Nos. 24-1965, 24-1966, 24-2082, 24-2083

In the 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., FORMYCON AG, AMGEN INC.,
Defendants,

SAMSUNG BIOEPIS CO., LTD.,
Defendant-Appellant,

Appeal from the United States District Court for the Northern District of West Virginia in No. 1:24-md-3103-TSK, Chief Judge Thomas S. Kleeh

NONCONFIDENTIAL BRIEF OF APPELLEE REGENERON PHARMACEUTICALS, INC.

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U.S. Patent 11,084,865, Claim 4

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.

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Confidential Material Omitted

Pursuant to Fed. Cir. R. 25.1(e)(1)(B), the material omitted on pages 15, 16, 18, 22-24, 26-30, 54, and 68 relates generally to information SB has deemed confidential relating to (1) commercialization plans for its proposed biosimilar product, and (2) data from SB's regulatory application concerning its proposed biosimilar product. Regeneron has no objection to the public

disclosure of this information and has not redacted any of its own confidential information.

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STATEMENT OF RELATED CASES

Regeneron Pharmaceuticals, Inc. ("Regeneron") filed several suits in the Northern District of West Virginia, *see Regeneron Pharm., Inc. v. Mylan Pharm. Inc.*, No. 1:22-cv-61 (N.D.W. Va.); *Regeneron Pharm., Inc. v. Samsung Bioepis Co., Ltd.*, Nos. 1:23-cv-94, 1:23-cv-106 (N.D.W. Va.); *Regeneron Pharm., Inc. v. Formycon AG*, No. 1:23-cv-97 (N.D.W. Va.); *Regeneron Pharm., Inc. v. Celltrion, Inc.*, Nos. 1:23-cv-89, 1:24-cv-53 (N.D.W. Va.). Regeneron also filed suit in the Central District of California, *Regeneron Pharm., Inc. v. Amgen, Inc.*, No. 2:24-cv-264 (C.D. Cal.), and the Judicial Panel on Multidistrict Litigation transferred the action to the Northern District of West Virginia, *Regeneron Pharm., Inc. v. Amgen, Inc.*, No. 1:24-cv-39 (N.D.W. Va.), and instituted a multidistrict litigation incorporating each of the aforementioned actions, *In re Aflibercept Patent Litigation*, No. 1:24-md-3103 (N.D.W. Va.). In January 2024, the parties to the *Mylan* litigation filed protective appeals to this Court, which ultimately dismissed the appeals. *Regeneron Pharm., Inc. v. Mylan Pharm. Inc.*, Nos. 2024-1402, 2024-1405 (Fed. Cir.).

Mylan has appealed from a judgment after a bench trial that it infringes U.S. Patent 11,084,865 ("'865 patent"), at issue here, and that the '865 patent

is not invalid. *Regeneron Pharm., Inc. v. Mylan Pharm. Inc.*, No. 2024-2002 (Fed. Cir.). Formycon AG and Celltrion, Inc. have each appealed from decisions of the District Court for the Northern District of West Virginia issuing preliminary injunctions based on the '865 patent. *Regeneron Pharm., Inc. v. Mylan Pharm. Inc.*, Nos. 2024-2009, 2024-2019, 2024-2156 (Fed. Cir.) (Formycon); *Regeneron Pharm., Inc. v. Mylan Pharm. Inc.*, Nos. 2024-2058, 2024-2147 (Fed. Cir.) (Celltrion). Each of the above-listed cases may affect or be affected by this Court's decision in the pending appeal.

STATEMENT OF THE ISSUES

1. Whether Regeneron established at least a reasonable probability of success on the question of personal jurisdiction, where SB: (i) took the costly and significant step of applying to FDA for approval to market SB15 throughout the U.S., including West Virginia, and (ii) engaged in additional acts demonstrating an intent to market throughout the U.S., including West Virginia.

2. Whether the district court's multiple factual findings underlying its conclusion that Defendant-Appellant failed to show a substantial question of obviousness-type double patenting were all clearly erroneous.

3. Whether the district court abused its discretion in holding that Defendant-Appellant failed to show a substantial question of written description.

4. Whether the district court abused its discretion in holding there was sufficient nexus to the irreparable harm that Defendant-Appellant's infringement would cause to Regeneron.

STATEMENT OF THE CASE

I. Introduction

Samsung Bioepis ("SB") attacks the district court's preliminary injunction without challenging the factual and legal findings that mandate affirmance. SB now acknowledges what it fiercely disputed below: that it infringes Regeneron's '865 patent. It likewise no longer disputes the previously contested issues central to its primary invalidity defense of obviousness-type double-patenting, including the meaning of the reference claim and asserted claims and the absence of inherent anticipation, motivation, or expectation of success. Nor does SB any longer dispute that its launch of a biosimilar product would harm Regeneron irreparably in multiple ways. SB abandons those arguments for good reason: the district court's thorough, exhaustive, and resounding rejection of SB's case is impervious to attack on the governing, deferential standard of review.

SB's appeal therefore presents the flotsam and jetsam of its failed case below: personal jurisdiction, double patenting, written description, and irreparable harm nexus arguments that it can advance only by ignoring this Court's controlling precedents and the district court's unchallenged and outcome-determinative factual findings. SB asks this Court to abrogate its

role as an appellate body that reviews preliminary injunctions deferentially, discard its repeated legal pronouncements and fabricate new bases for defeating jurisdiction and validity, and make factual findings that defy both the district court's reasoned conclusions and the clear—and often undisputed—record evidence. The Court should decline the invitation and affirm the preliminary injunction.

II. Background

This case concerns Regeneron's patent covering Eylea®. Regeneron invented and markets Eylea, an ophthalmic drug product containing the fusion protein aflibercept that is approved to treat the most common causes of blindness. Appx1-2. Regeneron discovered that aflibercept, although originally developed as a cancer therapeutic, could be used to treat eye disorders associated with angiogenesis, or uncontrolled blood vessel growth in the retina, by blocking the activity of a protein called VEGF. Appx2. Eylea is administered by intravitreal injection into the vitreous of a patient's eye. *Id.*

Eylea ultimately became the "gold standard of care" for treating ophthalmic disorders associated with angiogenesis. Appx2-3. In contrast to "the many clinical failures Regeneron had experienced during its decades of existence" as a research-driven biotechnology company, the claimed

composition—"40 mg/ml of aflibercept, with polysorbate 20, a buffer, and a stabilizing agent" "became the leading medicine in its class and a revolutionary treatment for treating angiogenic eye disorders." *Regeneron Pharm. v. Mylan Pharm.*, 2024 WL 382495, at *60 (N.D.W. Va. Jan. 31, 2024) ("*Mylan*").

A. Patent-in-Suit

At trial against Mylan and then in the subsequent preliminary injunction proceedings, Regeneron asserted the '865 patent. The '865 patent is directed to ophthalmic formulations of aflibercept, the fusion protein identified in the patent as a specific "VEGF antagonist" or "VEGF Trap." Appx187, 2:27-36. Fusion proteins are created by fusing domains from different proteins into a single, non-naturally-occurring molecule. Appx1963-1964; Appx103-104.

The patent teaches that the "VEGF antagonist" "may be modified post-translationally" and "[i]n a specific embodiment, the fusion protein comprises amino acids 27-457 of SEQ ID NO:4 and is glycosylated at [asparagine] residues 62, 94, 149, 222, and 308." Appx189, 6:34-39. Glycosylation refers to the attachment of sugar groups ("glycans") to certain amino acid residues, which increases the protein's size and may affect its properties. Appx1970, ¶ 105; *Mylan*, 2024 WL 382495, at *55. The glycosylated fusion protein

comprising "amino acids 27-457 of SEQ ID NO:4" is now called aflibercept and is required in each asserted claim.

The asserted claims—4, 7, 9, 11, 14-17, and 55—are directed to ophthalmic formulations comprising a specific concentration (40 mg/mL) of glycosylated aflibercept, an "organic co-solvent," a "buffer," and a "stabilizing agent," and a specific type of stability: "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." Illustrative Claim 4 recites:

> 1. A vial comprising an ophthalmic formulation suitable for intravitreal administration that comprises:
>
> a [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.

Appx196. Asserted claim 14 additionally recites that the VEGF antagonist "is glycosylated at asparagine residues corresponding to asparagine residues 62, 94, 149, 222 and 308 of SEQ ID NO: 4."

The protein's "native conformation" refers to "the original intact form of the VEGF antagonist, which is a form that does not exhibit chemical or physical instability." Appx20 (quoting *Mylan*, 2024 WL 382495, at *17). Proteins not in their native conformation can aggregate, reducing the protein's therapeutic activity and potentially leading to severe problems such as inflammation or an adverse immune response. Appx110; *Mylan*, 2024 WL 382495, at *27. The patent teaches that the protein preferably is "[s]ubstantially free of aggregates," which "means that at least 90% of the weight of fusion protein is not present in an aggregate at the time the fusion protein is used to prepare the pharmaceutically effective formulation." Appx189, 6:50-55.

The ’865 patent describes eight working examples of aflibercept formulations, varying in their ingredients and/or container systems. In each example, the formulations were evaluated for “visual appearance,” “turbidity” (cloudiness), pH, “% VEGF Trap Recovered,” and “% VEGF Trap Native Configuration” over time. *E.g.*, Appx190, 8:45-57. As relevant here, the reported “native configuration” (undisputedly synonymous with “native conformation,” Appx15154, 193:10-23; Appx20203, 13:7-8) in each example over 2-3 months is summarized below:

Example	**Native Conformation**	**Time (months)**
1	98.7	3
2	98.5	3
3	99.2	2
4	99.1	2
5	99.2	2
6	99.1	3
7	99.3	2
8	98.9	2

Appx190-192, 8:32-12:25. Thus, over this time period, the native conformations varied from 98.5% to 99.3%.

Examples 1-6 describe liquid formulations of aflibercept, while Examples 7-8 describe lyophilized (freeze-dried) formulations. Appx113-114. Examples 3 and 4 disclose the liquid formulation having the same components as the formulation now marketed as Eylea: “40 mg/ml VEGF Trap (SEQ ID

NO:4), 10 mM phosphate, 40 mM NaCl, 0.03% polysorbate 20, 5% sucrose." Appx191, 9:24-26.

B. Prosecution History

1. The '865 patent issued in 2021 from a continuation application claiming priority to a provisional application filed June 16, 2006 and a nonprovisional application filed June 14, 2007. Appx187, 1:35-38. The '865 patent has several parent patents. Appx187, 1:8-39. As relevant here, those parents include U.S. Patent 9,340,594, which shares the same inventors and specification as the '865 patent.

During prosecution of the '865 patent, the examiner rejected the claims for obviousness-type double patenting ("ODP") over several purported references, including the '594 patent. Appx4108. Regeneron responded that unlike the claims of the '594 patent, "[a]ll the independent claims include an element relating to the stability of the protein conformation in storage over a period of time." Appx4113; *see* Appx4117. The examiner thereafter withdrew the ODP rejection and allowed the claims. Appx4124.

