NOTE: This disposition is nonprecedential.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., CELLTRION, INC., SAMSUNG BIOEPIS CO., LTD., AMGEN INC.,
Defendants

FORMYCON AG,
Defendant-Appellant

2024-2009, 2024-2019, 2024-2156

Appeals from the United States District Court for the Northern District of West Virginia in Nos. 1:22-cv-0006l - 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: January 29, 2025

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

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SHAUN VAN HORN, Fish & Richardson P.C., Minneapolis, MN, argued for defendant-appellant. Also represented by LOUIS FOGEL, SARAH JACK; NITIKA GUPTA FIORELLA, ROBERT M. OAKES, Wilmington, DE.

Before MOORE, *Chief Judge*, REYNA and TARANTO, *Circuit Judges*.

TARANTO, *Circuit Judge.*

Appellant Formycon AG appeals a preliminary injunction that bars it—in the absence of a license from Regeneron Pharmaceuticals, Inc. to Regeneron's U.S. Patent No. 11,084,865–from marketing its biologic product approved by the Food and Drug Administration (FDA) as a biosimilar to Regeneron's FDA-approved aflibercept biologic product, EYLEA®. The district court's June 21, 2024 confidential opinion granting preliminary-injunctive relief is at J.A. 1–203, and the public version is available at *In re Aflibercept Patent Litigation*, No. 1:24-MD-3103-TSK, 2024 WL 3423047 (N.D. W. Va. July 9, 2024) (*Formycon D. Ct. Opinion*). The preliminary injunction itself, issued July 10, 2024, is at J.A. 204–06 (*Formycon Prelim. Inj.*). We affirm.

Today we also reject a challenge by Samsung Bioepis Co., Ltd. (SB) to a very similar preliminary injunction issued by the same district court against SB almost simultaneously with the injunction issued against Formycon. We affirm the preliminary injunction against SB in *Regeneron*

Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc., Fed. Cir. Nos. 2024-1965, -1966, -2082, -2083 (Fed. Cir. Jan. 29, 2025) (hereafter *SB Fed. Cir. Decision*). Because of the substantial overlap in facts, district-court analyses, and arguments in the Formycon and SB appeals, which were orally argued together to this panel, the present opinion avoids full repetition of common matter. For arguments made by Formycon here but already addressed in the *SB Fed. Cir. Decision*, we rely on that decision.

I

A

Regeneron holds Biologics License Application No. 125387—approved by the FDA—for EYLEA®, a therapeutic product that contains the fusion protein aflibercept and that is administered by injection into the vitreous body inside the eye. EYLEA® is used for the treatment of several angiogenic eye diseases due to aflibercept's ability to bind, or "trap," vascular endothelial growth factor (VEGF), a protein that stimulates blood vessel growth and, in some cases, overgrowth. In June 2023, Formycon AG filed abbreviated Biologics License Application (aBLA) No. 761378 with the FDA, seeking approval under the Biologics Price Competition and Innovation Act (BPCIA) to market "FYB203," its EYLEA® biosimilar. *See* 42 U.S.C. § 262(k)–(l). The FDA approved Formycon's aBLA on June 28, 2024.

Regeneron owns a family of ten patents that claim priority to a patent application filed in 2007. The patents in that Stability Family include both the '865 patent and another patent of relevance here, U.S. Patent No. 9,340,594, which share a specification that includes eight examples of VEGF-trap formulations, with stability data for each formulation. *See*, *e.g.*, '865 patent, col. 8, line 32, through col. 12, line 27. Examples 3 and 4 describe the formulation of EYLEA®. *Id.*, col. 9, line 19, through col. 10, line 12.

Starting in late 2022, Regeneron brought several infringement actions against aBLA applicants pursuant to the BPCIA, *see* 42 U.S.C. § 262(l)(6)(B), (l)(9)(A), seeking judgments of patent infringement under § 271(e) as well as declaratory judgments of patent infringement under 35 U.S.C. §§ 271(a)–(c) and (g). Regeneron began with Mylan Pharmaceuticals Inc., the earliest of the aBLA applicants, which Regeneron sued in the Northern District of West Virginia, where Mylan is incorporated. Regeneron then sued other, later aBLA applicants in West Virginia as well, including SB and Formycon near the end of 2023. As relevant here, Regeneron sought preliminary injunctions against SB and Formycon, relying on the '865 patent.

