

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FORMYCON AG,
Petitioner

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner

Case IPR2025-00233
Patent No. 11,084,865

REPLY TO PATENT OWNER'S PRELIMINARY RESPONSE

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1001	U.S. Patent No. 11,084,865 (“’865 Patent”)
1002	Forrest Declaration (“Forrest”)
1003	Forrest <i>Curriculum Vitae</i>
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1116	Executed Summons Returned in <i>Regeneron Pharmaceuticals, Inc. v. Formycon AG</i> , Civil Action No., 1:23-CV-97
1117	Minute entry for proceedings held before Chief District Judge Kleeh, scheduling conference held on 5/17/2024, <i>In Re: Aflibercept Patent Litigation</i> , 1:24-md-03103-TSK, D110

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1123	Lex Machina, Timing metrics for Federal District Court Cases for Judge Thomas Shawn Kleeh
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I. INTRODUCTION

A straightforward application of the *Fintiv* factors¹ weighs strongly against exercising discretion to deny institution in this case: (1) Petitioner has filed a *Sotera* stipulation, ensuring no duplication of efforts between the PTAB and the district court in the *MDL*,² (2) the district court has not scheduled a trial date nor given any indication that it will do so soon, (3) the parties to the preliminary injunction (“PI”) proceedings did not argue the obviousness grounds presented here, and (4) the ’865 patent should have never issued.

The ’865 patent is part of an expansive thicket of over 50 patents directed to various aspects of EYLEA®—an intravitreal formulation of aflibercept. Every patent claim challenged at the PTAB in this thicket has ultimately been either disclaimed by PO or found unpatentable by the Board. *See* IPR2023-00462 (adverse judgment on parent patent U.S. 10,464,992); IPR2023-00884 (adverse judgment on U.S. 11,253,572); IPR2023-00739 (adverse judgment on U.S. 10,888,601); IPR2022-01226 (all challenged claims of U.S. 10,888,601 unpatentable); PGR2021-00117 (disclaiming all claims of U.S. 10,857,231); IPR2023-00099 (disclaiming all claims of U.S. 10,857,205); IPR2023-00620 (disclaiming challenged claims of U.S. 10,406,226); IPR2023-00442 and IPR2022-01225 (all challenged claims of U.S.

¹ *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020).

² “*MDL*” refers to PO’s multidistrict litigation against Formycon, Samsung Bioepis (“SB”), Sandoz, and Celltrion in N.D.W.Va. Pet. 6-8.

10,130,681 unpatentable); IPR2022-00257 and IPR2021-00880 (all challenged claims of U.S. 9,669,069 unpatentable); IPR2021-00881 (all challenged claims of U.S. 9,254,338 unpatentable). The Board should review the merits of the '865 patent's claims because PO's own prior-art presentations—with Fraser and Wulff—provide strong evidence that these claims are equally unpatentable. Pet. 1-2.

PO's arguments misdirect the Board away from this straightforward application of *Fintiv*. As just one example, PO claims Petitioner delayed filing until "365 days after it was *sued*." POPR, 6. But 35 U.S.C. §315(b) considers only the date that a petitioner was properly served under Fed. R. Civ. Pro. 4. *GoPro, Inc. v. 360Heros, Inc.*, IPR2018-01754, Paper 38, 9 (PTAB Aug. 23, 2019) (precedential). Petitioner filed promptly after it was formally served on October 16, 2024. Ex.1116. There was thus no undue delay. This and many other examples of misdirection in the POPR do not withstand scrutiny. For the reasons described below, the Board should decline to exercise its discretion to deny institution.

II. ARGUMENT

A. *Fintiv* factor 4: Petitioner's *Sotera* stipulation weighs heavily against discretionary denial.

Petitioner stipulated that it "will not pursue in the parallel district court proceeding the same grounds as in the Petition or any grounds that could have reasonably been raised in the petition." Pet. 70-71. CJ Boalick's memo makes clear that a timely filed *Sotera* stipulation remains "highly relevant." However, the POPR

did not address Petitioner’s *Sotera* stipulation at all.