2. The '594 patent claims the same priority date as the '865 patent and thus ordinarily would expire on the same day, June 14, 2027. Due to a chain of terminal disclaimers, however, the term of the '594 patent beyond

2021 was disclaimed. Specifically, the '594 patent is terminally disclaimed to U.S. Patent 7,608,261, which is in the same family as the '865 and '594 patents. The '261 patent is terminally disclaimed to U.S. Patent 7,531,173, a patent from a different family claiming priority from an application filed February 2, 2006. '173 patent, 1:9-10. And the '173 patent is terminally disclaimed to U.S. Patent 7,374,757, a patent from yet another family that claims priority from an application filed in 2000, '757 patent, 1:10, and which expired in 2021.

The published disclosure of the '757 patent was § 102(b) prior art against both the '173 patent and the '865 patent, including as the Papadopoulos publication (WO 00/75319, Appx4859-5017) discussed as prior art below. Appx83-84; *Mylan*, 2024 WL 382495, at *18. In other words, regardless of the terminal disclaimer, the disclosure of the '757 patent was prior art against the '173 and '865 patents. *See Quad Env't Techs. Corp. v. Union Sanitary Dist.*, 946 F.2d 870, 873 (Fed. Cir. 1991).

C. District Court Proceedings

Numerous companies have filed abbreviated biologics license applications ("aBLAs") seeking to market biosimilar versions of Eylea. The first was Mylan, which Regeneron sued in 2022 in the Northern District of West Virginia, where Mylan is incorporated. *See Valeant Pharm. N. Am. LLC*

v. Mylan Pharm., 978 F.3d 1374, 1376 (Fed. Cir. 2020). SB, Celltrion, and Formycon—all foreign corporations—filed aBLAs after Mylan, and Regeneron sued each last fall in the same court. Amgen also filed an aBLA, and Regeneron sued Amgen in its home forum of the Central District of California. Regeneron moved to consolidate the proceedings under 28 U.S.C. § 1407 in the Northern District of West Virginia. Every defendant opposed. The Judicial Panel on Multidistrict Litigation centralized the actions against all five defendants (the "MDL cases") in West Virginia. *In re Aflibercept Pat. Litig.*, 2024 WL 1597512, at *1 (J.P.M.L. Apr. 11, 2024).

Over the past two years, the district court has presided over a claim construction hearing, a two-week bench trial, and four preliminary injunction proceedings. With respect to the preliminary injunction proceedings against SB, Celltrion, and Formycon alone, the district court resolved numerous motions over the past eight months. Pertinent aspects of these proceedings are summarized below.

1. The *Mylan* Bench Trial

Regeneron sued Mylan in 2022. The district court held a lengthy claim construction hearing and adopted Mylan's proposed constructions of the two disputed '865 patent claim terms, "organic co-solvent" and "present in native

conformation." *Regeneron Pharm. v. Mylan Pharm.*, 2023 WL 11891335, at *2-8 (N.D.W. Va. Apr. 19, 2023). In June 2023, the court presided over a two-week bench trial involving the '865 patent and two patents claiming aflibercept treatment regimens. Regeneron asserted '865 patent claims 4, 7, 9, 11, and 14-17 ("Trial Claims"; all are asserted against SB in seeking a preliminary injunction). The court heard testimony from two '865 patent inventors and three technical experts (including Regeneron's Dr. Bernhardt Trout) who analyzed infringement and validity of the '865 patent. After post-trial briefing, closing arguments, and proposed findings of fact and conclusions of law, the court issued a 313-page decision holding the '865 patent infringed and not invalid. Appx5400; *Mylan*, 2024 WL 382495, at *1, *96. The court held the two treatment patents invalid; those patents are not at issue on appeal. *Id.*

The court's post-trial opinion rejected each of Mylan's numerous defenses to the '865 patent—including noninfringement, anticipation, obviousness, lack of written description, nonenablement, and indefiniteness. *Id.* As the court's obviousness and written description findings are relevant to the ODP and written description SB raises in this appeal, Regeneron summarizes the court's holdings on those issues below.

Nonobviousness. Mylan asserted prior art directed to ranibizumab, the leading VEGF antagonist in 2006 developed for intravitreal use by Genentech. *Mylan*, 2024 WL 382495, at *14. As the district court found, "the prior art taught away from the claimed concentration of 40 mg/ml of glycosylated aflibercept." *Id.* at *51. Specifically, Gaudreault (Appx1462-1469), the "closest prior art" that disclosed a 40 mg/ml ophthalmic formulation of ranibizumab, *id.* at *59—taught away from the claimed compositions because its 40 mg/ml concentration resulted in moderate to severe inflammation. *Id.* at *51. As the court found, "the evidence at trial was unequivocal that 'moderate to severe' inflammation was an extremely concerning phenomenon for any intravitreal drug product to exhibit, as it could result in vision loss and thus defeat the purpose of using an ophthalmic drug product in the first place." *Id.*

The district court also found, based on extensive literature, that "the prior art would not have motivated the POSA to use a large molecule like aflibercept because it would have been considered too large to reach the retina and exert a therapeutic effect." *Id.* at *54. Glycosylating aflibercept would have further increased its molecular size. Accordingly, the court credited Dr. Trout's testimony "that the POSA would have sought to use nonglycosylated

aflibercept, because glycosylation increases size and thus decreases retinal penetration." *Id.* at *55.

The court also found that the POSA would not have reasonably expected to obtain a formulation meeting the 98% native conformation limitation. *Id.* Even if the POSA assumed that the prior art ranibizumab formulations achieved 98% native conformation, the "higher required concentration of aflibercept compared to the ranibizumab … and aflibercept's identity as a fusion protein undermine any reasonable expectation of success. It was undisputed at trial that higher protein concentrations increase the risk for instability …. Furthermore, Dr. Trout explained that because fusion proteins are synthetic 'Frankenstein' molecules that, unlike antibodies, did not evolve to possess inherent stability, the POSA would expect fusion proteins like aflibercept to have lower stability than antibodies (or antibody fragments like ranibizumab)." *Id.* at *56.

Finally, the court found that Regeneron's objective evidence "strongly supports nonobviousness." *Id.* at *59. First, the evidence of teaching away also "constitutes objective evidence of nonobviousness." *Id.* Second, the court found that "Eylea's unexpected properties are well supported in the scientific literature." *Id.* The court found that the patent's claimed composition of "40

mg/ml of aflibercept, with polysorbate 20, a buffer, and a stabilizing agent" became the leading, "revolutionary treatment for treating angiogenic eye disorders," *id.* at *60, exhibiting the unexpected combination of safety, efficacy, and durability (the ability to be dosed less frequently), *id.* at *59. Third, industry skepticism supported nonobviousness: Dr. Napoleone Ferrara, the renowned scientist who discovered VEGF, explained in a contemporaneous peer-reviewed publication that fusion proteins like aflibercept risked generating an immune response due to the "junctions between the various structural elements in such multi-component molecules." *Id.* at *60; Appx2076. Fourth, Mylan's copying of Eylea also supported nonobviousness. *Id.* at *61.

Written Description. The district court likewise held that the Trial Claims were not invalid for lack of written description. "Because the claims are drawn to a specific protein at a specific concentration with specific concentration ranges of polysorbate 20," "the specification allows the POSA 'to visualize or recognize the identity of the subject matter purportedly described' and thus meets the written description requirement." *Id.* at *63 (quoting *Allergan v. Sandoz*, 796 F.3d 1293, 1308 (Fed. Cir. 2015) ("*Sandoz*"). As to the 98% native conformation limitation, the court found that each

example met that limitation, *id.* at *64, and that "the evidence demonstrated that the examples in the specification were predictive of the performance of formulations that were not exemplified in the patent." *Id.* at *65. Thus, "there was a correlation between structure and function that informs the POSA which formulations possess the properties recited in the claims." *Id.* at *65 (cleaned up).

2. Preliminary Injunction Proceedings

a. SB's aBLA and [redacted] of [redacted]

In February 2023, SB filed BLA No. 761350, seeking FDA approval under the BPCIA, 42 U.S.C. §§ 262(k)-(l), to market and distribute its EYLEA biosimilar, "SB15," throughout the United States. Appx1523-1527; Appx2277-2304. On November 17, 2023, SB served its BPCIA [redacted] of [redacted] [redacted] ("[redacted]"), stating: "***[SB]*** hereby provides [redacted] that ***it*** will commence [redacted] of the biological product that is the subject of [SB's aBLA] on or after May 18, 2024[.]" Appx1529 (emphases added). The district court found that SB is the sole signatory to its [redacted]. Appx7-8 (citing Appx1529).

The district court found that SB established a robust U.S. distribution channel for SB15. Appx5-6 (citing Appx496-497 ¶ 11). Specifically, SB and

Biogen MA Inc. ("Biogen") entered into a Development and Commercialization Agreement ("DCA") to commercialize SB15 in the U.S. Appx496-497 ¶ 11; Appx502; Appx505; Appx515; Appx519.

Under the DCA, SB designated Biogen as the exclusive [redacted] authorized to [redacted], [redacted], and [redacted] SB15 in the U.S., including West Virginia. *See* Appx519. SB will provide SB15 to Biogen for sale, and SB retains significant [redacted] over Biogen's U.S. commercialization activities through various contractually-established mechanisms. *See id.*

SB does not deny that it will [redacted], [redacted], and [redacted] SB15 in West Virginia through Biogen. Appx464-494 ("MTD"); Appx495-497. And the DCA does not carve out any states, including West Virginia, from the U.S. market for SB15. Appx499-618.

b. Regeneron's Preliminary Injunction Motion and SB's Motion to Dismiss

After SB served its [redacted], Regeneron sued SB in the Northern District of West Virginia. Appx253-380. Regeneron moved for a preliminary injunction against SB, asserting the '865 patent. Appx1891-1924. Together with its briefing, Regeneron filed four fact and expert declarations pertinent to the '865 patent. SB deposed three of Regeneron's declarants but declined to depose the fourth. Along with its opposition, SB filed declarations from

three experts addressing the ’865 patent; Regeneron deposed all of them. Appx13.

SB moved to dismiss for lack of personal jurisdiction. Appx464-494. The parties engaged in jurisdictional document and deposition discovery.

The district court scheduled a hearing on Regeneron’s preliminary injunction motion but cancelled the hearing due to the court’s scheduling conflict. Neither party objected to the cancellation of the hearing or requested that the court reschedule it, including during a lengthy hearing to address disposition of the preliminary injunction motions. Appx20654-20675. Per the court’s request, Regeneron and SB both submitted proposed preliminary injunction orders. Appx21627-21675; Appx21676-21813.

