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Amgen v. Sandoz: Divided Federal Circuit Attempts to Unravel the BPCIA

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In its recent *Amgen Inc. v. Sandoz Inc.*[1] decision, the Federal Circuit decided two issues of first impression relating to the Biologics Price Competition and Innovation Act of 2009 ("BPCIA").[2] First, the Court held that the BPCIA does not require a biosimilar applicant to disclose its abbreviated biologics license application ("aBLA") and manufacturing information to the reference product sponsor ("RPS"). Second, the Court concluded that the BPCIA does require the biosimilar applicant to provide notice of commercial marketing to the RPS. However, effective notice of commercial marketing can only be given after the United States Food & Drug Administration ("FDA") licenses the aBLA product. This decision provides some of the first insight into how the Federal Circuit will, to quote Judge Lourie, "unravel the riddle, solve the mystery, and comprehend the enigma" that is the BPCIA.[3]

Background on the BPCIA

The BPCIA established an abbreviated regulatory pathway for FDA approval of follow-on biologic products that are "highly similar" to a previously-approved product ("reference product").[4] In particular, the BPCIA permits an aBLA applicant to rely on an RPS's clinical safety and efficacy data when seeking FDA approval to market a biosimilar product.

The BPCIA also creates a framework for biosimilar patent infringement litigation. Often referred to as the "patent dance," this framework includes "early phase" litigation involving information exchanges between the biosimilar applicant and the RPS, and "late phase" litigation triggered by the biosimilar applicant's 180-day notice of intent to market.[5]

More specifically, subsections 42 U.S.C. § 262(l)(1)-(2) provide for the biosimilar applicant, upon having submitted its aBLA to the FDA, to grant the RPS confidential access to the aBLA, the biosimilar applicant's manufacturing information, and additional information requested by the RPS. The parties then exchange patent information, leading to the possibility of an immediate patent infringement action brought by the RPS based on a negotiated list of patents (the early phase litigation).[6]

Subsection 262(l)(8) also provides that the biosimilar applicant shall provide notice to the RPS not later than 180 days before the date of the first commercial marketing of its biosimilar product. After receiving the 180-day notice and before the first commercial marketing of the biosimilar product, the RPS may seek a preliminary injunction prohibiting the commercial manufacture or sale of the biosimilar product until the court decides issues of patent validity, enforcement, and infringement (the late phase litigation). The scope of patents in the late phase litigation is defined by the statute as any patent included on one of the initial lists provided by either the RPS or the biosimilar application under § 262(l)(3) that is not included on the early phase negotiated list(s) under § 262(l)(4) or § 262(l)(5)(B) ("non-listed patents").[7]

Furthermore, the BPCIA provides that if the biosimilar applicant discloses information under § 262(l)(2)(A), then neither the RPS nor the biosimilar applicant may bring a declaratory judgment action based on any non-listed patent prior to the date the RPS receives the 180-day notice of commercial marketing.[8] However, the statute also provides that, if the biosimilar applicant fails to provide § 262(l)(2)(A) documents and information, then the RPS (but not the biosimilar applicant) may bring a declaratory judgment action against the biosimilar applicant.[9]

The District Court Lawsuit

Amgen's drug Neupogen® (filgrastim) is a biopharmaceutical used to boost the production of white blood cells in a variety of patients including cancer patients receiving chemotherapy or undergoing bone marrow transplantation, and patients with severe chronic neutropenia. Amgen has marketed Neupogen® since 1991. In May 2014, Sandoz filed an aBLA seeking FDA approval of a biosimilar filgrastim product, Zarxio™. Sandoz received notification on July 7, 2014, that the FDA accepted its aBLA for review, and on March 6, 2015, the FDA approved Sandoz's aBLA for Zarxio™ for all approved uses of Neupogen®.

Sandoz notified Amgen on July 8, 2014 (the day after learning its aBLA had been accepted) that it had filed an aBLA referencing Neupogen® and that it intended to launch its biosimilar product upon FDA approval, which it expected in the first or second quarter of 2015. Sandoz did not disclose its aBLA or manufacturing information to Amgen, nor did it engage in any of the other § 262(l) information exchanges. Upon receiving FDA approval of its aBLA in March 2015, Sandoz again informed Amgen of its intention to commercially market Zarxio™.

Amgen sued Sandoz, asserting California state law unfair competition claims based on alleged violations of the BPCIA, conversion based on the allegedly unlawful use of Amgen's Neupogen® license, and patent infringement. The district court granted Sandoz partial judgment on the pleadings, holding that (1) the BPCIA permitted Sandoz's decision not to disclose its aBLA and manufacturing information, (2) Sandoz's decision, alone, was not a basis for injunctive relief, and (3) Sandoz could give notice of commercial marketing prior to FDA

licensure. Accordingly, the district court dismissed Amgen's unfair competition and conversion claims with prejudice, as it found Sandoz had not violated the BPCIA. [10]

The Federal Circuit Opinion

Judges Lourie, Newman and Chen presided over Amgen's appeal at the Federal Circuit. Judge Lourie filed the opinion for the Court, joined in different parts by Judges Newman and Chen, each of whom also filed dissents-in-part.

