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Paper No. 12
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAMSUNG BIOEPIS CO., LTD.,
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

IPR2025-00176
Patent 11,084,865 B2

Before SUSAN L. C. MITCHELL, MICHAEL A. VALEK, and JAMIE T. WISZ, *Administrative Patent Judges.*

VALEK, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Samsung Bioepis Co., Ltd. ("Petitioner") filed a Petition (Paper 2, "Pet."), seeking *inter partes* review of claims 1–12, 14–17, 19, 20, 22–36, 39–42, 44, 45, and 47–55 of U.S. Patent No. 11,084,865 B2 (Ex. 1001, "the '865 patent"). Regeneron Pharmaceuticals, Inc. ("Patent Owner") filed a Preliminary Response. Paper 8 ("Prelim. Resp.").

In its Preliminary Response, Patent Owner asks that we exercise discretion to deny institution under 35 U.S.C. § 314(a) in view of parallel district court litigation involving the '865 patent. *See* Prelim. Resp. 6–17. With our authorization, Petitioner filed a reply to Patent Owner's arguments for discretionary denial under § 314(a) (Paper 10 ("Reply")) and Patent Owner filed a sur-reply (Paper 11 ("Sur-reply")).

For the reasons set forth below, we exercise discretion under 35 U.S.C. § 314(a) to deny institution of the Petition.

II. BACKGROUND

A. Real Parties in Interest

Petitioner and Patent Owner identify themselves as the only real parties in interest. Pet. 6; Paper 6, 1.

B. Related Matters

The '865 patent is currently asserted against Petitioner in *Regeneron Pharmaceuticals, Inc. v. Samsung Bioepis Co., Ltd.*, No. 1:23-cv-106 (N.D.W. Va.) and *Regeneron Pharmaceuticals, Inc. v. Samsung Bioepis Co., Ltd.*, No. 1:23-cv-94 (N.D.W. Va.). Pet. 6–7. The '865 patent has been asserted against a number of other defendants in the following matters:

Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc., No. 1:22-cv-61 (N.D.W. Va.) ("the Mylan case"); *Regeneron Pharmaceuticals, Inc. v. Formycon AG*, No. 1:23-cv-97 (N.D.W. Va.); *Regeneron Pharmaceuticals, Inc. v. Celltrion, Inc.*, Nos. 1:23-cv-89, 1:24-cv-53 (N.D.W. Va.); *Regeneron Pharmaceuticals, Inc. v. Amgen Inc.*, No. 2:24-cv-264 (C.D. Cal.); *Regeneron Pharmaceuticals, Inc. v. Sandoz Inc.*, No. 3:24-cv-876 (D.N.J.). Paper 6, 1–4. According to Patent Owner, "[t]he U.S. Judicial Panel on Multidistrict Litigation instituted a multidistrict litigation incorporating the aforementioned actions in the Northern District of West Virginia." *Id.* at 2. We refer to these cases collectively as "the MDL proceeding" and the cases against Petitioner specifically as "the SB case."

The first of these cases, the Mylan case, has already proceeded through trial. Following a 9-day bench trial, the district court issued a detailed opinion finding that Mylan[1] infringed claims 4, 7, 9, 11, and 14–17 of the '865 patent and had not shown that those claims are invalid under 35 U.S.C. §§ 102, 103, or 112. Ex. 2001 ("Mylan Decision"), 3, 311–312. The district court's judgment was appealed and later that appeal was dismissed by joint stipulation as part of agreement between Mylan and Patent Owner resolving their disputes. *See* Reply 2, n. 1; Ex. 1138, 1–2 (April 22, 2025 order entering joint stipulation and order offered by Patent Owner and Mylan).

The district court has also conducted preliminary injunction ("PI") proceedings and granted PIs based on the '865 patent against Petitioner and two other biosimilar applicant defendants in the MDL proceeding. Ex. 2002

[1] Mylan Pharmaceuticals Inc. and Biocon Biologics Inc. are joint defendants in this case. *See* Ex. 2001, 1. Here, we refer to them collectively as "Mylan."

