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

2024-1965, 2024-1966, 2024-2082, 2024-2083

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

Decided: January 29, 2025

DAVID I. BERL, Williams & Connolly LLP, Washington, DC, argued for plaintiff-appellee. Also represented by ARTHUR JOHN ARGALL, III, THOMAS S. FLETCHER, CHRISTIAN GLADDEN-SORENSEN, KATHRYN SCHLECKSER

KAYALI, RHOCHELLE KRAWETZ, SHAUN PATRICK MAHAFFY, ADAM PAN, ANDREW V. TRASK; JACOB HARTMAN, Kellogg, Hansen, Todd, Figel & Frederick, PLLC, Washington, DC; PRIYATA PATEL, Paul, Weiss, Rifkind, Wharton & Garrison LLP, Washington, DC; ELIZABETH WEISWASSER, New York, NY.

WILLIAM ADAMS, Quinn Emanuel Urquhart & Sullivan, LLP, New York, NY, argued for defendant-appellant. Also represented by LAURA FAIRNENY, RAYMOND NIMROD, MATTHEW D. ROBSON, MATTHEW A. TRAUPMAN; LAUREN MARTIN, Boston, MA.

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

TARANTO, *Circuit Judge.*

Regeneron Pharmaceuticals, Inc. holds Biologics License Application (BLA) No. 125387—approved by the Food and Drug Administration (FDA)—for EYLEA®, a therapeutic product that contains the fusion protein aflibercept. Aflibercept is known as a "VEGF antagonist" or "VEGF trap" due to its ability to bind, or "trap," a protein called vascular endothelial growth factor (VEGF) before VEGF can bind to receptors in the human body and stimulate blood-vessel growth. Aflibercept formulations have been approved by the FDA for the treatment of several angiogenic eye diseases (*i.e.*, diseases related to blood-vessel growth in the eye) via intravitreal administration (*i.e.*, injection into the vitreous body of the eye). Regeneron also owns U.S. Patent No. 11,084,865, which is directed to VEGF-trap formulations suitable for intravitreal injection, as well as methods for making and using such formulations. '865 patent, col. 1, lines 45–49.

Mylan Pharmaceuticals Inc. (Mylan), Samsung Bioepis Co., Ltd. (SB), Formycon AG (Formycon), and several other

companies filed abbreviated Biologics License Applications (aBLAs) with the FDA, seeking approval under the Biologics Price Competition and Innovation Act (BPCIA) to market EYLEA® biosimilars. *See* 42 U.S.C. § 262(k)–(l). In August 2022, Regeneron filed an action against Mylan (the earliest aBLA applicant) in the Northern District of West Virginia (where Mylan is incorporated), asserting infringement of a sizable set of patents related to EYLEA®, including the '865 patent. In late 2023, Regeneron sued three other biosimilar applicants in the same forum, including SB and Formycon, both of which are foreign companies. Regeneron also brought an action against a fifth biosimilar applicant in the Central District of California, where that applicant is headquartered. In April 2024, the Judicial Panel on Multidistrict Litigation, under 28 U.S.C. § 1407, granted Regeneron's motion to consolidate all the actions in the West Virginia forum. *In re Aflibercept Patent Litigation*, 730 F. Supp. 3d 1374, 1375–78 (J.P.M.L. 2024).

The present appeal involves Regeneron's two suits against SB. In these cases, as well as in the case against Formycon (decided today by this panel), Regeneron filed motions for a preliminary injunction. The district court granted the motions against both SB and Formycon, enjoining them from offering for sale or selling in the United States (without a license from Regeneron) the subject of their aBLAs—which were approved by the FDA very close in time to the preliminary-injunction rulings. Both SB and Formycon appealed, each of them challenging the district court's exercise of personal jurisdiction and awarding of preliminary-injunction relief. There is considerable overlap in the two appellants' arguments.[1] We decide the SB

[1] The present panel heard oral argument in the cases on the same day, and at the oral argument, counsel for SB and Formycon coordinated their arguments: SB's counsel

and Formycon appeals today—SB's in the present opinion, and Formycon's in *Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc.*, Fed. Cir. No. 2024-2009 (Fed. Cir. Jan. 29, 2025) (*Formycon Fed. Cir. Decision*).

In the present case, the district court's June 14, 2024 confidential opinion granting preliminary-injunctive relief is at J.A. 1–181, and the public version is available at *In re Aflibercept Patent Litigation*, No. 1:24-MD-3103-TSK, 2024 WL 3422971 (N.D.W. Va. June 24, 2024) (*SB D. Ct. Opinion*). The injunction itself, issued July 10, 2024, is at J.A. 182–84 (*SB Prelim. Inj.*). We see no reversible error in the district court's holding that it had personal jurisdiction over SB (on the facts established at this stage by Regeneron) or in the district court's holding that Regeneron had made out its affirmative case for a preliminary injunction, which included a determination that SB had not raised a substantial question of invalidity of the asserted claims of the '865 patent. Accordingly, we affirm.

I

A

Regeneron owns a family of ten patents that claim priority to a provisional application filed on June 16, 2006, and to a nonprovisional application filed on June 14, 2007. The patents in that Stability Family share a specification that presents eight examples of VEGF-trap formulations with stability data for each. *See*, *e.g.*, '865 patent, col. 8, line 32, through col. 12, line 25. Examples 3 and 4 describe

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discussed only the non-jurisdictional issues, Formycon's counsel only the personal-jurisdiction issue. *See* Oral Arg. (SB), available at https://oralarguments.cafc.uscourts.gov/default.aspx?fl=24-1965_12052024.mp3; Oral Arg. (Formycon), available at https://oralarguments.cafc.uscourts.gov/default.aspx?fl=24-2009_12052024.mp3.

the formulation of EYLEA®. *Id.*, col. 9, line 19, through col. 10, line 12.

Two of the Stability Family patents are relevant to the present cases: the '865 patent and U.S. Patent No. 9,340,594. The '865 patent is the patent that is the basis for the preliminary injunction. Representative claim 4 and the claims on which it depends state as follows, with emphasis on the terms at issue in this appeal:

> 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.

Id., col. 19, lines 29–48 (emphases added). The '865 patent is due to expire on June 14, 2027—twenty years after the filing of the nonprovisional application to which it claims priority. *SB D. Ct. Opinion*, at *18 & n.4.