3. Preliminary Injunction Decision

The district court granted Regeneron’s preliminary injunction motion. Appx1-181. The court found that Regeneron established a reasonable probability of success on the question of personal jurisdiction. Appx22-27. Particularly, the court applied *Acorda Therapeutics v. Mylan Pharmaceuticals*, 817 F.3d 755 (Fed. Cir. 2016), in which this Court held that “the minimum-contacts standard is satisfied” where a non-resident defendant

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files an application with FDA "for the purpose of engaging in … allegedly wrongful marketing conduct in the forum state." Appx25 (citing *Acorda*).

In view of the district court's prior decision in *Mylan* and the record evidence in the preliminary injunction proceeding, the court held that Regeneron was likely to succeed on both infringement and validity of the '865 patent. Appx39-117; *see* Appx32 (quoting *H.H. Robertson v. United Steel Deck*, 820 F.2d 384, 388 (Fed. Cir. 1987) ("Substantial weight may be given to a patent's litigation history in connection with a motion for relief *pendente lite*."), *abrogated on other grounds*, *Markman v. Westview Instruments*, 52 F.3d 967 (Fed. Cir. 1995) (en banc)). The court likewise found that Regeneron would be irreparably harmed absent an injunction by having to compete against its own invention, Appx117-167, and that the balance of equities and the public interest favored an injunction, Appx167-177.

SUMMARY OF THE ARGUMENT

I. The district court correctly rejected SB's assault on this Court's *Acorda* precedent, and the Court should affirm the finding that Regeneron established a reasonable probability of success regarding personal jurisdiction. SB filed an aBLA seeking approval to market its drug, Appx1523-1527, served Regeneron with [redacted] of its intent to market its drug, Appx1529,

and established a robust distribution channel, Appx6-7. Given these findings, the court correctly applied *Acorda*.

SB attacks these findings, suggesting that it somehow does not know where its drug will be sold. The court had an ample factual record to reject SB's purported naivete. *E.g.*, Appx11254-56; Appx11282.

II. Although SB appeals from the district court's ODP judgment, SB does not challenge the court's numerous findings that independently preclude ODP. SB does not dispute that the prior art motivated the POSA *against* using a glycosylated form of aflibercept required by every asserted claim. SB also does not dispute the court's findings that formulations within '594 claim 5 do not inherently possess 98% native conformation, or that the prior art would not have motivated the POSA with a reasonable expectation of success to achieve the 98% native conformation limitation. Lacking any basis in the prior art to show clear error in these outcome determinative findings, SB instead seeks to use the patent's specification as prior art, defying this Court's precedent.

The district court also concluded correctly that the '594 patent is not a proper double patenting reference patent, because foregoing term in the '594

patent in no way extends the 20-year term of the '865 patent. SB shows no error in this threshold determination.

III. The district court's written description holding correctly applied this Court's governing precedent to the largely undisputed facts before it. Under that precedent, a claim reciting "at least" 98% native conformation does not fail for lack of written description because the specification did not achieve 100%, a value the POSA would have understood was ordinarily not achieved in protein formulations. *Andersen Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1376-77 (Fed. Cir. 2007). Accordingly, the court did not clearly err in holding that the specification's disclosure of working embodiments with greater than 99% native conformation satisfied written description. SB cites no precedent where the Court held no written description on analogous facts.

SB's other argument—that the patent does not describe glycosylated aflibercept that obtained 98% native conformation—is bereft of supportive evidence, contravenes the expert testimony, the plain disclosure of the patent, and precedent requiring consideration of the patent specification as a whole. SB again cannot show clear error.

IV. The district court's irreparable harm holding, including its finding of nexus, was correct. Under this Court's precedent, nexus in this case is

apparent because the asserted claims cover the product itself instead of a single "feature." To the extent a demand-driver test is appropriate, the district court properly concluded the claimed elements would be responsible for SB15 demand. Further, the district court also correctly found that nexus exists because SB cannot make SB15 without infringing the '865 Patent. SB fails to provide precedent or evidence to show any error in these findings.

ARGUMENT

III. The District Court's Personal Jurisdiction Analysis Was Correct

A. Standard of Review

While this Court reviews the question of personal jurisdiction *de novo,* it reviews findings of fact that bear on personal jurisdiction for clear error, *Merial Ltd. v. Cipla Ltd.*, 681 F.3d 1283, 1292 (Fed. Cir. 2012).

B. Regeneron Established a Reasonable Probability of Success

Regeneron established at least a reasonable probability of success on the question of personal jurisdiction. This Court effectively decided this very issue in *Acorda*, which mandates affirmance on the unchallenged factual findings below. *Acorda* held that, in the context of generic FDA applications, minimum contacts are satisfied where an applicant: (1) takes the costly, significant step of submitting an aBLA, and (2) does so "with an intent to

distribute the [proposed] product in a given state." *Valeant*, 978 F.3d at 1384 (citing *Acorda*, 817 F.3d at 760, 762-63).

As to the first requirement, the Court found that filings like aBLAs "constitute formal acts that reliably indicate plans to engage in marketing of the proposed [] drugs." *Acorda*, 817 F.3d at 760. The Court found the second requirement, intent to market, to be satisfied in circumstances where the defendant "does not sell its drugs directly into" the forum state but rather contracts with a third-party wholesaler or distributor to do so. *Id.* at 763.

The district court's factual findings satisfy both requirements.

First, the district court found, and SB does not dispute, that SB took the costly and significant step of filing an aBLA for the very purpose of profiting from the distribution of SB15 nationwide. Appx1523-1527; Appx620 ¶ 7; Appx1391-1424. Indeed, "the economic realities of preparing an [FDA application] confirm that filing realistically establishes a plan to market." *Acorda*, 817 F.3d at 761.

Second, the district court found additional facts demonstrating SB's intent to market and distribute in West Virginia. SB served Regeneron with its Third Party Confidential Business Information, stating that "[SB] hereby provides Third Party Confidential Business Information that ***it will commence*** Third Party Confidential Business Information of [SB15]." Appx1529 (emphasis added). This

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explicitly communicates SB's own intent to market SB15. Indeed, SB had no statutory obligation to serve an [redacted] if it did not intend to market SB15. *See* 42 U.S.C. § 262(*l*)(8)(A). And SB does not deny Regeneron's complaint allegation that SB will [redacted], [redacted], and [redacted] SB15 in West Virginia through Biogen. Appx7 (citing Appx464-494); *see also* Appx495-497; Appx258 ¶ 12.

These facts alone are sufficient, but the district court proceeded to find that SB also established a robust U.S. distribution channel for SB15. Appx6-7. Specifically, it found that SB and Biogen entered into the DCA, which designates Biogen as the exclusive [redacted] authorized to [redacted], [redacted], and [redacted] SB15 in the U.S., including West Virginia. Appx6.

Further, as the district court found, SB will provide Biogen with SB15 for sale and will retain significant [redacted] over Biogen's commercialization activities through various contractually-established mechanisms, including (i) active participation in SB's and Biogen's joint steering committee; (ii) various [redacted] and [redacted] mechanisms that ensure that SB will itself establish and maintain all necessary [redacted] requirements for SB15; (iii) broad rights to inspect Biogen's documents, visit Biogen's offices, and interview Biogen's personnel concerning Biogen's

Third Party Confidential Business Information activities; (iv) the calculation and payment of Third Party Confidential Business Information and Third Party Confidential Business Information amounts; and (v) Third Party Confidential Business Information on a launch date for SB15. Appx6-7 (citing Appx496-497 ¶ 11); *see also* Appx1556-1560, Appx1659-1571, Appx1580-1581; Appx1789-1790, Appx1793, Appx1796-1797; Appx1855-1857; Appx1722-1759; Appx474 (citing Appx495 ¶ 12); Appx1662, 28:19-22; Appx1677-1682, 89:20-94:6; Appx1688-1690, 215:15-217:20; Appx1693-1694, 226:12-227:15; Appx1698-1700, 232:12-234:24; Appx1712-1713, 264:9-265:7.

Indeed, SB's corporate designee agreed that Biogen cannot launch SB15 without SB's Third Party Confidential Business Information. Appx499-618; Appx1677-1682, 89:7-94:6. And SB knows that Biogen plans to Third Party Confidential Business Information in West Virginia at least because SB received Biogen's slide deck showing how it divides up the United States into Third Party Confidential Business Information (Appx1755-1756), and SB's corporate designee could offer no basis to believe that Biogen would not market the drug in West Virginia (Appx1716-1718, 296:1-298:15).

Therefore, Regeneron established at least a reasonable probability of success on the question of personal jurisdiction.

C. SB's Personal Jurisdiction Arguments Are Meritless

1. SB's Burden Argument Is Forfeited and Irrelevant

For the first time on appeal, SB alleges that Regeneron bore the burden of demonstrating a "substantial probability" of success on personal jurisdiction. Br. 20-21. SB errs repeatedly.

First, SB waived any argument that the substantial probability standard applies by failing to raise it in the preliminary injunction proceedings below. Appx464-494; Appx11427-11462; Appx20494-20522; Appx21627-21675.

Second, Fourth Circuit law, which applies to such procedural issues not substantive to patent law, requires a reasonable probability. *Catalog Mktg. Servs., Ltd. v. Savitch*, 1989 WL 42488, at *2 (4th Cir. Apr. 24, 1989); *cf. DePuy Synthes Prod. v. Veterinary Orthopedic Implants*, 990 F.3d 1364, 1369 (Fed. Cir. 2021).

Third, even if Federal Circuit law governs, this Court refers to the "substantial probability" standard interchangeably with the reasonable probability standard. *See Celgard v. LG Chem*, 624 F. App'x 748, 751 (Fed. Cir. 2015) (citing *Enterprise Int'l v. Corporacion Estatal Petrolera Ecuatoriana*, 762 F.2d 464, 471 (5th Cir. 1985), which applies "reasonable

probability," to support application of "substantial" probability). SB does not articulate any daylight between the two burdens, and there is none. Br. 20-22.

Finally, as explained above and below, the district court's factual findings support affirmance under either standard.

2. SB Has Minimum Contacts With West Virginia

The Court should reject SB's argument that it lacks minimum contacts because SB (i) "has never had any presence in West Virginia;" (ii) "is not registered to do business in West Virginia, has not done business with any entities located in West Virginia, and has not designated an agent for service of process in West Virginia;" and (iii) "has not distributed, marketed, or sold any product in West Virginia."[1] Br. 22-24. Not one of these contacts is required under *Acorda*. *See Valeant*, 978 F.3d at 1384; *see also Millennium Pharm. v. Pharmascience*, 2016 WL 3382131, at *3 (D. Del. June 10, 2016) ("The *Acorda* court noted that Mylan was incorporated in West Virginia, prepared its ANDA primarily in West Virginia, and filed its ANDA in Maryland.... The court also acknowledged that Mylan was registered to do

[1] Similarly, SB argues that Biogen is not incorporated and does not have any places of business in West Virginia. Br. 23. These facts are also not required under *Acorda*, which requires that ***SB***, not its Third Party Confidential Business Information, have minimum contacts.

business in Delaware... however, the holding in the case was not based upon these facts."). *Acorda* and its progeny make clear that a court may exercise jurisdiction over a defendant that filed an application to market its proposed drug throughout the U.S., including in the forum state, and there are some additional indicia of intent to market its proposed drugs in the forum state. *See Acorda*, 817 F.3d at 762-63; *Valeant*, 978 F.3d at 1384. As explained above, *supra* III.B, the district court's factual findings clearly establish that, applying *Acorda*, the minimum contacts standard is met. Appx1523-1527; Appx1529. Whether SB has additional contacts to West Virginia is irrelevant as a matter of law. *See Valeant*, 978 F.3d at 1384.

