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Federal Circuit Finds Biosimilar Patent Dispute Resolution Procedures Optional

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In ***Amgen v. Sandoz***, a divided panel of the Federal Circuit issued its first decision interpreting the ***Biologics Price Competition and Innovation Act (BPCIA)***, and did so in a manner that appears to favor biosimilar applicants over owners of original biologic products ("*reference product sponsors*"). The court held that a biosimilar applicant does not have to share its biosimilar application with the reference product sponsor or follow the patent dispute resolution procedures set forth in the BPCIA. However, it does have to give 180 days' pre-marketing notice and cannot do so until after the FDA has "licensed" (approved) the biosimilar product. The end result for the parties is that Amgen's state law claims against Sandoz are dismissed or moot, while Sandoz can begin marketing Zarxio™ on September 2, 2015.

The Neupogen® // Zarxio™ Biosimilar Dispute

Sandoz' Zarxio™ (filgrastim-sndz) product is the first product approved under the BPCIA, and was approved as a biosimilar of Amgen's Neupogen® (filgrastim) product on March 6, 2015. At issue in this case is whether 42 USC § 262(*l*)(2)(A) ***required*** Sandoz to provide Amgen with a copy of its biosimilar application and other information describing how its product is made, and whether § 262(*l*)(8) required Sandoz to ***wait*** until its biosimilar application was approved before giving Amgen 180 days prior notice of commercial marketing. The district court ruled in favor of Sandoz on both issues.

(Please see this article for a more detailed discussion of the district court decision.)

The Federal Circuit's Interpretation Of The BPCIA

The Federal Circuit decision was authored by Judge Lourie. Judge Newman concurred in part, and dissented in part. Judge Chen also dissented in part. (As you can tell from my synopsis of the oral arguments in this article, I did not expect Judge Chen's dissent.)

Does The BPCIA Require A Biosimilar Applicant To Provide A Copy Of The Biosimilar Application To The Reference Product Sponsor? NO

The BPCIA includes a complicated process for addressing patent disputes surrounding biosimilar

products, laid out in 42 USC § 262(*l*). The first step is set forth in 42 USC § 262(*l*)(2):

(2) Subsection (k) application information
Not later than 20 days after the Secretary notifies the subsection (k) applicant that the application has been accepted for review, the subsection (k) applicant?
(A) ***shall provide*** to the reference product sponsor a copy of the application submitted to the Secretary under subsection (k), ***and*** such other information that describes the process or processes used to manufacture the biological product that is the subject of such application; and
(B) may provide to the reference product sponsor additional information requested by or on behalf of the reference product sponsor.

(Please see this article for an outline of the other steps.)

Sandoz notified Amgen of its biosimilar application, but did not provide Amgen with a copy of its application and did not follow any of the other patent dispute resolution procedures of the statute. The district court agreed with Sandoz that those procedures were optional, and the Federal Circuit affirmed:

[T]he "shall" provision in paragraph (l)(2)(A) cannot be read in isolation. In other provisions, the BPCIA explicitly contemplates that a subsection (k) applicant might fail to disclose the required information by the statutory deadline. It specifically sets forth the consequence for such failure: the [reference product sponsor] RPS may bring an infringement action under 42 U.S.C. § 262(l)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii). Those latter provisions indicate that "shall" in paragraph (l)(2)(A) does not mean "must." And the BPCIA has no other provision that grants a procedural right to compel compliance with the disclosure requirement of paragraph (l)(2)(A).

We therefore conclude that, even though under paragraph (l)(2)(A), when read in isolation, a subsection (k) applicant would be required to disclose its aBLA and the manufacturing information to the RPS by the statutory deadline, we ultimately conclude that when a subsection (k) applicant fails the disclosure requirement, 42 U.S.C. § 262(l)(9)(C) and 35 U.S.C. § 271(e) expressly provide the only remedies as those being based on a claim of patent infringement. Because Sandoz took a path expressly contemplated by the BPCIA, it did not violate the BPCIA by not disclosing its aBLA and the manufacturing information by the statutory deadline.

Judge Newman dissented from this portion of the decision:

The BPCIA reflects an explicit balance of obligations and benefits. When a beneficiary of the statute withholds compliance with provisions enacted to benefit others, the withholder violates that balance. The consequences of the majority's ruling are significant, for the structure of the BPCIA requires that the subsection (k) applicant comply with the information exchange provisions, as a threshold to resolution of the Sponsor's patent rights.

It is not denied that Sandoz obtained the benefit of the Amgen data in filing under subsection (k). Sandoz should be required to respect its obligations, in fidelity to the statute.

Can A Biosimilar Applicant Provide Notice Of Commercial Marketing Before The FDA Has Approved Its Biosimilar Application? NO

The BPCIA provides for another round of patent litigation to permit the reference product sponsor to seek a preliminary injunction before the biosimilar is marketed, in 42 USC § 262(*l*)(8) :

(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.

We believe that Congress intended the notice to follow licensure, at which time the product, its therapeutic uses, and its manufacturing processes are fixed. When a subsection (k) applicant files its aBLA, it likely does not know for certain when, or if, it will obtain FDA licensure. The FDA could request changes to the product during the review process, or it could approve some but not all sought-for uses. Giving notice after FDA licensure, once the scope of the approved license is known and the marketing of the proposed biosimilar product is imminent, allows the RPS to effectively determine whether, and on which patents, to seek a preliminary injunction from the court.

Thus, the Federal Circuit held that Sandoz' first pre-marketing notice to Amgen was ineffective, but its notice given on the date its biosimilar application was approved was effective, such that Sandoz can begin to market Zarxio™ 180 days later, on September 2, 2015.

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:

The majority … views (*l*)(8)(A) as a standalone notice provision that is not excused when the (k) applicant fails to comply with (*l*)(2). Yet, no one disputes that the requirements of (*l*)(3) through (*l*)(7) are certainly excused in such a case. …. The most persuasive reading of subsection (*l*) as a whole is that Congress provided two paths to resolve patent disputes: (1) the intricate route expressed in (*l*)(2)– (*l*)(8); and (2) the immediate, more flexible route provided in (*l*)(9), should the (k) applicant falter on any of its obligations recited in (*l*)(2)–(*l*)(8).

§262(*l*)(9)(C) provides as follows:

Subsection (k) application not provided.–If a subsection (k) applicant fails to provide the application and information required under paragraph (2)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of Title 28, for a declaration of

infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product.

As Judge Newman points out in her dissenting opinion, §262(l)(9)(C) does not appear to authorize declaratory judgment actions for infringement of ***process*** *patents, which can be particularly relevant for biologic products. Similarly, it is not clear that the related portion of the patent infringement statute, 35 U.S.C. § 271(e)(2)(C)(ii), encompasses process patents.*

Judge Chen suggests 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.

Will Anyone Opt In To The BPCIA?

If Judge Chen is right–if "Congress provided two [alternative] paths to resolve patent disputes"–why would any biosimilar applicant opt for the path that requires it to disclose highly confidential information and engage in the complicated biosimilar patent "dance" of § 262 (*l*)(2)– (l)(8)? Some say that many biosimilar applicants will want to resolve the patent issues early in the approval process, and so will avail themselves of these procedures even if it means sharing their biosimilar applications. However, since all of the biosimilar cases to date have involved applicants trying to avoid the patent dispute resolution procedures, I am not convinced that is the case.

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