The ’594 patent is relevant here because it is the “reference patent” invoked by SB in arguing that the ’865 patent is invalid under the doctrine of obviousness-type double patenting (ODP). Despite the family relationship, the ’594 patent does not share the 2027 expiration date of the ’865 patent—because Regeneron adopted a terminal disclaimer during prosecution of the ’594 patent, producing an expiration date in 2021. Claim 5, which the parties agree is representative for purposes of the ODP analysis, and the claims on which it depends state as follows, with emphasis on the terms at issue in this appeal:

> 1. A *pre-filled syringe* suitable for intravitreal administration comprising a 1 mL luer glass syringe fitted with a plunger and a *stable* ophthalmic formulation of a *vascular endothelial growth factor (VEGF) trap*, which consists of (i) a receptor component consisting essentially of an immunoglobulin-like domain 2 of a first VEGF receptor and an immunoglobulin-like domain 3 of a second VEGF receptor, and (ii) a multimerizing component, wherein the *stable* ophthalmic formulation comprises:
>
> (a) 1-100 mg/ml [of] a VEGF antagonist;
>
> (b) 0.01-5% of one or more organic co-solvent;
>
> (c) 5-40 mM of buffer; and
>
> (d) optionally comprising 1.0-7.5% of a stabilizing agent.
>
> 2. The *pre-filled syringe* of claim 1, wherein the first VEGF receptor is Flt1, and the second VEGF receptor is Flk1 or Flt4.
>
> 3. The *pre-filled syringe* according to claim 2, wherein the *VEGF trap* is *stable* for at least 4 months.
>
> 4. The *pre-filled syringe* according to claim 3, wherein the *VEGF trap* consists of amino acids 27-457 of SEQ ID NO:4.

> 5. The *pre-filled syringe* according to claim 4, wherein the *stable* ophthalmic formulation comprises 40 mg/mL of the *VEGF trap*, 10 mM phosphate, 40 mM NaCl, 0.03% polysorbate 20, 5% sucrose, at pH 6.2-6.4.

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

B

SB is a biosimilar-products company headquartered in Incheon, South Korea. J.A. 495. In November 2019, SB signed a Development and Commercialization Agreement (Biogen Agreement) with a U.S. company, Biogen MA Inc., related to various drugs, including what would become SB's FDA-approved EYLEA® biosimilar (SB15). J.A. 1531–1651. In the agreement, SB provided Biogen with exclusive rights to commercialize SB15 in the "United States," among other countries. J.A. 1534, 1551–52, 1568, 1628. SB declares that it does not have any facilities or employees in the U.S.; that it has not registered to do business in West Virginia, has not designated an agent for service of process in West Virginia, and does not currently do business with entities in West Virginia; and that, following SB's sale of the finished SB15 drug product to Biogen in a State other than West Virginia, it "will not distribute, market[,] or sell SB15 in the United States." J.A. 495–97. But SB's *involvement* with the distribution, marketing, or sale (*i.e.*, commercialization) of SB15 does not terminate upon its sale of SB15 to Biogen: Unsurprisingly, the Biogen Agreement gives SB certain responsibilities and rights as the agreement is implemented over time, which include, among others the parties have chosen to keep confidential, the right to active participation in a joint SB-Biogen steering committee. J.A. 1556–61.

In February 2023, SB filed aBLA No. 761350 with the FDA, seeking approval to market SB15 under the BPCIA, 42 U.S.C. § 262(k)–(l). J.A. 1523–27. SB's aBLA does not

identify any parts of the U.S. as places where SB does *not* intend to market and distribute the approved product. J.A. 1523–27. As statutorily required before marketing the biosimilar, 42 U.S.C. § 262(l)(8)(A), SB sent a Notice of Commercial Marketing to Regeneron, *SB D. Ct. Opinion*, at *2, stating that "it will commence commercial marketing" of SB15 "on or after May 18, 2024 following FDA approval." J.A. 1529.

The FDA approved SB's aBLA on May 20, 2024. J.A. 20686–92. SB15 has not yet been marketed in the United States.

C

In late 2023, Regeneron sued SB in the same West Virginia federal forum where it had pending a similar suit against Mylan since August 2022 (a suit that came to include Mylan's distributor, Biocon Biologics Inc.). Pursuant to 42 U.S.C. § 262(l)(6)(B) and (l)(9)(A), Regeneron filed two actions against SB—both of them seeking a judgment of infringement of a set of patents that claim EYLEA® under 35 U.S.C. § 271(e), based on the aBLA application. (One of the actions also requests a declaratory judgment of patent infringement under 35 U.S.C. § 271(a)–(c) and (g), but that additional claim for relief is immaterial to the issues before us and so is not further mentioned.) In both cases (treated together), SB moved to dismiss for lack of personal jurisdiction in January 2024, and Regeneron moved for a preliminary injunction in February 2024. Similar motions were filed in Regeneron's case against Formycon. To streamline the dispute, Regeneron ultimately asserted only the '865 patent in seeking preliminary-injunction relief. *SB D. Ct. Opinion*, at *3.

On April 11, 2024, the Judicial Panel on Multidistrict Litigation granted Regeneron's motion to consolidate in the Northern District of West Virginia six actions that it had brought (five in West Virginia, one in California) under the BPCIA against various applicants for aflibercept

biosimilar approvals. *In re Aflibercept Patent Litigation*, 730 F. Supp. 3d at 1377–78.

On June 14, 2024, the district court granted Regeneron's motions for preliminary injunction in the SB cases, treating them together.[2] *See generally SB D. Ct. Opinion*. The district court first rejected SB's assertion that the court lacked personal jurisdiction over SB. Applying *Acorda Therapeutics Inc. v. Mylan Pharmaceuticals Inc.*, 817 F.3d 755 (Fed. Cir. 2016), the district court concluded that the minimum-contacts standard was met based on the facts Regeneron established at this stage of the proceeding—SB's aBLA filing together with the evidence of distribution channels that SB had established for national marketing of its biosimilar (with no carve-out for West Virginia). *SB D. Ct. Opinion*, at *2, *8–9. It then concluded that Regeneron had satisfied all the preliminary-injunction factors: (1) Regeneron was likely to succeed on its infringement claim and SB had failed to raise a substantial question of invalidity either under the ODP doctrine or for lack of an adequate written description, *id.* at *12–35; (2) Regeneron had demonstrated that it was likely to suffer irreparable harm without injunctive relief, *id.* at *35–48; (3) the balance of hardships favored Regeneron, *id.* at *48–50; and (4) the public interest favored the grant of preliminary injunction, *id.* at *50–51. The district court ordered the parties to submit a proposed injunctive order consistent with guidance provided by the court. *Id.* at *52.

