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BPCIA: How Long Does The Party Last And Do I Have To Dance?

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On March 6, 2015, the U.S. Food and Drug Administration licensed the first ever U.S. biosimilar drug, Sandoz's Zarxio, a version of Amgen's Neupogen (filgrastim). On March 19, the Northern District of California denied Amgen's motion for a preliminary injunction against Sandoz's launch of Zarxio, removing the final barrier to U.S. consumers being able to obtain the drug.

In its ruling, the court held (1) that the information exchange procedures laid out in Section §262(l)(2)-(8) of the Biologics Price Competition and Innovation Act,[1] known as the "patent dance," are optional, and (2) that a biosimilar applicant may properly give the 180-day notice of commercial marketing required by §262(l)(8)(A) before obtaining its FDA license to sell its product. This ruling is the first to interpret these two key provisions of the BPCIA and, if upheld on appeal, will have a tremendous impact on the patent litigation strategies of both reference product sponsors and biosimilar applicants going forward.

The BPCIA permits the sponsor of a biosimilar drug application under §262(k) to rely on the safety, purity, and potency data from a reference product already licensed by the FDA under the more stringent provisions of §262(a). Sandoz relied on this section of the BPCIA when it submitted its license application to the FDA based on the data Amgen had developed for filgrastim. The BPCIA also contains §262(l), which sets forth detailed procedures for the §262(k) applicant to provide its biosimilar license application (BLA) to the reference product sponsor under confidentiality, and for the two parties to determine which patents held by the reference product sponsor the §262(k) applicant may infringe. Although Sandoz initially offered to provide its BLA application to Amgen, the parties could not agree on confidentiality procedures. Sandoz then decided not to provide Amgen its BLA and to forego the patent exchange provisions of the BPCIA.

Amgen took the position that provision of the BLA and the patent exchange procedures are required in exchange for a §262(k) applicant's reliance on a reference product sponsor's safety, purity, and potency data, and, argued that Sandoz had violated the law by failing to provide its BLA comply with the patent exchange provisions of §262(l)(2)-(6). Sandoz maintained that providing the BLA and participation in the patent exchange procedures were optional. In support of this argument Sandoz relied on §262(l)(9)(A)-(C), which allow a reference product sponsor to immediately bring a declaratory judgment action if a §262(k)

applicant fails to provide its BLA or complete any step of the patent dance.

In arguing that the information exchange provisions of §262(l) are mandatory, Amgen pointed to the consistent use of the words "shall" and "required" in the statute. For example, subsection 262(l)(2)(A) states that the applicant shall provide a copy of the BLA and information describing the manufacturing methods. Further, the BPCIA refers to the BLA and manufacturing methods as information the §262(k) applicant is required to produce[2] Sandoz countered that the provision of its BLA and manufacturing information under §262(l)(2) and the patent exchange procedures of §262(l)(3)-(8) are optional, and that the word "shall" in §262(l)(2)(A) is used only to indicate what applicants must do if they choose to use the procedures.

Sandoz asserted that if the provision of the BLA and manufacturing information and participation in the exchange procedures were mandatory then §262(l)(9)(B) and (C) would be superfluous. Sandoz argued that by enacting §262(l)(9)(C), Congress understood a §262(k) applicant would sometimes choose not to provide its BLA and manufacturing information to a reference product sponsor and balanced the disadvantage of not having immediate access to these materials by giving the reference product sponsor the right to immediately file a declaratory judgment.

The court was persuaded by Sandoz's argument. The court noted that for each use of the mandatory language "shall," the statute contemplates a decision by the §262(k) applicant not to provide the corresponding information. Namely, the statute provides a remedy, or "safe harbor" as the court phrased it, during which the reference product sponsor alone may initiate patent infringement litigation. The court further noted that the BPCIA included changes to the §271(e) of the Patent Act, which make it an act of infringement to submit a BLA under §262(k) and set forth remedies for such infringement. The court held that §262(l) and §271(e) together form an "integrated scheme that provides consequences for the choice either party makes at each step of subsection (l)'s information exchange to carry on the process, or end it and allow litigation to commence.[3]

Thus, the court ruled that providing the BLA and engaging in the patent exchange procedure of §262(l) are optional and, therefore, Sandoz did not violate the BPCIA by refusing to participate. This aspect of the court's holding is particularly significant for the enforcement of method patents. Without the BLA it is difficult for a reference product sponsor to determine whether one of its method patents is infringed. That being said, a reference product sponsor can file a declaratory judgment action in order to obtain the manufacturing information contained in the BLA through discovery. This can be done by either bringing an immediate declaratory judgment action on another of its patents that does not cover a method or by bringing a declaratory judgment action directly on the method patents. The first approach — bringing suit over a non-method-of-manufacture patent — suffers as reference product sponsors do not always have another patent to assert.

Further, if electing to proceed under the second approach of bringing suit directly over the method patents, attorneys must be cognizant of their duties under Rule 11 of the Federal Rules of Civil Procedure. That is, the reference drug sponsor attorneys must do a reasonable investigation under the circumstances that the factual contentions (i.e., that the biosimilar's manufacturing processes infringe the method patents) will likely have evidentiary support after a reasonable opportunity for further investigation or discovery. This can be a harrowing ledge to crawl on for attorneys, but a ledge that no doubt will have some company. In either the first or second strategy, however, it is not a given that discovery will provide the information it needs to add its method patents to the suit under the first approach or to maintain their cause of action under the second approach.