Representative claim 4 of the '865 patent and the claims on which it depends state as follows:

> 1. A *vial* comprising an ophthalmic formulation suitable for intravitreal administration that comprises:
>
> a vascular endothelial growth factor (VEGF) antagonist[,]
>
> an organic co-solvent,
>
> a buffer, and
>
> a stabilizing agent,
>
> wherein said VEGF antagonist fusion protein is *glycosylated* and comprises amino acids 27-457 of SEQ ID NO:4; and
>
> wherein *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 *vial* of claim 1, wherein the concentration of said VEGF antagonist fusion protein is 40 mg/ml, and wherein said organic co-solvent comprises polysorbate.
>
> . . .

> 4. The *vial* of claim 2, wherein said organic co-solvent comprises about 0.03% to about 0.1% polysorbate 20.

'865 patent, col. 19, lines 29–48 (emphases added).

Also relevant here is the '594 patent, which expired in 2021 (due to a terminal disclaimer) and which Formycon has invoked as the basis for its argument that the asserted '865 patent claims are invalid under the doctrine of obviousness-type double patenting (ODP). Claim 5, which the parties view as representative for purposes of the ODP analysis, and the claims on which it depends state as follows:

> 1. A *pre-filled syringe* suitable for intravitreal administration comprising a 1 mL luer glass syringe fitted with a plunger and a *stable* ophthalmic formulation of a *vascular endothelial growth factor (VEGF) trap*, which consists of (i) a receptor component consisting essentially of an immunoglobulin-like domain 2 of a first VEGF receptor and an immunoglobulin-like domain 3 of a second VEGF receptor, and (ii) a multimerizing component, wherein the *stable* ophthalmic formulation comprises:
>
> (a) 1-100 mg/ml [of] a VEGF antagonist;
>
> (b) 0.01-5% of one or more organic co-solvent;
>
> (c) 5-40 mM of buffer; and
>
> (d) optionally comprising 1.0-7.5% of a stabilizing agent.
>
> 2. The *pre-filled syringe* of claim 1, wherein the first VEGF receptor is Flt1, and the second VEGF receptor is Flk1 or Flt4.
>
> 3. The *pre-filled syringe* according to claim 2, wherein the *VEGF trap* is *stable* for at least 4 months.

> 4. The *pre-filled syringe* according to claim 3, wherein the *VEGF trap* consists of amino acids 27-457 of SEQ ID NO:4.
>
> 5. The *pre-filled syringe* according to claim 4, wherein the *stable* ophthalmic formulation comprises 40 mg/mL of the *VEGF trap*, 10 mM phosphate, 40 mM NaCl, 0.03% polysorbate 20, 5% sucrose, at pH 6.2-6.4.

'594 patent, col. 19, line 22, through col. 20, line 24 (emphases added).

B

Formycon is a biopharmaceutical company based in Bavaria, Germany. Formycon declares that it has no "direct" ties to West Virginia: It is not registered to do business there; has not appointed an agent for service of process there; has no assets or employees there; has not previously been sued there; and has not developed, manufactured, or packaged its drugs there. J.A. 26120 ¶ 15. Formycon's EYLEA® biosimilar, FYB203, will not be manufactured or prepared for commercial sale there either: Formycon has contracted for the manufacture of FYB203 in Washington and California, and for the packaging and labeling of the drug in another State. J.A. 26118 ¶¶ 5–7.

Formycon developed FYB203 pursuant to a development and licensing agreement (Licensing Agreement) with another German company, Klinge Biopharma GmbH.[1] J.A. 26117 ¶ 2; J.A. 26172–212; J.A. 26264–78. Formycon declares that, under that agreement, Formycon has no plans or rights to itself commercialize (market and

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[1] Formycon initially entered the Licensing Agreement with Santo Holding Deutschland GmbH in 2015, and Klinge assumed Santo's rights and obligations under that contract in 2020.

distribute, to use Formycon's public language) FYB203 in the United States. J.A. 26119–20 ¶¶ 9, 13. Rather, Formycon will sell FYB203 to another company (yet to be selected at the time Regeneron sued), which will commercialize the drug in the United States—including in West Virginia. J.A. 26119 ¶ 9; J.A. 26337; J.A. 26258–60; Appellant's Br. at 6, 28; Oral Arg. at 15:04–15, 17:29–39.[2] Formycon declares that it has no control over the selection of that marketer/distributor or over that company's decisions regarding how to commercialize FYB203 in the United States. J.A. 26119–20 ¶¶ 11, 13.