Petitioner’s *Sotera* stipulation obviates any overlap with the district court and ensures that this IPR will be a “true alternative” to the *MDL. Motorola Solutions, Inc. v Stellar, LLC*, IPR2024-01205, Paper 19, 3-4 (Stewart March 28, 2025). For example, as a biosimilar, no “system prior art” exists in this field that would call Petitioner’s stipulation into question. *Cf. id.* (discounting *Sotera* stipulation where petitioner’s invalidity arguments included combinations with “unpublished system art”). Thus, if Petitioner ultimately serves invalidity contentions in the *MDL*, Petitioner’s arguments will be tailored to grounds not available by statute here.³

Under these circumstances, the Board should find that the *Sotera* stipulation weighs heavily against exercising discretion to deny. *See Sotera*, Paper 12, 19 (holding that stipulation “mitigates any concerns of duplicative efforts” and “concerns of potentially conflicting decisions,” and “weighs strongly in favor of not exercising discretion to deny institution”).

B. *Fintiv* Factor 2: The lack of a scheduled trial date weighs heavily against discretionary denial.

The *MDL* is still in its early stages. There is *no* trial date nor do the parties have any indication the district court will set a trial date any time soon. The parties

³ In compliance with certain BPCIA pre-suit requirements, Petitioner served invalidity contentions (“3(B) statements”) during the “Patent Dance.” But these contentions were merely preliminary and are not binding on the parties. *See, e.g., Genentech, Inc. v. Amgen Inc.*, 2020 WL 636439, at *5 (D. Del. Feb. 11, 2020).

were last before the district court in May 2024. Ex.1117. Since then, the district court has not responded to the four status conference requests made by *MDL* parties over the past seven months. Ex.1118, Ex.1119, Ex.1120, Ex.1121. Nor is there a case schedule in place yet at the district court. And most recently, PO proposed that trial should occur after the district court entertains a PI against yet another (new) potential defendant, which—based on the completed PI proceedings—would result in further delay of no less than 8 months.⁴ Ex.1122. This lack of a trial date weighs heavily against discretionary denial. *See, e.g., Aptiv Servs. US, LLC v. Microchip Tech.*, IPR2024-00646, Paper 11, 32 (PTAB Sept. 25, 2024) (other *Fintiv* factors do not outweigh lack of trial date).

Even using median times-to-trial as a guide, the expected statutory deadline for a FWD here (June 17, 2026) is well before any trial could occur in the *MDL*. The median time-to-trial in civil cases for Judge Kleeh is 627 days (~1.72 years) (Ex.1123) and for N.D.W.Va. is 676 days (~1.85 years) (Ex.1124). Thus, even if the court set a trial date tomorrow, based on these statistics (discounting Judge Kleeh's median 3 months for the PI proceedings), trial would not be expected until September 2026 at the earliest—three months after an expected FWD. An institution

⁴ Petitioner and PO are continuing to discuss raising a status conference with the district court. Although the parties require further guidance from the district court before proposing any schedule, if institution is granted Petitioner will not seek a trial date on the '865 patent before the expected FWD.

decision on the merits is especially important here given the June 2027 expiration date of the '865 patent coupled with the slow pace of the district court proceeding.

PO argues this factor weighs for discretionary denial because **SB** proposed a scheduling order with a trial set for March 2026. POPR, 16. Not so. First, the district court has not yet responded to any parties' schedule-related motions, underscoring the glacial pace of the *MDL*. Ex.2008. Second, Formycon joined SB **only** to request a status conference—not a trial date. Ex.1120, 1. Lacking any significant relationship, SB's actions cannot be imputed to Formycon. *Am. Honda Motor Co., v. Neo Wireless LLC*, IPR2023-00797, Paper 27, 3 (PTAB Mar. 22, 2024). Third, Petitioner was diligent in filing because it was not served until October 16, 2024, (Ex.1116), and the accorded filing date for this IPR is December 2, 2024. Paper 4.

Further, the timing of this Petition is proportional to PO's thicket. Before PO filed the complaint, it accused Petitioner of infringing **fifty-five** patents during the Patent Dance preceding litigation. And even when PO filed its complaint, Petitioner could not know which patents PO would ultimately move forward on from its "narrower" group of **thirty-nine** asserted patents. *See Fintiv*, 11 (recognizing that it is reasonable for a petitioner to wait to file its petition until it learns which claims are being asserted against it in a parallel proceeding).

C. *Fintiv* Factors 3 & 5: Neither the *MDL* nor the *Mylan* matter counsel discretionary denial.

Almost all of PO's discretionary-denial arguments focus on "investment" in

the wrong proceeding, *i.e.*, the *Mylan* matter,⁵ in which Formycon was not involved and that ended over five months ***before*** PO filed its complaint against Petitioner. POPR, 7. But the *Fintiv* “framework generally addresses the impact of an ***ongoing*** proceeding in another tribunal that is progressing in parallel with the Board proceeding.” *Hulu, LLC v. Piranha Media Dist., LLC*, IPR2024-01252, Paper 27 (Stewart Apr. 17, 2025). Here, the only ongoing proceeding involving Petitioner is the *MDL*, not the *Mylan* matter.

