No. 2015-1499

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

AMGEN INC., AMGEN MANUFACTURING LIMITED,

Plaintiffs-Appellants,

v.

SANDOZ INC.,

Defendant-Appellee.

Appeal from the United States District Court for the Northern District of California, case no. 3:14-cv-04741-RS, Judge Richard Seeborg

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SANDOZ INC.'S STATEMENT IN SUPPORT
OF REMAND TO THE DISTRICT COURT

This case will soon formally return to this Court after the Supreme Court's remand. Defendant-Appellee Sandoz Inc. ("Sandoz") respectfully requests that this Court in turn remand the case to the district court at that time. Because the district court is now addressing other claims in this case, such a remand would promote judicial efficiency by avoiding further serial appellate proceedings. A remand would also allow the district court in California, rather than this Court, to first address questions of California law posed by the Supreme Court's remand. If

this Court chooses not to remand, however, it should order full briefing on the questions left open by the Supreme Court's decision.

BACKGROUND

This Court is familiar with the history of this case, so Sandoz provides only a brief summary.

Sandoz's biosimilar. On July 7, 2014, the Food & Drug Administration ("FDA") accepted for review Sandoz's application for a biosimilar of filgrastim, a biologic medicine that Plaintiff-Appellant Amgen Inc. ("Amgen") had long marketed. *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1352 (Fed. Cir. 2015); 42 U.S.C. § 262(k) (abbreviated approval pathway for biosimilars established by Biologics Price Competition and Innovation Act of 2009 ("Biosimilars Act" or "BPCIA")). The next day, Sandoz notified Amgen that Sandoz had filed the application and that Sandoz expected FDA approval in the first half of 2015. 794 F.3d at 1352-53. Sandoz also provided notice that it intended to begin commercial marketing of its biosimilar filgrastim product in the United States immediately upon FDA approval. *Id.*; *see* 42 U.S.C. § 262(*l*)(8)(A) (notice of commercial marketing provision). On July 25, 2014, Sandoz informed Amgen that it had "opted not to provide Amgen with Sandoz's biosimilar application within 20 days of the FDA's notification of acceptance" and that the Biosimilars Act thus permitted Amgen to bring a declaratory judgment action for patent infringement

against Sandoz. A1495-A1497 (citing 42 U.S.C. § 262(*l*)(9)(C)).

Initial district court proceedings. In October 2014, Amgen sued Sandoz in the Northern District of California. 794 F.3d at 1353. Amgen brought a claim under California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code § 17200 et seq., which provides a cause of action against "any unlawful, unfair or fraudulent business act or practice." *Id.* at 1360. Amgen asserted a claim only under the "unlawful" prong of the UCL, alleging Sandoz violated the Biosimilars Act. *Id.* at 1353. Specifically, Amgen alleged that Sandoz violated the statute (1) by not providing Amgen with Sandoz's biosimilar application within 20 days of FDA's acceptance of Sandoz's application and (2) by giving an allegedly premature, ineffective notice of commercial marketing before FDA approval. *Id.*

Expressly invoking the recourse provided by the Biosimilars Act, 35 U.S.C. § 271(e)(2)(C)(ii), Amgen also brought a claim for artificial infringement of Amgen's U.S. Patent No. 6,162,427, which claims a method of treating a patient using filgrastim. 794 F.3d at 1353; A79. Sandoz answered and counterclaimed, seeking declaratory judgments, among other things, concerning the correct interpretation of the Biosimilars Act. 794 F.3d at 1353. Sandoz's answer included as an affirmative defense that Amgen's "claims of Unfair Competition and Conversion are preempted by federal law." A275.

On March 6, 2015, the FDA approved Sandoz's filgrastim product Zarxio®. 794 F.3d at 1353. Although Sandoz "maintained that it gave an operative notice of commercial marketing in July 2014"—just after the FDA accepted its biosimilar application, *see supra* p. 2—Sandoz "nevertheless gave a 'further notice of commercial marketing' to Amgen on the date of FDA approval." 794 F.3d at 1353.

Both parties moved for partial judgment on the pleadings. A2. On March 19, 2015, the district court ruled for Sandoz on Amgen's state law claims and on Sandoz's Biosimilars Act counterclaims. A1-A19.