Formycon's involvement, however, does not terminate after its sale of FYB203 to the commercializing company. Formycon will sign a manufacturing and supply agreement (Supply Agreement) with that company, under which Formycon will supply FYB203 to it for sale in the United States, including in West Virginia. J.A. 26119 ¶ 12; J.A. 26337; J.A. 26258–60; J.A. 26343–74. The various contracts, including the Licensing and Supply Agreements, provide Formycon with continuing rights and responsibilities regarding FYB203, including regular meetings and phone calls with a partner regarding commercialization of FYB203; liability for drug manufacture, technical release, packaging, and testing; audits of a partner's books and records; the receipt of royalty payments based on aggregate net sales; and mutual agreement on a launch date for FYB203, among others. J.A. 26118–19 ¶¶ 8, 12; J.A. 26184–88; J.A. 26350; J.A. 26271–72; J.A. 26226–40, 26246–49, 26252–53.

Formycon filed an aBLA with the FDA in June 2023, seeking approval to market FYB203 under the BPCIA, 42 U.S.C. § 262(k)–(l). J.A. 26156–68. As statutorily required prior to marketing of the biosimilar, Formycon sent a

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[2] Available at https://oralarguments.cafc.uscourts.gov/default.aspx?fl=24-2009_12052024.mp3.

Notice of Commercial Marketing to Regeneron, which states: "As the subsection (k) applicant, Formycon AG hereby provides notice of its intent to begin commercial marketing of its biosimilar product FYB203 (aflibercept), as described in aBLA No. 761378, after FDA's licensure to do so." J.A. 26170; 42 U.S.C § 262(l)(8)(A). The FDA approved Formycon's aBLA on June 28, 2024.

C

Among other proceedings, Regeneron filed a motion for a preliminary injunction in February 2024. The district court granted the motion and enjoined Formycon from offering for sale or selling any product approved under its aBLA in the United States without a license from Regeneron. The district court, relying on *Acorda Therapeutics Inc. v. Mylan Pharmaceuticals Inc.*, 817 F.3d 755 (Fed. Cir. 2016), first determined that it had personal jurisdiction over Formycon. *Formycon D. Ct. Opinion*, at *2, *8–10. It then concluded that Regeneron had satisfied all the preliminary injunction factors: (1) Regeneron was likely to succeed on its infringement claim and Formycon had failed to raise a substantial question of invalidity due to ODP or lack of written description, *id.* at *17–40; (2) Regeneron had demonstrated that it was likely to suffer irreparable harm without injunctive relief, *id.* at *40–54; (3) the balance of hardships favored Regeneron, *id.* at *54–56; and (4) the public interest favored the grant of preliminary injunction, *id.* at *56–57.

On July 10, 2024, the district court issued the preliminary injunction itself. *Formycon Prelim. Inj.* The court enjoined Formycon and any and all business partners "from offering to sell or selling within the United States without a license from Regeneron of any product that is the subject of BLA No. 761378." *Id.* at 1.

Formycon timely appealed, first from the June 21, 2024 opinion, then from the July 10, 2024 order. We have jurisdiction under 28 U.S.C. § 1292(c)(1).

II

Like SB, Formycon makes two sets of arguments on appeal. First, Formycon challenges the district court's exercise of personal jurisdiction over it. Second, Formycon argues that the district court erred in granting the preliminary injunction because Formycon had raised substantial questions of invalidity of the asserted claims of the '865 patent (under the ODP doctrine and for inadequate written description), and because Regeneron had failed to establish a causal nexus between Formycon's infringement and the irreparable harms the district court found Regeneron would suffer without injunctive relief. We consider and reject each argument in turn. We do not repeat here, but incorporate by reference, the recitation of the legal standards (including standards of review) set out in our opinion today in *SB Fed. Cir. Decision*.

