NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

REGENERON PHARMACEUTICALS, INC.,
Plaintiff-Appellee

v.

MYLAN PHARMACEUTICALS INC., AMGEN USA, INC., BIOCON BIOLOGICS INC., SAMSUNG BIOEPIS CO., LTD., FORMYCON AG, AMGEN INC.,
Defendants

CELLTRION, INC.,
Defendant-Appellant

2024-2058, 2024-2147

Appeals from the United States District Court for the Northern District of West Virginia in Nos. 1:22-cv-00061-TSK-JPM, 1:23-cv-00089-TSK-JPM, 1:23-cv-00094-TSK-JPM, 1:23-cv-00097-TSK-JPM, 1:23-cv-00106-TSK-JPM, 1:24-cv-00039-TSK-JPM, 1:24-cv-00053-TSK, 1:24-md-03103-TSK-JPM, Chief Judge Thomas S. Kleeh.

Decided: March 5, 2025

DAVID I. BERL, Williams & Connolly LLP, Washington, DC, argued for plaintiff-appellee. Also represented by

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JONATHAN YATES ELLIS, McGuireWoods LLP, Raleigh, NC, argued for defendant-appellant. Also represented by CORINNE STONE HOCKMAN; ROBERT V. CERWINSKI, MICHAEL BRETT COTTLER, LORA MARIE GREEN, AVIV ZALCENSTEIN, Gemini Law LLP, New York, NY; MATTHEW S. FREIMUTH, MICHAEL JOHNSON, Willkie Farr & Gallagher LLP, New York, NY.

Before PROST, WALLACH, and CHEN, *Circuit Judges*.

PROST, *Circuit Judge*.

Celltrion, Inc. ("Celltrion") appeals a preliminary injunction that bars Celltrion from launching its biosimilar version of Regeneron Pharmaceuticals, Inc.'s ("Regeneron") FDA-approved aflibercept biologic product EYLEA®. *In re: Aflibercept Patent Litig.*, No. 24-3103, ECF No. 215 (N.D.W. Va. June 28, 2024), J.A. 4–185 ("*Celltrion Preliminary Injunction Opinion*"). We affirm.

BACKGROUND

I

This court previously rejected challenges by Samsung Bioepis Co., Ltd. ("SB") and Formycon AG ("Formycon") to a similar preliminary injunction issued by the same district court. *See Regeneron Pharms., Inc. v. Mylan Pharms. Inc.*, 127 F.4th 896 (Fed. Cir. 2025) ("*SB Opinion*"); *Regeneron Pharms., Inc. v. Mylan Pharms. Inc.*, No. 2024-2009, 2025

WL 324288 (Fed. Cir. Jan. 29, 2025) ("*Formycon Opinion*"). Because of the substantial overlap in facts and district court analyses in this appeal and the SB and Formycon appeals, this opinion does not repeat those facts or analyses that were already addressed in the *SB* and *Formycon Opinions*.

II

Celltrion is a Korean biopharmaceutical company based in Incheon, South Korea. Celltrion developed EYLEA® biosimilar CT-P42. Regeneron sued Celltrion in the Northern District of West Virginia alleging, among other things, infringement of U.S. Patent No. 11,084,865 ("the '865 patent"). Regeneron moved for a preliminary injunction to bar Celltrion's launch of CT-P42. On June 28, 2024, the district court granted Regeneron's motion for a preliminary injunction. *See Celltrion Preliminary Injunction Opinion*. Celltrion timely appeals, and we have jurisdiction under 28 U.S.C. § 1292(c)(1).

