Portfolio Media. Inc. | 111 West 19th Street, 5th Floor | New York, NY 10011 | www.law360.com
Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

Dance Marches On For Biosimilars In Amgen V. Sandoz

By **Scott Pierce, Hamilton Brook Smith Reynolds PC**

Law360, New York (January 13, 2017, 4:08 PM EST) -- Two sections of the Biologics Price Competition and Innovation Act of 2009 are the subject of writs of certiorari that have just been granted by the U.S. Supreme Court to the parties in Amgen Inc. v. Sandoz Inc. Ultimately at stake is billions of dollars in annual revenue generated in the burgeoning biologics industry. At issue is congressional intent settling patent disputes prior to expiry of a 12-year exclusivity period granted to the first licensee approved for commercialization of a biological product by the U.S. Food and Drug Administration.

Section (k) of the BPCIA (42 U.S.C. §262(k)) enables approval of products that are "biosimilar" to a "biological product." Section (l), also known as the "patent dance," prescribes a procedure for exchange of information, including patents and potentially confidential information. Both sections are intended to expedite identification and resolution of any possible patent disputes after filing of an abbreviated biologics license application ("subsection (k) application"). "Biological products" are distinct from drugs regulated under the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act") in that biological products generally are derived from nature. "Biosimilarity" under the BPCIA is based on lack of "clinically meaningful differences" from a previously approved "reference product."

Sandoz filed a subsection (k) application in 2014 to obtain approval for a biosimilar to filgrastim, which Amgen had been marketing under the name of Neupogen and which had been licensed by the FDA 23 years before. Sandoz's filgrastim product was to be launched under the trade name of Zarxio. Amgen sued Sandoz in 2014 in the Northern District of California asserting unfair business practices, conversion for wrongful use of Amgen's FDA-approved license, infringement of Amgen's patent 6,162,427, and violation of two provisions of the BPCIA, namely 42 U.S.C. §§ 262(l)(2)(A) and 262(l)(8)(A) by failing to provide information to Amgen as required under the act. Sandoz, in turn, filed counterclaims regarding interpretation of the BPCIA. The district court dismissed Amgen's claims because it held that Sandoz acted properly under the BPCIA.

Following appeal, the Federal Circuit in Amgen v. Sandoz held that the term "shall" in 42 U.S.C. § 262(l)(2)(A) did not mandate that the applicant ("subsection (k) applicant") actually provide a copy of the subsection (k) application to the first licensee under the FDA ("reference product sponsor") within 20 days of filing because the statute sets forth alternatives in the event that the applicant fails to comply. At the same time, however, the majority also held that another provision of the BPCIA, 42 U.S.C. §262(l)(8)(A), which uses the same term, "shall," does mandate compliance because, according to the court, it is a "stand alone" provision. 42 U.S.C. §262(l)(8)(A) provides that the "subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of first commercial marketing of the biological product licensed under subsection (k)." Further, the court held

that, at the time of such notification, licensure by the FDA to the applicant must be approved, meaning that notification of impending commercialization and commencement of the 180 day period must occur after approval.

Judge Pauline Newman, taking the literal meaning of "shall" to be a "command," concurred that notice of future commercialization is mandatory and that an FDA license is necessary to enable commencement of the 180-day stay of commercial marketing under (l)(8)(A). She dissented from the court's holding that a copy of the section (k) application within 20 days of filing under (l)(2)(A) is not mandated by the act.

Judge Raymond T. Chen, dissenting in part, came to opposite conclusions with respect to these two sections. While agreeing with the majority that failure to supply a copy of the application to the reference product sponsor under (l)(2)(A) does not violate the BPCIA because the statute provides for alternative measures, he dissented from the majority's conclusion that, unlike Section (l)(2)(A), the word "shall" in (l)(8)(A) mandates compliance. Contrary to the majority's dicta, Judge Chen reasoned that the 180-day notification does not "stand alone" because, as with Section (l)(2)(A), alternatives for noncompliance were provided by the statute, in this case Sections (l)(9)(A)-(C). He also argued that the act does not require FDA approval prior to commencement of the 180-day notification period preceding commercialization under (l)(8)(A).

A brief for the United States as amicus curiae was filed in December of 2016 in response to an invitation from the Supreme Court to the solicitor general to express the views of the United States. Largely agreeing with Judge Chen, the brief summarized resolution of patent disputes under the act as a "four-phase process" that includes an information phase, a comprehensive list phase, and two phases of patent litigation. The 20-day and the 180-day notification periods were classified in the information phase and the second phase of litigation, respectively. Recognizing the detailed steps to be taken in the event that the subsection (k) applicant fails to provide a copy of the application submitted to the FDA, and that the act "already specifies under (l)(9)(c) that the sponsor may bring suit on any relevant patent following" failure to meet the 20-day deadline, the government asserted that there is, therefore, no need for any additional consequence for noncompliance with the 180-day notification period, such as an injunction, as was imposed by the Federal Circuit. As a result, the government recommended grant of the petition and the conditional cross-petition for writs of certiorari, which the Supreme Court has now done.

The need for resolution of ambiguity in the statute is clear. If a subsection (k) applicant can disregard the BPCIA altogether, then there may be little incentive to exchange information under the act because it could expose the applicant to liability and potentially weaken their market position. At the other extreme, mandatory compliance with the notice provisions of the BPCIA, including requirement for approval from the FDA prior to availability of the 180-day period antecedent to commercialization, would prolong the exclusivity period set by statute.

As noted by the government, "[d]eveloping a biosimilar generally is substantially more expensive and time-consuming than developing a generic drug." The government also noted the importance of the "carefully calibrated legislative effort [represented by the BPCIA] to promote innovation and competition in this important field," particularly given that, in "2013, biologics accounted for $80 billion in spending in the United States, constituting approximately 25% of all pharmaceutical expenditures."

The Biosimilars Council, in an amicus brief, indicated that the cost for treatment of arthritis with Humira, for example, is $50,000 per year. Pfizer Inc. recently announced positive results for a biosimilar to

Humira, their third biosimilar to be favorably reported, and among eight biosimilars the company has in mid- to late-stage testing. (TheStreet, Jan. 5, 2017.) On the other hand, despite an apparent need for "competition in this field" as stated by the government, according to the Biosimilars Resource Center (Oct. 3, 2016), only four biosimilars have been approved since enactment of the BPCIA. Only one of the four, Zarxio, the subject of this suit, is commercially available.

N. Scott Pierce is a principal in the Concord, Massachusetts, office of Hamilton Brook Smith Reynolds PC.