Published on *The National Law Review* https://natlawreview.com

Sandoz Asks Supreme Court To Reverse Biosimilar Decision

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On February 16, 2016, Sandoz, Inc. filed a petition for writ of *certiorari* to the **Supreme Court**, asking the Court to overturn the Federal Circuit decision that interpreted the "patent dance" provisions of the ***Biologics Price Competition and Innovation Act (BPCIA)*** as requiring the biosimilar applicant to give 180 days' pre-marketing notice that cannot be given until after the FDA has "licensed" (approved) the biosimilar product. The Supreme Court may be inclined to hear this case, since it involves an important provision of the BPCIA, and because the decision in effect delays the commercial availability of less expensive biosimilar products that the BPCIA was enacted to provide.

The Neupogen® // Zarxio™ Biosimilar Dispute

Sandoz's Zarxio™ (filgrastim-sndz) is a biosimilar of Amgen's Neupogen® (filgrastim) product, and is the first product approved under the BPCIA. Although the BPCIA includes a complicated process for addressing patent disputes surrounding biosimilar products, Sandoz chose not to engage in that process. (Please see this article for a summary of the "patent dance" procedures set forth in 42 USC § 262(*l*).)

Amgen sued Sandoz for violating the BPCIA, and the Federal Circuit decided that a biosimilar applicant does not have to engage in the patent dance, but does have to comply with the pre-marketing notice provision of §42 USC 262(*l*)(8). (Please see this article for a discussion of the Federal Circuit decision in *Amgen v. Sandoz*.)

Amgen did not petition the Supreme Court to review the Federal Circuit decision regarding the patent dance, but Sandoz has sought review of its decision as to pre-marketing notice.

The Pre-Marketing Notice Requirement

The notice requirement at issue is set forth in 42 USC § 262(*l*)(8)(A):

> (8) Notice of commercial marketing and preliminary injunction
> (A) Notice of commercial marketing
> The subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product

licensed under subsection (k).
(B) Preliminary injunction
After receiving the notice under subparagraph (A) and before such date of the first commercial marketing of such biological product, the reference product sponsor may seek a preliminary injunction prohibiting the subsection (k) applicant from engaging in the commercial manufacture or sale of such biological product until the court decides the issue of patent validity, enforcement, and infringement with respect to any patent that is [included in either of the first lists but not included on the agreed upon list or the second lists].

Sandoz first gave notice of its plans to commercially market Zarxio™ before the FDA had approved its application. Amgen argued that notice was ineffective because the statute requires notice of a "***licensed***" product, which only can be given once the product is approved. The district court agreed with Sandoz on this issue, but the Federal Circuit agreed with Amgen:

We agree with Amgen 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. The statutory language compels such an interpretation. It means that notice, to be effective under this statute, must be given only after the product is licensed by the FDA.

Judge Chen dissented from this portion of the decision, based on his view that § 262(*l*)(8) only comes into play if the patent dispute resolution procedures of (*l*)(2)-(7) have been followed. Judge Chen suggested that the majority's position on this issue gives reference product sponsors a "windfall" by effectively extending the 12-year period of market exclusivity embodied in the BPCIA an additional 6 months.

The Questions Presented

Sandoz has asked the Court to consider two questions:

> Whether notice of commercial marketing given before FDA approval can be effective and whether, in any event, treating Section 262(l)(8)(A) as a stand-alone requirement and creating an injunctive remedy that delays all biosimilars by 180 days after approval is improper.

Sandoz's primary argument is that the Federal Circuit's interpretation of the statute "grant[s] a 180-day 'exclusivity windfall' to reference product sponsors" that is not supported by the language or purpose of the statute, and that "will delay the availability of all biosimilars for 180 days more than Congress intended—even if the sponsor has no valid patent claims and even if the sponsor already has had the opportunity to pursue any valid claims."

Addressing the "licensed" term that the Federal Circuit focused on, Sandoz argues that the phrase "biological product licensed under subsection (k)" simply distinguishes a biosimilar product from a biological product licensed under subsection (a) (*e.g.*, an original biological product). Sandoz also argues that the Federal Circuit's interpretation "disrupts the careful balance struck by Congress," by in effect extending the 12-year exclusivity period of § 262(k)(7)(A) by an additional 180

days.

Sandoz argues that the Federal Circuit's interpretation also frustrates "the BPCIA's early patent resolution regime." According to Sandoz's reading of § 262(*l*)(8), the reference product sponsor cannot seek a preliminary injunction based on any patents not litigated pursuant to the patent dance until the notice of commercial marketing has been given. Under the Federal Circuit's interpretation of § 262(*l*)(8)(A), this means that the actions authorized by § 262(*l*)(8)(B) cannot be commenced until the biosimilar product has been approved. According to Sandoz, that result "is entirely inconsistent with a statute structured to maximize the chance that any patent disputes will be resolved before FDA approval."

Sandoz also argues that the Federal Circuit's interpretation creates "a private right of action for an automatic injunction" by "bar[ring] the marketing of the already approved biosimilar until 180 days after the post-approval notice—without regard to whether the sponsor could show any valid patent rights or any irreparable harm." Turning to the facts of this case, Sandoz notes that "[t]he majority enjoined Sandoz without regard to traditional equitable factors, despite the district court's undisturbed findings that Amgen would suffer no irreparable harm."

Can 42 USC § 262(*l*)(8)(A) Stand Alone?

As explained in this article, the dispute between Amgen and Apotex over Apotex's biosimilar version of Amgen's Neulasta® (pegfilgrastim) product raises a similar but different issue regarding the pre-marketing notice requirement. In that case, Apotex agreed to litigate all the patents proposed by Amgen, and argued that it is not required to provide pre-marketing notice under § 262(*l*)(8)(A), since there are no other patents that Amgen could assert under § 262(*l*)(8)(B). The district court ruled in favor of Amgen on that issue, applying the Federal Circuit decision in *Amgen v. Sandoz.* The Federal Circuit is hearing Apotex's appeal on an expedited basis.

If one of the parties to that case petitions for Supreme Court review, it is possible that the Court could review both cases, and provide important guidance on the meaning of § (*l*)(8)(A), and when an approved biosimilar product is permitted to enter the market.

National Law Review, Volume VI, Number 49