DISCUSSION

We review the grant of a preliminary injunction under the law of the regional circuit, here the Fourth Circuit. *Natera, Inc. v. NeoGenomics Labs. Inc.*, 106 F.4th 1369, 1374 (Fed. Cir. 2024). "Both the Fourth Circuit and the Federal Circuit review the grant or denial of a preliminary injunction for abuse of discretion." *Id.* at 1375. "An abuse of discretion may be established by showing that the court made a clear error of judgment in weighing relevant factors or exercised its discretion based upon an error of law or clearly erroneous factual findings." *Id.* (quoting *Novo Nordisk of N. Am., Inc. v. Genentech, Inc.*, 77 F.3d 1364, 1367 (Fed. Cir. 1996)). "To the extent a decision to grant a preliminary injunction rests on questions of law, including claim construction, our review is *de novo*." *Tate Access Floors, Inc. v. Interface Architectural Res., Inc.*, 279 F.3d 1357, 1364 (Fed. Cir. 2002) (citations omitted).

I

As a preliminary matter, we address which Celltrion arguments were resolved by this court's *SB Opinion*. First, Celltrion challenges the district court's exercise of personal jurisdiction over it. During oral argument, Celltrion conceded that the *SB Opinion* controls on this issue. Oral Arg. at 1:40–54.[1] Thus, as in the *SB Opinion*, we conclude, "based on the record and findings presented to us, that [Celltrion's] conduct satisfies the minimum-contacts requirement for personal jurisdiction in West Virginia," and the "record as a whole supports the district court's finding that [Celltrion] intends to distribute [CT-P42] nationwide, including in West Virginia." *SB Opinion*, 127 F.4th at 908.

Second, Celltrion challenges the district court's grant of a preliminary injunction. "A party may obtain a preliminary injunction by showing that (1) it is likely to succeed on the merits, (2) it is likely to suffer irreparable harm in the absence of preliminary relief, (3) the balance of equities tips in [its] favor, and (4) an injunction is in the public interest." *BlephEx, LLC v. Myco Indus., Inc.*, 24 F.4th 1391, 1398 (Fed. Cir. 2022) (internal quotation marks omitted). "A patent owner's ability to establish a likelihood of success can depend on whether the accused infringer presents an invalidity defense in opposing a preliminary injunction." *SB Opinion*, 127 F.4th at 910. Celltrion challenges the district court's conclusion that Regeneron had established a nexus between Celltrion's alleged infringement and the irreparable harm Regeneron would suffer without injunctive relief, and the district court's finding of no substantial question concerning the invalidity of the '865 patent for obviousness-type double patenting ("ODP"). As to the former, during oral argument, Celltrion conceded that the nexus issue is also controlled by the *SB Opinion*. Oral Arg. at

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[1] No. 24-2058, https://oralarguments.cafc.uscourts.gov/default.aspx?fl=24-2058_02072025.mp3.

1:40–54. Thus, we reject Celltrion's argument on the nexus issue, because Celltrion has presented no argument we have not already considered and rejected in the *SB Opinion*. *SB Opinion*, 127 F.4th at 917–19. Therefore, the only issue left to be resolved on this appeal is whether Celltrion has raised a "substantial question of invalidity."

II

Turning to the merits of this appeal, Celltrion argues that the district court erred in granting the preliminary injunction because Celltrion had raised substantial questions of invalidity of the asserted claims of the '865 patent under the ODP doctrine. We disagree on this record.

Celltrion challenges the district court's determination that the differences between the asserted claims of the '865 patent and claim 5 of U.S. Patent No. 9,340,594 ("the '594 patent") constitute a patentable distinction that precludes ODP. Specifically, the district court found the following differences: (1) the stability requirement that "at least 98% of the VEGF antagonist is present in native conformation following storage at 5° C. for two months as measured by size exclusion chromatography"; (2) the requirement that aflibercept is glycosylated; and (3) the use of a vial versus a pre-filled syringe. Celltrion also challenges the district court's determination that objective indicia support the nonobviousness of the asserted claims. During oral argument, Celltrion agreed that to succeed on this appeal it would have to show that there was at least a substantial question that none of the patentable distinctions are in fact patentable distinctions. Oral Arg at 2:15–44.[2]

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[2] The parties also dispute whether the '594 patent is a proper ODP reference patent. Because the district court did not err in determining that, on this record, Celltrion