First, the district court concluded that it was lawful for Sandoz not to provide Amgen its biosimilar application within 20 days of acceptance by the FDA. A9-A12. Second, the district court concluded that it was lawful for Sandoz to provide its notice of commercial marketing before FDA approval, meaning that Sandoz's July 2014 notice was effective. A12-A14.

The district court later entered final judgment under Federal Rule of Civil Procedure 54(b) on Amgen's state law claims and Sandoz's Biosimilars Act counterclaims. 794 F.3d at 1353-54.

Proceedings in this Court. In May 2015, this Court issued an injunction pending appeal, barring Sandoz from marketing, selling, offering for sale, or importing into the United States its FDA-approved Zarxio® product. *Id.* at 1362;

CAFC Dkt. No. 105.

On July 21, 2015, the Court affirmed the dismissal of Amgen's state law claims, vacated the judgment on Sandoz's counterclaims, and remanded. 794 F.3d at 1347.

The majority (Judge Lourie joined by Judge Chen) agreed with Sandoz that the Biosimilars Act "explicitly contemplates" that an applicant might not take the first step in the information exchange process: disclosing its application to the sponsor under subsection (*l*)(2)(A). *Id.* at 1355. "Because Sandoz took a path expressly contemplated by the BPCIA, it did not violate the BPCIA by not disclosing its [application] and the manufacturing information by the statutory deadline." *Id.* at 1357.

The Court next interpreted the Biosimilars Act's notice of commercial marketing provision to mean that the "applicant may only give effective notice of commercial marketing *after* the FDA has licensed its product." *Id.* (emphasis added). Based on that interpretation, a different majority (Judge Lourie joined by Judge Newman) "order[ed] that the injunction pending appeal be extended through September 2, 2015"—that is, 180 days from Sandoz's post-approval notice of commercial marketing. *Id.* at 1362.

Upon expiration of this Court's injunction, Sandoz began shipping its biosimilar filgrastim product Zarxio® in the United States on September 3, 2015.

Proceedings in the Supreme Court. The Supreme Court granted Sandoz's petition for a writ of certiorari challenging this Court's holding on the notice of commercial marketing provision and Amgen's conditional cross-petition challenging this Court's holding on Sandoz's decision not to provide its application. 137 S. Ct. 808 (2017). The Supreme Court subsequently vacated in part and reversed in part, and remanded for further proceedings. *See Sandoz Inc. v. Amgen Inc.*, Nos. 15-1039, 15-1195, 2017 WL 2507337 (June 12, 2017).

The Supreme Court held that a biosimilar "applicant may provide notice [of commercial marketing] either before or after receiving FDA approval." *Id.* at *14. "[B]ecause Sandoz fully complied with § 262(*l*)(8)(A) when it first gave notice (before licensure) in July 2014," the Supreme Court concluded that this Court had "erred in issuing a federal injunction prohibiting Sandoz from marketing Zarxio until 180 days after licensure." *Id.* at *16. And "because Amgen's request for state-law relief is predicated on its argument that the BPCIA forbids prelicensure notice," the Court held that "its claim under California's unfair competition law also fails." *Id.*

The Supreme Court also addressed "whether § 262(*l*)(2)(A)'s requirement that an applicant provide the sponsor with its application and manufacturing information is enforceable by an injunction under either federal or state law." *Id.* at *10. The Court answered no to the first question: "an injunction under federal

law is not available to enforce § 262(*l*)(2)(A)." *Id.*

The Supreme Court then considered whether a state law remedy might be available for non-provision of the application. The Supreme Court observed that this Court had "rejected Amgen's request for [such] an injunction under state law for two reasons." *Id.* at *13. First, this Court had noted that "California's unfair competition law [does not] provide a remedy when the underlying statute specifies an 'expressly . . . exclusive' remedy." *Id.* (quoting 794 F.3d at 1360). This Court had "held that [35 U.S.C.] § 271(e)(4), by its text, 'provides the "only remedies"' for non-disclosure of its application. *Id.* The Supreme Court disagreed with this interpretation of Section 271(e)(4), concluding that the provision did not provide a remedy for failure to provide a biosimilar application. *Id.*