In the *MDL*, the “investment” PO touts is simply not there. Outside of the early PI phase (discussed more below), the case involving Formycon has hardly begun. The parties have not exchanged infringement or invalidity contentions, claim construction has not started, discovery outside of the jurisdictional and PI phase has not begun, no case schedule is in place, and there is no trial date. Because neither the parties nor the district court have expended significant time, effort, or resources beyond the PI phase, *Fintiv* factor 3 weighs against the Board exercising its discretion to deny institution. *Sotera*, 16-17. Indeed, the Board has declined to exercise its discretion to deny under similar facts. *See Duke Mfg. Co. v. Low Temp Indus., Inc.*, IPR2021-00415, Paper 13, 13-14 (PTAB July 20, 2021) (“Although we appreciate that the court and the parties have invested effort and time in the

⁵ “*Mylan* matter” refers to PO’s action against Mylan in N.D.W.Va. Pet. 8. PO and Mylan jointly requested that the court vacate its permanent injunction against Mylan and dismiss all claims with prejudice, which was so ordered. Ex.1125.

preliminary injunction proceedings, it remains that much work lies ahead despite the district court having granted the preliminary injunction.”).

PO argues that the PI constitutes substantial investment. POPR, 7-8. But neither the parties nor the district court invested substantial resources *related to the arguments raised in the Petition*. Formycon argued different invalidity grounds for the '865 patent in the PI proceedings: obviousness-type double patenting (“OTDP”) and lack of written description.⁶ Ex.2006, 8. Thus, this is not a case where the PI favors denial, and PO’s cited cases do not counsel otherwise. *See E-One, Inc. v. Oshkosh Corp.*, IPR2019-00162, Paper 16, 8-9 (PTAB June 5, 2019) (discretionarily denying institution due to “*extensive overlap* of the asserted prior art, expert testimony, and the disputed claim terms” following “claim construction order and preliminary injunction order”).⁷

Moreover, the Federal Circuit has not decided the obviousness issues raised in the Petition. POPR, 6. Rather, the court addressed only OTDP and written description. As to OTDP, the court analyzed whether claim 4 of the '865 patent was invalid for OTDP over claim 5 of PO’s own reference patent. *See, e.g.*, Ex.2006, 12; Ex.2005, 18. The court did so under a different analysis than the obviousness

⁶ SB also argued invalidity for OTDP and lack of written description (Ex.2005, 9), while Celltrion argued OTDP only (Ex.2007, 5).

⁷ PO also cites to *IBM Corp. v. Trusted Knight Corp.*, IPR2020-00323, but the panel in that case declined to exercise discretionary denial under *Fintiv*.

standard applicable here, as OTDP requires comparison between *claims*, not disclosures. *See Geneva Pharms., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1385 (Fed. Cir. 2003) (“Because [OTDP] compares earlier and later claims, an earlier patent’s disclosure is not available to show [OTDP].”).

The *Mylan* matter also does not counsel for discretionary denial. First, those parties settled following oral argument at the Federal Circuit, and the district court has now *vacated* final judgment and *dismissed* all claims with prejudice, on the request of PO and Mylan. Ex.1125.⁸ Second, the claims at issue in that proceeding were just a subset of the claims at issue here, with Mylan challenging the validity of only claims 4, 7, 9, 11, and 14-17. Ex.2001, 1. But here, Petitioner challenges almost every claim of the ’865 patent: 1-12, 14-17, 19-20, 22-36, 39-42, 44-45, and 47-55. Pet. 1. And claim 1 is *substantially broader* in scope than claim 4. Unlike claim 4, claim 1 encompasses *any concentration* of VEGF antagonist fusion protein, *any* organic co-solvent, and *any amount* of organic co-solvent. The district court’s findings on validity in *Mylan* focused on a concentration requirement—“40 mg/ml” VEGF antagonist fusion protein—not recited in claim 1. For example, the district court found that disclosure of “10-50 mg/ml” in primary reference Dix did not teach

⁸ At oral argument, the Federal Circuit panel cast serious doubt on whether the law supported the district court’s ’865 patent validity findings. *See, e.g.*, Ex.1126, 22:19-25 (Judge Prost, concerning invalidity: “[B]ack to criticality . . . and I’ll discuss with [PO’s counsel] why I think the District Court’s findings may have put the [] wrong burden and asked the wrong question.”).

