circuit affirmed on one issue and reversed on the other.

The Patent Dance Is Optional

On the first issue, the court determined that a biosimilar applicant is not absolutely ***required*** to give a copy of its biosimilar application to the reference product sponsor, and is not required to engage in the patent dance. According to the court, biosimilar applicants who elect not to share their applications could be subject to an immediate declaratory judgment action that the reference product sponsor could bring to assert any patent that claims the product or a use of the product (but perhaps not a patent that only claims a method of ***making*** the product).

Premarketing Notice Must Be Given After Approval

On the issue of whether and when a biosimilar applicant is required to give premarketing notice to the reference product sponsor, the court ruled that the 180 day premarketing notice provision is a "standalone requirement" that cannot be given until the biosimilar product is approved. In his dissenting opinion, Judge Chen characterized this ruling as giving reference product sponsors a "windfall" of an additional market exclusivity period beyond the 12 years expressly provided in the statute.

Unanswered Questions

While the decision in *Amgen v. Sandoz* answers two key questions about the BPCIA, it leaves open many others. For example, there are many questions regarding the complicated patent dance provisions of 41 USC § 262(*l*), and many questions regarding the infringement, damages and estoppel provisions of 35 USC § 271(e)(2)-(6). Thus, it still could be some time before we have a better understanding of the most complex aspects of the BPCIA.

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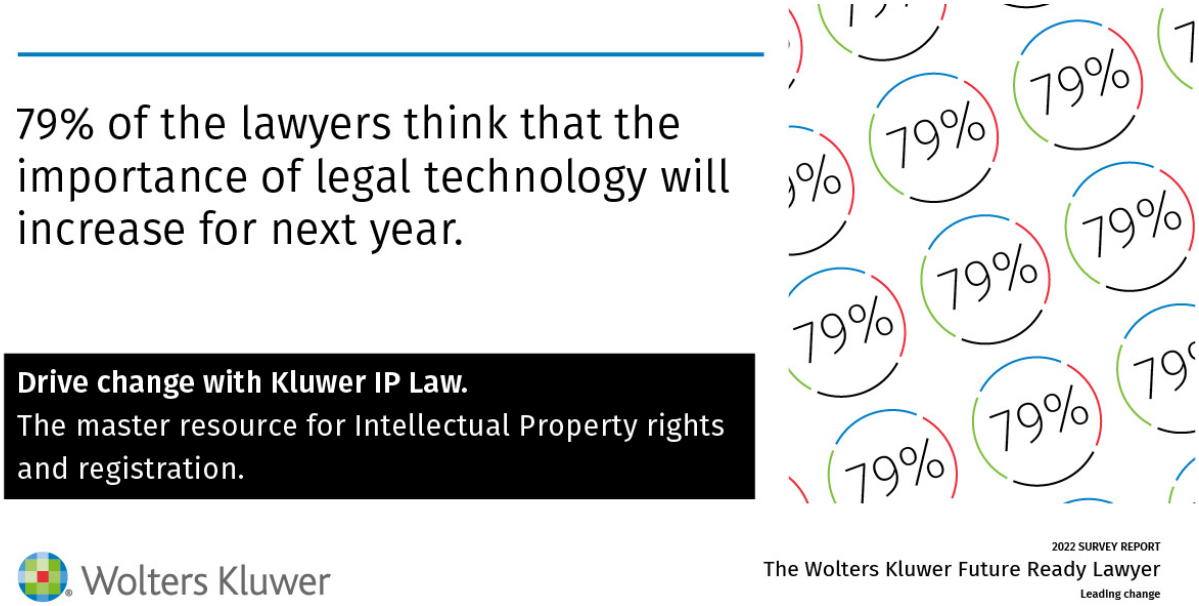

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