On July 10, 2024, the district court issued the detailed preliminary injunction (covering both cases against SB). *SB Prelim. Inj.* Specifically, the court enjoined SB, and its marketer/distributor Biogen, from engaging in "the offer for sale or sale within the United States without a license

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[2] The FDA approved SB's aBLA on May 20, 2024, but a temporary restraining order barred the launching of SB15 until June 14, 2024.

from Regeneron of any product that is the subject of BLA No. 761350 that the FDA approved May 20, 2024." *Id.*

SB timely appealed the *SB D. Ct. Opinion* and filed an amended notice of appeal following the entry of the *SB Prelim. Inj.* order. We have jurisdiction under 28 U.S.C. § 1292(c)(1).

II

On appeal, SB challenges the district court's exercise of personal jurisdiction over it. "We review a district court's exercise of personal jurisdiction over an accused infringer without deference, applying Federal Circuit law rather than the law of the regional circuit." *Merial Ltd. v. Cipla Ltd.*, 681 F.3d 1283, 1292 (Fed. Cir. 2012). "Findings of fact that bear on personal jurisdiction are reviewed for clear error." *Id.* The district court made findings on the present record (under the standards appropriate to this stage of proceedings) and concluded that personal jurisdiction exists. We agree. Unless the evidence and factual determinations change in further proceedings, the personal-jurisdiction issue is resolved.

Under Federal Rule of Civil Procedure 4(k)(1)(A), a district court has personal jurisdiction over a defendant if that defendant would be "subject to the jurisdiction of a court of general jurisdiction in the state where the district court is located." Making that determination entails two inquiries: "whether a forum state's long-arm statute permits service of process, and whether the assertion of jurisdiction would be inconsistent with due process." *Electronics for Imaging, Inc. v. Coyle*, 340 F.3d 1344, 1349 (Fed. Cir. 2003). Here, West Virginia's long-arm statute is "coextensive with the full reach of due process." *In re Celotex Corp.*, 124 F.3d 619, 627 (4th Cir. 1997); *see* W. VA. CODE § 56-3-33. Therefore, this personal-jurisdiction dispute turns on the question of whether an exercise of jurisdiction comports with due process. *Electronics*, 340 F.3d at 1350.

In arguing against satisfaction of the constitutional standard (even at the preliminary-injunction stage), SB highlights its lack of direct contacts with West Virginia and asserts that there is no evidence that it plans to commercialize SB15 in West Virginia in particular. Rather, SB contends, it will make one sale of SB15 in a different State to Biogen, which then has exclusive rights to determine where to market SB15 in the U.S. Regeneron responds that, under *Acorda*, 817 F.3d 755, SB's filing of its aBLA, serving of its Notice of Commercial Marketing, failure to deny the allegation that it would commercialize SB15 in West Virginia through Biogen, and establishment of a robust distribution channel that includes West Virginia suffice to satisfy the minimum-contacts standard for personal jurisdiction over SB when it is sued for infringement under 35 U.S.C. § 271(e). We agree with Regeneron.

A court may constitutionally exercise specific personal jurisdiction when the defendant "ha[s] certain minimum contacts with [the forum] such that the maintenance of the suit does not offend 'traditional notions of fair play and substantial justice.'" *International Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945) (citation omitted). The minimum-contacts inquiry requires that "the defendant's suit-related conduct . . . create a substantial connection with the forum State." *Walden v. Fiore*, 571 U.S. 277, 284 (2014). This inquiry "focuses on 'the relationship among the defendant, the forum, and the litigation,'" *Keeton v. Hustler Magazine, Inc.*, 465 U.S. 770, 775 (1984) (citation omitted), "including specifically the nature of the claim asserted," *Acorda*, 817 F.3d at 759.

In *Acorda*, we confronted the question of whether defendant Mylan's conduct satisfied the minimum-contacts requirement in the context of an infringement suit brought under § 271(e)(2). 817 F.3d 755. *Acorda* involved an Abbreviated New Drug Application (ANDA) under 21 U.S.C. § 355(j), but no party has argued that the personal-jurisdiction standards are different for an aBLA, which is also

covered by § 271(e)(2). We answered the question in *Acorda* by concluding that "it suffices for Delaware to meet the minimum-contacts requirement in the present cases that Mylan's [ANDA] filings and its distribution channels establish that Mylan plans to market its proposed drugs in Delaware and the lawsuit is about patent constraints on such in-State marketing." *Id.* at 762–63. As we later summarized *Acorda*'s holding, the ANDA "submission with an intent to distribute the generic product in a given state was sufficient for personal jurisdiction purposes." *Valeant Pharmaceuticals North America LLC v. Mylan Pharmaceuticals Inc.*, 978 F.3d 1374, 1384 (Fed. Cir. 2020).

Elaborating on the basis for our holding, we reasoned in *Acorda* that "Mylan's ANDA filings constitute[d] formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs"—acts "taken . . . for the purpose of engaging in that injury-causing and allegedly wrongful marketing conduct" and "tightly tied, in purpose and planned effect," to that conduct. 817 F.3d at 760. We also observed that Congress, in enacting the Hatch-Waxman Act, recognized the "close connection between an ANDA filing and the real-world acts that approval of the ANDA will allow and that will harm patent-owning brand-name manufacturers," *id.*, and we understood "the economic realities of preparing an ANDA" to "confirm that filing realistically establishes a plan to market," *id.* at 761. We noted that Mylan's other conduct further indicated that Mylan planned to make direct sales of its generic product into Delaware: Mylan had developed its drugs for the entire U.S. market and did some business in every State, either directly or indirectly; had registered to do business in Delaware; had appointed an agent to accept service of process in Delaware; and had registered as a seller and distributor/manufacturer with the Delaware Board of Pharmacy. *Id.* at 763. But we also made clear: "And even if Mylan does not sell its drugs directly into Delaware, it has a network of independent wholesalers and distributors

with which it contracts to market the drugs in Delaware. Such directing of sales into Delaware is sufficient for minimum contacts." *Id.*

Here, we conclude, based on the record and findings presented to us, that SB's conduct satisfies the minimum-contacts requirement for personal jurisdiction in West Virginia.[3] The record as a whole supports the district court's finding that SB intends to distribute SB15 nationwide, including in West Virginia.