III

Regarding personal jurisdiction, the record as a whole reliably shows Formycon's plan to market FYB203 in West Virginia, and in other States. *See SB Fed. Cir. Decision*, at Part II (discussing in further detail the significance of this evidence). Formycon filed an aBLA with the FDA, seeking approval of its proposed drug, and served Regeneron with a Notice of Commercial Marketing—neither of which exclude regions of the United States from the areas in which FYB203 will be marketed. J.A. 26156–68; J.A. 26170. Formycon has also engaged companies to manufacture, package, and label its product for sale in the United States.[3] J.A. 26118 ¶¶ 5–7. In addition, Formycon has

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[3] Formycon contended at oral argument that many biosimilars do not launch and do not ultimately sell in all the States, and thus that the use of potential future sales as a hook runs afoul of the requirements for personal

taken concrete steps to establish a distribution channel through which to commercialize FYB203 in the United States, with no basis whatever for inferring that West Virginia will not be included. Formycon repeatedly asserts that it has no control over Klinge's selection of the marketer/distributor or the marketer/distributor's commercialization activity in the United States, but the record adequately supports the district court's contrary finding that Formycon intends to market, sell, and distribute FYB203 in West Virginia through the marketer/distributor. As the district court found, Formycon plans to enter into the Supply Agreement with that entity, under which Formycon will provide it with FYB203 for sale, and that entity will sell FYB203 in West Virginia (and elsewhere). *See Formycon D. Ct. Opinion*, at *2–3, *10; J.A. 26118–19 ¶ 8; J.A. 26337 (showing a map of markets where the marketer/distributor "will" target "key Eylea stakeholders," including West Virginia); J.A. 26258–60; Oral Arg. at 15:04–15, 17:29–39 (agreeing that FYB203 will be marketed in the United States at large and not denying that this includes West Virginia); *see also* J.A. 26184–88; J.A. 26350; J.A. 26271–72; J.A. 26226–40, 26246–49, 26252–53 (providing for Formycon's continued involvement with the activities of Klinge and the marketer/distributor via contractual mechanisms).

On this record as a whole, we see no result-altering distinction between Formycon's and SB's situations and no basis for disturbing the district court's findings relevant to

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jurisdiction. Oral Arg. at 16:44–58. Given the prospective nature of the relief sought (injunctive relief), the nature of the claim asserted (under 35 U.S.C. § 271(e)), and the evidence in the record (uniformly indicating a current intent to sell across the United States), we do not find this argument persuasive. *See Acorda*, 817 F.3d at 759–62.

personal jurisdiction or its conclusion that it has personal jurisdiction over Formycon in the present case.

IV

We also conclude that Formycon has not raised a substantial question of invalidity of the representative claim 4 of the '865 patent under the ODP doctrine or for lack of an adequate written description, and that the district court did not err in determining that Regeneron established a causal nexus.

A

Regarding ODP, Formycon, like SB, challenges the district court's determinations that three limitations of claim 4 of the '865 patent (actually, in claim 1, on which claim 4 depends) are likely to render the claim patentably distinct from claim 5 of the '594 reference patent: (1) the particular stability requirement, "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 the VEGF antagonist is "glycosylated"; and (3) the use of a vial, rather than a pre-filled syringe. Appellant's Br. at 34–44. Formycon, like SB, also argues that the district court erred in finding the objective indicia to support nonobviousness. *Id.* at 45–47. And Regeneron, here as in the SB appeals, contends that the '594 patent is not a proper reference patent for ODP purposes in the first place. Appellee's Br. at 34–39. In our *SB Fed. Cir. Decision*, at Part III.A, we agreed with the district court on the first two limitations, and that agreement sufficed to affirm the district court's ruling on the ODP defense without our reaching the other issues. We do the same here. We do not repeat our discussion of points made by Formycon in a manner not materially distinguishable from SB's arguments.