(order granting motion for preliminary injunction against Samsung Bioepis) ("SB PI order"); *see also* Ex. 2003 (order granting motion for preliminary injunction against Formycon) ("Formycon PI order"); Ex. 2004 (order granting motion for preliminary injunction against Celltrion) ("Celltrion PI order"). Each of those decisions was appealed and recently affirmed by the Federal Circuit. *See* Ex. 2005–2007. The district court also considered and denied Patent Owner's motion for a preliminary injunction against Amgen. Paper 6, 3. According to Patent Owner, the Amgen PI motion was denied because the district court found it "was not likely to succeed on infringement." *Id.*

The '865 patent is also the subject of petitions for *inter partes* review filed by other defendants in the MDL proceeding, i.e., IPR2025-00233 ("the Formycon IPR") and IPR2025-00456 ("the Celltrion IPR"). The petition in the Formycon IPR is a "copycat" of the Petition here, filed along with a motion for joinder. IPR2025-00233, Paper 2, 1. The petition in the Celltrion IPR raises different grounds of unpatentability for a largely overlapping set of challenged claims. *Compare* IPR2025-00456, Paper 2, 21, *with* Pet. 10 (identifying different grounds of unpatentability).

In addition, the parties identify IPR2021-00402, IPR2023-01312, and IPR2023-00462 as matters involving U.S. Patent No. 10,464,992 B2, which is related to the '865 patent. Pet. 6; Paper 6, 4–5; *see also* Ex. 1001, code (60).

C. The '865 Patent

The '865 patent issued on August 10, 2021, and claims priority to a series of applications, the earliest of which was filed on June 16, 2006. Ex. 1001, codes (45), (60).

The '865 patent relates to "pharmaceutical formulations suitable for intravitreal administration comprising agents capable of inhibiting vascular endothelial growth factor (VEGF), and to methods for making and using such formulations." Ex. 1001, 1:45–49. According to the Specification, "[a] VEGF antagonist is a compound capable of blocking or inhibiting the biological action of vascular endothelial growth factor (VEGF), and includes fusion proteins capable of trapping VEGF." *Id.* at 6:27–30. Relevant to the claims challenged here, "the fusion protein comprises amino acids 27-457 of SEQ ID NO:4." *Id.* at 6:34–37. The parties refer to the fusion protein comprising this amino acid sequence as aflibercept. *See, e.g.*, Pet. 38; Prelim. Resp. 28, 32, 39 (referring to the "aflibercept amino acid sequence"). According to the Specification, in "a specific embodiment" this protein is "glycosylated at Asn residues 62, 94, 149, 222 and 308." Ex. 1001, 6:35–37.[2]

The '865 patent describes a "stable liquid ophthalmic formulation" comprising aflibercept, one or more organic co-solvents, e.g., polysorbate, one or more tonicity agents, e.g., sodium or potassium chloride, a buffering agent, e.g., phosphate buffer, and a stabilizing agent, e.g., sucrose, in varying

[2] According to Petitioner's declarant, "glycosylation refers to the process by which 'glycans' are created, altered, and attached to proteins," and because the '865 patent describes glycosylation at asparagine residues, it is referring to "N-linked glycosylation," i.e., "glycans attached to the side-chain nitrogen atoms of asparagine residues." Ex. 1007 ¶¶ 27–29.

amounts. *See id.* at 2:33–4:6. Such formulations may be "provided in a pre-filled syringe or vial, particularly suitable for intravitreal administration." *Id.* at 5:23–25.

D. Challenged Claims

The Petition challenges claims 1–12, 14–17, 19, 20, 22–36, 39–42, 44, 45, and 47–55. Pet. 9. Of these, claims 1, 26, and 51 are independent. Claim 1 is illustrative and reads as follows:

> 1. A vial comprising an ophthalmic formulation suitable for intravitreal administration that comprises:
> a vascular endothelial growth factor (VEGF) antagonist
> an organic co-solvent,
> a buffer, and
> a stabilizing agent,
> wherein said VEGF antagonist fusion protein is glycosylated and comprises amino acids 27-457 of SEQ ID NO:4; and
> wherein at least 98% of the VEGF antagonist is present in native conformation following storage at 5° C. for two months as measured by size exclusion chromatography.

Ex. 1001, 19:29–40, 22:18–30. Claim 26 is nearly identical to claim 1, but recites the formulation in a "pre-filled syringe" instead of a vial. *Id.* at 20:66–21:12. Claims 2 and 27 depend from claims 1 and 26 respectively and further recite that the concentration of VEGF antagonist fusion protein is "40 mg/ml" and that the co-solvent comprises polysorbate. *Id.* at 19:41–43, 21:13–16. Claim 51 recites a similar ophthalmic formulation with the same limitations requiring, *inter alia*, that the VEGF antagonist fusion protein be glycosylated and have a 40 mg/ml concentration. *Id.* at 22:19–31.

