AMGEN V. SANDOZ - NEW DEVELOPMENTS IN BIOSIMILARS LITIGATION

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INTRODUCTION & BACKGROUND

On May 8, 2019 in *Amgen, Inc. v. Sandoz International GmbH*, [1] the Federal Circuit Court affirmed the district court's judgment, [2] concluding that the district court correctly construed the claims and granted summary judgment of noninfringement, removing a barrier to launch for Sandoz International GmbH's ("Sandoz") biosimilars.

The biologics filgrastim (Neupogen®) and pegfilgrastim (Neulasta®), created and commercialized by Amgen, Inc. ("Amgen"), are used to treat patients afflicted with a deficiency of white blood cells. [3] While both biologics stimulate the production of neutrophils, [4] Neupogen® is further indicated to mobilize stem cells from the bone marrow. [5] In 2014, Sandoz filed an abbreviated Biologics License Application ("aBLA") with the Food and Drug Administration ("FDA") to market its biosimilar filgrastim product. [6] Although Sandoz referenced Neupogen® in its aBLA, it did not provide the application or manufacturing information to Amgen. [7]

In October 2014, Amgen filed a complaint seeking a declaratory judgment that Sandoz's proposed filgrastim biosimilar would infringe its U.S. Patent No. 6,162,427 ("the '427 patent"). [8] After Sandoz received FDA approval and launched its filgrastim biosimilar, Zarxio®, in 2015, Amgen amended its complaint to additionally plead infringement of its U.S. Patent No. 8,940,878 ("the '878 patent"). [9] Later, Sandoz submitted a second aBLA to market its pegfilgrastim biosimilar product, referencing Neulasta®. [10] In 2016, Amgen responded with a complaint that Sandoz's proposed pegfilgrastim biosimilar would also infringe its '878 patent. [11] The cases were consolidated and the following matters were addressed together on appeal.

After the district court construed the method of treatment claim ('427 patent), Amgen stipulated to noninfringement "contingent upon its right to appeal from the district court's claim construction order." [12] With respect to the process claim ('878 patent), the district court granted summary judgement finding that Sandoz's separation process, used for both Zarxio® and its proposed pegfilgrastim biosimilar, did not infringe. [13] Amgen appealed.

COURT ANALYSIS

The operative claims of the '427 patent require that a chemotherapeutic agent be administered in a "disease treating effective amount." On appeal, Amgen argued that the district court should not have construed the term as "an amount sufficient to treat a disease for which at least one chemotherapeutic agent is prescribed" and instead the term should only limit the amount of the agent administered and not require that the agent be used to directly

treat an underlying disease. In other words, Amgen argued that the claim should read on uses such as stem cell mobilization rather than direct treatment of an underlying disease. [14] The Federal Circuit disagreed and asserted that "Amgen's construction would broaden [the claim] . . . to cover administration of . . . a chemotherapeutic agent solely for the purpose of mobilizing stem cells . . . requiring 'disease treating' to be interpreted as 'stem cell mobilizing.'" [15] The Court explained that "our precedent instructs that different claim terms are presumed to have different meaning . . . [and] [h]ad Amgen simply wanted to claim a method of mobilizing stem cells . . . it could have done so." [16]

Amgen also maintained that the district court erred in its claim construction and summary judgment decisions relating to the process claim of the '878 patent. [17] The Federal Circuit likewise disagreed, holding that "Sandoz's one-step, one-solution process does not function in the same way as the claimed [three-step, three-solution] process." [18] The Federal Circuit likewise held the claims did not infringe under the doctrine of equivalents cautioned that the equivalency argument should only be used when warranted. The Court emphasized, "[t]he doctrine of equivalence applies only in exceptional cases and is not 'simply the second prong of every infringement charge, regularly available to extend protection beyond the scope of the claims.'" [19]

Amgen also maintained that the district court abused its discretion by denying Amgen's motion for a continuance. [20] Sandoz had previously disclosed that it intended to "modify its purification processes for both [biosimilar products] . . . to accommodate the use of a different resin in its separation matrix [in the future]". [21] Amgen asserted that Sandoz has not submitted an amendment to its aBLA or provided Amgen with the details of that modification. [22] Under Federal Rule of Civil Procedure 56(d), a district court may deny or postpone summary judgment if the nonmovant shows that "it cannot present facts essential to justify its opposition." [23] Therefore, Amgen argued that judgment could not be rendered under 35 U.S.C. § 271(e)(2) when "a biosimilar applicant plans to submit a modification of a relevant process to the FDA but has not yet done so." [24] Amgen claimed it would be "'effectively deprived of the ability to allege infringement in the future,' and Sandoz [would] be free 'to make any changes it wishe[d] to the modified process because it ha[d] been declared non-infringing in advance.'" [25]