Like the defendant in *Acorda*, SB filed an application (here, an aBLA) with the FDA—an action that "reliably confirm[s] a plan to engage in real-world marketing" of SB15 within the U.S. *Id.* at 761. SB also served Regeneron with a Notice of Commercial Marketing, in which SB expressly communicated an intent to begin marketing of SB15 upon FDA approval. 42 U.S.C. § 262(l)(8)(A). SB has engaged several manufacturing, testing, labeling, and/or packaging partners within the U.S. J.A. 21391. And it has entered into an elaborate distribution agreement with Biogen to commercialize SB15 in the U.S., and as SB has noted to us, the district court found that "the agreement between SB and Biogen did not 'carv[e] any states out of the United States market.'" Appellant's Br. at 27 (quoting J.A. 7; redacted in *SB D. Ct. Opinion*, at *2).

Regarding the distribution agreement in particular: SB has signed multiple contracts with Biogen covering numerous aspects of the commercialization of SB15 within the U.S. and detailing the two companies' responsibilities and rights. J.A. 1531–1651; J.A. 1786–1824. The contents of

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[3] Because we determine that SB's conduct suffices to meet the minimum-contacts requirement, we do not decide whether Regeneron may establish that specific personal jurisdiction exists via any other legal authority, such as Federal Rule of Civil Procedure 4(k)(2).

these agreements and other business materials, some of which are confidential and thus not disclosed here, support the district court's finding that SB "retains significant . . . involvement in Biogen's U.S. commercialization activities through various contractually[] established mechanisms." *SB D. Ct. Opinion*, at *2 (redacted); J.A. 6–7. These mechanisms include, but are not limited to, active participation in a joint steering committee composed of representatives from SB and Biogen. *See*, *e.g.*, J.A. 1556–60. This court and other appellate courts have concluded that "purposeful shipment [or plans to do so] . . . through an established distribution channel"—such as the one SB has created—can establish personal jurisdiction. *Beverly Hills Fan Co. v. Royal Sovereign Corp.*, 21 F.3d 1558, 1565 (Fed. Cir. 1994); *Acorda*, 817 F.3d at 763 (determining that Mylan's establishment of "a network of independent wholesalers and distributors with which it contracts to market the drugs in Delaware" constitutes "directing of sales" that is "sufficient for minimum contacts"); *see also*, *e.g.*, *Clune v. Alimak AB*, 233 F.3d 538, 544 (8th Cir. 2000).

The record also supports the district court's finding that SB's distribution channels are of a nationwide nature. *SB D. Ct. Opinion*, at *2, *9. SB has not sought to limit the States where SB15 will be marketed, distributed, or sold—for example, it has not selected distributors that (collectively) reach only a limited region within the United States. *See*, *e.g.*, *Clune*, 233 F.3d at 544 ("[A] foreign manufacturer that successfully employs one or two distributors to cover the United States intends to reap the benefit of sales in every state where those distributors market."). A Biogen slide deck that was shared with SB indicates nationwide coverage. J.A. 1753–56. Furthermore, as the district court found, SB has not denied that Biogen, under the distribution agreement with SB, plans to market SB15 in West Virginia. *SB D. Ct. Opinion*, at *2 ("SB does not deny that it will market, sell, and distribute SB15 in West Virginia **through Biogen**." (emphasis in original)); J.A. 258

¶¶ 12, 14 (first complaint); J.A. 386–87 ¶¶ 12, 14 (second complaint). SB argues that it disputed this fact but cites only to filings where it repeats that SB itself will not market, distribute, or sell SB15 within the U.S. and that Biogen has "sole control over, and sole decision-making with respect to" doing so. Appellant's Br. at 27 n.5 (citing J.A. 469, 484–85, 11201–02). And the district court did not clearly err in finding that SB will retain a significant role in Biogen's activities through contractually established mechanisms.

SB's argument comes down to two assertions, neither of which is enough. The first is that there is a crucial, bright-line constitutional difference between SB doing its own distribution and SB contracting with a national distributor, even when it remains significantly engaged with that distributor. Consistent with the practical focus of the constitutional standard, we rejected such a distinction in *Acorda*. 817 F.3d at 763 ("And even if Mylan does not sell its drugs directly into Delaware, it has a network of independent wholesalers and distributors with which it contracts to market the drugs in Delaware. Such directing of sales into Delaware is sufficient for minimum contacts."). The second of SB's crucial assertions is that what Regeneron needs is affirmative evidence of SB (or perhaps Biogen) calling express attention to West Virginia as a target market. But there is simply no good reason, under the constitutional standard, for demanding such singling-out evidence as a substitute for persuasive evidence of nationwide targeting without a carve-out. Indeed, in *Acorda*, we relied on evidence that reliably indicated Mylan's plans to market its proposed drug in Delaware *and* other States. *See id.* at 759 (noting that Mylan's activities "will be purposefully directed at Delaware (and, it is undisputed, elsewhere)"); *id.* at 760 (noting that the ANDA filings are "tightly tied" to "sales in Delaware (at least)"); *id.* at 762 (similar). We conclude that personal jurisdiction lies against SB in West Virginia, and we turn to the district court's ruling that

Regeneron justified issuance of the preliminary injunction entered against SB.

III

"A party may obtain a preliminary injunction by showing that (1) it is likely to succeed on the merits, (2) it is likely to suffer irreparable harm in the absence of preliminary relief, (3) the balance of equities tips in [its] favor, and (4) an injunction is in the public interest." *BlephEx, LLC v. Myco Industries, Inc.*, 24 F.4th 1391, 1398 (Fed. Cir. 2022) (internal quotation marks omitted). A patent owner's ability to establish a likelihood of success can depend on whether the accused infringer presents an invalidity defense in opposing a preliminary injunction. "[I]f the accused infringer presents a substantial question of validity, *i.e.*, asserts an invalidity defense that the patentee cannot prove lacks substantial merit, the preliminary injunction should not issue." *Id.* at 1399 (internal quotation marks omitted). The accused infringer's burden of persuasion on invalidity is taken into account in assessing the substantiality of an invalidity question. *Id.*

"We review the grant or denial of a preliminary injunction under the law of the regional circuit, here the Fourth Circuit." *Natera, Inc. v. NeoGenomics Laboratories, Inc.*, 106 F.4th 1369, 1374 (Fed. Cir. 2024). We "give[] dominant effect to Federal Circuit precedent insofar as it reflects considerations specific to patent issues." *Id.* at 1375 (quoting *Murata Machinery USA v. Daifuku Co.*, 830 F.3d 1357, 1363 (Fed. Cir. 2016)). "Both the Fourth Circuit and the Federal Circuit review the grant or denial of a preliminary injunction for abuse of discretion." *Id.* "An abuse of discretion may be established by showing that the court made a clear error of judgment in weighing relevant factors or exercised its discretion based upon an error of law or clearly erroneous factual findings." *Id.* (quoting *Novo Nordisk of North America, Inc. v. Genentech, Inc.*, 77 F.3d 1364, 1367 (Fed. Cir. 1996)). Under the clear error standard, we defer

to the district court's findings of fact "unless there is a definite and firm conviction that a mistake has been made." *Biogen International GmbH v. Mylan Pharmaceuticals Inc.*, 18 F.4th 1333, 1341 (Fed. Cir. 2021) (internal quotation marks omitted). We reject SB's various challenges to the determination to issue the preliminary injunction.