E. Asserted Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability:

Claim(s) Challenged	35 U.S.C. §[3]	Reference(s)/Basis
1–12, 14–17, 19, 20, 22–25, 51–53, 55	103(a)	Fraser,[4] Wulff,[5] 2006 Presentations,[6] '319 Publication,[7] FDA Guidance[8]
26–36, 39–42, 44, 45, 47–50, 54	103(a)	Fraser, Wulff, 2006 Presentations, '319 Publication, Nayar[9]

[3] The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) ("AIA"), included revisions to 35 U.S.C. § 103 that became effective after the filing of the applications to which the '865 patent claims priority. Therefore, we apply the pre-AIA version of 35 U.S.C. § 103.

[4] Fraser et al., "Single Injections of Vascular Endothelial Growth Factor Trap Block Ovulation in the Macaque and Produce a Prolonged, Dose-Related Suppression of Ovarian Function," 90(2) J. Clin. Endocrinol. Metab. 1114–22 (2005) (Ex. 1009) ("Fraser").

[5] Wulff et al., "Prevention of Thecal Angiogenesis, Antral Follicular Growth, and Ovulation in the Primate by Treatment with Vascular Endothelial Growth Factor Trap R1R2," 143(7) Endocrinology 2797–807 (2002) (Ex. 1016) ("Wulff").

[6] The Petition refers to the three presentations in Exhibits 1011–1013, which were apparently obtained from the Internet Archive's Wayback Machine, as the "2006 Presentations." *See* Pet. 26–27.

[7] WO 00/75319 A1, published December 14, 2000 (Ex. 1029) ("'319 Publication").

[8] U.S. Dept. of Health and Human Serv., "Guidance for Industry Container Closure Systems for Packaging Human Drugs and Biologics" (May 1999) (Ex. 1038) ("FDA Guidance").

[9] Rajiv Nayar & Mark C. Manning, *High Throughput Formulation: Strategies for Rapid Development of Stable Protein Products*, *in* RATIONAL DESIGN OF STABLE PROTEIN FORMULATIONS: THEORY AND PRACTICE (John F. Carpenter & Mark C. Manning eds., 2002) (Ex. 1020) ("Nayar").

Petitioner further relies on the declarations of Dr. Alpaslan Yaman (Ex. 1002), Dr. Edward Chaum (Ex. 1005), and Dr. Michael Butler (Ex. 1007) submitted with the Petition.

III. DISCRETION UNDER 35 U.S.C. § 314(A)

We begin by addressing Patent Owner's arguments for discretionary denial. As explained below, we find those arguments persuasive. Thus, we exercise discretion to deny institution of the Petition under 35 U.S.C. § 314(a) without reaching the merits of Petitioner's asserted grounds of unpatentability.

A. The Parties' Arguments

Patent Owner argues that we should exercise discretion under 35 U.S.C. § 314(a) to deny institution of *inter partes* review in view of the Mylan case and related MDL proceeding. Prelim. Resp. 6–17. In particular, Patent Owner argues the Petition was filed 365 days after Petitioner was sued and "implicates the same or substantially similar claims, prior-art references, and issues that have been decided repeatedly by the district court and the Federal Circuit" in "seven court decisions."[10] *Id.* at 6–7. According to Patent Owner, these decisions contain "hundreds of pages" on obviousness and obviousness-type double patenting ("ODP") addressing disputes that overlap with the issues raised in the Petition, and that "[g]iven

[10] The seven decisions Patent Owner refers to are the district court's bench trial opinion in the Mylan case (Ex. 2001), the district court's three orders granting Patent Owner's motions for preliminary injunction against Petitioner, Formycon, and Celltrion (Ex. 2002–2004), and the Federal Circuit's three decisions affirming those preliminary injunction orders (Ex. 2005–2007). *See* Prelim. Resp. 1.

the considerable investment of the parties and the courts in these proceedings, institution would be highly inefficient." *Id.* For these and other reasons, Patent Owner urges that the *Fintiv*[11] factors favor the exercise of discretion to deny institution under § 314(a). *Id.* at 6–17.