A

One difference the district court identified was the stability of the VEGF trap described in claim 5 of the '594 patent and claim 4 of the '865 patent. Claim 5 of the '594 patent, by its dependency from claim 3, recites that the VEGF trap be "stable for at least 4 months." In comparison, claim 4 of the '865 patent, by its dependency from claim 1, recites that "at least 98% of the VEGF antagonist is present in native conformation following storage at 5° C. for two months as measured by size exclusion chromatography." The district court concluded that the 98% native conformation claim limitation is neither inherent nor obvious in the subject matter claimed in claim 5 of the '594 patent. *Celltrion Preliminary Injunction Opinion*, at J.A. 100–13. In disputing this conclusion, Celltrion raises two claim construction arguments regarding the stability limitation and an obviousness challenge. None of Celltrion's arguments are persuasive.

First, Celltrion challenges the district court's construction of "stable" in claim 5 of the '594 patent. The district court declined to construe "stable" to require "the VEGF trap protein to be in at least 98% native conformation as measured by size-exclusion chromatography ("SEC") after 2-month storage at 5 degrees C, the requirement recited in the asserted claims of the" '865 patent. *Celltrion Preliminary Injunction Opinion*, at J.A. 77–78; *see also Celltrion Preliminary Injunction Opinion*, at J.A. 79–80 ("'stable' has

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has not established that at least one claim difference between the '865 patent claims and claim 5 of the '594 patent—the stability limitation as discussed herein—is not patentably distinct, we need not reach the parties' dispute as to whether the '594 patent qualifies as a proper ODP reference patent. *See also SB Opinion*, 127 F.4th at 911.

a broader meaning than the particular SEC measurements of aggregation and threshold levels (98%) to which Celltrion attempts to limit the term."). Celltrion argues that the district court's construction "failed to consider how a [person of ordinary skill in the art] would understand the scope and meaning of the full phrase 'stable for at least 4 months,'" because "the only description of stability at four months for the claim 5 formulation is the four-month stability testing reported in Examples 3 and 4." Appellant's Br. 59. But the district court found to the contrary, concluding that the "specification of the '594 patent has numerous descriptions of stability beyond simply 98% native conformation as measured by SEC." J.A. 78. The district court observed that "'at least 90%' non-aggregated protein is preferred, thereby confirming that levels of non-aggregation below 98% in the patent's formulations are not only permissible, but desirable," J.A. 78–79 (citing '594 patent col. 6 ll. 15–25); that the '594 patent "describes multiple aspects of stability, including aggregation, deamination, and precipitation," J.A. 79 (citing '594 patent col. 5 ll. 27–34); and that the '594 patent "describes multiple ways to determine stability, including visual inspection of color and appearance, SDS-PAGE, isoelectric focusing, and SEC," J.A. 79 (citing '594 patent col. 6 ll. 42–48). The district court also supported its conclusion that "stable" in claim 5 of the '594 patent is not limited to 98% native conformation as measured by SEC by reviewing the parties' expert's testimony. *See* J.A. 80–81. None of Celltrion's arguments are persuasive given the disclosures identified by the district court. On this record, under de novo review, we agree with the district court's construction of "stable." Accordingly, we must also reject Celltrion's argument that "[c]laim 5's requirement that its formulation be 'stable for at least 4 months' expressly anticipates the stability limitations in the asserted claims [of the '865 patent]." Appellant's Br. 56.

Second, Celltrion challenges the district court's conclusion that the 98% native conformation claim limitation is not inherent in claim 5 of the '594 patent, which according to Celltrion appears to have been based on an incorrect, implicit claim construction. Appellant's Br. 60–62. The district court determined that 98% native conformation was not inherent in the compositions of claim 5 of the '594 patent because claim 5 does not "necessarily" meet the 98% native conformation limitation. J.A. 115; *see also* J.A. 108 ("Celltrion's reliance on the native conformation data in Examples 3 and 4 is legally inadequate to prove inherency. That the practice of '594 claim 5 <u>sometimes</u> results in 98% native conformation is insufficient; inherency requires that the 98% native conformation limitation be present <u>necessarily</u>, not just possibly or probably." (emphasis in original)).