1

Formycon's only argument arguably falling outside the category with respect to the 98% native conformation limitation is its argument that the limitation is inherent in the "stable" limitation of claim 5 of the '594 reference patent.[4] But given that Formycon does not challenge the district court's claim construction, this argument must fail. The district court construed the "stable" limitation in claim 5 to be broader than the '865 patent's requirement of 98% native conformation. *Formycon D. Ct. Opinion*, at *26–28. Formycon has not shown how the latter is "necessarily present" in the former, broader limitation (which does not refer to a 98% level defined by native conformation and measured in a particular way). *See Allergan, Inc. v. Apotex Inc.*, 754 F.3d 952, 958 (Fed. Cir. 2014); *Par Pharmaceutical, Inc. v. TWi Pharmaceuticals, Inc.*, 773 F.3d 1186, 1195–96 (Fed. Cir. 2014).

Formycon argues for inherency on the ground that the "native conformation" limitation in the '865 patent and the "stable" limitation in the '594 patent both refer "not [to] the starting point . . . but [to] the amount of change in the percentage of native conformation after [the] period of time" specified in the claims. Appellant's Br. at 41. But this is necessarily a claim-construction assertion, yet Formycon presents no claim-construction analysis to support it—reflecting Formycon's insistence that it does not challenge the district court's claim construction. *Id.* at 34. The point is forfeited, and we see no basis for excusing the forfeiture, as a substantial argument would be needed to overcome the apparent meaning of the claim language on its face, which requires that "at least 98% of the VEGF antagonist

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[4] Formycon makes an obviousness argument that is concededly new on appeal and is therefore forfeited. *See* Appellant's Br. at 43; *In re Google Technology Holdings LLC*, 980 F.3d 858, 863 (Fed. Cir. 2020).

is present in native conformation following storage . . . for two months,"—a reference simply to a property at that time—without calling for a comparison to an earlier time. '865 patent, col. 19, lines 38–40 (emphasis added).

For those reasons, we see no reversible error in the district court's rejection of the ODP challenge based on the 98%-native-conformation limitation. As we explained in *SB Fed. Cir. Decision*, at Part III.A.1, that conclusion suffices, even by itself, to reject the ODP challenge.

2

Nevertheless, as in the SB decision, *see id.* at Part III.A.2, we address the requirement of claim 4 of the '865 patent that the VEGF trap be "glycosylated" as an additional ground for rejecting an ODP conclusion. The district court held this requirement to be an additional basis for a conclusion of patentable distinctness, defeating the ODP challenge. *Formycon D. Ct. Opinion*, at *28–32. Formycon adds some arguments to those presented by SB on this point. We find these arguments unavailing.

Formycon first argues that glycosylated aflibercept is not only obvious, but also anticipated, because "aflibercept can exist in either of two states—glycosylated or not." Appellant's Br. at 35. Thus, Formycon contends that a relevant artisan reading the reference claim would understand it to present a "binary choice between just two species and would immediately envisage both options." *Id.* (citing *AbbVie Inc. v. Mathilda & Terence Kennedy Institute of Rheumatology Trust*, 764 F.3d 1366, 1379 (Fed. Cir. 2014) ("When a genus is so limited that a person of ordinary skill in the art can at once envisage each member of this limited class, a reference describing the genus anticipates every species within the genus." (cleaned up))). We disagree that the genus at issue is so limited as to come within the invoked anticipation standard. The specification of the '865 patent discloses five potential glycosylation sites, meaning that "there are at least thirty possible glycosylated forms

of aflibercept . . . in addition to the nonglycosylated form," as Formycon's expert testified. *Formycon D. Ct. Opinion*, at *29; J.A. 25585 at 130:21–131:8. The district court correctly observed that "[t]his is not a 'very small genus' for purposes of a finding of anticipation." *Formycon D. Ct. Opinion*, at *29 (quoting *Atofina v. Great Lakes Chemical Corp.*, 441 F.3d 991, 999 (Fed. Cir. 2006)).

Formycon next addresses obviousness, contending that the district court clearly erred in finding no motivation to pursue glycosylated aflibercept. Appellant's Br. at 37; *see Formycon D. Ct. Opinion*, at *30–32. We reject each of Formycon's four arguments on this score, and we see no clear error in the district court's finding.