Petitioner disputes Patent Owner's assessment of the *Fintiv* factors and contends these factors do not favor the exercise of discretion to deny institution. *See* Pet. 69–70; Reply 1–2, 8–10. In particular, Petitioner contends the obviousness grounds in the Petition "rely on a combination of three primary references—*Fraser*, *Wulff*, and the *2006 Presentations*—that has never been previously asserted and was not the subject of any prior decision." Reply 4. Petitioner also points out that no trial date has been set in its district court case. *Id.* at 8. Moreover, in an attempt to "avoid any risk of overlap or duplication," Petitioner stipulates that if institution is granted: (1) it "will not pursue an invalidity defense in the parallel litigations . . . that the claims subject to the instituted IPR are invalid based on the grounds that were raised or any grounds Petitioner reasonably could have raised in this IPR," i.e., a *Sotera*[12] stipulation; and (2) "it will not seek a trial date on the '865 patent before the FWD is due." *Id.* at 9–10. Finally, Petitioner contends

[11] *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020) (precedential) ("*Fintiv*").
[12] *Sotera Wireless, Inc. v. Masimo Corp*., IPR2020-01019, Paper 12 (PTAB Dec. 1, 2020) (precedential as to § II.A.) ("*Sotera*"). Petitioner's stipulation differs from that in *Sotera* because Petitioner limits it to just "the claims subject to the instituted IPR," which suggests its stipulation would apply only to the subset of the'865 patent's claims challenged in the Petition. *Compare* Reply 10, *with Sotera* 18. For sake of argument, we do not address this distinction because it does not affect the outcome of the *Fintiv* analysis here.

it did not delay in filing the Petition because Patent Owner "did not serve Petitioner with the complaint until October 16, 2024" and "Petitioner filed its Petition just one month later, after it became clear the district court did not intend to act quickly." *Id.* at 10.

Patent Owner responds, reiterating its position that the disputed issues in this proceeding are the same or substantially similar to those the district court and Federal Circuit have already addressed and resolved in its favor. *See* Sur-reply 1–9. Patent Owner further contends that Petitioner's *Sotera* stipulation does not mitigate concerns with duplication, and "[t]he current lack of a scheduled trial date does not outweigh the massive overlap with and investment in the parallel proceedings." *Id.* at 9–10.

B. The Fintiv Factors and Related Guidance

The Board's precedential decision in *Fintiv* outlines factors that balance considerations of system efficiency, fairness, and patent quality when a patent owner raises an argument for discretionary denial due to the advanced state of a parallel proceeding, such as the MDL proceeding here. *Fintiv* 5–6. These factors are:

> 1. whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted;
>
> 2. proximity of the court's trial date to the Board's projected statutory deadline for a final written decision;
>
> 3. investment in the parallel proceeding by the court and the parties;
>
> 4. overlap between issues raised in the petition and in the parallel proceeding;

> 5. whether the petitioner and the defendant in the parallel proceeding are the same party; and
>
> 6. other circumstances that impact the Board's exercise of discretion, including the merits.

Id. "[I]n evaluating the factors, the Board takes a holistic view of whether efficiency and integrity of the system are best served by denying or instituting review." *Id.* at 6.

The Office recently rescinded an earlier memorandum titled "Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation," and offered new guidance regarding the *Fintiv* analysis.[13] This guidance states that the recission "restore[s] policy in this area to the guidance in place before the Interim Procedure," including by making clear that a *Sotera* "stipulation (*i.e.*, a stipulation from a petitioner that, if an IPR or PGR is instituted, the petitioner will not pursue in district court . . . any ground raised or that could have been reasonably raised in the IPR/PGR) is highly relevant, but will not be dispositive by itself" and that "compelling merits alone is not dispositive." Guidance Memo, 1–3.

C. Analysis

We now consider these factors to assess whether to exercise discretion to deny institution under 35 U.S.C. § 314(a) in this case.

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[13] Memorandum from the Chief Administrative Patent Judge, *Guidance on USPTO's recission of "Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation* (March 24, 2025), available at https://www.uspto.gov/sites/default/files/documents/guidance_memo_on_interim_procedure_recission_20250324.pdf ("Guidance Memo"), 1.

i. Factor 1: likelihood of a stay in the MDL proceeding

No stay has been granted, nor is there any evidence of record that either party has asked for one. Moreover, Patent Owner represents that it "does not intend to seek a stay." Prelim. Resp. 15.

Petitioner does not address whether it would seek a stay if institution were granted. But the fact that Petitioner is presently enjoined from launching its biosimilar product (*see* Ex. 2005, 3) and that it has repeatedly sought the entry of a schedule with an earlier trial date than that proposed by Patent Owner (*see* Ex. 1110, 1135), suggests Petitioner is unlikely to seek a stay.

