Trials@uspto.gov
571-272-7822

Paper No. 15
Date: June 2, 2025

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FORMYCON AG,
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

IPR2025-00233
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

Formycon Ag ("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"). According to Petitioner, the Petition is a "copycat" of the one filed in IPR2024-00176, and Petitioner has filed a motion for joinder to that proceeding. (Paper 1, "Joinder Motion"). Regeneron Pharmaceuticals, Inc. ("Patent Owner") filed a Preliminary Response. Paper 10 ("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 12 ("Reply")) and Patent Owner filed a sur-reply (Paper 13 ("Sur-reply")).

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

II. BACKGROUND

A. Real Parties in Interest

Petitioner and Patent Owner identify themselves as the only real parties in interest. Pet. 6; Paper 5, 1.

B. Related Matters

The '865 patent is currently asserted against Petitioner in *Regeneron Pharmaceuticals, Inc. v. Formycon AG*, No. 1:23-cv-97 (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"); *Samsung Bioepis Co., Ltd.*, No. 1:23-cv-106 (N.D.W. Va.); *Regeneron Pharmaceuticals, Inc. v. Samsung Bioepis Co., Ltd.*, No. 1:23-cv-94 (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 5, 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 case against Petitioner specifically as "the Formycon 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 the appeal was dismissed by joint stipulation as part of agreement between Mylan and Patent Owner resolving their disputes. *See* Ex. 1138, 1–2 (April 22, 2025 order entering joint stipulation and order offered by Patent Owner and Mylan).

[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."

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. 2003 (order granting motion for preliminary injunction against Formycon) ("Formycon PI order"); *see also* Ex. 2002 (order granting motion for preliminary injunction against Samsung Bioepis ("SB")) ("SB 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., IPR2025-00176 (filed by SB) and IPR2025-00456 ("the Celltrion IPR"). The Celltrion IPR involves different grounds of unpatentability than those asserted here. *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. 7; Paper 5, 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 ¶¶ 26–27.

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. 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] Nayar et al., *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 1st eds.) (2002) (Ex. 1020) ("Nayar").

Petitioner further relies on the declarations of Dr. Laird Forrest (Ex. 1002), Dr. Todd Lefkowitz (Ex. 1005), and Dr. Zhaohui Sunny Zhou (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 disputed issues 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 generally* Reply. As an initial matter, Petitioner offers a *Sotera*[12] stipulation (Pet. 69–70), urging that it "obviates any overlap with the district court and ensures that this IPR will be a 'true alternative' to the [MDL proceeding]." Reply 3 (citing *Motorola Solutions, Inc. v. Stellar, LLC,* IPR2024-01205, Paper 19, 3–4 (PTAB Mar. 28, 2005)). Petitioner further points out that no trial date has been set in the MDL proceeding and that based on median time-to-trial data "trial would not be expected until September 2026 at the earliest—three months after an expected [Final Written Decision]." *Id.* at 3–4 (citing Ex. 1123; Ex. 1124).

Regarding the issue of the investment in the parallel proceeding, Petitioner argues that Patent Owner's reliance on the Mylan case is misplaced because that case is not ongoing and did not involve Petitioner. Reply 5–6. According to Petitioner, "the only ongoing proceeding involving Petitioner is the" MDL proceeding and there has been no substantial investment there "beyond the PI phase." *Id.* Even there, Petitioner contends there was no investment of "substantial resources ***related to the arguments***

[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*").

raised in the Petition" because the PI proceedings involved only ODP and written description defenses. *Id*. at 7–8. Finally, Petitioner argues the merits of its Petition favor institution. *Id.* at 9–10.

Patent Owner responds, reiterating its position that the disputed issues in this proceeding are the same or substantially similar to issues that the district court and Federal Circuit have already addressed and resolved in its favor. *See* Sur-reply 1–3, 5–7. Patent Owner further contends that Petitioner's *Sotera* stipulation "does not remedy [the] substantial overlap—*e.g.*, motivation, reasonable expectation of success, and objective evidence––with its ODP arguments, which [Petitioner] remains free to advance." *Id.* at 8–9. Patent Owner also argues that "even were trial not to occur until September 2026, the investment in the parallel proceedings strongly favors discretionary denial." *Id.* at 9.

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.

[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.

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.