“40 mg/ml” for anticipation. Ex.2001, 154-64.⁹

Finally, even if the Board considers the *Mylan* matter, then *Fintiv* factor 5 still weighs against exercising discretion.¹⁰ *Fintiv*, 13-14. The district court’s findings in *Mylan* were made on a different record with different parties and a narrower set of claims. *See Smith v. Bayer Corp.*, 564 U.S. 299, 312 (2011) (“A court’s judgment binds only the parties to a suit, subject to a handful of discrete and limited exceptions.”). And because *Mylan* has no preclusive effect to Formycon, the district court must still conduct a trial on the ’865 patent in the Formycon case. PO’s argument that the Board must defer to the court’s previous judgment (that the district court has vacated, no less) is not correct.

D. *Fintiv* Factor 1: The circumstances of a stay are neutral.

The Board routinely considers this factor neutral where, as here, neither party has requested a stay. *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 15, 12 (PTAB May 13, 2020) (informative).

E. *Fintiv* Factor 6: Other circumstances strongly favor institution.

Finally, the merits of the Petition here favor institution. *Supra* §I. In IPR2023-

⁹ The district court also found that claim 4 was not obvious because other prior art taught away from a 40 mg/ml formulation. Ex.2001, 165.

¹⁰ *Fintiv* factor 5 is neutral even considering just the *MDL*. Although the parties are the same, Petitioner’s *Sotera* stipulation ensures lack of overlap with the district court. *Snap, Inc. v. SRK Tech. LLC*, IPR2020-00820, Paper 15, 16 (PTAB Oct. 21, 2020) (precedential as to §II.A).

00462, for example, the Board found a reasonable likelihood that claims substantially similar to claim 1 were unpatentable over Fraser and instituted trial. Ex.1127. In particular, the Board found that “[o]n the current record, Petitioner sufficiently demonstrates that Fraser’s VEGF Trap_{R1R2} formulation includes an organic co-solvent, i.e., Tween 20 (polysorbate 20); buffer, i.e., phosphate, citrate, and NaCl (pH 6.0); and a stabilizing agent, i.e., glycerol or sucrose” and that the claimed 98% native conformation limitation “is necessarily a natural result of the formulation ingredients,” all elements claimed by the ’865 patent. *Id.*, 29-30, 31-32.

Efficient use of Board resources also favors institution. Formycon’s Petition is a copycat of SB’s Petition in IPR2025-00176; Formycon has requested conditional joinder and has agreed to act as an understudy. Mot. (Paper 1), 2, 4-5. Considering these Petitions together (with, if necessary, an extended deadline available under 35 U.S.C. §316(a)(11)) would efficiently resolve the patentability of the ’865 patent consistent with the goals of the AIA.

III. CONCLUSION

A comprehensive assessment of the *Fintiv* factors indicates that they weigh against discretionary denial or are neutral. Formycon respectfully requests that its Petition for *inter partes* review be instituted.

Respectfully submitted,

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/Kristi L. R. Sawert/
Louis E. Fogel (Reg. No. 54,731)
Grace Kim (Reg. No. 71,977)
Kristi L. R. Sawert (Reg. No. 45,702)
Fish & Richardson P.C.
60 South Sixth Street, Suite 3200
Minneapolis, MN 55402
T: 202-783-5070
F: 877-769-7945

(Control No. IPR2025-00233)

Attorneys for Petitioner

CERTIFICATE OF SERVICE

Pursuant to 37 CFR § 42.6(e), the undersigned certifies that on April 23, 2025, a complete and entire copy of this Petitioner's Reply to Patent Owner's Preliminary Response to Address Discretionary Denial and corresponding exhibits were provided via email to the Patent Owner by serving the correspondence email addresses of record as follows:

David I. Berl
Andrew V. Trask
Arthur J. Argall III
Elizabeth S. Weiswasser
WILLIAMS & CONNOLLY LLP
680 Maine Avenue SW
Washington, DC 20024

Priyata Y. Patel
PAUL, WEISS, RIFKIND, WHARTON &
GARRISON LLP
2001 K Street, NW
Washington, DC 20006

Email: Eylea@wc.com
GRP-PW-EYLEA-Biosimilars@paulweiss.com

/Anastasia Renard/
Anastasia Renard
Fish & Richardson P.C.
60 South Sixth Street, Suite 3200
Minneapolis, MN 55402
renard@fr.com