A

SB argues that it raised a substantial question as to the invalidity of the '865 patent for obviousness-type double patenting in light of the '594 reference patent (of Regeneron's).

"Obviousness-type double-patenting is a judicially created doctrine intended to prevent *improper* timewise extension of the patent right by prohibiting the issuance of claims in a second patent which are not 'patentably distinct' from the claims of a first patent. The doctrine has also been phrased as prohibiting claims in the second patent which define 'merely an obvious variation' of an invention claimed in the first patent." *In re Braat*, 937 F.2d 589, 592 (Fed. Cir. 1991) (internal citations omitted). The comparison thus is between *claims* of the later and earlier patents. "First, the court construes the claim[s] in the earlier patent and the claim[s] in the later patent and determines the differences. Second, the court determines whether those differences render the claims patentably distinct." *AbbVie Inc. v. Mathilda & Terence Kennedy Institute of Rheumatology Trust*, 764 F.3d 1366, 1374 (Fed. Cir. 2014) (internal quotation marks omitted); *see Eli Lilly & Co. v. Barr Laboratories, Inc.*, 251 F.3d 955, 967–68 (Fed. Cir. 2001). The second step is "analogous to an obviousness analysis under 35 U.S.C. § 103," but "the nonclaim portion of the earlier patent ordinarily does not qualify as prior art against the patentee." *AbbVie*, 764 F.3d at 1378–79 (citations omitted); *see Eli Lilly & Co. v. Teva Parenteral Medicines, Inc.*, 689 F.3d 1368, 1379 (Fed. Cir. 2012); *Amgen Inc. v. F. Hoffman–La Roche Ltd.*, 580 F.3d 1340, 1361 (Fed.

Cir. 2009); *In re Kaplan*, 789 F.2d 1574, 1580 (Fed. Cir. 1986); *In re Longi*, 759 F.2d 887, 892 n.4 (Fed. Cir. 1985).

The parties accept that the analysis here is properly limited to three limitations that appear in claim 1 of the '865 patent (and hence in its dependent claims) and in claim 5 of the '594 reference patent. SB challenges the district court's conclusion that each of three limitations of claim 1 of the '865 patent were patentably distinct over claim 5 of the '594 patent: (1) a very specific stability requirement—that "at least 98% of the VEGF antagonist is present in native conformation following storage at 5° C. for two months as measured by size exclusion chromatography"; (2) a requirement that the VEGF antagonist is "glycosylated"; and (3) a "vial." As part of its challenge, SB submits that the district court erred in finding that the objective indicia supported nonobviousness. Regeneron argues to the contrary—and also contends that the '594 patent is not a proper reference patent for ODP purposes in the first place.

"[O]bviousness-type double patenting is an issue of law premised on underlying factual inquiries." *Eli Lilly v. Teva*, 689 F.3d at 1376 (citation omitted). "Accordingly, we consider the district court's ultimate conclusion on obviousness-type double patenting without deference, but we review any predicate findings of fact for clear error." *Id.* It suffices for us to conclude that two claim differences—"at least 98%" stability and glycosylation—render the '865 and '594 claims patentably distinct. We need not and do not reach SB's argument about the "vial" limitation or Regeneron's argument that the '594 patent does not qualify as an ODP reference patent at all.

1

The first difference that the district court identified as one that renders the '865 patent claims patentably distinct from claim 5 of the '594 patent relates to the stability of the VEGF trap. Claim 1 of the '865 patent requires that "at

least 98% of the VEGF antagonist is present in native conformation following storage at 5° C. for two months as measured by size exclusion chromatography." '865 patent, col. 19, lines 38–41. In comparison, claim 5 of the '594 patent requires, by its indirect dependency on claim 3, simply that the VEGF trap be "stable for at least 4 months." '594 patent, col. 19, line 39; *id.*, col. 20, lines 21–24.

The district court concluded that the '594 patent's stability requirement was "broader than, and not limited to," the stability requirement in the '865 patent. *SB D. Ct. Opinion*, at *24. The court reached that conclusion based in part on the teaching in the specification (which is shared by the two patents) of a preferred level of stability ("at least 90%") lower than the '865 patent's claimed 98%, "multiple aspects of stability" (not only in terms of native conformation), and "multiple ways to determine stability" (not only by size exclusion chromatography). *Id.* at *22. The district court then found that the '865 patent's requirement of 98% native conformation for two months (as measured by size exclusion chromatography) was not inherent in (and thus not anticipated by) the '594 reference patent's claim 5 and that it was non-obvious because a relevant artisan would not have been motivated to arrive at this requirement with a reasonable expectation of success. *Id.* at *31.

SB argues that the '865 patent's 98% native conformation limitation is an obvious variant because it is "simply an additional property of the composition claimed in the '594 reference patent and thus, as a matter of law, does not render the '865 patent distinct." Appellant's Br. at 39. SB also points out that the "specific" stability values in the '865 patent claims "are encompassed by" the "generic" stability requirement in the '594 reference patent claims and that Examples 3 and 4 (*i.e.*, the EYLEA® formulations) are embodiments of both the '594 and '865 patent claims. *Id.* at 40–41. These arguments—for what amounts to bypassing the focused factual analysis of

motivation and reasonable expectation of success—are unpersuasive.