Second, the Supreme Court observed that this Court had rejected Amgen's state law claim for non-disclosure on the ground that non-disclosure "does not violate the BPCIA" and for that reason cannot be "'unlawful' under California's unfair competition law." *Id.* The Supreme Court concluded that the Biosimilars Act itself did not render non-provision of the application unlawful or lawful—that was not a "question of federal law." *Id.* at *14. Instead, all that mattered for purposes of federal law was the consequence of failure to disclose the application, which was authorization for "an immediate declaratory-judgment action pursuant to § 262(*l*)(9)(C)." *Id.*

The Supreme Court thus remanded for consideration of the question "whether California law would treat noncompliance with § 262(*l*)(2)(A) as 'unlawful.'" *Id.* "If the answer is yes," the Supreme Court instructed, the question would be "whether the BPCIA pre-empts any additional remedy available under state law for an applicant's failure to comply with § 262(*l*)(2)(A) (and whether Sandoz has forfeited any pre-emption defense)." *Id.* (citing 794 F.3d at 1360 n.5). The Supreme Court also noted that "the pre-emption question" could be considered "first by assuming that a remedy under state law exists." *Id.*

Absent a rehearing petition, the Supreme Court will return the case to this Court approximately 25 days after the date of its opinion, *i.e.*, on or after July 7, 2017. *See* S. Ct. R. 45.

Ongoing district court proceedings. After issuance of this Court's mandate (794 F.3d at 1362; CAFC Dkt. No. 162), the district court granted the parties' joint motion to lift the stay of litigation imposed during the appeal to this Court (ECF 133), and the district court resumed proceedings on Amgen's patent claims. Fact discovery closed on June 23, 2017. ECF 248. Expert reports will be exchanged in summer 2017. ECF 248. Summary judgment motions are due on October 25, 2017. ECF 248. Trial is scheduled for March 2018. ECF 253.

ARGUMENT

On remand from the Supreme Court, this Court "may require additional briefs, schedule oral argument, summarily dispose of the case, remand to the trial court, or take any other action consistent with the opinion of the Supreme Court." Fed. Cir. IOP 15.3. Here the Court should remand to the district court, where this case is ongoing. If the Court chooses not to remand, it should order full briefing on the matters left open by the Supreme Court.

As noted above, this case is being actively litigated in the district court. Rather than conducting another separate appellate proceeding on only one part of this case, the Court should remand. That would allow the district court, as part of the ongoing proceedings, to address the remaining questions on Amgen's state law claim in light of the Supreme Court's ruling on federal law. Then, if necessary, this Court can address those questions in one appeal after final judgment along with any issues arising from resolution of Amgen's patent claims.

Such a remand would preserve this Court's role as one of review, rather than of first view. And it would have the added benefit of allowing the California-based district court to first address what the Supreme Court has characterized as a

question of California unfair competition law. *See* 2017 WL 2507337, at *14.[1]

If this Court remands to the district court, Sandoz will ask the district court to align briefing on Amgen's remaining state law claim (and whether it is preempted) with the schedule already set for summary judgment briefing. Such an approach would not prejudice Amgen, which has known since Sandoz filed its answer that Sandoz has a preemption defense. *See* A1869 (Amgen's counsel: "[W]e very much believe that there is a preemption argument made." (citing Sandoz's answer)).

Remand also would make it unnecessary to address the waiver question flagged by the Supreme Court. 2017 WL 2507337, at *14. As this Court noted, Sandoz did not rely on preemption in the briefing on the motions for judgment on the pleadings that resulted in "this appeal." 794 F.3d at 1360 n.5. But Sandoz preserved the defense by advancing preemption in its answer (A6, A275, A285) and made clear that it simply had not placed the defense at issue in these motions.