3. SB's aBLA Filing Squarely Supports Personal Jurisdiction Under *Acorda*

SB's argument that the district court erred in concluding that the past act of submitting an FDA application subjects the filer to "personal jurisdiction in *every state*" is a straw man. Br. 24-26. The district court did not assess personal jurisdiction based only on SB's aBLA. Rather, as explained *supra* III.B, it also found that SB's [redacted], failure to deny that SB would [redacted] in West Virginia through Biogen, and established distribution channels through the DCA all further supported reasonable probability of success on personal jurisdiction under *Acorda*.

4. Biogen's Future Commercialization Activities Support Personal Jurisdiction Over SB

SB makes several arguments that "[t]he district court … erred to the extent it ruled that *Biogen's* future commercialization activities support personal jurisdiction over SB." Br. 26-31. The Court should reject these arguments.

First, SB argues that the district court did not identify any evidence that Biogen intends to [redacted], or [redacted] SB15 in or to West Virginia. Br. 27-28. As discussed above, however, the court identified evidence that: (i) the Biogen DCA does not carve out any state (Appx7 (citing Appx499-618)); (ii) SB's [redacted] does not exempt any states from SB15 marketing (Appx1529); and (iii) SB has not denied Regeneron's Complaint allegation that it will [redacted], and [redacted] SB15 in West Virginia through Biogen (Appx7; Appx258 ¶ 12).

Second, SB argues that it has no [redacted] over Biogen's commercialization activities. Br. 28-31. This argument is astonishing in view of the record developed below. Pursuant to the DCA, SB retains significant [redacted] over and involvement in Biogen's commercialization activities through at least the contractually-established mechanisms described above. *Supra*

III.B. The district court's factual finding on this point is correct, not clearly erroneous.

This Court squarely has rejected the argument that generic drug manufacturers can hide behind contracts with third-party distributors to evade jurisdiction in states where they will, through those distributors, market and sell their products, *Acorda*, 817 F.3d at 762-63; *Beverly Hills Fan Co. v. Royal Sovereign Corp.*, 21 F.3d 1558, 1565-66 (Fed. Cir. 1994), and district courts have followed suit, *e.g.*, *Apicore US v. Beloteca*, 2019 WL 1746079, at *3 (E.D. Tex. Apr. 18, 2019) (rejecting defendant's argument that it "is a small startup company that 'did not yet have any marketing or distribution channels set up'" based on its distribution agreement that did not "include a carve-out for [the forum state]"). That is precisely what SB is attempting to do here. SB does not identify any authority declining to apply *Acorda* where an applicant contracts with exclusive Third Party Confidential Business Information.

Indeed, SB's argument would vitiate *Acorda*. According to SB, an applicant can avoid suit in disfavored fora (or, by contracting only with foreign entities, a suit in *any forum*) by entering into a contract with a third-party Third Party Confidential Business Information in a desired venue to Third Party Confidential Business Information, Third Party Confidential Business Information, and Third Party Confidential Business Information its product throughout the U.S. This would be so even where, as here, the applicant filed

an aBLA with the intention of securing approval to market and sell its product nationwide, including in the forum. The outcome SB urges would traduce fundamental principles governing jurisdiction, turning contracts like the DCA into a license to forum shop. *See Apotex v. Daiichi Sankyo*, 781 F.3d 1356, 1365 (Fed. Cir. 2015) ("When a generic manufacturer seeks to enter the market, the concrete stakes are the market sales upon entry.").

Finally, SB resists jurisdiction because Biogen is an ***exclusive*** [redacted]. Br. 23, 28-31. But that is a distinction without a difference. SB will deliver SB15 to Biogen so that Biogen, upon SB's [redacted], may [redacted] and [redacted] to consumers in West Virginia, Br. 23, and SB will profit from that [redacted] and those [redacted], *see* Appx543-547 §§ 8.4, 8.5.

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SB's personal jurisdiction arguments are meritless. But even if they had merit, they are Pyrrhic. If personal jurisdiction were lacking, the remedy is transfer to another district. 28 U.S.C. § 1631; Appx1495-1497, 1517-1518 (requesting transfer if jurisdiction lacking). That district court would then transfer the case ***back*** to West Virginia as part of the MDL, Appx21814-21818, and there is no dispute that the MDL court has jurisdiction to issue a preliminary injunction. *In re FMC Corp. Pat. Litig.*, 422 F. Supp. 1163, 1165

(J.P.M.L. 1976). Accepting SB's invitation to require this jurisdictional merry-go-round would "exalt form over substance," contrary to this Court's precedent. *See N. Am. Philips Corp. v. Am. Vending Sales, Inc.*, 35 F.3d 1576, 1579 (Fed. Cir. 1994).

IV. The District Court Correctly Found No Substantial Question Regarding the '865 Patent's Validity

A. The District Court Correctly Found No Substantial Question of Obviousness-Type Double Patenting

"As with statutory obviousness under 35 U.S.C. § 103, obviousness-type double patenting is an issue of law premised on underlying factual inquiries." *Eli Lilly & Co. v. Teva Parenteral Meds.*, 689 F.3d 1368, 1376 (Fed. Cir. 2012). Contra SB, those "underlying factual inquiries" are not reviewed "without deference," Br. 32, but rather "for clear error," *Eli Lilly*, 689 F.3d at 1376; *Otsuka Pharm. v. Sandoz*, 678 F.3d 1280, 1290 (Fed. Cir. 2012). That is consistent with how the Court reviews factual findings generally. *See Teva Pharm. v. Sandoz*, 574 U.S. 318, 333 (2015).

Crucially, SB does not challenge the district court's factual findings, which dispose of SB's ODP arguments. The court found that (1) SB's reference claim does not explicitly or inherently disclose the "glycosylated" VEGF trap required by each asserted claim, Appx76-80; (2) SB's reference

claim does not explicitly or inherently disclose "at least 98% native conformation" by SEC required by each asserted claim, Appx70-76; (3) the POSA would not have been motivated to use glycosylated aflibercept in an ophthalmic formulation, Appx80-91; (4) the POSA would not have been motivated to obtain 98% native conformation with a reasonable expectation of success, Appx103-104; and (5) the POSA would not have been motivated to replace a pre-filled syringe ("PFS") with a vial, Appx106-107. The court also found that (6) objective evidence supported nonobviousness, Appx108-110. SB does not even challenge findings (1)-(4) above based on the prior art, much less demonstrate they are all clearly erroneous, as is required for reversal. And even that would not be enough—SB must also show legal error in the Court's correct threshold determination that the '594 patent is not a proper ODP reference.

1. The Related '594 Patent Is Not a Proper Double-Patenting Reference

The '594 patent is not a proper ODP reference patent to the '865 patent, because the two patents claim the same priority date, and Regeneron has done nothing to extend the '865 patent's 20-year statutory term. Appx56-68. This is not a case where different priority dates were claimed among near-identical patents, or where the asserted patent has been granted an adjustment or

extension of its 20-year term. Rather, this case is far simpler, and the district court's straightforward holding is correct: where "there is no extension of the original monopoly period, i.e., the statutory term of the patent grant, there cannot be ODP." Appx58.

This Court already has rejected SB's faulty premise (Br. 33-34) that ODP is triggered whenever patents expire on different dates. *Allergan USA v. MSN Labs.*, --- F.4th ----, 2024 WL 3763599, at *6 (Fed. Cir. Aug. 13, 2024). As the Court explained, "[i]t does not follow ... that the [asserted] patent *must* be invalidated by the [reference] patents simply because it expires later." *Id.* Rather, the Court must consider "the purpose of the ODP doctrine," *id.*, that is, the "public policy that prevent[s] the *extension* of the term of a patent." *Otsuka*, 678 F.3d at 1297 (emphasis added) (cleaned up). Here, there is no extension of term.

As is undisputed, Br. 35, the '594 patent expires before the '865 patent solely because Regeneron relinquished part of the '594 patent's term by filing a terminal disclaimer. No authority supports SB's argument that a patent may be held invalid for ODP merely because the patentee *surrendered* term in a related patent. SB's cited cases do not address that scenario. As the Court recently explained, in SB's cited *Gilead* and *AbbVie* cases (Br. 33-34),

"gamesmanship during prosecution" resulted in the asserted patent having "a later priority date than" the reference patent, which gave the asserted patent "an unwarranted extension of patent term" compared to the reference patent. *Allergan*, 2024 WL 3763599, at *7-8 (discussing *Gilead Scis. v. Natco Pharma*, 753 F.3d 1208 (Fed. Cir. 2014); *AbbVie v. Mathilda & Terence Kennedy Inst. of Rheumatology Tr.*, 764 F.3d 1366 (Fed. Cir. 2014)). In *In re Cellect*, the challenged patent had an extended term by virtue of a patent-term adjustment, which gave rise to an ODP issue, 81 F.4th 1216, 1228-29 (Fed. Cir. 2023); *Cellect* did "not address, let alone resolve, any variation of the question presented here—namely, under what circumstances can a claim properly serve as an ODP reference." *Allergan*, 2024 WL 3763599, at *6. This case, by contrast, involves neither the *Gilead/AbbVie* nor the *Cellect* scenario: the '594 and '865 patents undisputedly claim the same priority date, and the '865 patent has no extensions. Appx67.

The Court's precedent on terminal disclaimers is contrary to SB's premise that surrendering term in one patent may trigger ODP in another. As the district court recognized, "the filing of a terminal disclaimer simply serves the statutory function of removing the rejection of double patenting, and raises neither presumption nor estoppel on the merits of the rejection."

Quad, 946 F.2d at 874; *see Motionless Keyboard Co. v. Microsoft Corp.*, 486 F.3d 1376, 1385 (Fed. Cir. 2007) (similar); *Ortho Pharm. Corp. v. Smith*, 959 F.2d 936, 941 (Fed. Cir. 1992) (rejecting argument that patent applicant admitted to obviousness-type double patenting by filing terminal disclaimer). The Court's refusal to elevate the prosecution expedient of a terminal disclaimer is particularly apt here, where the 2021 expiration date of the '594 patent results from a chain of numerous terminal disclaimers between different patent families, ending in a patent with a disclosure available as prior art under § 102(b), *supra* II.B, which would not change with a terminal disclaimer, *Quad*, 946 F.2d at 873.