First, Formycon challenges the district court's finding that a relevant artisan would deem glycosylation undesirable because it increases the size of the protein and thus reduces its ability to penetrate into the retina, which is important for the desired therapeutic effect. Appellant's Br. at 37–38. Formycon states that non-glycosylated aflibercept is already above the "retinal exclusion limit" and the glycosylated version is only "slightly" larger. *Id.* at 38. But Formycon has not pointed to evidence to suggest that protein size above the specified limit would cease to matter to a relevant artisan. At least without such evidence, the district court did not clearly err in finding that a relevant artisan would be motivated to minimize protein size in pursuit of greater retinal penetration and lower systemic exposure and inflammation risk. *Formycon D. Ct. Opinion*, at *30; *see also* J.A. 837–38 ¶¶ 376–79; J.A. 1462, 1467; J.A. 1998–99 ¶¶ 38, 43.

Second, Formycon challenges the district court's finding that a relevant artisan would have been motivated to pursue non-glycosylated aflibercept, which has a shorter half-life and thus diminishes undesirable effects of extended trapping of VEGF outside the eye (systemic exposure). Appellant's Br. at 38–39. Formycon argues that the

half-life would not have mattered to a relevant artisan given the small amount of the medicine used in the ophthalmic context. *Id.* In finding that a shorter half-life was desirable, the district court relied on expert testimony, as well as prior art indicating that systemic exposure was a concern regarding intravitreally injected drugs and anti-VEGF agents. *Formycon D. Ct. Opinion*, at *31; *see also* J.A. 838 ¶ 379 (Trout declaration); J.A. 1467 (Gaudreault); J.A. 1999 ¶ 43 (Daly). We discern no clear error in the district court's finding.

Third, Formycon challenges the district court's finding that a relevant artisan would have been deterred from pursuing glycosylation due to evidence that it might lead to inflammation. Appellant's Br. at 39. Formycon argues that the prior-art reference cited by the district court suggests that a skilled artisan would have been motivated to modify the level of glycosylation, not to avoid glycosylation altogether. *Id.* The reference in question, however, states that mutant cell lines may be used, "which either eliminate glycosylation *or* modify the extent of glycosylation." J.A. 1998 ¶ 38 (emphasis added). Based on this reference and expert testimony, there is no clear error in the district court's finding that a relevant artisan would avoid glycosylation to minimize the risk of inflammation—"an extremely concerning phenomenon for any intravitreal drug product to exhibit." *Formycon D. Ct. Opinion*, at *31.

Fourth, Formycon argues that the district court discounted the evidence about the benefits of glycosylation—specifically, improvement of binding activity and stability. Appellant's Br. at 39–40. But the district court was entitled to weigh the evidence as it did. As to binding activity, the district court noted the lack of prior-art support for Formycon's position and credited Regeneron's unrebutted expert testimony that glycosylated and non-glycosylated aflibercept are comparable in this respect. *Formycon D. Ct. Opinion*, at *31. As to stability, the district court noted that Formycon's expert did not present any prior art

comparing the stability of glycosylated and non-glycosylated aflibercept and that the '594 reference patent claims recite that the VEGF trap is already "stable for at least 4 months" without glycosylation, which suggests a lack of motivation to pursue additional stability. *Id.* at *32.

Based on all the above reasons, we affirm the district court's finding that, "[c]umulatively, the evidence sufficiently points against a motivation to glycosylate." *Id.*

B

Formycon argues, contrary to the district court's determination, *id.* at *38–40, that it raised a substantial question of invalidity for lack of written description for the "at least 98% . . . native conformation" requirement. Appellant's Br. at 47–50. We see no material difference between Formycon's arguments and those presented by SB, which we have today held unpersuasive. *See SB Fed. Cir. Decision*, at Part III.B.

C

Formycon argues that the district court erred in finding, *see Formycon D. Ct. Opinion*, at *52–53, that Regeneron had established a causal nexus between the infringement and the irreparable harm the court found Regeneron would suffer without injunctive relief. Appellant's Br. at 50–51. On this issue, too, Formycon has presented no argument we have not already considered and rejected in the SB decision. *See SB Fed. Cir. Decision*, at Part III.C.

V

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

AFFIRMED