Client Alert | Intellectual Property

Amgen Inc. v. Sandoz Inc. Federal Circuit Decision on BPCIA

August 2015

Authors: Dimitrios Drivas, Jeffrey Oelke, Ryan Johnson

On July 21, 2015, the United States Court of Appeals for the Federal Circuit issued its decision in *Amgen Inc. v. Sandoz Inc.*, interpreting key provisions in the Biologics Price Competition and Innovation Act ("BPCIA"). In a previous client alert,[1] we provided background on the BPCIA and the District Court decision in the *Amgen* case. In short, the District Court held that: (1) the BPCIA's patent negotiation provisions (often termed the "patent dance") are not mandatory; and (2) the BPCIA permits biosimilar applicants to provide the required notice of commercial marketing before they receive FDA approval. In a 2-1 decision accompanied by two partial dissents, the Federal Circuit affirmed on the first issue, but reversed on the second, holding that notice must come after FDA licensure.

If it stands, the *Amgen* decision provides some measure of clarity on the BPCIA's convoluted patent negotiation and notice provisions. Under *Amgen*, biosimilar applicants can choose whether to disclose their application and other confidential information to the reference product sponsor. Doing so initiates the BPCIA's negotiation process and forestalls an immediate infringement action. Conversely, if a biosimilar applicant chooses not to disclose its application to the reference product sponsor, the BPCIA (1) authorizes the sponsor to file an immediate infringement action, and (2) requires applicants to provide 180 days of advance notice of commercial marketing *after* they receive FDA approval.

The *Amgen* decision creates a regime that provides a biosimilar applicant with some measure of control over the posture and pace of patent litigation: it can set the parties on the path of a lengthy negotiation process that is presumably followed by a standard patent infringement suit, or it can choose to risk immediate suit, but without giving the reference product sponsor a preview of its application.

Background: The BPCIA & *Amgen v. Sandoz*

The BPCIA's patent dance begins when the biosimilar applicant provides the sponsor with a copy of its application:

> Not later than 20 days after the Secretary notifies the subsection (k) applicant [i.e., the biosimilar applicant] that the application has been accepted for review, the subsection (k) applicant *shall provide* a copy of the application…[2]

---

1 Client Alert: *Amgen Inc. v. Sandoz Inc.*, available at http://www.whitecase.com/sites/whitecase/files/files/download/publications/alert-amgen-inc-v-sandoz-inc.pdf.

2 42 U.S.C. § 262(l)(2)(A) (emphasis added).

The parties then engage in several rounds of exchanges and negotiations regarding the patents that should be the scope of an infringement suit, which is the expected outcome of the process.[3] While the process is ongoing, neither party may file a declaratory judgment action.[4] However, if the applicant does not provide a copy of its application or fails to complete the process, the BPCIA expressly authorizes the sponsor to file suit, while the applicant may not do so.

Also at issue in *Amgen* was the BPCIA's provision requiring applicants to notify the reference product sponsor at least 180 days before the applicant markets its product:

> 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)*.[5]

After receiving that notice, the sponsor may seek an injunction on grounds of patent infringement, including in the case any patents that were the subject of the parties' exchanges and negotiations.

Amgen argued that Sandoz had failed to complete the BPCIA's patent negotiation process, which Amgen argued was mandatory, and failed to comply with the terms of the commercial marketing notice provision by providing notice before receiving FDA approval.[6] Sandoz disagreed, arguing that applicants may forego the negotiation process, and that notice of commercial marketing could come at any time. The parties cross-moved for judgment on the pleadings regarding their respective statutory interpretations.

The BPCIA's Patent Negotiation Provisions Are Optional

The District Court agreed with Sandoz that biosimilar applicants need not participate in the BPCIA's patent negotiation process. The court explained that the BPCIA offers biosimilar applicants benefits for participating in the negotiations, including a temporary safe harbor from litigation, and sets consequences for electing not to do so, including the threat of an immediate lawsuit. The court reasoned that Sandoz was free to "trade[] in the chance to narrow the scope of potential litigation…[through the BPICA's process] in exchange for the expediency of an immediate lawsuit."[7]

The Federal Circuit (Judges Lourie and Chen) affirmed under the same rationale: despite the statute's clear language ("shall provide"), the overall statutory scheme "explicitly contemplates that a subsection (k) applicant might fail to disclose the required information" and "specifically sets forth the consequence for such failure" (i.e., an immediate infringement action).[8] Amgen's interpretation could not be correct, the court held, because it would render "superfluous" the remainder of the statute.[9]

In dissent, Judge Newman argued that congressional intent to make the patent negotiation provisions mandatory "pervades the legislative record, as interested persons debated which provisions would be mandatory, and which permissive."[10] Neither Judge Lourie (who wrote for the court), nor Judge Chen (who only concurred on the portion of the opinion holding that the aBLA disclosure is optional), nor the District Court discussed the BPCIA's legislative history in their respective opinions.