This complex chain of terminal disclaimers has nothing to do with ODP of the '865 patent, which was not terminally disclaimed to any patent in the chain. While the '594 patent's terminal disclaimer did surrender patent term for *that patent*, Br. 35 (citing *In re Yamazaki*, 702 F.3d 1327, 1333 (Fed. Cir. 2012)), a difference in the term alone does not cause ODP, *Allergan*, 2024 WL 3763599, at *6. As the district court observed, *Yamazaki* did not concern ODP, and no court has extended it to the ODP context, much less to the scenario here, where no prosecution gamesmanship or extension of patent term occurred. Appx62-63. In contrast, the district court cited cases rejecting ODP

based on a patentee's benign surrender of related patents. For example, in *Hoffmann-La Roche v. Orchid Chems. & Pharm.*, 2011 WL 4433575, at *3 (D.N.J. Mar. 17, 2011), there was no ODP where an alleged reference patent expired before its statutory term due to nonpayment of maintenance fees, "since it does nothing to effectuate the prohibition against double patenting." *Id.*; Appx63. The same is true here, where surrendering term in the '594 patent in no way extends the term of the '865 patent.[2]

The district court also relied on an analogous case, *Merck Sharp & Dohme v. Teva Pharm.*, 217 F. Supp. 3d 782, 787-88 (D. Del. 2016). Appx60-62. There, the court similarly held that a patent "from the same family" as the asserted patent could not serve as an ODP reference patent where it expired earlier "solely due to a terminal disclaimer." Appx61 (citing *Merck*, 217 F. Supp. 3d at 787-88). SB notes that in *Merck* the reference patent issued after

[2] The district court addressed *Eli Lilly & Co. v. Barr Labs.*, 251 F.3d 955, 959 (Fed. Cir. 2001), where a patentee "attempted to circumvent [a] typical ODP scenario" with an unrelated reference patent "by disclaiming the reference patent during the course of the litigation." Appx66-67. This Court rejected that tactic, but as the district court held, merely because "statutory disclaimer of a proper reference patent could not be used to 'avoid' ODP" does not address "whether a terminal disclaimer in the '594 patent (filed years before this lawsuit) *creates* ODP." Appx67 (quoting *Barr*, 251 F.3d at 967 n.5). SB does not cite *Barr* and points to no error in the court's analysis of it.

the asserted patent—which was also the case in *Allergan*, 2024 WL 3763599, at *6—whereas here the asserted patent issued later. Br. 36. But that is a distinction without a difference. Regardless of the respective issuance dates, relinquishing term in the '594 patent does not extend the '865 patent's 20-year term. *See Allergan*, 2024 WL 3763599, at *6 ("It does not follow … that the [asserted] patent must be invalidated by the [reference] patents simply because it expires later").

2. The District Court's Factual Findings Are Not Clearly Erroneous

Even were the '594 patent a proper reference patent, the district court correctly determined on the merits that multiple differences between '594 claim 5 and the asserted claims precluded ODP. Under this Court's precedent, ODP requires a two-step analysis: "First, the court construes the claims in the earlier patent and the claims in the later patent and determines the differences. Second, the court determines whether those differences render the claims patentably distinct." *UCB v. Accord Healthcare*, 890 F.3d 1313, 1323 (Fed. Cir. 2018) (cleaned up). To assess whether the claims are "patentably distinct" from the reference claim, courts conduct a "traditional obviousness analysis." *Otsuka*, 678 F.3d at 1297-98. Familiarly, in the obviousness analysis, the reference patent's specification may not be used as

prior art, either to supply a motivation or expectation of success in achieving the asserted claims. *Eli Lilly*, 689 F.3d at 1378-79; *In re Kaplan*, 789 F.2d 1574, 1580 (Fed. Cir. 1986).

Remarkably, SB challenges neither aspect of the district court's two-part ODP analysis. It does not dispute the district court's construction of either the asserted claims or reference claim, including the holdings that the latter did not require either glycosylation or 98% native conformation. Appx70-80; Br. 42 n.10, 39-43. Nor does SB challenge the findings of no explicit anticipation (Appx81-83), no inherency (Appx91-101), or no obviousness under the traditional motivation and reasonable expectation of success inquiries (Appx83-91, Appx103-104). Indeed, SB nowhere alleges clear error in the district court's dispositive findings in view of the prior art that (1) the POSA would not have been motivated to use "glycosylated" aflibercept, Appx83; (2) that the 98% native conformation limitation was not inherent or obvious, Appx91, Appx103; and (3) that objective evidence strongly supports no ODP, Appx108.

Lacking any basis to show clear error in the district court's detailed analysis of the prior art and expert testimony, SB instead asks the Court to discard its settled precedent to conjure a brand-new basis for ODP: replacing

the requisite obviousness based "on a comparison between a patentee's earlier and later *claims*," *Eli Lilly*, 689 F.3d at 1378, with an inquiry as to whether one of the specification's *embodiments* falls within both the reference claim and asserted claim. Br. 41-43. SB's argument that double patenting results from the both the reference claim and asserted claims covering the formulations of Example 3 and Eylea "confuse[s] double patenting with 'domination' which, by itself, does not give rise to double patenting." *Kaplan*, 789 F.2d at 1577-78 ("Domination is an irrelevant fact."). In SB's precedentially-foreclosed approach, 689 F.3d at 1378-79, SB asks the Court to read the '594 patent's specification—the same as the '865 patent's—as prior art, thereby turning the patent's written description support against it. "This has repeatedly been held in our precedents to be impermissible," including where a single example meets both the reference and asserted claims. *Kaplan*, 789 F.2d at 1580 (citing *In re Vogel*, 422 F.2d 438 (C.C.P.A. 1970)). SB's effort to derive the POSA's motivation from the patent's own teachings is the epitome of hindsight, contradicts controlling precedent, and should be rejected.

a. The District Court Did Not Clearly Err in Finding No Motivation To Use Glycosylated Aflibercept

The asserted '865 patent claims require a "glycosylated" VEGF antagonist, Appx196, claim 1; contra its position below, Appx76-80, SB does

not challenge the finding of no anticipation, Appx81-83; Br. 41-43, and agrees (Br. 42 n.10) that its reference claim does not require glycosylation, Appx4542. Consistent with the "traditional obviousness analysis" required by ODP, *Otsuka*, 678 F.3d at 1298, the district court properly analyzed whether that difference constituted a patentable distinction in view of the prior art and found that "the prior art's teachings would have motivated the POSA against using glycosylated aflibercept." Appx84. The finding—unchallenged by SB, Br. 41-43—was supported by the prior art and testimony of both experts. Appx80-91.

First, the district court considered the issue of penetration into the retina—the site where intravitreally injected drugs must reach to exert a therapeutic effect. "[T]he art showed that a POSA would *avoid glycosylation* because it would increase the size of aflibercept, thereby reducing retinal penetration." Appx84 (emphasis added). The court relied on Dr. Trout's analysis of scientific literature, including Genentech's Gaudreault reference's teaching that "'[p]enetration of ranibizumab into the retina is critical for its clinical use' and ranibizumab's 'ability [to penetrate the retina] has been attributed to [its] small molecule size.'" Appx85 (quoting Appx3496, Appx3501). Aflibercept is over twice the size of ranibizumab, and

glycosylating aflibercept further increases its size. *Mylan*, 2024 WL 382495, at *55; Appx3496. Further, the prior art taught that Regeneron's alternative "mini-Trap" candidate, which included a "smaller, non-glycosylated mini-trap" protein with a size similar to ranibizumab, "has optimized characteristics for local, intravitreal delivery." Appx84 (quoting Appx4034-4035, ¶¶ 38, 43)]. Thus, for an ophthalmic formulation administered intravitreally to treat retinal disease, "the POSA would have been motivated to avoid increasing the molecular size of aflibercept by using its glycosylated form." Appx85.

Second, the district court also found that the pharmacokinetics of glycosylated aflibercept would have motivated the POSA against glycosylation. The undisputed expert testimony established that glycosylation *lengthened* the half-life of proteins in the serum; whereas "the prior art relating both to VEGF Traps and ranibizumab taught that, for ophthalmic use, '*shorter* serum half life' was desirable." Appx87 (quoting Appx4035 ¶ 43); *see also* Appx3501 (("The low circulating concentrations of ranibizumab after [intravitreal] administration may be important in the clinical setting, because VEGF is necessary for normal physiological functions such as tissue repair and reproduction."). This teaching also "would motivate a POSA against using glycosylated aflibercept." Appx87.

SB points to no error in any of these findings refuting motivation to glycosylate. Appx84-91; Br. 41-43. Rather, SB ignores them entirely and instead resorts to the patent's specification, seeking to displace the prior art's teachings with the inventors' chosen path to use glycosylated aflibercept. Br. 41-43 That approach inverts the "traditional obviousness analysis" required in ODP, where "[t]he inventor's own path itself never leads to a conclusion of obviousness; that is hindsight." *Otsuka*, 678 F.3d at 1296, 1298; *Millennium Pharm. v. Sandoz*, 862 F.3d 1356, 1367 (Fed. Cir. 2017).

The district court properly applied this Court's precedent holding that "ODP 'turn[s] on a comparison between a patentee's earlier and later claims, with the earlier patent's written description considered *only to the extent necessary to construe its claims*.'" Appx33 (emphasis added) (quoting *Eli Lilly*, 689 F.3d at 1378-79). (As discussed below, a court may also consult the specification for the "intended use" of a claimed composition. *Eli Lilly*, 689 F.3d at 1379.) Crucially—and fatally for SB's argument—"the correct double patenting analysis in this case turns on an evaluation of what [patentee] has claimed, not what it has disclosed." *Id.* at 1380. SB shows no error in the court's adherence to *Eli Lilly* and instead simply ignores it. Br. 37-38.

SB pays lip service to the principle that the reference patent's "disclosure may not be used as prior art," but then creates an exception to swallow that rule: that the specification may supplant the prior art and the POSA's motivation. Br. 37, 43. Although "certain instances may exist where a patent's disclosure may be used" to assess claim scope in addressing whether the asserted claims recite an obvious variation of the reference claims, *In re Basell Poliolefine Italia S.P.A.*, 547 F.3d 1371, 1378 (Fed. Cir. 2008), no precedent supports SB's bald assertion that the district court "was *required* to consider the '594 patent specification in its OTDP analysis," Br. 38-39.

