Introduction

The statute that created a regulatory pathway for the approval of biosimilar products in the U.S. is known as the Biologics Price, Competition and Innovation Act of 2009 ("BPCIA" for short). While the BPCIA has been praised for its policy goal of expanding patient access to biologic medicines, few have lauded it as a model of legislative clarity. In the landmark case *Amgen v. Sandoz*, in which the U.S. Court of Appeals for the Federal Circuit first attempted to clarify the BPCIA's labyrinthine patent infringement resolution scheme commonly referred to as "the patent dance," Judge Lourie (channeling Winston Churchill) declared the statute "a riddle wrapped in a mystery inside an enigma."[1] After wrestling with fundamental ambiguities in the statute, such as whether the patent dance is mandatory and whether its steps are enforceable by a reference product sponsor or biosimilar applicant, Judge Lourie appended a footnote to the court's opinion that suggested more than a little judicial frustration with the statute's lack of clarity: "[i]n these opinions, we do our best to unravel the riddle, solve the mystery, and comprehend the enigma."[2]

The *Amgen v. Sandoz* opinion issued in 2015, at a time when the biosimilar industry had very limited experience with the BPCIA. Only one biosimilar had been approved by the U.S. Food & Drug Administration (Sandoz's Zarxio® (filgrastim-sndz)) and only two patent infringement litigations had been brought under the BPCIA (against Zarxio® and Celltrion's Inflectra® (infliximab-dyyb)). In the ten years that have elapsed since then, much has happened to clarify the BPCIA and regulatory pathway for biosimilars. The initial trickle of applications into the U.S. Food & Drug Administration ("FDA") has become a steady stream, and the FDA has gotten increasingly comfortable and efficient in approving products that meet the BPCIA's threshold requirements for biosimilarity.

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[1] *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1351 n.1 (Fed. Cir. 2015), *rev'd in part, vacated in part*, 137 S. Ct. 1664 (2017).

[2] *Amgen*, 794 F.3d at 1351 n.1. Given that the U.S. Supreme Court ultimately disagreed with the way in which Judge Lourie and the Federal Circuit resolved some of the statutory ambiguities, Judge Lourie's frustration was not misplaced.

Unsurprisingly, reference product sponsors have defended their markets aggressively. Patent infringement lawsuits have been filed or threatened numerous biosimilars submitted to the FDA for approval. The initial wave of high-stakes litigation following the enactment of the BPCIA have substantially clarified the mechanics of the patent dance, including whether a party may enforce compliance with the dance, the penalties for not dancing, and when notice of first commercial marketing to initiate the second wave of the dance may be given.[3] Today, courts and litigants familiar with how the dance works in practice, as well as the tactical advantages of dancing or not dancing depending on the particular circumstances of the biosimilar being litigated.

As the FDA continues to issue guidance on biosimilar approval and cases continue to be litigated in the U.S. district courts and elsewhere, legal, regulatory, and market developments will continue at a rapid pace. As the landscape continues to evolve, the Guide endeavors to serve as a helpful companion for those just getting acquainted with biosimilars, those who have been involved from the start of the legislative process that resulted in the BPCIA, and anyone in between. In addition to the Guide, the authors write about developments on a daily basis at www.bigmoleculewatch.com, the award-winning biosimilar blog published by Goodwin Procter LLP, and the companion blog at www.bigmoleculewatch.cn, which tracks biosimilar developments in the rapidly-evolving life sciences market in China. We hope this Guide and our daily blog coverage will continue to serve as useful and complementary reference tools for all stakeholders in the global biosimilar industry.

— [the Editorial Staff]

[3] *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664 (2017).