It is possible the parties could change their minds or that the district court could enter a stay *sua sponte*. However, that possibility seems remote given our understanding that the MDL proceeding involves a number of Patent Owner's other patents and also several other biosimilar applicant defendants who may seek to raise different issues than those presented here. In any event, we decline to give substantial weight to such speculation. Accordingly, this factor is neutral.

ii. Factor 2: proximity of the trial date to the final written decision deadline

The projected statutory deadline for a final written decision in this case is one year after the entry of this decision, i.e., in June 2026.

We understand a trial date has not yet been set for the SB case or any of the other pending cases in the MDL proceeding. *See* Sur-reply 10 (acknowledging "[t]he current lack of a scheduled trial date"). According to Petitioner, the SB case has been "stagnant" or "essentially stayed" since at

least the time when the PI proceeding ended and the SB PI Order was entered in June 2024. *See* Reply 3.[14]

Patent Owner suggests the delay in entering a schedule following issuance of the SB PI Order (and the district court's subsequent PI orders) was to allow time for the appeals of those decisions and for the Mylan Decision to be resolved. *See* Prelim. Resp. 16 (explaining that while Petitioner sought an earlier trial schedule, Patent Owner "proposed that the district court convene a status conference upon resolution of the remaining pending appeals and then determine an appropriate schedule"). "Given the conclusion of the appeals," the parties in the MDL proceeding have now jointly requested "an in-person status conference" with the district court "to set a case schedule for further proceedings." Ex. 2035, 1 (email on behalf of all parties to the MDL proceeding dated April 30, 2025). Thus, the parties in the MDL proceeding appear to be working toward entry of a trial schedule.

Nevertheless, at present, there is no set trial date and outside of the now-completed PI proceedings, no schedule has been set in the MDL proceeding. This suggests that the trial in the SB case may occur after the projected statutory deadline of June 2026. For this reason, factor 2 weighs against discretionary denial.

[14] Petitioner asserts the district court case has been stagnant for "20 months." Reply 3. Petitioner's math is hard to follow given that the first SB case was filed in November 2023, less than 20 months ago. SB PI Order 8. To the extent Petitioner suggests nothing has happened in the MDL proceeding since the SB case was filed, we disagree, because that suggestion ignores the substantial investment the district court and parties have made in litigating the PI proceedings and subsequent appeals.

But we disagree with Petitioner that this factor alone is dispositive. According to Petitioner, in the absence of a trial date there is no need to engage in a full *Fintiv* analysis because there is no basis for discretionary denial. Reply 8 (citing *Beckman Coulter, Inc. v. Sirigen II Ltd.*, IPR2022-01203, Paper 12, 18 (PTAB Jan. 6, 2023)). This is a bridge too far. "[T]he factors considered in the exercise of discretion are part of a balanced assessment of all the relevant circumstances in the case." *See* Guidance Memo, 3 (explaining that for this reason "compelling merits alone is not dispositive"). Because the *Fintiv* factors are considered together as part of a "holistic" analysis, we decline Petitioner's invitation to cut the *Fintiv* analysis short here by only considering the current lack of a trial date under factor 2. *See Fintiv* 6.

iii. Factor 3: investment in the parallel proceedings

Patent Owner asserts that the district court's consideration and grant of the PI against Petitioner alone constitutes a substantial investment, but that the district court did even more by conducting "a two-week trial in the *Mylan* case and three other preliminary-injunction proceedings focused on validity of the '865 patent." Prelim. Resp. 8. We agree.

Just within the context of the PI proceeding involving Petitioner, the district court considered testimony from seven different witnesses. *See* SB PI Order 13 (identifying witnesses).[15] It issued a thorough 181-page decision with voluminous citations to the record evidence, including more than 50

[15] The parties waived an evidentiary hearing, so the PI motion was decided on written submissions. SB PI Order, 12–13. Direct testimony was submitted in the form of declarations and both sides conducted cross-examination by deposition, which the district court also considered. *Id.* at 13; *see*, *e.g.*, *id.* at 48, 87–88, 143 (citing transcripts).

pages addressing Petitioner's ODP defense. *Id.* at 54–110. As explained in more detail below, that ODP defense presents a number of disputed issues that are the same or substantially similar to the disputed issues in this proceeding. On the preliminary record, the district court resolved those issues in Patent Owner's favor, finding that Petitioner had not raised a substantial question of validity. *Id.* at 54. The Federal Circuit affirmed that decision. Ex. 2005. The effort taken to litigate and decide the myriad issues raised by Patent Owner and Petitioner's PI filings demonstrates a substantial investment by the district court and the parties.