In *In re Vogel*, the C.C.P.A. contemplated a scenario where it was "difficult, if not meaningless, to try to say what is or is not an obvious variation" because claim scope cannot be determined in a vacuum. 422 F.2d at 442. There, the Court used the prior art—not the specification— to assess obviousness. *Id.* (citing "Ellies" reference). Thus, the Court's narrow use of the specification to construe what fell within the claim scope was consistent with this Court's longstanding precedent, including *Eli Lilly*. The same is true of *In re Basell*, where again the Court used the specification to determine what compounds fell "within the scope" of the reference claim, not to define the POSA's motivation to bridge the difference between the reference claim and

the asserted claim. 547 F.3d at 1378. As to that question, the Court simply upheld the Board's "carefully considered" obviousness findings. *Id.* at 1379.

Here, unlike *Vogel*, there is no difficulty in articulating the pertinent obviousness question. The parties agree on the claims' scope and differences: The asserted claims require "glycosylated" aflibercept; the reference claim does not. *See* Br. 42 n.10. The straightforward obviousness question addressed by the parties and court below is whether the POSA would have been motivated to use a glycosylated form of aflibercept in view of the prior art's teachings, "putting aside the teachings" in the reference patent's specification. *Eli Lilly*, 689 F.3d at 1380; *UCB*, 890 F.3d at 1324. "There is no other way to consider the obviousness" of the claimed invention in ODP. *Otsuka*, 678 F.3d at 1298. SB's attempt to ignore the prior art and instead rely on the specification is particularly perverse here, where the reference patent and asserted patent share the same specification; it would negate the requisite comparison of the claims based on the prior art and invariably result in ODP by using the inventors' own disclosure against them, which is hindsight. *Millennium*, 862 F.3d at 1367. Neither *Vogel* nor *Basell* suggests—let alone mandates—that unlawful approach. *See Vogel*, 422 F.2d at 442-43; *Basell*, 547 F.3d at 1373.

This Court expressly rejected SB's approach in *In re Kaplan*, clarifying that *Vogel* does not support it. The Board in *Kaplan* used the reference patent's specification as prior art and, like SB, "relied on no other reference" in the prior art. 789 F.2d at 1580. Likewise, the reference patent specification overlapped with the application at issue, as both shared "a disclosure of appellants' own joint invention which had been incorporated in the [reference patent's] sole disclosure" relied on by the Board. *Id.* The Court, however, rejected the Board's attempt to use the "applicant's invention disclosure ... as prior art against him," which "is impermissible." *Id.* The law requires "some clear evidence to establish why the variation would have been obvious *which can properly qualify as 'prior art.'*" *Id.* Because SB does not dispute the district court's finding based on the prior art, its ODP argument fails.

b. The District Court Did Not Clearly Err in Finding 98% Native Conformation Not Inherent or Obvious

The asserted claims require "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," Appx196, claim 1; '594 claim 5 requires a VEGF trap that is "stable for at least 4 months." Under the district court's unchallenged claim construction, which SB does not dispute, "stable"

is "broader" than the 98% native conformation limitation in two critical respects. First, it covers "types of stability other than those measured by SEC." Appx72. Second, "stable" does not require 98% native conformation, Appx76, but rather must encompass more than 10% aggregates, Appx73-74. In the district court, SB argued that the 98% native conformation limitation was (1) an "inherent property" of reference claim 5 or (2) obvious over reference claim 5 in view of the prior art. Appx11443-11444. Consistent with the examiner's consideration of the '865 patent's claims, Appx4113, Appx4124, the district court rejected both theories, Appx91-106. SB now abandons them entirely and raises a new theory using the specification's examples as prior art, which is supported by no evidence or precedent. Br. 39-41. SB's new argument should be rejected.

The district court found that, starting with reference claim 5, "the POSA would not have reasonably expected to obtain 98% native conformation after two-months' storage given the absence of any relevant prior art teachings as to aflibercept's stability." Appx103; *see also Mylan*, 2024 WL 382495, at *55-56. "Dr. Trout explained that because fusion proteins are synthetic 'Frankenstein' molecules," the POSA would expect "aflibercept to have lower stability than antibodies[.]" Appx103-104 (quoting *Mylan*, 2024 WL 382495,

at *56); Appx2068-2069; Appx2086-2090, ¶¶ 339-340, 383-391. SB declines to acknowledge these findings, let alone seek to overturn them, instead asking the Court to substitute the patent's specification for the prior art. Br. 39-41. As with glycosylation, SB cannot show reversible error by ignoring the record evidence and the court's detailed analysis.

Given the court's well-supported nonobviousness findings in *Mylan*, SB relied on inherency to attempt to meet the 98% native conformation limitation. Appx11443-11444. As the '594 patent's disclosure of 98% native conformation is not prior art, *Eli Lilly*, 689 F.3d at 1378-79, SB invoked inherency to "supply a missing claim limitation in an obviousness analysis" with non-prior-art data, *Par Pharm. v. TWI Pharm.*, 773 F.3d 1186, 1194-95 (Fed. Cir. 2014); *see* Appx93 n.9; Appx11444, n.4. The court rejected that argument, citing this Court's inherency precedents, expert testimony, and fact testimony. Appx91-101. SB does not even try to show clear error in the findings that 98% native conformation is not inherent in '594 claim 5; indeed, SB's brief never mentions inherency.

Instead, SB now vaguely asserts that 98% native conformation is an "additional property" of formulations within '594 claim 5, by improperly reading the specification as prior art. Br. 39-41. No precedent supports SB's

new theory. And because SB relied on the '594 patent's disclosure and data only to support its inherency theory, Appx11443-11444, it has forfeited its new "additional property" argument.

Regardless, SB's new arguments show no abuse of discretion for at least two reasons. First, precedent forecloses SB's use of the specification's embodiments as prior art. Second, SB's argument is premised on equating the specification's example 3 with '594 claim 5, Br. 41, but the court found to the contrary, and SB does not attempt to show clear error in that finding.

1. SB invokes precedent permitting reliance on the specification for the "intended use" of a composition in a reference claim. Br. 40; *Eli Lilly*, 689 F.3d at 1379-80. That exception is irrelevant here—the reference claim itself recites the use of its "ophthalmic formulation" explicitly: "intravitreal administration." Appx4542, claim 1. SB does not contend that 98% native conformation is merely a "use" of the claimed ophthalmic formulations. That would make no sense; 98% native conformation is the claimed formulations' stability level, not their use. SB's cited authority (Br. 40) is thus inapplicable. *See Eli Lilly*, 689 F.3d at 1380 (rejecting use of specification where ODP comparison was not between "a composition and a previously disclosed use").

SB also invokes *Basell* (Br. 39-40), but as discussed above with respect to glycosylation, *Basell* only examined the specification to ascertain claim scope in affirming the Patent Office's obviousness findings, 547 F.3d at 1378-79; *supra* IV.A.2.a, not to supply the missing motivation or expectation of success. Here, in contrast, the district court's unchallenged findings demonstrate *nonobviousness*. Appx103-104.

2. SB asserts, without citation, that '594 claim 5 "recites the Example 3" formulation and thus must also achieve 98% native conformation. Br. 41. But the district court rejected that argument in its unchallenged findings regarding inherency. Appx97. Thus, even if the specification could be considered, the court's judgment should still be affirmed.

As the court found, although Examples 3 and 4 did possess 98% native conformation after two months, '594 claim 5 "is not limited to those embodiments." Appx97. SB ignores entirely, and thereby does not challenge, this crucial finding as well. Reference claim 5 is broader, in multiple respects, than Example 3, including with respect to glycosylation, pH, and stability and native conformation. Another embodiment of the reference claim, also containing the same ingredients and amounts as Example 3, possessed *less* than 98% native conformation. Appx94 (discussing Appx11398-11405;

Appx20334-20335, ¶ 11). Citing the testimony of '865 patent inventor Dr. Graham, the court found that this formulation (tested in "SS195") "possessed less than 98% native conformation by SEC even at time zero, before any storage." Appx94 (citing Appx20334-20335, ¶ 11). There was no dispute that "the percent native conformation will be the same or lower after two months' storage, as compared to time zero," such that the SS195 formulation could not possess 98% native conformation at two months. Appx96 (citing Appx12997, ¶ 52 n.2; Appx2141, ¶ 55); *Mylan*, 2024 WL 382495, at *32. As SB's expert acknowledged, claim 5 (unlike Example 3) is not directed to a particular lot of aflibercept, Appx94 (quoting Appx20220, 84:4-6); accordingly, the formulations of claim 5 do not always achieve the 98% native conformation after 2 months achieved in Example 3 and required by the asserted claims, foreclosing a finding of inherency. *See Allergan v. Apotex*, 754 F.3d 952, 960-61 (Fed. Cir. 2014); Appx94.

Likewise, "'594 claim 5 recites a pH range of 'pH 6.2-6.4,'" Appx98, while Examples 3 and 4 describe a formulation with pH 6.3, Appx191, 9:26, 9:52. SB identified below no reason to select a pH of 6.3, and pointed to no native conformation data for a formulation with pH 6.4. Appx98-99. SB fails to even acknowledge these findings, let alone challenge them, but they foreclose its

theory that '594 claim 5 and Example 3 are interchangeable. *Id.* (citing *Kaplan*, 789 F.2d at 1580).

At bottom, SB attempts to fabricate a new basis for ODP that requires neither a finding of anticipation nor obviousness—only an embodiment covered by both the reference claim and asserted claim. Br. 39-41. That is not the law. This Court's case law consistently requires a finding of anticipation or obviousness—under the traditional applications of those doctrines—as a predicate to a finding of ODP. *Otsuka*, 678 F.3d at 1298. There is no third category of ODP for claims that cover the same embodiment as a reference claim; SB has invented it out of whole cloth. *Id.* Because SB disputes neither the inherency nor the nonobviousness findings below (including lack of motivation or expectation of success), its ODP argument fails as a matter of law.

c. The District Court Did Not Clearly Err in Finding No Motivation To Switch From a PFS to a Vial

The asserted claims also require a "vial," Appx196, claim 1; '594 claim 5 requires a different storage device, a "pre-filled syringe," Appx4542, claim 5. The district court therefore addressed whether the POSA would have been motivated to modify the reference claim's PFS to the asserted claim's vial. Appx106; *e.g.*, *Otsuka*, 678 F.3d at 1298-99. The court found no such

motivation, as the prior art taught that a PFS was more convenient for the administering physician. Appx106-107 (citing Appx2090, ¶ 393); Appx3654-3655. The court also found that the potential for improved stability would not have motivated the POSA to switch to a vial, because the reference claim already specified that the formulation is stable for at least 4 months in a PFS. Appx107 (citing Appx2091, ¶ 395). Again, SB does not challenge the court's findings, and shows no clear error. Br. 43-44.

Rather, SB insists that both a vial and PFS are obvious options. Br. 44. But "[t]he mere fact that the prior art could be so modified would not have made the modification obvious unless the prior art suggested the *desirability* of the modification," or some other evidence did. *Orexo AB v. Actavis*, 903 F.3d 1265, 1272-73 (Fed. Cir. 2018) (emphasis added) (cleaned up). Here, the evidence suggested the opposite, foreclosing obviousness.