First, SB offers no support for the suggestion that it is enough to defeat patentable distinctness (without the usual obviousness inquiry) that a later patent's limitation requires an "additional property" beyond what the reference patent requires. The notion of "additional property" is not meaningfully defined, let alone sufficiently defined to distinguish the mine-run of new limitations and justify truncating the obviousness inquiry. The authorities SB cites are about a much more limited situation that is not present here. Specifically, SB relies on the narrow category of cases that involve a later patent's "claim to a method of using a composition" where the reference patent claimed the composition and disclosed the later-claimed use in its specification to establish utility. *Sun Pharmaceutical Industries, Ltd. v. Eli Lilly & Co.*, 611 F.3d 1381, 1385–88 (Fed. Cir. 2010); *see Pfizer, Inc. v. Teva Pharmaceuticals USA, Inc.*, 518 F.3d 1353, 1363 (Fed. Cir. 2008); *see also AbbVie*, 764 F.3d at 1380; *Geneva Pharmaceuticals, Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1386 (Fed. Cir. 2003). But the present cases are not within that category: A newly demanding requirement of stability is not a new method of using the earlier-claimed VEGF-trap formulations.

Second, the fact that the '865 patent's narrower stability limitation is "encompassed" by the reference patent's stability limitation does not change the outcome: We have made clear that "domination"—where one patent with a broader claim reads on an invention defined by another patent's narrower claim, as a genus does a species, it "dominates" the latter patent—"by itself[] does not give rise to 'double patenting.'" *In re Kaplan*, 789 F.2d at 1577; *see also AbbVie*, 764 F.3d at 1379 ("[O]bviousness is not demonstrated merely by showing that an earlier expiring patent dominates a later expiring patent. . . . It is well-settled that a narrow species can be non-obvious and patent eligible

despite a patent on its genus."). Of course, "not every species of a patented genus is separately patentable"—even for anticipation purposes, *AbbVie*, 764 F.3d at 1379 (discussing a type of sufficiently small genus), much less for obviousness, *id.* But SB has not challenged the district court's finding that the genus (of "stable" VEGF-trap formulations) is not so small that it anticipates the limitation at issue in claim 1 of the '865 patent or made a showing of clear error in the district court's findings regarding motivation and reasonable expectation of success. And simply pointing to Examples 3 and 4 of the specification incorrectly shifts the focus away from the claims, where longstanding ODP principles require it to be.

We are not persuaded that SB has put forth a substantial basis for questioning that the 98% native conformation limitation of claim 1 of the '865 patent makes the claim patentably distinct from claim 5 of the reference patent. SB has not appealed the district court's construction of "stable" in the '594 reference patent to mean something broader than the "at least 98% . . . native conformation" limitation. *SB D. Ct. Opinion*, at *22–24. Nor does SB challenge the district court's factual findings that this requirement was not inherent in the '594 patent's claim 5, *id.* at *28–31; that a relevant artisan would not have had the motivation to obtain such a high level of native conformation, *id.* at *31; and that a relevant artisan would not have reasonably expected to succeed in doing so, *id.* For those reasons, we conclude that SB has not presented a substantial question of lack of patentable distinctness of the 98% native conformation limitation of claim 1 of the '865 patent.

That conclusion suffices to reject the ODP assertion, given that one patentably distinct limitation is enough. Accordingly, we hold that SB has not presented a substantial question of invalidity under the ODP doctrine.

2

Although the foregoing suffices regarding the ODP issue, it is worth adding that we also agree with the district court about a second claim limitation. Claim 1 of the '865 patent requires the VEGF trap to be "glycosylated." '865 patent, col. 19, lines 35–36. The district court construed the '594 reference patent's claim 5—which says nothing about glycosylation, '594 patent, col. 20, lines 21–24—to embrace both glycosylated *and* non-glycosylated aflibercept. *SB D. Ct. Opinion*, at *24–25. The court held the difference to defeat SB's argument for lack of patentable distinctness, finding that a relevant artisan lacked the motivation to use glycosylated aflibercept because, among other reasons, the prior art showed that glycosylation would increase the size of aflibercept, thus reducing retinal penetration, and would increase systemic exposure and inflammation risk. *Id.* at *25–28.

SB has presented no persuasive argument for disturbing the district court's ruling on this point. SB has not challenged the district court's claim construction of "VEGF trap" in the '594 reference patent to cover both glycosylated and non-glycosylated aflibercept. Instead, SB argues that glycosylation is "just an additional property of the composition claimed in the '594 reference patent," Appellant's Br. at 41, and that if the '594 reference patent's claim 5 "encompasses" glycosylated aflibercept, then the '865 patent must be obvious, because the '865 patent "simply restricts the claimed formulation to those in which aflibercept is glycosylated," *id.* at 42–43. But those contentions—which seek to sidestep the district court's particularized motivation and related findings—embody the same errors regarding ODP doctrine that we identified in discussing the 98% native conformation limitation. SB does not challenge the district court's finding that a relevant artisan lacked the motivation to use glycosylated aflibercept because such an artisan would know that glycosylation would increase the size of aflibercept, which would hamper retinal penetration

(needed for the desired therapeutic effect) and increase risks such as inflammation. *SB D. Ct. Opinion*, at *25–28.

We therefore conclude that the glycosylation requirement of claim 1 of the '865 patent is a second basis for rejecting SB's argument of lack of patentable distinctness from claim 5 of the '594 patent.

3

Finally, SB challenges the district court's determination that certain objective indicia support nonobviousness. *Id.* at *33. We need not and do not address this challenge. The district court stated that, "[e]ven without objective evidence of nonobviousness, the Court would find that SB has not raised a substantial question that the ['865 patent] is invalid for ODP." *Id.* We agree with the district court on the two points addressed above, which suffice to support the district court's conclusion.

B

SB argues that it raised a substantial question of invalidity for lack of an adequate written description under 35 U.S.C. § 112(a). "Written description is a question of fact, judged from the perspective of one of ordinary skill in the art as of the relevant filing date." *Immunex Corp. v. Sandoz Inc.*, 964 F.3d 1049, 1063 (Fed. Cir. 2020) (citation omitted); *see Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). The written description test requires "an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art. Based on that inquiry, the specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed." *Immunex*, 964 F.3d at 1063 (quoting *Ariad*, 598 F.3d at 1351); *see also Allergan, Inc. v. Sandoz Inc.*, 796 F.3d 1293, 1308 (Fed. Cir. 2015). In an alternative expression of the same substantive standard, we have said that the document must show that the

inventor "had possession of" the invention. *Ariad*, 598 F.3d at 1351.

The district court in the present cases held that "SB ha[d] not raised a substantial question of invalidity due to a lack of written description with respect to any asserted claim of the Product Patent." *SB D. Ct. Opinion*, at *35. SB argues to the contrary, pointing to three limitations of the '865 patent as not adequately supported by the specification: glycosylation, the upper bound of the "at least 98%" stability requirement, and the lower bound of that stability requirement. Appellant's Br. at 46–55. We reject these arguments.

