

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
U.S. Patent No. 11,084,865

PATENT OWNER'S SURREPLY
IN SUPPORT OF PRELIMINARY RESPONSE

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TABLE OF EXHIBITS

Exhibit	Description
2001-2032	<i>Previously presented</i>
2033	YESAFILI™ Label
2034	Formycon's Reply ISO Its Motion to Partially Adopt SB's Motion, 24-md-3103, Dkt. 502 (N.D.W. Va.)
2035	Email from D. Berl to District Court

Formycon contorts the law and rewrites the facts to seek institution of an IPR that would be astoundingly inefficient—retreading the same art, issues, and arguments that two courts already have addressed across seven thoroughly reasoned decisions. Despite *Fintiv*’s requirement that petitioners address “*any* other district court or Federal Circuit proceedings involving the challenged patent,” Formycon’s Petition instead ignored entirely the district court’s post-trial *Mylan* decision. *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, 2020 WL 2126495, at *6 (P.T.A.B. Mar. 20, 2020) (precedential) (emphasis added). Formycon tries to excuse its omission by arguing that *Mylan* is the “wrong proceeding” and is not “ongoing.” Reply 5-6. *Fintiv* dictates otherwise: The Board may deny institution “[e]ven when a petitioner is unrelated to a defendant” in a parallel proceeding, and even when the issues were “already ... litigated.” 2020 WL 2126495, at *6. Again flouting precedent, Formycon also seeks to dismiss the preliminary-injunction decisions—including the ones involving Formycon—because they involve “only OTDP.” Reply 7. But as Formycon does not dispute, the courts’ detailed ODP analyses addressed a multitude of issues overlapping directly with the obviousness arguments in Formycon’s Petition, again supporting denial. *Fintiv*, 2020 WL 2126495, at *5-6.

To justify disregarding the parties’ and courts’ investment in the parallel proceedings, Formycon invents from whole cloth a new set of rules governing the propriety of discretionary denial. Applying the correct law, however, it is clear that

Formycon's Petition is wastefully duplicative of the parallel proceedings and that *Fintiv* factors three through five thus decisively favor discretionary denial. The remaining factors favor denial as well or are neutral.

I. Investment in Overlapping Parallel Litigation (*Fintiv* Factors 3-5)

A. The *Mylan* Litigation

The parties and district court invested heavily in the *Mylan* litigation, which implicated substantially similar prior-art references and obviousness issues to those in Formycon's Petition. As explained previously, Paper 10 ("POPR") 4-6, 13-15, the Petition relies on Fraser and other art already addressed in *Mylan*, and it re-raises many arguments that were already considered and rejected in *Mylan*, namely, that: (1) the person of skill in the art ("POSA") would have "optimize[d]" Fraser to arrive at the claimed formulation; (2) the POSA would have had a reasonable expectation of success in achieving 98% native conformation; (3) 98% native conformation is inherent; (4) aflibercept necessarily is glycosylated; and (5) the objective evidence does not support nonobviousness. Pet. 30, 33-48, 62-63; *Regeneron Pharm., Inc. v. Mylan Pharm. Inc.*, 714 F. Supp. 3d 652, 723, 741-48 (N.D.W. Va. 2024) ("*Mylan*").

Formycon does not dispute that the obviousness references and arguments addressed in *Mylan* are substantially similar to those in its Petition, nor does Formycon deny that Regeneron, Mylan, and the district court invested heavily in the

Mylan litigation. Reply 5-9. Instead, Formycon concocts a number of excuses to avoid consideration of *Mylan*. None are availing.

First, Formycon suggests that only investments in proceedings to which Formycon is a party are relevant. *Id.*, 5-6; *id.*, 9 (“no preclusive effect”). But *Fintiv* expressly held the contrary. 2020 WL 2126495, at *6 (explaining that “[e]ven when a petitioner is unrelated to a defendant,” “[a]n unrelated petitioner should ... address any other district court or Federal Circuit proceedings involving the challenged patent to discuss why addressing the same or substantially the same issues would not be duplicative of the prior case” (emphases added)). Because *Mylan* and the Petition are substantially similar, which Formycon does not deny, the *Mylan* investment is relevant to the *Fintiv* analysis. And Formycon has not even attempted to explain why its Petition “would not be duplicative of [*Mylan*].” *Id.*

Second, Formycon argues that past investments are irrelevant. Reply 6. Again, not so. *Fintiv*, 2020 WL 2126495, at *6 (denial appropriate “if the issues are the same as, or substantially similar to, those *already ... litigated*, or other circumstances weigh against *redoing the work of another tribunal*” (emphases added)); Interim Processes for PTAB Workload Management (Mar. 26, 2025) (considering “[w]hether ... another forum *has already adjudicated* the validity ... of the challenged patent claims” (emphasis added)).

Third, Formycon suggests that *Mylan* does not count because Regeneron and Mylan ultimately settled. Reply 6 n.5, 8. Although the permanent-injunction order and final judgment were vacated, the district court’s bench-trial decision analyzing validity was not. Ex.1125, 2. Formycon has cited no authority for disregarding the district court’s detailed trial decision, which remains in force.

Fourth, Formycon implies that *Mylan* can be disregarded based on a comment by a member of the panel during the appeal argument. Reply 8 n.8. Even assuming that comment was relevant, the line quoted by Formycon pertained to an argument regarding anticipation by Dix, a ground not raised in Formycon’s Petition. Ex.1126, 22:19-23:2. Furthermore, Regeneron explained that Dix is not prior art to the ’865 patent, POPR 51 n.6, and Formycon did not even contest that issue.

