HAS AMGEN ALREADY WON ITS BPCIA DISPUTE WITH SANDOZ?

By Brian Coggio & Ron Vogel, Fish & Richardson

Brian Coggio is Of Counsel to the New York Office of Fish & Richardson. He has extensive experience as a senior trial attorney, litigating disputes across a wide range of technology, with a particular focus on chemical, pharmaceutical, medical device and biotechnology.

He has been involved in cases before the International Trade Commission and in various foreign countries including Germany, Great Britain, Switzerland, Italy and the Netherlands. Mr. Coggio has also represented clients in numerous cases under the Hatch Waxman Act.

In advance of his panel on Litigating Biosimilars at the C5 Life Sciences IP Summit in Munich, Mr. Coggio has written a piece on whether Amgen has already succeeded in their BPCIA dispute with Sandoz following their Supreme Court decision.

Based on the Supreme Court's decision in *Sandoz Inc. v. Amgen, Inc.*, 137 S. Ct. 1664 (2017), many have concluded that a Biosimilar applicant ("Biosimilar") has the 'option' to disclose its application and manufacturing information to the Research Sponsor ("Sponsor"), but need not do so. While Sandoz apparently had this choice, it may be argued that the Court's decision will likely require Sandoz to disclose such information to Amgen. This is because the Court held that the "requirement" that a Biosimilar "must" provide the Sponsor with the former's application and manufacturing information is not enforceable by an injunction under federal law, and nothing more. The action was remanded to the Federal Circuit to decide if Sandoz violated California unfair competition law by failing to disclose its confidential information and whether that statute provides for an injunction requiring such disclosure. This, of course, assumes that federal remedies (which are non-existent) are not exclusive.

In its decision, however, the Supreme Court already determined that Sandoz "violated" the BPCIA by failing to disclose its confidential information to Amgen. And according to the Court, this violation is "unlawful" under California unfair competition law. Accordingly, has the disclosure issue been resolved?

I. A Biosimilar "Must" Disclose Its Application and Related Manufacturing Information to the Research Sponsor

In the opening section of its decision, the Supreme Court per Justice Thomas summarized the workings of the BPCIA. As relevant here, Justice Thomas stated:

> Under § 262(l), an applicant that seeks FDA approval of a biosimilar **must** provide its application materials and manufacturing information to the manufacturer of the corresponding biologic within 20 days of the date the FDA notifies the applicant that it has accepted the application for review.

Id. at 1679 (emphasis added).

The Court never explicitly decided whether the Biosimilar has a choice, *i.e.*, whether disclosure is truly "optional." Rather, the sole question presented to and decided by the Court was "whether the **requirement** that an applicant provide its application and manufacturing information to the manufacturer of the biologic is enforceable by injunction." *Id.* (emphasis added). The Court twice restates the question, and the term "requirement" is mentioned both times. *Id.* at 1671, 1676.

II. The Underlying Facts and the Federal Circuit Decision

After Sandoz refused to provide its application and manufacturing information to Amgen, Amgen instituted suit for patent infringement. It also asserted two claims under California's unfair competition law, which "prohibits 'any unlawful business acts or practice.'" *Id.* at 1673 (citation omitted). In this regard, Amgen alleged that Sandoz engaged in "unlawful" conduct under California's unfair competition law when, *inter alia*, it failed to provide its application and manufacturing information pursuant to § 262(l)(2)(A) of the BPCIA, which requires such disclosure. In its opinion, the Supreme Court stated that a "'business or practice'" is "'unlawful'" under California unfair competition law if the conduct "**violates** a rule contained in some other state **or** federal law." *Id.* (emphasis added).

The Federal Circuit held that "Sandoz did not violate the BPCIA in failing to disclose its application and manufacturing information [to Amgen]" and "that the remedies contained in the BPCIA are the ***exclusive*** remedies for failure to comply with § 262(l)(2)(A)." *Id.* (citation omitted) (emphasis added). In reaching its decision, the Federal Circuit held that Sandoz's failure to disclose the information was not "unlawful" under California law because its conduct was contemplated by § 262(l)(9)(C) and § 271(e)(2)(C)(ii)[1], and therefore, its conduct did not "violate" the BPCIA. In sum, Federal Circuit held that the two sections are the **exclusive** remedies for a violation of § 262(l)(2)(A), and neither authorizes an injunction to compel a Biosimilar to disclose its confidential information to the Sponsor.