1

SB argues that there is no support in the '865 patent's specification for glycosylated aflibercept formulations with the claimed level of stability. Appellant's Br. at 47–49. SB states that the specification has only one "generic disclosure" of glycosylation that "precedes the examples and is not connected in any way to them." *Id.* at 48. SB also asserts that the district court contradicted itself by finding (in its ODP analysis) that a relevant artisan would have been motivated to use *non-glycosylated* aflibercept and then finding (in its written-description analysis) that the same artisan would have understood the example embodiments in the '865 patent to be glycosylated. *Id.* at 48–49.

We disagree. "[T]he disclosure must be considered as a whole, as the person of ordinary skill in the art would read it, to determine if it *reasonably* conveys possession." *Allergan USA, Inc. v. MSN Laboratories Private Ltd.*, 111 F.4th 1358, 1375 (Fed. Cir. 2024). The '865 specification, in discussing the preparation of the VEGF trap, states that the VEGF trap "in a specific embodiment" "comprises amino acids 27-457 of SEQ ID NO:4," *i.e.*, aflibercept, "and is glycosylated at Asn residues 62, 94, 149, 222 and 308." '865 patent, col. 6, lines 34–37. The specification then provides several embodiments along with their stability data,

including Examples 3 and 4, which comprise the same amino-acid sequence ("SEQ ID NO:4") and have stability measurements that fall within the claimed range. *Id.*, col. 9, line 19, through col. 10, line 12. Regeneron presented expert testimony that a relevant artisan reading those examples "would look to the rest of the specification to see how the VEGF trap was made," would note the specification's disclosure that glycosylation results from a particular method of manufacture, and would understand the VEGF trap to be glycosylated at those specific residues. J.A. 15135–36. SB has not cited any evidence in rebuttal. The district court did not clearly err in finding, on this record, that a relevant artisan, reading the specification "as a whole," *Allergan USA v. MSN Laboratories*, 111 F.4th at 1375, would understand the specification to disclose glycosylation as claimed.

We do not understand the district court's ODP and written description findings to be contradictory. The ODP analysis is focused on the earlier patent's *claims*, and what a relevant artisan would find obvious based on them, whereas the written-description analysis is focused on what is disclosed in the *specification*. The '594 reference patent's claims say nothing about glycosylation, so they do not differentiate between glycosylated and non-glycosylated versions of the VEGF trap, and the district court found that a relevant artisan would not have been motivated to choose a glycosylated version with a reasonable expectation of success. *SB D. Ct. Opinion*, at *24–28. That determination is not inconsistent with the finding that a relevant artisan reading the specification would have understood the inventors to have actually invented the non-preferred glycosylated version(s) claimed in the '865 patent.

2

SB argues that the district court clearly erred in finding that there was adequate support in the specification for

the upper bound of the claimed stability range ("at least 98% . . . native conformation following storage . . . for two months") because the highest two-month stability level disclosed in the specification is 99.3%—whereas, SB says, the upper bound of "at least 98%" is 100%. Appellant's Br. at 49–53 (discussing the '865 patent, Examples 3–4, 11). SB faults the district court for crediting the testimony of its own expert, Dr. Tessier, who stated that "*most proteins* are not purified to [100%]" but who did not state the same about aflibercept in particular. *Id.* at 50 (emphasis in brief). Finally, SB argues that the court conflated enablement and written description when it stated that the claims need only "enable" a relevant artisan to approach the upper limit. *Id.* at 52.

SB's arguments are not persuasive. The specification does not need to describe "every conceivable and possible future embodiment of [the] invention." *Cordis Corp. v. Medtronic AVE, Inc.*, 339 F.3d 1352, 1365 (Fed. Cir. 2003) (internal quotation marks omitted). "There is no rigid requirement that the disclosure contain 'either examples or an actual reduction to practice'; the proper inquiry is whether the patentee has provided an adequate description that 'in a definite way identifies the claimed invention' in sufficient detail such that a person of ordinary skill would understand that the inventor had made the invention at the time of filing." *Allergan v. Sandoz*, 796 F.3d at 1308 (quoting *Ariad*, 598 F.3d at 1352). We have affirmed findings of adequate written description for "open-ended claims" where the upper bound "would be limited by what a person skilled in the art would understand to be workable" and where the patent's specification adequately supported that range. *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1576 (Fed. Cir. 1985); *see also Andersen Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1376–77 (Fed. Cir. 2007) (affirming jury verdict of written description where there was evidence that a relevant artisan would recognize an inherent upper limit); *Nalpropion*

Pharmaceuticals, Inc. v. Actavis Laboratories FL, Inc., 934 F.3d 1344, 1349–51 (Fed. Cir. 2019) (affirming adequate written description for an "at least 99% [dissolution]" limitation without disclosure of results at or above 99%).

Here, the district court appropriately credited expert testimony that "most proteins are not purified to [100%]" to conclude that "the maximum percent native conformation 'would be limited by what a [relevant artisan] would understand to be workable.'" *SB D. Ct. Opinion*, at *34 (first quoting J.A. 20252; and then quoting *Ralston Purina*, 772 F.2d at 1576). SB has not pointed to any evidence that aflibercept differs from "most proteins" in this regard, nor has SB shown that even a small change in native conformation above 99.2% would be both possible and so difficult to achieve that formulations with stability percentages within the 99.3–100% are significantly different inventions, making it improper to view the inventors as having invented them based on the 99.2% figure in the specification. The district court relied appropriately on expert testimony—this time from Dr. Trout—to find that "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 that those "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)" showed possession of the claimed range. *Id.* at *35; *see Novo Nordisk Pharmaceuticals, Inc. v. Bio-Technology General Corp.*, 424 F.3d 1347, 1353 (Fed. Cir. 2005) ("[W]here the record viewed in its entirety renders the district court's account of the evidence plausible or discloses two permissible readings of the evidence, the fact-finder has committed no clear error." (citation omitted)).

We also reject SB's argument, relying on the district court's quotation of a portion of *Andersen* stating what was sufficient to meet the enablement requirement, that the district court committed legal error by confusing the written description and enablement requirements. The district

court's quote is part of a broader discussion in *Andersen* discussing why *both* the written description and enablement requirements were met for the same open-ended claim. *See SB D. Ct. Opinion*, at *34 (quoting *Andersen*, 474 F.3d at 1376–77 (quoting *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1572 (Fed. Cir. 1991))).