Celltrion does not appear to dispute the district court's findings underpinning the district court's inherency analysis. Instead, Celltrion appears to make a claim construction argument that the asserted claims of the '865 patent "require only that the formulation be sufficiently stable so that no more than 2% of whatever un-aggregated VEGF antagonist is present prior to storage aggregate[s] during the claimed storage period." Appellant's Br. 62. According to Celltrion, the "common knowledge" of a person of ordinary skill in that art "and the intrinsic evidence make clear that" the "at least 98%" limitation in the '865 patent "defines a rate of aggregation over a particular time, under particular conditions." Appellant's Br. 57. We disagree.

Celltrion's argument contradicts the plain claim language, which states that "at least 98% of the VEGF antagonist *is present* in native conformation following storage . . . for two months" as measured by SEC. '865 patent claim 1 (emphasis added). Nothing in the claims or specification suggests that a "rate" must be calculated. Rather, the claim states that after two months, the formulation is measured by SEC, and the result is either above 98%—

within the scope of the claim—or below 98%—outside the scope of the claim. On this record and even under de novo review of the claim construction issue, we discern no error in the district court's analysis.

Third, Celltrion challenges the district court's finding that "the 98% native conformation limitation would not have been obvious." J.A. 113. In finding that the 98% native conformation limitation would not have been obvious, the district court relied on expert testimony to conclude that a person of ordinary skill in the art "beginning with claim 5 of the '594 patent would not have been motivated to achieve the 98% native conformation limitation and would not have had a reasonable expectation of achieving that level of native conformation after two-months' storage." J.A. 112. We discern, on this record, no clear error in the district court's finding.

For these reasons, we agree with the district court's conclusion that Celltrion did not raise a substantial question of validity based on the stability limitation. As we explained in the *SB Opinion*, it suffices for us to conclude that one claim difference—the stability limitation—renders claim 5 of the '594 patent patentably distinct from the asserted claims of the '865 patent. *SB Opinion*, 127 F.4th at 913.

B

While we need not address Celltrion's remaining arguments to resolve the ODP issue, we briefly address one of Celltrion's glycosylation arguments and arguments made at oral argument.

Claim 1 of the '865 patent requires the VEGF trap to be glycosylated, while the district court construed claim 5 of the '594 patent to include both glycosylated and non-glycosylated aflibercept. J.A. 85–88. One of Celltrion's arguments is that claim 5 of the '594 patent anticipates the asserted claims of the '865 patent because claim 5 covers a

genus that includes only two species—glycosylated and non-glycosylated. The district court rejected Celltrion's argument "[b]ecause aflibercept has five distinct glycosylation sites," "there are at least thirty possible glycosylated forms of aflibercept . . . in addition to the nonglycosylated form." J.A. 90.[3] For the purposes of anticipation, the district court concluded that this was not a "very small genus." J.A. 90 (cleaned up). During oral argument, Regeneron's counsel agreed that while for the purposes of the preliminary injunction, the district court concluded that this was not a very small genus, Celltrion will have the opportunity to fully develop the question about the size of the genus disclosed in the '594 patent as the case progresses. However, given that our identification of one patentably distinct limitation is enough (the stability limitation), we need not reach the merits of Celltrion's challenges regarding the glycosylation limitation. *See SB Opinion*, 127 F.4th at 913; Oral Arg. at 27:10–17 (Regeneron's counsel confirming that if we affirm the district court's finding on the stability limitation, then it would end the appeal).

CONCLUSION

We have considered Celltrion's remaining arguments and find them unpersuasive. For the foregoing reasons, we affirm the district court's grant of a preliminary injunction.

AFFIRMED

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[3] During oral argument, Regeneron's counsel stated that for the purposes of this inquiry, the "genus" here is thirty-two possible forms of aflibercept, thirty-one of which would be glycosylated. Oral Arg. at 28:32–42.