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

No stay has been granted and neither party has asked for one. Prelim. Resp. 15; Reply 9. 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 ("FWD") 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 Formycon case or any of the other pending cases in the MDL proceeding. *See* Sur-reply 9 (acknowledging the lack of a scheduled trial date). According to Petitioner, there is no schedule in place following the PI proceedings and "the district court has not responded to the four status conference requests made by the *MDL* parties over the past seven months." Reply 4.

Patent Owner suggests the delay in entering a schedule following issuance of court's 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 one defendant sought an earlier trial date, 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 Formycon case may occur after the projected statutory deadline of June 2026. For this reason, factor 2 weighs against discretionary denial.

That said, we do not credit Petitioner's argument that trial "would not be expected until September 2026 at the earliest." Reply 4. Petitioner calculates this date based on statistics showing that the district court has a median time-to-trial of 627 days. Ex. 1123, 1. This median is presumably measured from the time the case was filed. Here, the Formycon case was filed in November 2023 and served in October 2024. Ex. 1116. But Petitioner inexplicably uses the time of its Reply (April 2025) as the starting point for its calculation "discounting [the district court's] median 3 months for the PI proceedings" to arrive at an expected September 2026 trial date. Reply 4. That calculation does not make sense. There are also a number of factors that distinguish the MDL proceeding from the average case,[14] which suggests that a prediction based on median time-to-trial statistics is unlikely to be accurate.

iii. Factor 3: investment in the parallel proceeding

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

[14] For example, the MDL proceeding involves a number of defendants and patents, PIs, and extensive prior decisions involving the '865 patent.

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 eight different witnesses. *See* Formycon PI Order 13 (identifying witnesses).[15] It issued a thorough 203-page decision with voluminous citations to the record evidence, including more than 50 pages addressing Petitioner's ODP defense. *Id.* at 69–129. 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 71. The Federal Circuit affirmed that decision. Ex. 2006. 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

[15] The parties waived an evidentiary hearing, so the PI motion was decided on written submissions. Formycon 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 88, 103, 105–106, 108, 110, 112, 114 (citing transcripts).

[16] Petitioner suggests the investment in the Mylan case is not relevant because the case is not ongoing and Petitioner was not a party to it. *See* Reply 5–6. We disagree. Indeed, *Fintiv* directly addresses this issue,

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 5, 3. Similar to the Formycon PI Order, the district court's decisions granting preliminary injunctions against SB and Celltrion involve lengthy analysis of an ODP defense that overlaps with several of the disputed issues here. *See* SB PI Order 54–110; Celltrion PI Order 61–118 (analyzing ODP). These decisions were likewise affirmed by the Federal Circuit. Ex. 2005; Ex. 2007. All told, the district court's substantive decisions 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 29, 2024, a year after the filing of the Formycon case in the district court. Petitioner points out that the complaint in the Formycon case was not formally served until October 16, 2024. Reply

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explaining that "[e]ven when a petitioner is unrelated to a defendant . . . if the issues are the same as, or substantially similar to, those already . . . litigated . . . the Board may . . . exercise the authority to deny institution." *Fintiv* 14. Petitioner also points out that the permanent injunction against Mylan was vacated and all claims dismissed with prejudice pursuant to the parties' settlement of that case. *See* Reply 6 n. 5. But the Mylan Decision was not vacated (*see* Ex. 1138, 2) and even if it had been, this would not diminish the district court's extensive investment in the same.

2 (citing Ex. 1116). According to Petitioner, it is the date of service, not filing, that matters because "35 U.S.C. § 315(b) considers only the date that a petitioner was properly served." *Id*. (citing *GoPro, Inc. v. 360Heros, Inc.*, IPR2018-01754, Paper 38, 9 (PTAB Aug. 23, 2019) (precedential)). We disagree because Petitioner's argument confuses the date for calculating a time bar under section 315(b) with the concern over undue delay in filing a petition to challenge a patent asserted in a parallel proceeding. Here, it is beyond dispute that Petitioner was aware of and actively litigating the Formycon case soon after it was filed. *See* Formycon PI Order 9–13 (describing district court proceedings, including a scheduling conference on January 5, 2024). Accordingly, the fact that Formycon was not formally served until October 2024 does not explain why Petitioner waited a year after it was sued to initiate this separate proceeding challenging the '865 patent. *See Fintiv* 11–12 (explaining that if "petitioner did not file the petition expeditiously" or "cannot explain the delay. . . these facts have favored denial").