SB argues that obviousness does not require the vial to be "the best option." Br. 44 (citing *Galderma Labs. v. Tolmar*, 737 F.3d 731, 738 (Fed. Cir. 2013)). That is true, but also irrelevant: the district court considered both potential advantages and disadvantages of a vial, and found no motivation to make the modification required by SB's obviousness theory, which is precisely what this Court's cases require. *See Henny Penny Corp. v. Frymaster LLC*,

938 F.3d 1324, 1332 (Fed. Cir. 2019) ("The benefits, both lost and gained, should be weighed against one another.") (quoting *Winner Int'l Royalty Corp. v. Wang*, 202 F.3d 1340, 1349 n.8 (Fed. Cir. 2000)).

d. The District Court Did Not Clearly Err in Crediting the Objective Evidence

The district court credited Regeneron's objective evidence of nonobviousness, including industry skepticism, unexpected properties, and copying. Appx108-110. SB first challenges the district court's nexus analysis (Br. 45), arguing that the court failed to address the particular differences between the reference claim and the asserted claims. But the court addressed that issue and found that the objective evidence could be "probative of nonobviousness even if it was not precisely limited to the point of novelty of the claimed combination." Appx108 (quoting *Henny Penny*, 938 F.3d at 1334).

Regardless, the district court also credited the objective evidence that addressed the differences between the reference claim and the asserted claims, finding that Eylea's unexpected properties derived in part from the 98% native conformation limitation. Appx110 (citing *Mylan*, 2024 WL 382495, at *60; Appx2079-2080, ¶ 369). The court found that "Eylea demonstrated three critical and unexpected properties: comparable (1) safety and (2) efficacy to ranibizumab, along with (3) the durability to be dosed half as frequently as

ranibizumab (after three loading doses for wet AMD)." *Mylan*, 2024 WL 382495, at *59; Appx108. This combination of properties "was not only unexpected, but revolutionary." *Mylan*, 2024 WL 382495, at *59; *see* Appx3828 (describing "captivating" properties of Eylea). And in particular, the court found because "the required 98% native conformation[] indicated to the POSA that ... 'there's a relatively lower risk of inflammation' as compared to a formulation with lower native conformation," the 98% native conformation limitation that distinguishes the asserted claims confers a safety benefit. Appx110 (quoting *Mylan*, 2024 WL 382495, at *60); Appx2079-2080, ¶ 369.

SB points to no clear error in that finding. SB argues that there was no evidence of "superior clinical results" of Eylea compared to a formulation with more aggregates (*i.e.*, lower percent native conformation), Br. 45, but offers no reason why such evidence was necessary. SB's expert, Dr. Tessier, offered no opinion on the documents SB cites on appeal (Br. 46), and did not rebut Dr. Trout's opinion setting forth the relationship between protein aggregation and inflammation, Appx2077-2078, Appx2079-2080, ¶¶ 365, 369. SB's new attorney argument on appeal (citing its own aBLA permitting [redacted] purity, Br. 45-46)[3] is

[3] SB relies on its release specifications requiring at least [redacted] native conformation, Br. 45-46, but its aBLA's measured data for SB's formulation showed at least [redacted] native conformation after 2 months, Appx53.

not even supported by its own expert, does not address the prior art, and cannot show clear error in the court's contrary findings.

B. The District Court Correctly Found No Substantial Question of Written Description

SB's written description argument (Br. 46-55) is premised on both legal error and an absence of any supportive evidence. The written description requirement is met when a patent's disclosure "reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad Pharm. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). Because the '865 patent describes both glycosylated aflibercept and formulations meeting the 98% native conformation requirement, SB can show no clear error in the court's holding.

1. The Patent Describes Glycosylated Aflibercept

SB's principal alleged defect—that the patent's examples do not disclose that the formulations used glycosylated aflibercept, Br. 47-49—was raised only in a footnote to SB's opposition, Appx11446, n.8, and contradicted by Dr. Trout, Appx15122-15123, 161:14-162:1; Appx15135-15136, 174:6-175:7. Tellingly, SB does not cite a shred of expert testimony in support of its argument. Even assuming SB preserved this argument, it requires improperly ignoring parts of the specification instead of reading it as a whole.

The written description inquiry proceeds "from the perspective of a [POSA]," *Allergan*, 2024 WL 3763599, at *9 (quoting *Ariad*, 598 F.3d at 1351), and only Dr. Trout addressed whether the POSA would read the patent's disclosure as a whole, or would instead read the examples in isolation as SB now maintains. Dr. Trout was clear: when reading the examples, "the [POSA] would look to the rest of the specification to see how the VEGF trap was made," Appx15135, 174:11-13, and would understand that the patent "specifically says [the VEGF antagonist is] 'glycosylated at Asparagine Residues 62, 64, 149, 222, and 308,'" Appx15136, 175:4-5 (quoting Appx189, 6:36-37). That undisputed testimony from the relevant POSA's perspective conclusively refutes SB's citation-free assertion that the patent's disclosure of glycosylation "is not connected in any way to" the examples. Br. 48; *Ariad*, 598 F.3d at 1351. Dr. Trout's testimony accords with this Court's guidance that "*the disclosure must be considered as a whole*, as the [POSA] would read it." *Allergan*, 2024 WL 3763599, at *11 (emphasis added). SB's attorney argument does not.

SB cites no testimony from Dr. Tessier on this issue. Dr. Tessier appeared to agree with Dr. Trout that the POSA would look to the rest of the specification when viewing the examples, in support of SB's now-abandoned

effort to read a glycosylation limitation into '594 claim 5. Br. 42 n.10; Appx13041, ¶ 170. But Dr. Tessier also asserted in a footnote that the claims would lack written description absent such a claim construction. Appx13041, ¶ 170 n.13. The court did not clearly err in disregarding this equivocal testimony.

SB mistakenly argues that the court was inconsistent between its ODP and written description analyses. Br. 48-49. SB's argument is premised on improperly reading the patent's description of glycosylation in total isolation. *Id.* Furthermore, for ODP, the court properly addressed what the *prior art* taught the POSA regarding glycosylation, while the court's written description analysis focused on the *patent's disclosure*. This approach, not SB's erroneous one, is legally mandated: "[t]he obviousness inquiry turns on what the *prior art* would have taught a [POSA] and whether the claimed invention would have been obvious in view of the *prior art*," whereas enablement turns on the POSA's understanding "after reading the *specification*." *Sandoz*, 796 F.3d at 1310 (first emphasis added). The same is true of written description, which likewise focuses on the patent's disclosure. *See id.* at 1308. SB identifies no error in the court's analysis.

2. The Patent Supports 98% Native Conformation

SB also argues that the district court clearly erred in upholding written description of the 98% native conformation limitation, asserting that the specification does not support the "claimed range." Br. 49-54. However, SB ignores the weight of the court's analysis and application of this Court's precedent addressing "[o]pen-ended claim[]" limitations, like the "at least 98%" native conformation limitation. Appx111-117. The court's analysis was correct, and SB's novel written description argument is unsupported by precedent.

As the district court explained, written description for an open-ended claim "need not be supported by an embodiment at th[e] upper limit; the patent need only 'enable[] [the POSA] to approach that limit.'" Appx113 (quoting *Andersen*, 474 F.3d at 1377); *see Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1576 (Fed. Cir. 1985) ("[O]pen-ended claims, however, would be limited by what a person skilled in the art would understand to be workable."). And the upper limit need not be "precisely known." *Andersen*, 474 F.3d at 1376-77. Here, as the court found, "the results in the patent show between 98.5 and 99.2% native conformation for the liquid formulations tested after storage for 2-3 months," and Example 3—reciting a vial undisputedly

within the claims—achieved 99.2% native conformation. Appx114-115; Appx190-191, Examples 1-6. The court thus found that the patent's "multiple disclosures of native conformations less than 1% shy of 100% (the absolute upper limit for the claim term, which 'in general' is not met for proteins)" satisfied written description. Appx115 (quoting Appx20252, 210:4-211:2).

1. SB argues that the "upper end" of the "range" is not supported, but does not meaningfully engage with the court's analysis. First, SB quibbles (Br. 50-51) that the court accepted Dr. Tessier's testimony that "in general, most proteins are not purified to a hundred percent and often have some impurity in them." Appx20252, 210:21-211:1. Although this testimony was not directed solely to aflibercept, Br. 50, it was not clearly erroneous for the court to find it relevant to the POSA's understanding. And regardless, the court considered both the "theoretical maximum" of 100% and the practical limit of "somewhat less than 100%" in reaching its conclusion. Appx112-113, Appx115.

Second, SB complains that the examples do not possess native conformations above 99.3% (Br. 51), but the court did not clearly err in rejecting SB's theory that the examples must meet every decimal point up to the theoretical limit, which is supported by no precedent and refuted by *Andersen* and other cases. 474 F.3d at 1376-77 (upholding written description

to claim reciting "rating of greater than 500,000," despite no results greater than 1.2 million); *Nalpropion Pharm. v. Actavis Labs.*, 934 F.3d 1344, 1349-51 (Fed. Cir. 2019) (upholding claims requiring "at least 99% [dissolution]" despite no results discussed between 99-100%); *Indivior v. Dr. Reddy's Labs.*, 930 F.3d 1325, 1347-48 (Fed. Cir. 2019) (upholding claim requiring "about 60% or more" L-PEO despite no cited disclosure greater than 75% L-PEO). Axiomatically, written description does not require "either examples or an actual reduction to practice," let alone the expansive and undefined number of examples SB requests. *Sandoz*, 796 F.3d at 1308; *see Cordis v. Medtronic Ave*, 339 F.3d 1352, 1365 (Fed. Cir. 2003) (specification need not describe "every conceivable and possible future embodiment of [the] invention").

SB ignores the weight of the court's cited authority (Appx111-114), and its cursory discussion of *Andersen* is wrong. SB argues that *Andersen* addressed enablement, not written description, Br. 52 n.12, but the evidence cited by the Court established that the claims were both "described and enabled." 474 F.3d at 1377. Likewise, *Nalpropion* and *Ralston Purina*, ignored by SB, are also written description cases consistent with *Andersen*, as the district court explained. Appx113-114.

2. SB also argues that the claims are invalid because "there is no way to discern the lower bound of" 98%. Br. 53-55. Not even Formycon joins this baseless assertion. No. 24-2009, Formycon Br. 47-50, ECF No. 20. The patent discloses native conformations for the liquid formulation examples from 98.5 to 99.2% at 2-3 months. Appx114; Appx190-191, Examples 1-6. As the court found, the claims simply recite "the highest whole number achieved in each example." Appx116; *see* Appx2110-2113 (¶¶ 446-451). The claims are not limited to the examples, and no precedent requires a patentee to recite in the claims the same level of numerical precision used in the specification.