But this is far from the only substantial investment the district court has made. The district court completed claim construction proceedings and a full trial on the '865 patent in the Mylan case, issuing a more than 300-page trial decision.[16] That decision includes analysis of obviousness defenses based on one of the references (Fraser) in Petitioner's grounds and extensive fact-finding regarding Fraser and other references (e.g., Ex. 1029; Ex. 1039) that both sides rely on to support their positions in this proceeding. *See* Mylan Dec. 170–202. Moreover, the district court analyzed and credited the same objective indicia arguments Patent Owner raises here. *Id.* at 194–202; *see* Prelim. Resp. 60–63 (discussing objective indicia of non-obviousness).

In addition, the district court has decided PI motions based on the '865 patent for three other biosimilar applicants in the MDL proceeding. *See* Paper 6, 3. Similar to the SB PI Order, the district court's decisions

[16] While the district court agreed to vacate its final judgment and order for injunctive relief against Mylan in light of a settlement agreement between the parties, the trial decision itself was not vacated. *See* Ex. 1138, 2. Even if it had been, this would not diminish the district court's extensive investment in that proceeding.

granting preliminary injunctions against Formycon and Celltrion involve lengthy analysis of an ODP defense that overlaps with several of the disputed issues here. *See* Formycon PI Order 69–129; Celltrion PI Order 61–118 (analyzing ODP). These decisions were likewise affirmed by the Federal Circuit. Ex. 2006; Ex. 2007. All told, the district court's substantive decisions in the MDL proceeding to date total almost a thousand pages, much of it directed to issues relating to claim construction and the validity of the '865 patent claims.

There is also the issue of Petitioner's delay in filing the Petition. The Petition was filed on November 20, 2024, about a year after the filing of the first SB case before the district court. According to Petitioner, the complaint in the SB case was not *served* until October 16, 2024. Reply 10. But this does not explain why Petitioner waited a year after it was sued to initiate this proceeding challenging the '865 patent. Petitioner points out that there are "40+ patents" asserted in the SB case. *Id.* at 1. However, Patent Owner's PI motion was filed on February 22, 2024 and asserts only four patents.[17] That motion also identifies a particular subset of the '865 patent's dependent claims Petitioner is accused of infringing. SB PI Order 9; *see also Fintiv* 11 ("[I]t is often reasonable for a petitioner to wait to file its petition until it learns which claims are being asserted against it."). Thus, Petitioner was aware of the particular claims being asserted against it as early as February 2024 and could have filed a Petition challenging them far earlier than it did.

[17] Patent Owner later withdrew its motion with respect to three of those patents, limiting it to just the '865 patent. *See* SB PI Order 9 (stating Patent Owner did this to "streamline the issues in dispute").

Petitioner's delay in doing so is another fact in favor of denial.[18] *See Fintiv* 11–12 (explaining that if "petitioner did not file the petition expeditiously" or "cannot explain the delay. . . these facts have favored denial").

For these reasons, factor 3 weighs heavily in favor of discretionary denial.

iv. Factor 4: overlap in issues

Patent Owner asserts that *Fintiv* factor four "weighs heavily in favor of discretionary denial" because the issues in the Petition substantially overlap with the MDL proceeding. Prelim. Resp. 11–15 (citing Pet. 1, 18 n.1, 23–30, 33–66, 69–70). Specifically, Patent Owner contends that, like Petitioner here, the defendants in the MDL proceeding have asserted that: (1) one of ordinary skill would have "had motivation to use 40 mg/mL aflibercept in an ophthalmic formulation"; (2) "aflibercept is necessarily glycosylated;" (3) "98% native conformation is inherent in formulations with the ingredients, concentrations, and pH recited by the claims [and] that the POSA was motivated with a reasonable expectation of success to make formulations with 98% native conformation;" and (4) "no objective evidence supported nonobviousness." Prelim. Resp. 14.

