Health Reform WK-EDGE Wrap Up, LIFE SCIENCES TOP STORY: Reversal of fortune: Sandoz seeks Supreme Court review in Amgen biosimilars battle, (Feb. 24, 2016)

By Anthony H. Nguyen, J.D.

Sandoz filed a petition for a writ of certiorari, asking the Supreme Court to review the Federal Circuit’s interpretation of the Biologics Price Competition and Innovation Act’s (BPCIA) “notice of commercial marketing” provision. In its February 16, 2016, filing, Sandoz asked the Court to decide the validity of the Federal Circuit’s ruling in Amgen v. Sandoz, which held that the 180-day notice of commercial marketing can only be given after a proposed biosimilar product receives FDA approval (see Court interprets biosimilar ‘enigma’ in favor of abbreviated biologic license applicant, July 22, 2015).

Just last month Amgen declined to file its own free-standing cert petition. Under the Supreme Court’s rules, however, Amgen could file a “conditional cross-petition,” requesting that if the Court chooses to take up Sandoz’s petition, it would address the issue Amgen lost before the Federal Circuit, specifically whether the BPCIA’s patent “dance” was mandatory.

In an interview with Wolters Kluwer, Courtenay C. Brinckerhoff, a partner with Foley & Lardner and editor of Foley’s PharmaPatents blog, noted that the Supreme Court may be inclined to hear the case because (1) Sandoz presented an issue of statutory construction of an important provision of the BPCIA; and (2) district courts are already applying the Federal Circuit’s interpretation of the BPCIA in other biosimilars cases.

Federal Circuit ruling. The BPCIA, which was passed in 2010 as sections 7001-7003 of the Patient Protection and Affordable Care Act (ACA) (P.L. 111-148), created an abbreviated pathway for FDA approval of a “biosimilar” biologic product. Amgen brought originally brought suit against Sandoz in federal court asserting various violations of Amgen’s approved license for its cancer-fighting biologic Neupogen® (filgrastim) and infringement of Amgen’s patent for a particular method of using filgrastim. The FDA previously accepted Sandoz’s application for the filgrastim biosimilar Zarxio in July 2014 and approved the application in early 2015 (see FDA enters new era with approval of first biosimilar, March 6, 2015). Although the BPCIA includes a complicated process for addressing patent disputes surrounding biosimilar products, known as the “patent dance,” Sandoz chose not to engage in that process (see Shall we dance? Biosimilars step toward new legal and regulatory future, August 5, 2015).

Amgen sued Sandoz for violating the BPCIA. Upon reviewing the lower court’s decision, the Federal Circuit decided that an abbreviated biologic license application (aBLA) applicant did not need to engage in the patent dance with the reference product sponsor (RPS), but did need to comply with the pre-marketing notice provision of 42 U.S.C. §262(l)(8). Specifically to the latter, the appellate panel held that notice of commercial marketing, to be effective under the BPCIA, must be given only after the product is licensed by the FDA. In a dissent from this portion of the decision, Judge Chen wrote that the majority’s position extra-statutorily extended RPS’ 12-year market exclusivity as established in the BPCIA by an additional six months.

Commercial marketing notice. The majority’s decision in Amgen v. Sandoz acknowledged that its ruling could establish additional six months exclusivity for the RPS, but found that it was consistent within the four- and 12-year exclusivity periods in the BPCIA. Under the Federal Circuit’s interpretation of 42 U.S.C. §262(l)(8) (A), actions authorized by §262(l)(8)(B) cannot be commenced until the biosimilar product has been approved. Sandoz’s argument is that this interpretation is not supported by either the BPCIA’s language or purpose. According to Brinckerhoff, the majority’s rationale seems to rest on the assumption that, if a biosimilar application is filed during the 12-year exclusivity period, the FDA will “license” the biosimilar product before the 12-year period has run, in which case the pre-marketing notice could be given before the 12-year period has run. However, the 12-year period is embodied in 42 U.S.C. §262(k)(7)(A), which states that “[a]pproval of [a biosimilar
application] may not be made effective” until the 12-year period has run. Thus, Brinckerhoff said, it is not clear that the FDA has the statutory authority to “license” a product before the 12-year period has run.

In addition, the appellate ruling leaves some uncertainty about whether an aBLA applicant engaging in the BPCIA’s patent dance needs to provide this notice of commercial marketing to an RPS if the patents cannot be litigated until after FDA approval. Brinckerhoff said one purpose of the pre-marketing notice is to give the RPS an opportunity to seek a preliminary injunction based on patents that were not litigated in the patent dance litigation, for instance with patents that were not selected after the exchange of patent lists. Thus, there is still some benefit in the patent dance, as it provides a mechanism to litigate patents before the biosimilar is approved.

**Biosimilar availability.** Sandoz also noted in its petition that the Federal Circuit’s ruling would create a delay in availability for all biosimilars. Brinckerhoff stated that whether the post-approval notice requirement itself would keep a biosimilar product off the market in another case would depend on the circumstances, including whether the RPS had obtained a preliminary injunction based on any patents being litigated. She noted that it was possible that in other cases the notice requirement would be the only factor keeping the biosimilar product off the market.

**Patent dance.** As discussed earlier, while not addressed in Sandoz’s petition, the Federal Circuit also held that the patent dance was optional. A consequence of an optional patent dance is that the biosimilar applicant would be subject to patent infringement action. By not filing a petition, Amgen implied that it was content with an optional patent dance.

Under an optional patent dance scheme, Brinckerhoff said that the RPS can benefit because it can bring an immediate declaratory judgment action without having to go through the patent dance procedures. The RPS can litigate all patents that it believes should be litigated instead of being limited to the patents agreed upon after the exchange of patent lists. Conversely, biosimilar applicants may find it beneficial not to share the confidential information that may be in their biosimilar applications with the RPS during the patent dance, or at least be able to keep the information confidential unless and until the RPS initiate litigation (when the application may be discoverable).

Brinckerhoff also said that the latter strategy presented its own problems for the biologic applicant. If the patents are not litigated until later in the approval process or after the product is approved, the biosimilar applicant may have to choose between delaying market entry until the patent litigation is resolved or launching at risk, e.g., entering the market at the risk of being held liable for willful patent infringement. Brinckerhoff said that given the costs of biologics and the risk of treble damages, a launch at risk could be associated with significant financial risk.

**Attorneys:** Courtenay C. Brinckerhoff (Foley & Lardner LLP)

**Companies:** Amgen, Inc.; Sandoz, Inc.

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