The district court addressed SB's only cited case (Br. 53), *Indivior UK v. Dr. Reddy's Labs.*, 18 F.4th 1323, 1328 (Fed. Cir. 2021) ("*Indivior II*"). Appx115-116. SB ignores the court's cogent analysis: in *Indivior II*, the Court rejected 'the post hoc attempt to 'select several components [in the example tables], add up the individual values, determine the aggregate percentages, and then couple those aggregate percentages with other examples' to arrive at the claimed range." *Id.* (alteration in original) (quoting *Indivior II*, 18 F.4th at 1328). No such gymnastics are necessary here; the POSA need only read the examples' native conformation data to recognize that the inventors

possessed formulations with at least 98% native conformation over two months. *Ariad*, 598 F.3d at 1351; *Sandoz*, 796 F.3d at 1308.

SB argues that 98% is "plucked out of thin air" because the examples (in SB's view) round to 99%. Br. 53. But again, no case supports the bizarre notion that where an embodiment reports 98.5% native conformation, Appx190-191, Example 2, a claim to at least 99%, but not to at least 98%, is described. *See Ariad*, 598 F.3d at 1351.

Regardless, SB undisputedly infringes claim 16, which recites "at least 99%" native conformation. Appx9, Appx54. SB raises no challenge to this elevated lower threshold; even if SB's argument about 98% had any merit—and it does not—the preliminary injunction should still be affirmed.

V. The District Court's Irreparable Harm Analysis Was Correct

SB challenges only the nexus findings in the district court's irreparable harm holding, and its arguments are unavailing. First, SB (Br. 58-61) fundamentally misreads this Court's nexus jurisprudence to import the *Apple II* standard into a context that this Court has deemed inappropriate. But even under SB's own incorrect standard, SB's argument reads out nearly every limitation of the asserted claims. It also ignores the district court's unchallenged factual finding that the "claimed compositions as a whole"—not

parceled out limitation by limitation—cover the Eylea (and SB15) product and drive consumer demand. Second, SB's nexus argument (in Parts III.A and III.B.2) that it *could* produce SB15 without practicing the asserted claims is both false and an improper collateral attack on the infringement findings SB *has not appealed*. Third, SB's argument (in Part III.B.3) that the district court failed to find irreparable harm with sufficient specificity cannot withstand scrutiny of the actual opinion below. In short, SB cannot show clear error.

A. SB Misstates the Appropriate Test for Causal Nexus

SB's nexus argument relies entirely on misapplication of *Apple II*, in large part by ignoring subsequent authority.

Contrary to SB's insistence, the causal nexus inquiry need not be complicated—it simply requires that a patentee "show that [it] is irreparably harmed *by the* [defendant's] *infringement*." *Apple Inc. v. Samsung Elecs. Co., Ltd.*, 735 F.3d 1352, 1363-64 (Fed. Cir. 2013) ("*Apple III*"); Appx160. As the district court explained, determining whether a causal nexus exists "can be complicated" in cases involving products with multiple features, like smartphones, requiring assessment of whether a particular patented feature of a complex product drives consumer demand. Appx160. But where the product is a medicine, the nexus question can be "simpler." Appx161 (citing

Apple III, 735 F.3d at 1361-62). In recognizing that simplicity, the district court did not hold, as SB misleadingly contends (Br. 58), that the nexus analysis "applies only in the context of 'multifeatured products.'" Rather, the district court conducted its nexus analysis at the level of granularity demanded by the claims at issue and controlling precedent. Appx163.

That precedent reflects that in cases involving products with a "small number of features," like medications, "the impact that the infringing features ha[ve] on demand for the products may never [be] in doubt" and nexus "may be more easily satisfied." *Apple III*, 735 F.3d at 1361-62. That is because the nexus inquiry has "little work to do ... when the infringing product contains no feature relevant to consumers' purchasing decisions other than what the patent claims." *Genband US LLC v. Metaswitch Networks, Corp.*, 861 F.3d 1378, 1384 n.2 (Fed. Cir. 2017). The nexus analysis is thus straightforward for patents that cover the product itself instead of a "feature" or "attribute[] of the finished consumer good" because "it is not possible to separate" the patent "from the product itself in evaluating consumer demand and nexus." *Janssen Prods. v. Lupin*, 109 F. Supp. 3d 650, 700 (D.N.J. 2014). In such cases, nexus is "apparent." *Genband*, 861 F.3d at 1384 n.2. Indeed, when the connection between the infringed patent and the harm is undeniable, this Court affirms

findings of irreparable harm supported by little or no discussion of nexus below. *Metalcraft of Mayville, Inc. v. The Toro Co.*, 848 F.3d 1358, 1368-69 (Fed. Cir. 2017); *In re Depomed*, 2016 WL 7163647, at *78-79 (D.N.J. Sept. 30, 2016), *aff'd sub nom. Grunenthal GmbH v. Alkem Labs.*, 919 F.3d 1333 (Fed. Cir. 2019). The district court faithfully applied precedent in finding the nexus analysis straightforward.

The district court also found that even applying the demand-driver test employed for "multi-feature" products, Regeneron demonstrated nexus, as the claimed elements imbue Eylea and SB15 with demand-driving properties—safety, efficacy, and opportunities for extended dosing intervals. Appx166-167. Specifically, the court found that SB15's safety flows from its stability, "including the required 98% native conformation" and that its efficacy and extended dosing derive from the claimed VEGF antagonist as well as the claimed 40 mg/mL concentration, which is "critical" to the drug's half-life. Appx166-167. In other words, SB's "infringing features drive consumer demand for" SB15, which "satisfies the causal nexus inquiry." *Apple Inc. v. Samsung Elecs. Co.*, 809 F.3d 633, 641 (Fed. Cir. 2015) (*Apple IV*). SB seeks to set aside that factfinding by arguing (Br. 59-61) that causal nexus requires Regeneron to show that only one of the claim limitations—the 98% native

conformation limitation—drives consumer demand. That argument is wrong for three reasons.

First, SB's approach demands that a "feature" refer to one claim limitation. SB offers no support for that proposition, or for the notion that Regeneron must prove that every claim limitation, rather than the claim as a whole, drives demand. To the contrary, in *Apple II*—the only case cited that requires feature-driven demand—the "feature" comprised an entire claim, not individual limitations. *Apple Inc. v. Samsung Elecs. Co.*, 695 F.3d 1370, 1372-73 (Fed. Cir. 2012) (*Apple II*). That is consistent with long-settled precedent: "all limitations of a claim must be considered in deciding what invention is defined." *Maxwell, Ltd. v. Amperex Tech. Ltd.*, 94 F.4th 1369, 1373 (Fed. Cir. 2024) (quoting *Hall v. Taylor*, 332 F.2d 844, 848 (C.C.P.A. 1964)). SB's legal error provides no basis to disturb the district court's unchallenged factfinding.

Second, SB cannot show error in the finding that Eylea "is the invention disclosed and claimed in the [product] patent." Appx164. Unlike *Apple II*, where the patentee failed to connect the claimed "unified search" feature to the economic impact from sales of the infringing smartphone, 695 F.3d at 1372-73, here the court found that the asserted claims, comprising *all* their limitations, cover the entire formulation of Eylea and SB15, and that "the

claimed compositions as a whole"—not arbitrary subdivisions thereof—provide the safety, efficacy, and dosing durability that drive consumer demand. Appx 164, Appx166-167 (emphasis added).

Third, SB's proposed requirement defies this Court's ruling in *Genband*. *Genband* found that the nexus inquiry has "little work to do … when the infringing product contains no feature relevant to consumers' purchasing decisions other than what the patent claims." 861 F.3d at 1384 n.2. Without addressing *Genband*, SB argues (Br. 59) that this standard does not apply. SB, though, has identified nothing in the SB15 formulation relevant to consumer demand that is separate from the asserted claims covering the entire product.

B. Nexus Exists Because SB Cannot Make SB15 Without Infringing the '865 Patent

SB concedes that the nexus requirement is necessarily satisfied under *Mylan Institutional v. Aurobindo Pharma*, 857 F.3d 858, 873 (Fed. Cir. 2017), if it cannot sell SB15 "without infringing." But SB's argument (Br. 57, 62-63) that it can market SB15 without infringing is contravened by factual findings on the record, placing SB15 on all fours with the infringing generic in *Aurobindo*.

First, SB's suggestion now that it *could* make SB15 with only [redacted] native conformation rings hollow, given that SB failed to challenge the district court's independently sufficient findings on infringement, and thus forfeited any argument to the contrary. *Aventis Pharma v. Hospira*, 675 F.3d 1324, 1332-33 (Fed. Cir. 2012). SB concedes that its approved manufacture of SB15 infringes. *Aurobindo* requires nothing further.

Second, contrary to SB's claims (Br. 62) about what FDA approved, the undisputed facts show that the only native conformation data that FDA actually *considered* all confirmed greater than [redacted] native conformation. *See* Appx2138-2142. SB presented no evidence that it produced SB15, or could produce SB15, without possessing [redacted] native conformation. SB is thus situated precisely like the infringers in *Aurobindo*. As there, the only record evidence shows that SB cannot produce SB15 without infringing—every batch tested has [redacted] native conformation as claimed. As in *Aurobindo*, all the harm Regeneron will suffer from SB15's launch necessarily results from SB's infringement. *See also Janssen*, 109 F. Supp. 3d at 706 ("Without infringing …, Lupin would not have generics to sell").

SB's failure to present evidence that it would sell non-infringing SB15 likewise disposes of SB's assertion (Br. 57) that if it launched SB15, Regeneron

would lose EYLEA sales "*regardless* of whether SB15 meets the limitation of all asserted claims requiring a stability of 98% over two months."

C. The District Court's Factual Findings that Regeneron Would Be Irreparably Harmed Are Not Clearly Erroneous

SB's final argument (Br. 63-64), that the court failed to find irreparable harm with sufficient specificity, cannot be squared with its detailed, fifty-page analysis finding that the launch of SB15 would harm Regeneron across five different dimensions (loss of sales and market share (Appx118-129), irreversible price erosion (Appx129-141), disruption of patentee-payor relationships (Appx141-146), reputational harm (Appx146-148), and increased marketing and training costs (Appx148-150)). SB hopes to erase those myriad findings (Br. 63) because they do not relate solely to the 98% native conformation limitation. That argument is meritless, as explained above. SB offers no other reason why the district court's detailed findings are insufficient to support its ultimate, sensible conclusion—the launch of biosimilar SB15 would harm Regeneron irreparably.

CONCLUSION

The judgment below should be affirmed.

AUGUST 26, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that today, August 26, 2024, I electronically filed the foregoing Brief for Plaintiff-Appellee with the Clerk of the Court for the U.S. Court of Appeals for the Federal Circuit using the appellate CM/ECF system. Counsel of record for all parties will be served by the appellate CM/ECF system.

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1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) and Federal Circuit Rule 32(b). This brief contains 13,930 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f) and Federal Circuit Rule 32(b).

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