III. The Supreme Court's Decision

The Supreme Court agreed with the Federal Circuit that "an injunction under federal law is not available to enforce § 262(l)(2)(A)." *Id*. But, according to the Court, the Federal Circuit decision "rests on an incorrect interpretation of federal law," because federal law provides "no remedy at all, much less an 'expressly. . . exclusive' one for Sandoz failure to comply with § 262(l)(2)(A)." *Id*. at 1676. Thus, the Federal Circuit's holding that Amgen had no remedy whatsoever is incorrect — only *federal* remedies are unavailable. As the Supreme Court held:

> Congress did not intend sponsors to have access to injunctive relief, at least as a matter of **federal law**, to enforce the disclosure **requirement**.

Id. at 1675 (emphasis added).

The parties had contested whether the § 262(l)(2)(A) "requirement" of disclosure is mandatory in all circumstances. That is, does applicant have the option to disclose or not. But as noted above, the Court did not decide whether such disclosure is mandatory under federal law. *Id.* Rather, the mandatory or conditional nature of BPCIA's disclosure requirements matters only for purpose of California unfair competition law. Thus, the case was remanded to determine whether Sandoz's noncompliance with the disclosure "requirement" of § 262(l)(2)(A) was "unlawful" under California unfair competition law. But the Supreme Court may have already decided this issue.

IV. Has Sandoz Violated California's Unfair Completion Law?

As noted above, the Supreme Court stated that a Biosimilar "must" provide its application and manufacturing information to the Sponsor. Indeed, Justice Thomas repeatedly states that this disclosure is a "requirement" of the BPCIA. Perhaps most telling, however, is the Court's observation on the possibility of preliminary injunctive relief:

> In holding that ¶262(l)(9)(C) represents the exclusive remedy for an applicant's failure to provide its application and manufacturing information, we express no view on whether a district court could take into account an applicant's violation of ¶262(l)(2)(A) (or any other BPCIA procedural requirement) in deciding whether to grant a preliminary injunction under 35 U.S.C. § 271 (e)(4)(B) or 283 against marketing the biosimilar.

Id. at 1678 n.2 (emphasis added). Accordingly, the Court seems to hold, at least in dicta, that a Biosimilar's failure to disclose its confidential information — a "requirement" of the BPCIA — is a "violation" of § 262(l)(2)(A) — a federal statute. But conduct is "unlawful" under California unfair competition law if it "violates" a state or federal law. *Id.* at 1673. Here, the Supreme Court seemingly determined that Sandoz's failure to disclose its application and manufacturing information to Amgen "violated" the BPCIA.[2] Thus, has the issue been decided under California law.

It would appear that the Federal Circuit may well rule that Amgen's claim of unfair competition will succeed because a federal law — the BPCIA — was "violated" when Sandoz refused to provide its application and related manufacturing information to Amgen. It remains to be seen if this conduct will be remedied by an injunction requiring Sandoz to disclose such information to Amgen.

On July 26, 2017, the Federal Circuit ordered the parties to address whether the federal remedies preempted state remedies; whether Sandoz waived this argument; and whether California law would treat Sandoz's noncompliance with 42 U.S.C. 262 (l)(2)(A) as "unlawful" under its unfair competition law.

Accordingly, these issues should be resolved in the near future.

[1] Both sections provide remedies for when a Biosimilar fails to provide its application and manufacturing information to the Sponsor.

[2] The basis for the Federal Circuit's ruling, i.e., that Sandoz did not "violate" the BPCIA in failing to disclose the confidential information was reversed.

Life Sciences IP Summit 2017

Proven strategies to maximise commercial return through your patent portfolio

11th & 12th October 2017
HOTEL VIER JAHRESZEITEN KEMPINSKI
Munich, Germany

JOIN BRIAN COGGIO AT THE IP SUMMIT ON OCTOBER 11TH & 12TH IN MUNICH, GERMANY

Mr Coggio will be joined by Jonathan Singer, Principal of Fish Richardson to tackle the topic of Litigating Biosimilars

Their panel will discuss:

- The BPCIA procedures between the biosimilar applicant and the innovator
- What the basic framework for biosimilar patent litigation is post *Amgen v Sandoz*
- Whether the patent dance remains

CLICK HERE TO VIEW THE FULL AGENDA

THE 2017 IP SUMMIT WILL ALSO INCLUDE PANELS ON:

The scope of SPC Regulations

The future of the Unitary Patent Court

Effective lifecycle management strategies

The PTAB and alternatives to litigation

EPO & Early Certainty

The challenges and systems of emerging markets

Maximise the power of your patent portfolio.