[1] Although the Supreme Court stated that this Court should decide the remanded questions, 2017 WL 2507337, at *14, courts of appeals frequently remand to district courts when the Supreme Court has remanded a case to them. *See, e.g.*, *Checkpoint Sys., Inc. v. All-Tag Sec. S.A.*, No. 16-1397, 2017 WL 2407853, at *1 (Fed. Cir. June 5, 2017); *Intermatic Inc. v. Lamson & Sessions Co.*, 60 F. App'x 805, 805-06 (Fed. Cir. 2003); *United States v. Barnette*, 644 F.3d 192, 196 (4th Cir. 2011); *Homar v. Gilbert*, 149 F.3d 1164 (3d Cir. 1998) (Table). The court of appeals may then review the district court's resolution of the remanded questions in the ordinary course.

A1877 (Sandoz's counsel before district court: "[W]e did not move on that counterclaim [discussing preemption]. So it is just not before the Court *right now*. The Court: Right, I understand." (emphasis added)). The defense thus remains available to Sandoz. "[T]he failure to raise an affirmative defense by motion will not result in a waiver as long as it is interposed in the answer." 5 Charles Alan Wright, et al., Fed. Prac. & Proc. Civ. § 1277 (3d ed. Apr. 2017); *see* Fed. R. Civ. P. 12(h)(2), (i). A defendant is free to move for judgment on only some of its substantive defenses without waiving its right to assert other pleaded defenses later in the case. *See, e.g.*, *Daingerfield Island Protective Soc'y v. Babbitt*, 40 F.3d 442, 445 (D.C. Cir. 1994) (rejecting argument that defendant had waived statute of limitations defense preserved in its answer by not asserting it in first motion for summary judgment); *English v. Dyke*, 23 F.3d 1086, 1089-91 (6th Cir. 1994) (defendant permitted to move for judgment on the pleadings or summary judgment based on defense preserved in answer but not asserted in earlier motion to dismiss). Accordingly, regardless of whether preemption was waived for purposes of this particular appeal, Sandoz could still assert it on remand by later motion, such as in a summary judgment motion.

For all these reasons, Sandoz respectfully submits that an immediate remand would be the most judicially efficient course for the parties and the courts. If, however, this Court chooses not to remand to the district court, it should order full

briefing on the questions left open by the Supreme Court. The parties should be allowed an opportunity to address those questions in light of the Supreme Court's decision. And, to address all related issues and provide guidance to industry, the Court could choose to address preemption as well, even in the current posture. As this Court has recognized, upon remand from the Supreme Court, "a court of appeals may 'consider relevant decisions and arguments that were not previously before it' to promote fairness." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 234 F.3d 558, 590 n.8 (Fed. Cir. 2000) (en banc) (quoting *Stutson v. United States*, 516 U.S. 193, 197 (1996)), *vacated on other grounds*, 535 U.S. 722 (2002).

CONCLUSION

When this case returns to this Court on remand from the Supreme Court, it should be remanded to the district court for further proceedings. In the alternative, the Court should recall its mandate and order full briefing on the questions left open by the Supreme Court.

Respectfully submitted,

/s/ Deanne E. Maynard

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Dated: June 29, 2017

CERTIFICATE OF INTEREST

Counsel for defendant-appellee Sandoz Inc. certifies the following:

1. The full name of every party or amicus represented by me is:

Sandoz Inc.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

N/A

3. All parent corporations and any publicly held companies that own 10% or more of the stock of the party or amicus curiae represented by me are:

Sandoz Inc. is an indirect subsidiary of Novartis AG, which trades on the SIX Swiss Exchange under the ticker symbol NOVN and whose American Depository Shares are publicly traded on the New York Stock Exchange under the ticker symbol NVS.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or are expected to appear in this court are:

Morrison & Foerster LLP: Rachel Krevans, David C. Doyle, Deanne E. Maynard, Grant J. Esposito, Anders T. Aannestad (no longer with firm), Erik J. Olson, Marc A. Hearron, Stephen D. Keane, Joseph R. Palmore, Julie Y. Park, Bryan J. Leitch, Lena H. Hughes, Brian M. Kramer, Eric C. Pai, Jessica A. Roberts. Kirkland & Ellis LLP: James F. Hurst, Michael D. Shumsky, John K. Crisham, Reid P. Huefner, James W. Beard.

Dated: June 29, 2017 /s/ Deanne E. Maynard

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the appellate CM/ECF system on June 29, 2017.

I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

Dated: June 29, 2017 /s/ Deanne E. Maynard

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