3

SB argues that the district court clearly erred in finding that the written-description requirement was met for the lower bound of the claimed stability range because the lowest *three*-month stability level disclosed for any formulation in the specification was 98.5%, and the two-month stability levels disclosed for Examples 3 and 4 (*i.e.*, EYLEA®) were, again, 99.1% and 99.2%. Appellant's Br. at 53–55. Thus, SB contends, a relevant artisan cannot "reasonably discern" the 98% lower bound. *Id.* at 53.

The district court did not clearly err in finding SB's challenge on this ground not to raise a substantial question. In reaching its conclusion, the district court correctly distinguished the present cases from the case SB relied on: *Indivior UK Ltd. v. Dr. Reddy's Laboratories S.A.*, 18 F.4th 1323 (Fed. Cir. 2021). There, the Board found inadequate written-description support for a claim limitation of "about 40 wt % to about 60 wt %." *Id.* at 1329. We agreed, stating that a disclosed embodiment of "at least 25%" was "quite out of the [claimed] range" and that an alternative of "at least 50%" was "hardly clear support in light of other inconsistent language." *Id.* We also rejected an approach proposed by the appellant that required "select[ing] several components, add[ing] up the individual values, determin[ing] the aggregate percentages, and then coupl[ing] those aggregate percentages with other examples . . . to create an otherwise unstated range." *Id.* Here, no cobbling together of numbers is necessary—the '865 patent contains "multiple disclosures of native conformations throughout

the range of 98% to 100%." *SB D. Ct. Opinion*, at *35. Thus, the district court could properly find that "it is clear to a [relevant artisan] reading the ['865 patent] that inventors possessed the entirety of the claimed subject matter." *Id.*

C

Finally, SB argues that the district court erred in finding that Regeneron had established a causal nexus between SB's infringement and the irreparable harm Regeneron would incur without injunctive relief. Appellant's Br. at 55–64. SB makes two main arguments, both of which we reject.

First, SB points out that its aBLA, which the FDA approved, requires only 96% stability after two months of storage. *Id.* at 57. SB argues that SB/Biogen can sell "lots of SB15 that are only 96% stable at two months and that therefore do not infringe the '865 patent," causing the same harms to Regeneron. *Id.*; *see* Oral Arg. at 5:36–5:59, 23:55–24:38.

This argument is unavailing. There is no evidence that SB possesses or plans to sell or offer to sell a non-infringing biosimilar under its approved aBLA. Indeed, the evidence in the record indicates otherwise. *See SB D. Ct. Opinion*, at *47–48 (noting, among other evidence, that "SB has sought and received FDA approval only for SB15" and not "some non-infringing alternative biosimilar product"); J.A. 2120 ¶ 5 (Dr. Trout's testimony on difficulty of altering formulation to avoid infringement by obtaining a stability level below 98%); J.A. 2138–42 ¶¶ 51–57 (Dr. Trout's testimony on SB's FDA data, which show only an infringing biosimilar (discussing J.A. 2753, 2820–22)). And the district court credited Regeneron's expert testimony that altering SB15 to achieve a non-infringing formulation was no easy matter. *SB D. Ct. Opinion*, at *48 (crediting testimony that SB could not "simply alter the SB15 formulation to attempt to avoid infringement" and that "any necessary changes

would require additional testing and other product changes, with no guarantee that a non-infringing product would work as intended" (quoting J.A. 2120 ¶ 5)). On this record, the fact that the scope of SB's approved aBLA is broader than that of the '865 patent's claims does not defeat causal nexus; Regeneron's harms are likely to flow from SB's *infringing* conduct.[4]

Second, SB argues that Regeneron must establish a causal nexus between the irreparable harms and the *unique* limitations of the '865 patent (as opposed to the limitations that are also in the '594 reference patent). SB argues that the 98% native conformation feature "is what must drive demand for SB15 to meet the causal nexus requirement." Appellant's Br. at 59. SB accuses the district court of misreading our precedents to hold that the causal-nexus requirement applies only to multi-featured products (*e.g.*, smartphones) and thus concluding that Regeneron did not need to establish a causal nexus for a simpler product like SB15. *Id.* at 58–61.

We reject SB's arguments. The district court correctly noted that the causal-nexus inquiry is often distinctly complicated for "complex, multi-featured" products, where a

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[4] For much the same reasons, the preliminary injunction order, which enjoins SB "from the offer for sale or sale within the United States without a license from Regeneron of *any* product that is the subject of BLA No. 761350 that the FDA approved May 20, 2024," *SB Prelim. Inj.*, at 1 (emphasis added), is not overbroad. The record indicates that the only "product that is the subject of BLA No. 761350" that SB plans to sell is an infringing one. If SB were to create a non-infringing formulation of SB15 that falls within the scope of FDA approval, nothing in this opinion would prevent SB from returning to the district court to seek modification of the preliminary injunction order under Federal Rule of Civil Procedure 65.

court must analyze whether the patented feature is a driver of consumer demand for the accused infringer's product. *SB D. Ct. Opinion*, at *46–47; *see Apple Inc. v. Samsung Electronics Co.*, 735 F.3d 1352, 1362–64 (Fed. Cir. 2013) (*Apple III*). In contrast, "[t]he causal-nexus inquiry may have little work to do in an injunction analysis when the infringing product contains no feature relevant to consumers' purchasing decisions other than what the patent claims," as is the case with SB15 and the '865 patent. *Genband US LLC v. Metaswitch Networks Corp.*, 861 F.3d 1378, 1384 n.2 (Fed. Cir. 2017); *see Apple III*, 735 F.3d at 1362.

SB cites no authority that involves a product that essentially *is* the claimed invention, with no significant additional features, and holds the causal-nexus requirement not to be met because a nonexistent, noninfringing different product—one that does not meet all the claim limitations—might cause the same irreparable harms. Here, moreover, the district court made findings to the effect that the combination of limitations in the '865 patent's claims drives demand. *SB D. Ct. Opinion*, at *48. The record therefore is sufficiently similar to the one in *Mylan Institutional LLC v. Aurobindo Pharma Ltd.*, 857 F.3d 858, 873 (Fed. Cir. 2017), where we found the causal nexus requirement met, that the same result follows. As already noted, *supra* n.4, if SB produces a noninfringing product within the scope of its aBLA, it may seek modification of the injunction from the district court.

IV

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

AFFIRMED