We agree these arguments are the same or similar to the arguments in the Petition. *See* Pet. 49–51 (arguing one of ordinary skill would have been

[18] Petitioner claims it was "forced to limit its defenses" in view of the page limit for its opposition to the preliminary injunction motion and "accordingly did not raise any obviousness combinations as to the '865 patent during the PI proceedings." Reply 1, 10. But that begs the question: if Petitioner believed it could not effectively raise the grounds in the Petition in its opposition to the PI, why did it wait 9 months after the PI motion was filed and 5 months after the SB PI Order was entered to file the Petition?

motivated to set the concentration at 40 mg/ml), 38–41 (arguing that even though the asserted references do "not expressly teach glycosylated aflibercept" Wulff and the '319 publication teach expression in Chinese Hamster Ovary ("CHO") cells, which a skilled artisan would have known would result in the glycosylated protein); 40–48 (arguing that the claimed 98% native conformation after two months is inherent and/or obvious); 62–63 (arguing there are no objective indicia of non-obviousness for lack of nexus).

We also agree with Patent Owner that the district court made a number of fact findings in the SB PI Order and Mylan Decision that bear on these arguments, even though the grounds in the Petition are based on different combinations of art. *See* Prelim. Resp. 14–15 (identifying specific findings). For example, in the Mylan case, the district court found that the prior art taught away from the claimed 40 mg/ml concentration. Mylan Dec. 172–179. It also found that "objective evidence strongly supports nonobviousness" and that Patent Owner had established a sufficient nexus between that evidence and the '865 patent claims. *Id.* at 194–202; *see also* SB PI Order 108–110 (similar). Moreover, in the PI proceeding, the district court found that "aflibercept is not necessarily glycosylated" even when produced in a CHO cell and that one of ordinary skill in the art would not be motivated to use the glycosylated form of the protein in an ophthalmic formulation. SB PI Order 79–91; *see also* Ex. 2005, 22–23 (noting on appeal that "SB does not challenge . . . the district'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 . . . and increase risks such as inflammation").

Petitioner attempts to distinguish these and other findings from the district court by pointing to teachings in some of its cited references that differ from those considered in the Mylan case and the reference claims in Petitioner's ODP defense. *See* Reply 3–8. Those differences, however, appear to be relatively minor on the record before us. At most, they show that some of the disputed issues that have already been considered by the district court in its Mylan Decision and PI Orders, and that remain before it now in those cases still pending in the MDL proceeding, are substantially similar, as opposed to identical, to the disputed issues in the Petition. Either way, there is substantial overlap between the issues both previously litigated and currently pending in the district court and the grounds in the Petition.

The *Sotera* stipulation is an attempt to counterbalance the concerns raised by this overlap, but given the circumstances, it does not effectively mitigate them. First, the disputed issues for Petitioner's ODP defense are the same or substantially similar to those for the obviousness grounds in the Petition, but the *Sotera* stipulation does not prevent Petitioner from litigating those issues before both the district court (as part of its ODP defense) and here in the event an IPR is instituted.[19] Second, the MDL proceeding

[19] ODP or nonstatutory double patenting is, as the name implies, not premised on any statute. *See, e.g.*, *Ostuka Pharm. Co., Ltd. v. Sandoz, Inc.*, 678 F.3d 1280, 1297 (Fed. Cir. 2012) ("Nonstatutory double patenting is a judicially created doctrine grounded in public policy."). Accordingly, it is *not* a ground Petitioner reasonably could have raised in this IPR. *See* 35 U.S.C. § 311(b) (inter partes review may be requested "only on a ground that could be raised under section 102 or 103").

includes other biosimilar applicant defendants who are similarly motivated to try to invalidate the '865 patent claims, but who are not subject to any *Sotera* stipulation. Even if we institute review on Petitioner's grounds here, those other defendants remain free to litigate the same grounds in the consolidated MDL proceeding. For these reasons and given the particular circumstances of this case, Petitioner's *Sotera* stipulation does not sufficiently mitigate the risks of duplicated efforts or inconsistent decisions by making this IPR a "true alternative" to resolution of these issues by the district court. *See Motorola Solutions, Inc. v. Stellar, LLC,* IPR2024-01205, Paper 19, 3–4 (PTAB Mar. 28, 2005) (determining on Director Review that a *Sotera* stipulation did not ensure IPR would be a "true alternative" because Petitioner's invalidity arguments "include combinations of the prior art asserted in these proceedings with unpublished system prior art, which Petitioner's stipulation is not likely to moot" and thus the same or similar issues would remain in the parallel proceeding); *SAP America, Inc. v. Cyandia, Inc.*, IPR2024-01496, Paper 13, 8–9 (PTAB Apr. 7, 2025) (similar).

Finally, while the Petition appears to challenge a broader set of claims than those asserted in the SB case, that difference does not materially affect the overlap. The claims challenged in the Petition collectively raise the same disputed and overlapping issues identified above.