First, the Court stated that the plain language of § 262(l)(2)(A), which recites that the biosimilar applicant "shall provide" to the RPS a copy of the aBLA and manufacturing information, would require the biosimilar applicant to disclose the recited documents and information if that section were read in isolation. However, the Court concluded that subsection (l)(2) had to be read in the context of other BPCIA provisions explicitly contemplating that the biosimilar applicant may fail to disclose the recited information by the statutory deadline. In particular, the Court stated that the consequence of such a failure is that the RPS may bring an infringement action under 42 U.S.C. § 262(l)(9)(C) and 35 U.S.C. § 262(e)(2)(C)(ii). The Court concluded that, in this context, "'shall' in paragraph (l)(2)(A) does not mean 'must.'"[11] In other words, the information exchange under § 262(l)(2) is optional.

Second, the Court held that a biosimilar applicant can only give effective notice of commercial marketing under § 262(l)(8)(A) after the FDA has licensed its product, based on that paragraph's reference to "the biological product licensed under section (k)." The Court reasoned that requiring the product to be licensed before notice "ensures the existence of a fully crystallized controversy regarding the need for injunctive relief."[12] Although the Court recognized that its ruling would give Amgen an additional 180 days of market exclusivity in this case, it said that "will not likely be the usual case, as aBLAs will often be filed during the 12-year exclusivity period for other products."[13] The Court further concluded that the paragraph (l)(8)(A) notice is mandatory because paragraph (l)(8)(A)'s phrase "shall" presumptively signals a statutory requirement and, unlike for paragraph (l)(2)(A), there is no BPCIA provision contemplating non-compliance with paragraph (l)(8)(A). In this case, the Court concluded that Sandoz's July 2014 notice was ineffective, but its March 2015 "further" notice was effective. Accordingly, the Court held that Sandoz may not market its biosimilar product before 180 days from March 6, 2015, i.e., September 2, 2015.

The Court then affirmed the dismissal of Amgen's state law unfair competition and conversion claims because Sandoz had not violated the BPCIA.

The Dissents-in-Part

Judge Newman agreed that § 262(l)(8)(A) requires the biosimilar applicant to provide notice of the FDA license, which starts the 180-day stay of commercial marketing. However, she dissented from Judge Lourie's opinion with respect to § 262(l)(2)(A), opining that notice of the FDA's acceptance of a biosimilar application is also mandatory, as are the accompanying documentary and information exchanges under § 262(l)(2).

Judge Chen agreed with Judge Lourie that the BPCIA does not require a biosimilar applicant to submit § 262(l)(2) information to the RPS. However, he opined that the § 262(l)(8) notice of commercial marketing is also not required because, in his view, § 262(l)(3)-(l)(8) cease to matter if the biosimilar applicant does not comply with § 262(l)(2). Judge Chen opined that, in such a situation, the RPS has the right to immediately pursue patent infringement litigation unfettered by the timing controls and limits on the number of asserted patents imposed by § 262(l)(2)-(l)(8). Judge Chen further opined that the majority's interpretation of § 262(l)(8) provides an inherent right to an automatic 180-day injunction, which he views as "an atextual 180-day exclusivity windfall" in tension with the purpose of paragraph (l)(8). [14]

Conclusion

The divided nature of the Federal Circuit panel's decision has invited speculation that the case may be taken up *en banc* by the Federal Circuit[15] or even appealed to the Supreme Court. And further issues regarding the BPCIA remain to be addressed by the courts.[16] However, for now, the Federal Circuit has offered some initial insight and guidance regarding BPCIA litigation for both RPSs and biosimilar applicants who are treading in otherwise largely uncharted waters.

1 *Amgen Inc. v. Sandoz Inc.*, No. 2015-1499, 2015 WL 4430108 (Fed. Cir. July 21, 2015).
2 Pub. L. No. 111-148, §§ 7001-7003, 124 Stat. 119, 804-21 (2010).
3 *Amgen*, 2015 WL 4430108, at *1 n.1.
4 *See* 42 U.S.C. § 262(k).
5 *See* 42 U.S.C. § 262(l).
6 *See* 42 U.S.C. § 262(l)(3)-(6).
7 42 U.S.C. § 262(l)(8)(B).
8 42 U.S.C. § 262(l)(9)(A); *see Amgen*, 2015 WL 4430108, at *3
9 42 U.S.C. § 262(l)(9)(C); *see Amgen*, 2015 WL 4430108, at *3.
10 *See Amgen Inc. v. Sandoz Inc.*, Case No. 14-cv-04741, 2015 WL 1264756 (N.D. Cal. Mar. 19, 2015).
11 *Amgen*, 2015 WL 4430108, at *6.
12 *Id.* at *8.
13 *Id.* at *9.
14 *Id.* at *21.
15 Both Amgen and Sandoz have filed petitions for rehearing *en banc*.
16 For example, the Federal Circuit's opinion declined to address whether the BPCIA preempted Amgen's state law claims, as that question was not squarely presented on appeal. *See id. at* *11 n.5.