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Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

Apotex Sets Stage For Next Fed. Circ. BPCIA Dispute

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Margaret E. Ives

Last October, Apotex Inc. filed an abbreviated biologic license application (aBLA) seeking to market a biosimilar version of Amgen Inc.'s Neulasta. Apotex's application was accepted for review in December 2014, and Apotex promptly sent notification to Amgen. Shortly thereafter, Apotex provided Amgen with a copy of its aBLA pursuant to the Biologics Price Competition and Innovation Act's confidentiality provisions and the parties engaged in the BPCIA's patent dance. During that process, Apotex also provided its notice of commercial marketing to Amgen. Apotex's biosimilar pegfilgrastim product has still not yet been approved by the U.S.Food and Drug Administration. Notably, Apotex was the first subsection (k) applicant to actually complete all of the steps of the patent dance.

In contrast, when Sandoz Inc.'s aBLA for a biosimilar version of Amgen's Neupogen was accepted for review, Sandoz promptly notified Amgen, but demanded in its notice letter that certain conditions be met before it would disclose its application. Sandoz also provided its notice of commercial marketing to Amgen at that time. When Amgen did not agree to Sandoz's proposed conditions, however, Sandoz opted not to disclose its application. Amgen filed suit. The parties then cross-moved for partial judgment on the pleadings based on their respective interpretations of the disputed provisions of the BPCIA, and Amgen sought a preliminary injunction to prevent Sandoz from launching its biosimilar product.

In Amgen v. Sandoz, the Northern District of California held that subsection (k) applicants need not comply with the BPCIA's disclosure procedures, and the reference product sponsor's sole remedy for the applicant's failure to disclose its application and manufacturing information is the ability to file an immediate action for a declaratory judgment of infringement, validity or enforceability of any patent that claims the biological product or its use. The district court also found that subsection (k) applicants need not wait for FDA approval before giving the reference product sponsor (RPS) notice of commercial marketing. Amgen appealed.

On July 21, 2015, after Apotex and Amgen had finished the patent dance, but before Amgen filed its complaint against Apotex, the Federal Circuit issued its decision on Amgen's appeal in the Sandoz case, vacating the Northern District of California's decision. The Federal Circuit agreed with the district court that an applicant's failure to participate in the patent dance was not a violation of the BPCIA, but disagreed that the applicant may give notice of commercial marketing prior to approval.

On Aug. 6, 2015, Amgen sued Apotex in the Southern District of Florida. Amgen's complaint for patent infringement included four causes of action: (1) infringement of U.S. Patent No. 8,952,138 (the '138 patent); (2) declaratory judgment of infringement of the '138 patent, (3) declaratory judgment of U.S. Patent No. 5,824,784 (the '784 patent); and (4) declaratory judgment that Apotex's notice of commercial marketing violated section (l)(8)(A) of the BPCIA. With respect to the fourth cause of action, Amgen alleged that Apotex's purported notice of commercial marketing was premature and ineffective because (like Sandoz's) it was sent prior to any approval for licensure by the FDA.

Apotex filed its answer and counterclaims on Oct. 5, 2015. In response to Amgen's allegation that "Apotex will not provide Amgen with an effective Notice of Marketing under 42 U.S.C. § 262(l)(8)(A)," Apotex responded as follows:

[W]here a biosimilar applicant has provided the reference product sponsor with the required information pursuant to § 262(l)(2)(A), the BPCIA gives such biosimilar applicant the option to either provide the reference product sponsor a Notice of Commercial Marketing under 42 U.S.C. § 262(l)(8)(A) or to face an action under 28 U.S.C. § 2201 for a declaration of patent infringement. Any other interpretation of the BPCIA would render superfluous subsection (l)(9)(B). ... [T]he BPCIA expressly contemplates and provides for the situation where a biosimilar applicant declines to provide a Notice of Commercial Marketing, which triggers a reference product sponsor's right to bring suit under BPCIA subsection (l)(9)(B).

Apotex repeated this refrain throughout its answer and counterclaims, noting that 45 U.S.C. § 262(l)(9)(B) provides that "[i]f a subsection (k) applicant fails to complete an action required of the subsection (k) applicant under ... paragraph (8)(A), the reference product sponsor ... may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability."

Amgen has now also sued Apotex in the Southern District of Florida with respect to its aBLA for a biosimilar of Amgen's Neupogen. According to that complaint, filed Oct. 2, 2015, the parties had similarly engaged in the full patent dance with respect to Neupogen, and Apotex had provided notice of commercial marketing during the process. A week after the Federal Circuit's Amgen v. Sandoz decision was issued, Amgen purportedly asked Apotex to confirm that it would not be providing notice of commercial marketing until after licensure by the FDA. According to the complaint, Apotex responded that, "because Apotex followed the pathway and provided Amgen with its application and manufacturing information, providing a notice of commercial marketing is not mandatory."

