LEGAL UPDATES

PUBLISHED: JUNE 22, 2017

Supreme Court Offers Biosimilar Drug Companies a Quicker Path to Market

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On June 12, 2017, the U.S. Supreme Court reversed a Federal Circuit decision in a case involving pre-market patent disputes over biosimilar drugs. At its core, the Supreme Court's holding provides generic biologic drug companies the opportunity to go to market much sooner than the Federal Circuit's holding allowed.

In *Sandoz Inc. v. Amgen Inc.*, the Court considered the Biologics Price Competition and Innovation Act of 2009 (BPCIA), which was enacted during the Obama administration to govern approval of biologic drugs derived from natural, biological sources. A primary goal of the BPCIA is to resolve questions of patent infringement and validity prior to commercial marketing of the drug. To achieve this goal, the BPCIA requires an applicant to provide its application materials and manufacturing information to the manufacturer ("sponsor") of the corresponding biologic. The BPCIA further requires the applicant to give notice to the sponsor at least 180 days before marketing the biosimilar commercially. The BPCIA encourages compliance with these disclosure provisions by providing the applicant significant control over the identity of the patents that may be litigated as part of the BPCIA's complex pre-commercial marketing phase. If the applicant does not comply, however, the BPCIA allows the sponsor to bring a declaratory judgment action with respect to a wider range of patents.

Sandoz did not provide the requisite materials to Amgen. Rather, one day after the Food and Drug Administration (FDA) notified Sandoz that the agency had accepted Sandoz's application for review, Sandoz notified Amgen both that Sandoz had filed an application and that Sandoz intended to commercially market the drug immediately upon receiving FDA approval. Sandoz further informed Amgen that Sandoz would not provide its application and related materials, and that Amgen could bring instead a declaratory judgment action.

The Supreme Court considered: (1) whether the requirement that an applicant provide its application and manufacturing information to the sponsor is enforceable by injunction under federal law, and (2) whether an applicant must provide notice to the sponsor of its intent to market a biosimilar before obtaining a license from the FDA to market the product. The Supreme Court resolved both of these issues in favor of the generic drug company.

The Court found that an injunction under federal law is not available to enforce compliance with the mandatory disclosure provisions of the BPCIA, although it left open the door for a lower court finding that such an injunction could be available under state law. Failure to comply with such disclosure provisions may be used against the biosimilar manufacturer in other ways as well. The Supreme Court also held that the applicant may provide notice of intent to commercially market the biosimilar either before or after receiving FDA license.

What This Means to You

At its core, the Supreme Court's holding provides generic companies the opportunity to go to market much sooner than the Federal Circuit's holding allowed.

Contact Us

For more information on how this decision may affect your company's ability to bring a biosimilar drug to market, please contact Don J. Mizerk and Edward P. Gamson of Husch Blackwell's Life Sciences Intellectual Property Litigation group.