For these reasons, factor 4 weighs in favor of discretionary denial.

v. Factor 5: same or different parties

Petitioner and Patent Owner are both parties to the MDL proceeding. Therefore, this factor weighs in favor of exercising discretion to deny the Petition.

vi. Factor 6: other circumstances, including the merits

This factor accounts for other relevant circumstances, including whether "the merits of a ground raised in the petition seem particularly strong on the preliminary record," which favors institution. *Fintiv* 14–15. "By contrast, if the merits of the grounds raised in the petition are a closer call, then that fact has favored denying institution when other factors favoring denial are present." *Id.* at 15.

The merits in this case are in the latter category, particularly as they relate to the limitations requiring an "ophthalmic formulation" containing "glycosylated" aflibercept. *See, e.g.*, Ex. 1001, 19:29–37 (claim 1). Based on the record in the PI proceeding, the district court found that one of ordinary skill in the art would not have been motivated to use glycosylated aflibercept in an ophthalmic formulation for several reasons, including that the larger glycosylated form of the protein would reduce retinal penetration, undesirably increase systemic exposure, and increase the risk of inflammation. SB PI Order 84–91. Petitioner did not challenge that finding on appeal. Ex. 2005, 22. Nevertheless, Petitioner ignores the substance of the district court's reasoning and the supporting evidence cited by Patent Owner in its Preliminary Response. Instead, Petitioner contends:

> Petitioner need not show motivation to glycosylate aflibercept because [it] relies on prior art that the POSA would understand discloses glycosylated aflibercept. Specifically the *Wulff*

> reference teaches the VEGF trap was expressed in CHO cells, which by the priority date, were known and expected to glycosylate aflibercept. . . . Thus, a POSA would have understood the aflibercept disclosed in the primary reference (*Wulff*) ***was*** glycosylated—no motivation is needed to do more.

Reply 5 (internal quotations/citations omitted).

In our view, Petitioner's response is unsatisfactory because the challenged claims require more than just glycosylated aflibercept—they require glycosylated aflibercept in "an ophthalmic formulation suitable for intravitreal administration." *See, e.g.*, Ex. 1001, 19:29–30 (claim 1). Petitioner concedes Wulff does not disclose the use of its VEGF trap in an ophthalmic formulation, urging instead that one of skill in the art would have been motivated to make changes to Fraser and Wulff's intravenous formulation to convert it to an intravitreal one. *See* Pet. 30–35. But it appears to be undisputed that one of ordinary skill in the art would have understood that aflibercept could be produced in either a glycosylated or unglycosylated form. SB PI Order 79 ("As explained by experts on both sides, aflibercept . . . can be produced from different cells, only some of which result in glycosylation of aflibercept."); *see also* Ex. 1029 (teaching expression in systems other than CHO cells); Ex. 1039 ¶ 38 (teaching glycosylation may be eliminated by using mutant CHO cell lines). Accordingly, to demonstrate that the claimed ophthalmic formulation is obvious, Petitioner would need to articulate some reasoning to explain why one of ordinary skill in the art would choose to use the glycosylated version in that formulation. The fact that Petitioner elected not to mention, much less attempt to address the substance of the district court's findings that such a

motivation was lacking, suggests a weakness in this aspect of its asserted grounds.[20]

For these reasons, factor 6 weighs in favor of discretionary denial.

D. Weighing of Fintiv Factors

Considering the *Fintiv* factors as part of a holistic analysis of all of the relevant circumstances of this case, we are persuaded that the interests of the efficiency and integrity of the system are served by invoking our authority under 35 U.S.C. § 314(a) to deny institution of a potentially meritorious Petition. That is, while the lack of a trial date (factor 2) weighs against denial, that single factor is solidly outweighed by the sum of the others, particularly factors 3, 4, and 6, which reflect the substantial investment in, and particular circumstances of, the parallel district court proceedings.

IV. CONCLUSION

For the foregoing reasons, we exercise discretion under 35 U.S.C. § 314(a) to deny the Petition.

V. ORDER

Accordingly, it is:

ORDERED that the Petition is denied, and no *inter partes* review is instituted.

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[20] We also have concerns regarding Petitioner's decision not to address the district court's prior finding that the art taught away from a 40 mg/ml concentration (*see* Mylan Dec. 172–179) and what that may signal regarding the relative strength of Petitioner's arguments regarding that limitation. That limitation, however, is recited in only a subset of the challenged claims.

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