Again, the Federal Circuit sided with the district court. Citing *Glaxo*, [26] the Court explained that a proper infringement analysis under § 271(e)(2) requires a "hypothetical inquiry"—"a determination of whether '[w]hat is likely to be sold' will infringe 'in the conventional sense' of patent infringement." [27] The Court further explained that "[t]his 'hypothetical inquiry' may be complex, given that [Abbreviated New Drug Applications (ANDA)] and biosimilar applicants often make changes to their applications while they are pending." [28] The Court continued, "[w]e have thus recognized that, while a district court cannot ignore amendments to an ANDA or aBLA, it also has a broad mandate to render a 'just, speedy, and inexpensive' decision, based upon the evidence of record." [29]

The Court distinguished the present case by reiterating the fact that Amgen's process claim "does not distinguish between types of resins" and "there is no genuine dispute that the process Sandoz will likely use[,] . . . whether it uses the current resin or [a] new resin[,] will not infringe." [30] The Federal Circuit did not agree that Amgen would be "left without a remedy for possible future infringement if the facts change," noting that Amgen may plead infringement in a future action "to the extent permitted by the Patent Act and the principles of *res judicata* and collateral estoppel." [31]

CONCLUSION

The Federal Circuit resolved the majority of the questions on appeal by applying traditional principles from patent law and from cases brought under the Hatch-Waxman Act to this biosimilar litigation. Going forward, it is likely that the Federal Circuit will continue to analogize to Hatch-Waxman litigation, particularly for procedural matters such as the applicability of a continuance in view of an amendment to an aBLA.

This case represents an important step toward bringing additional biosimilars to market and expanding the scope of biosimilar access in the United States.

NOTES:

[1] *Amgen, Inc. v. Sandoz Int'l GmbH*, Appeal No. 2018-1551, slip op. (Fed. Cir. May 8, 2019).
[2] *Amgen, Inc. v. Sandoz Int'l GmbH*, 295 F.Supp.3d 1062 (N.D. Cal. Dec. 19, 2017).
[3] *Amgen*, slip op. at 3.
[4] Neutrophils are a type of white blood cell.
[5] *Amgen*, slip op. at 3.
[6] *Amgen*, slip op. at 3.
[7] *Amgen*, slip op. at 3.
[8] *Amgen*, slip op. at 3. Infringement under 35 U.S.C. § 271(e)(2)(C) and declaratory judgment under 42 U.S.C. § 262(l)(9)(C).
[9] *Amgen*, slip op. at 4. Infringement under 35 U.S.C. § 271(e)(2)(C)(ii), (g).
[10] *Amgen*, slip op. at 4.
[11] *Amgen*, slip op. at 4. Infringement under 35 U.S.C. § 271(e)(2)(C)(i) and a declaratory judgment under 42 U.S.C. § 262(l)(6)(A).
[12] *Amgen*, slip op. at 6.
[13] *Amgen*, slip op. at 7.
[14] *Amgen*, slip op. at 14.
[15] *Amgen*, slip op. at 15.
[16] *Amgen*, slip op. at 15.
[17] *Amgen*, slip op. at 8.
[18] *Amgen*, slip op. at 11.
[19] *Amgen*, slip op. at 11 (quoting *London v. Carson Pirie Scott & Co.*, 946 F.2d 1534, 1538 (Fed. Cir. 1991)).
[20] *Amgen*, slip op. at 11.
[21] *Amgen*, slip op. at 12.
[22] *Amgen*, slip op. at 12.
[23] *Amgen*, slip op. at 12.
[24] *Amgen*, slip op. at 12.
[25] *Amgen*, slip op. at 12.
[26] *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997).
[27] Amgen, slip op. at 12–13.
[28] Amgen, slip op. at 13 (internal citations omitted).
[29] Amgen, slip op. at 13 (internal citations omitted).

[30] *Amgen*, slip op. at 13.
[31] *Amgen*, slip op. at 14.

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