---

3 *Id.* §§ 262(l)(3)-(6).

4 *Id.* § 262(l)(9).

5 *Id.* § 262(l)(8) (emphasis added).

6 *Amgen Inc. v. Sandoz Inc.*, No. 14-CV-04741-RS, 2015 WL 1264756, at *3-4 (N.D. Cal. Mar. 19, 2015) ("*Amgen I")*.

7 *Id.* at *5-7.

8 *Amgen Inc. v. Sandoz Inc.*, No. 2015-1499, 2015 WL 4430108, at *6 (Fed. Cir. July 21, 2015) ("*Amgen II")*.

9 *Id.* at *9.

10 *Id.* at *16.

180 Days' Notice Cannot Precede FDA Approval

Amgen also argued that the BPCIA's 180-day notice provision requires biosimilar applicants to provide notice of commercial marketing *after* the biosimilar is "licensed under" the BPCIA, making Sandoz's pre-approval notice improper. The District Court disagreed, holding that the term "licensed under" simply reflects the reality that an applicant cannot sell an un-licensed product, not Congressional intent to require notice *after* approval, which could automatically extend the statutory 12-year "data exclusivity" period by another six months.[11] The court also suggested (in a footnote) that providing 180 days' notice is merely optional, much like the patent negotiation process.[12]

The Federal Circuit (Judges Lourie and Newman) reversed, holding that the clear statutory language indicates that the product must be approved ("licensed") when notice is given. The court rejected Sandoz's concern (shared by the district court) that requiring notice after approval could grant reference product sponsors an additional six months of exclusivity. In most cases, the court explained, a biosimilar applicant will file (and presumably obtain approval) well within the reference product sponsor's 12-year data exclusivity period. Under those facts, the 180-day notice period would not be likely to extend the 12-years of exclusivity. In contrast to that typical scenario, Sandoz filed its biosimilar application 13 years after Amgen's reference product (Neupogen®) was approved. The Federal Circuit declined to let the "untypical facts" of the case at bar control its statutory interpretation.[13]

The court also rejected Sandoz's argument that the notice provision provides consequences for noncompliance, thus indicating that the notice is optional. The court explained that those consequences apply only when a biosimilar applicant has disclosed its application and participated in the patent negotiation process. Because Sandoz did not do so, its obligation to provide the proper notice was not optional.[14]

The court did not squarely address the question of whether, if the applicant does participate in the patent negotiation process, providing notice of commercial marketing is optional. However, the court appears to have reasoned that compliance with a BPCIA provision is not mandatory where the statute provides consequences for noncompliance. Accordingly, it appears that notice of commercial marketing is not mandatory where the applicant has participated in the patent negotiation process, because the statute establishes consequences (an immediate infringement suit) for applicants who (1) participate in the patent negotiation process, but (2) do not provide the required notice.[15]

Judge Chen dissented from this portion of the Court's opinion, agreeing instead with Sandoz and the District Court. In his view, "when, as here, the [biosimilar] applicant fails to comply with (l)(2) [by providing a copy of the application], the provisions in (l)(3)-(l)(8) [including the notice provision] cease to matter."[16]

Future Considerations for Biologic Sponsors and Biosimilar Applicants

Given the somewhat unusual nature of the Federal Circuit panel's decision, with two dissenting opinions, the *Amgen* case may be ripe for review *en banc* or on writ of *certiorari* the Supreme Court. It remains to be seen whether Judge Newman's citation to the legislative history will be seen as persuasive if either court undertakes further review.

If the Federal Circuit's decision stands, it will have significant implications for biologic sponsors and biosimilar applicants alike. Biosimilar applicants will have to weigh the benefits of participating in the patent negotiation process against the potential strategic advantages of waiting until it has approval to notify the sponsor. Biologic sponsors will have to consider whether they can bring immediate infringement suits without the benefit of seeing the biosimilar applicant's aBLA or be prepared for the possibility of having only a six-month window to file a patent infringement suit and obtain injunctive relief before the launch of a competing biosimilar.

---

11 *Amgen I*, 2015 WL 1264756 at *7-8.

12 *Id.* at *8 n.8.

13 *Amgen II*, 2015 WL 4430108 at *9.

14 *Id.* at *10.

15 42 U.S.C. §§ 262(l)(8)(A), (9)(B).

16 *Amgen II*, 2015 WL 4430108 at *17.

White & Case LLP
1155 Avenue of the Americas
New York, New York
10036-2787
United States

T +1 212 819 8200