The second question at issue in Amgen's motion was whether Sandoz's 180-day notice of commercial marketing was sufficient under the BPCIA. The BPCIA requires a §262(k) applicant to provide the reference product sponsor notice at least 180 days before the "date of first commercial marketing of the biological product licensed under [the act]."[4]

It was undisputed by the parties that Sandoz sent a letter to Amgen on July 8, 2014, indicating Sandoz's intent to market its biosimilar product as soon it obtained its FDA license, which Sandoz did in fact receive on March 6. As such, Sandoz's July notice was provided more than 180 days prior to commercial marketing. Amgen, however, contended notice could only be given after Sandoz obtained its FDA license for its biosimilar filgrastim. The BPCIA prohibits approval of a §262(k) application until 12 years after the date the reference product was first licensed. Amgen's reading of the law would have extended a reference product's exclusivity period another 6 months by barring the §262(k) applicant from giving the 180 notice before reference product's 12-year exclusivity period had ended.

Amgen claimed that § 262(l)(8)(A) unambiguously refers to the "biologic product licensed under subsection (k)" and that the plain language of "licensed" is "[t]o whom or for which a license has been granted; provided with a license.[5]" Second, Amgen contrasted this provision of the BPCIA — stating "biologic product licensed under subsection (k)" — with other provisions that state "a biologic product that is the subject of the subsection (k) application." Amgen's point being that Congress clearly knew how to differentiate between an application and a licensed product and thus Congress's intent for this notice provision is that it cannot be given until the license has Amgen argued that "Congress would have deferred additional burdens on the court from actions for declaratory judgment until a time when the uncertainty of regulatory approval is removed."[6]

Sandoz took the position that Amgen's period of exclusivity, at 21 years, had lasted long enough and certainly far exceeds the 12 years of exclusivity established by the BPCIA for a reference product sponsor. Sandoz further relied on statutory interpretation arguing that Amgen's interpretation was by the statute's text. Specifically, Sandoz argued that the "licensed" term refers to the product and not to the triggering time for the required notice.

During oral argument, the court acknowledged that a previous decision in the Northern District[7] mentioned in dicta that the 180-day notice provision does not begin to run until after the biosimilar product is licensed by the FDA. The court noted, however, that the issue of the 180-day notice provision was not before the court in that case and that while the Federal Circuit affirmed the earlier decision on other grounds it specifically chose not to address the question of the 180-day notice provision.

The court was completely unpersuaded by Amgen's argument. Instead, the court concluded that the statute referred to the biosimilar product as the "biological product licensed under subsection (k)" in §262(l)(8)(A) simply because it would be nonsensical to refer to it as the subject of a §262(k) application upon its first commercial marketing.[8]

The court was even more adamant that Amgen's interpretation was not reasonable in view of the statutory scheme established by the BPCIA. Amgen's reading of the law would give reference product sponsors an additional 180 days of exclusivity. The court reasoned that Congress intended to provide 12 and a half years of exclusivity to a reference product sponsor rather than the 12 years plainly stated in the statute, it would not have done so in such a convoluted way.[9] The court held that Sandoz had provided adequate notice with its July 8, 2014, letter to Amgen.

The holding that the 180-day notice of marketing can be given prior to the licensure of the biosimilar

product means that reference products may not know which of its patents may be infringed prior to the launch of a biosimilar product, even if the §262(k) supplies its BLA. This is due, in part, to the fact that the biosimilar applicant can amend their §262(k) application prior to its approval. For example, Sandoz made numerous changes to its §262(k) application during the approval process and other §262(k) applicants will likely do the same. Thus, the 180-day notice provision, from the reference drug sponsor's perspective, lacks some of its possibly intended utility as there are likely to be many unanswered questions at the time that the reference drug sponsor receives notice going forward.

Amgen and Sandoz previously represented that they will jointly seek an expedited briefing schedule in the Federal Circuit upon appeal of the preliminary injunction decision. It is expected that Amgen will appeal. Given the importance of these issues to the biological products industry, a potential Federal Circuit opinion is eagerly awaited.

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[1] 42 USC §262.

[2] 42 USC §262(l)(1)(A).

[3] See 42 USC §262(l)(3)(A), 3(C), and 7(B) which list information the reference product sponsor shall provide to the §262(k) applicant and §262(l)(2)(A), (3)(B)(ii), (3)(B)(iii), (7)(B), and (8)(A) which list information the §262(k) applicant shall provide to the reference product sponsor.

[4] Amgen Inc. v. Sandoz Inc., No. 3:14-cv-04741 (N.D. Cal. Filed Oct. 24, 2014),. Order on Cross Motions for Judgment on the Pleadings , p. 4, l. 27 – p. 5, l. 2.

[5] 42 USC §262(l)(8)(A).

[6] Id., Amgen Mot. for J. 21:22-26.

[7] Id., Amgen Mot. for J. 22:14-18.

[8] Sandoz Inc. v Amgen Inc., 773 F.3d. 1274, 1282 (Fed. Cir. 2014).

[9] Id., Order on Cross Motions for Judgment on the Pleadings , p. 13, ll. 15-19.

[10] Id., 13, l. 21-14, l. 1