Rather than attempting to argue that its pre-approval notice was effective, Apotex's strategy appears to be based on the following language from the Federal Circuit's July 21, 2015, decision — arguably distinguishing an applicant who complies with Paragraph (l)(2)(A) from one who does not:

While it is true that paragraph (l)(9)(B) specifies the consequence for a subsequent failure to comply with paragraph (l)(8)(A), after the applicant has complied with paragraph (l)(2)(A), it does not apply in this case, where Sandoz did not comply with paragraph (l)(2)(A) to begin with. Indeed, the consequence specified in paragraph (l)(9)(B) is a declaratory judgment action brought by the RPS based on "any patent included in the list described in paragraph (3)(A)". ... Here, however, because Sandoz did not provide the required information to Amgen under paragraph (l)(2)(A), Amgen was unable to compile a patent list as described. ... [N]othing in subsection (l) excuses the applicant from its obligation to give notice of commercial marketing to the RPS after it has chosen not to comply with paragraph (l)(2)(A). ... We therefore conclude that, where, as here, a subsection (k) applicant completely fails to provide its aBLA and the required manufacturing information to the RPS by the statutory deadline, the requirement of paragraph (l)(8)(A) is mandatory.

Notably, the Federal Circuit also stated in its decision — consistent with Apotex's current position — that "the BPCIA explicitly contemplates that a subsection (k) applicant might fail to comply with the requirements of paragraph (l)(2)(A) and further specifies the consequences for such failure in 42 U.S.C. § 262(l)(9)(C)."

Despite the language above, however, the Federal Circuit's decision is less than clear with respect to whether an applicant who has completed the patent dance must also give the RPS notice of commercial marketing. For example, the Federal Circuit definitively stated that "under paragraph (l)(8)(A), a subsection (k) applicant may only give effective notice of commercial marketing after the FDA has licensed its product," and that "notice, to be effective under this statute, must be given only after the product is licensed by the FDA." In fact, the Federal Circuit went so far as to say that it was their belief that "Congress intended the notice to follow licensure" and that "[t]he purpose of paragraph (l)(8)(A) is clear: requiring notice of commercial marketing be given to allows the RPS a period of time to assess and act upon its patent rights."

Considering "the consequence" of its interpretation, the Federal Circuit also concluded that the "shall" provision in subsection (l)(2)(A) is mandatory and noted that they did "not find any provision in the BPCIA that contemplates, or specifies the consequence for, noncompliance with paragraph (l)(8)(A)." On the contrary, the Federal Circuit's majority opinion stated that "Paragraph (l)(8)(A) is a standalone notice provision ... [and] [u]nlike the actions described in paragraphs (l)(3) through (l)(7), which all depend on, or are triggered by, the disclosure under paragraph (l)(2)(A), nothing in paragraph (l)(8)(A) conditions the notice requirement on paragraph (l)(2)(A) or other provisions of subsection (l)."

Judge Raymond T. Chen's dissenting opinion points out the inconsistency in the majority's approach to subsection (l)(8)(A). As he states:

[T]he majority's opinion creates an uncomfortable result in which the language of (l)(8)(A) is interpreted in two different ways, based on the (k) applicant's actions. ... [I]f a (k) applicant complies with all the requirements specified in (l)(2)-(l)(7), then the (k) applicant may still refuse to comply with the 180-day notice provisions. In this scenario, there would be no automatic injunction because (l)(9)(B) provides the RPS with the authorization to immediately file suit on any patent it listed under (l)(3). Thus, in one scenario, (l)(8)(A) provides a 180-day injunction, but in the second scenario it does not.

Given these inconsistencies, one thing is near certain: The Federal Circuit will surely have the opportunity to revisit its earlier opinion and to clarify its statements with respect to the interplay between subsections (l)(8)(A) and (l)(9)(B). On Oct. 16, 2015, Amgen filed its motion for preliminary injunction. Amgen's two cases against Apotex in the Southern District of Florida will likely soon be consolidated and this issue addressed by the court in a single preliminary injunction decision. That decision will immediately be appealed by the losing side.

Notably, however, the Federal Circuit has already passed on a potential opportunity to revisit this issue. On Oct. 16, 2015, the Federal Circuit surprisingly denied rehearing en banc with respect to the July 21, 2015, decision, even though rehearing en banc was sought by both parties, amicus curiae briefs were submitted, and the judges involved in that decision were divided on each of the issues involved.

Amgen and Sandoz are now each free to seek U.S. Supreme Court review, and it is very likely that both will do so.

—By Margaret E. Ives, Choate Hall & Stewart LLP

Margaret Ives is a partner at Choate in Boston.