Petitioner argues at the time the complaint was filed, it "could not know which patents [Patent Owner] would ultimately move forward on from . . . [the] group of ***thirty-nine*** asserted patents" in the complaint. Reply 5. 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. Formycon PI Order 10; *see also Fintiv* 11 ("[I]t is often reasonable for a

[17] Patent Owner later withdrew its motion with respect to three of those patents, limiting it to just the '865 patent. *See* Formycon PI Order 11 (stating Patent Owner did this to "streamline the issues in dispute").

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. Petitioner's delay in doing so is another fact in favor of denial. *See Fintiv* 11–12.

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 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 motivated to set the concentration at 40 mg/ml), 38–40 (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 Formycon 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* Formycon PI Order 126–129 (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. Formycon PI Order 94–106; *see also* Ex. 2006, 14–16 (rejecting Petitioner's arguments that "the district court clearly erred in finding no motivation to pursue glycosylated aflibercept").

Petitioner attempts to distinguish these and other findings from the district court by arguing that the present obviousness grounds differ from its ODP defense, which "requires comparison between ***claims***, not disclosures," and that the findings in the Mylan case "were made on a different record with different parties and a narrower set of claims." Reply 7–9. 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 before 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.[18] Second, the MDL proceeding involves other biosimilar applicant defendants who are similarly motivated to try to invalidate the '865 patent claims, but 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

[18] 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").

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,* IPR2024-01205, Paper 19 at 3–4 (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 challenges a broader set of claims than those asserted in the Formycon 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. Accordingly, even if some of the findings from the district court's prior decisions are not pertinent to some of the claims challenged in the Petition (*see* Reply 8 (comparing the "substantially broader" scope of claim 1 to claim 4)), the same issues would still need to be addressed by both the district court *and* the Board in our analysis of Petitioner's challenges to the narrower claims.

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. Formycon PI Order 99–106. Petitioner's challenges to those findings were rejected on appeal. *See* Ex. 2006, 14–16. 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 asserts that the merits of its grounds favor institution because in IPR2023-00462, "the Board found a reasonable likelihood that claims substantially similar to claim 1 were unpatentable over Fraser and instituted trial." Reply 9–10 (citing Ex. 1127). This argument is unpersuasive for several reasons. First, even if we agreed the claims in the two cases were substantially similar, there was no finding in IPR2023-00462 suggesting that the merits of the grounds there seemed "particularly strong

on the preliminary record" as opposed to merely meeting the threshold for institution. *See Fintiv* 14–15.

Second, the claims challenged in IPR2023-00462 are not similar to the presently challenged claims in at least one key regard, i.e., they do not recite a "glycosylated" VEGF antagonist fusion protein in an "ophthalmic formulation suitable for intravitreal administration," *Compare* Ex. 1127, 6–7 (claims 1 and 10) *with* Ex. 1001, 19:29–41, 20:66–21:12; 22:18–31 (claims 1, 26, and 51). Rather, the claims in IPR2023-00462 recite a formulation containing a VEGF antagonist fusion protein produced in a CHO cell. *Id.* This difference is significant because while Wulff teaches that its VEGF trap was produced in a CHO cell, Petitioner concedes that Fraser and Wulff do not disclose that protein in an ophthalmic formulation, urging instead that one of skill in the art would have been motivated to make changes to those references' 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. Formycon PI Order 95 ("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 such a 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.[19]

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 proceedings before the district court.

IV. CONCLUSION

For the foregoing reasons, we exercise discretion under 35 U.S.C. § 314(a) to deny the Petition. Because *inter partes* review has not been instituted, the Joinder Motion is denied.

[19] 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 its arguments regarding that limitation. That limitation, however, is recited in only a subset of the challenged claims.

V. ORDER

Accordingly, it is:

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

ORDERED that the Joinder Motion is denied.

For PETITIONER:

Louise E. Fogel
Grace Kim
Kristi L. R. Sawert
fogel@fr.com
PTABInbound@fr.com
sawert@fr.com

For PATENT OWNER:

David I. Berl
Andrew V. Trask
Arthur J. Argall
WILLIAMS & CONNOLLY LLP
dberl@wc.com
atrask@wc.com
aargall@wc.com

Elizabeth S. Weiswasser
Priyata Y. Patel
PAUL, WEISS, RIFKIND, WHARTON & GARRISON LLP
eweiswasser@paulweiss.com
ppatel@paulweiss.com

TDW