Fifth, Formycon argues that nonoverlap in claims between its Petition and *Mylan* weighs against discretionary denial. Reply 8-9. Formycon is incorrect. *Next Caller, Inc. v. TRUSTID, Inc.*, IPR2019-00961, Paper 10 at 14 (P.T.A.B. Oct. 16, 2019) (denying institution where petition challenged 52 claims, 7 of which were at issue before district court, because petitioner did “not argue that the nonoverlapping claims *differ significantly in some way*” or “*whether it would be harmed* if we do not institute on the nonoverlapping claims” (emphases added)). None of the additionally challenged claims have been asserted against Formycon before the district court, and it has not articulated how it would be harmed by non-adjudication of unasserted

claims. Nor does Formycon argue that any of the additionally challenged claims (save claim 1) “differ[s] significantly in some way” from the *Mylan* claims. *Id.* As for claim 1, Formycon notes that it does not recite the 40 mg/mL concentration, Reply 8-9, but ignores that it recites glycosylation and 98% native conformation, which the district court found nonobvious over Fraser, *Mylan*, 714 F. Supp. 3d at 740-42, 744-45. And Formycon’s challenge to claim 1 is no different from its other challenges, likewise asserting that claim 1 is obvious because the POSA would have “ma[d]e a set of obvious modifications ... *resulting in a 40 mg/mL concentration*” and “contain[ing] *0.1% wt/vol of an organic co-solvent (polysorbate 20).*” Pet. 35-37 (emphases added). Formycon’s purported distinction (at 8) that “claim 1 is substantially broader in scope than claim 4” thus rings hollow, as its claim 1 arguments fully overlap with those previously addressed in parallel proceedings.

B. The Preliminary-Injunction (“PI”) Decisions and Appeals

The investment of the parties, district court, and Federal Circuit in three PI proceedings and appeals further favors discretionary denial. Formycon was a party to one of those proceedings, so *Fintiv* factor five heavily favors discretionary denial. Formycon does not deny that the proceedings against Samsung Bioepis (“SB”) and Celltrion involved substantially similar obviousness-type double patenting (“ODP”) issues. Reply 7-8. Instead, Formycon contends that the PI decisions and appeals are irrelevant because they addressed ODP, not obviousness. *Id.* But Formycon cannot

dispute that a POSA's motivation and reasonable expectation of success, as well as objective evidence, apply to both ODP and obviousness. *Otsuka Pharm. Co. v. Sandoz, Inc.*, 678 F.3d 1280, 1298 (Fed. Cir. 2012); *Eli Lilly & Co. v. Teva Parenteral Medicines, Inc.*, 689 F.3d 1368, 1381 (Fed. Cir. 2012). And the courts' specific findings directly address (and foreclose) the bases of the Petition.

Formycon's Petition asserts that glycosylation is disclosed, 98% native conformation is inherent and would have been obvious, and objective evidence does not favor nonobviousness. Pet. 38-48, 62-63. The PI decisions and appeals found precisely the opposite on each point. *In re Aflibercept Pat. Litig.*, 2024 WL 3422971, at *24-33 (N.D.W. Va. June 24, 2024); *In re Aflibercept Pat. Litig.*, 2024 WL 3423047, at *28-38 (N.D.W. Va. July 9, 2024); Ex.2004 (*Celltrion PI Decision*) at 82-118; *Regeneron Pharm., Inc. v. Mylan Pharm. Inc.*, 127 F.4th 896, 912-14 (Fed. Cir. 2025); *Regeneron Pharm., Inc. v. Mylan Pharm. Inc.*, 2025 WL 324288, at *5-7 (Fed. Cir. Jan. 29, 2025); *Regeneron Pharm., Inc. v. Mylan Pharm. Inc.*, 2025 WL 706079, at *2-3 (Fed. Cir. Mar. 5, 2025). Those now-foreclosed ODP theories were "substantially similar" to the Petition's obviousness arguments, so the investment in those decisions and appeals is relevant. *Fintiv*, 2020 WL 2126495, at *6. Complete overlap is unnecessary. *Edwards Lifesciences Corp. v. Evalve, Inc.*, IPR2019-01479, 2020 WL 927867, at *4 (P.T.A.B. Feb. 26, 2020) (denying institution where "Petition challenges validity on two grounds that will, arguably, not be fully

developed before the district court,” because “arguments for all four grounds ... present the same underlying question” as “arguments made in the district court”).

Contra Reply 6, that investment is clearly significant. The likelihood-of-success standard for instituting IPR is the same as for granting a PI. *Ethicon Endo-Surgery v. Covidien*, 812 F.3d 1023, 1030 (Fed. Cir. 2016). Across three PI proceedings, the district court considered hundreds of pages of briefing and thousands of pages of expert testimony on the ’865 patent, and issued three decisions with hundreds of pages on ODP alone, each of which was subsequently affirmed. Where, as here, the three PI decisions “extensively overlap” with the Petition, each was affirmed prior to the Board’s decision on institution, and Formycon unduly delayed filing its Petition, *see infra* § I.C, the parties’ and courts’ investment in the PI decisions and appeals overwhelmingly favors discretionary denial. *E-One, Inc. v. Oshkosh Corp.*, IPR2019-00162, Paper 16 at 8-9 (P.T.A.B. June 5, 2019); *Fintiv*, 2020 WL 2126495, at *4 & n.16. In contrast, Formycon’s sole authority is inapposite. Reply 6-7 (citing *Duke Mfg. v. Low Temp Indus.*, IPR2021-00415, Paper 13 at 13-14 (P.T.A.B. July 20, 2021)). There, the petition was filed *five months before*—not *five months after*—the PI was granted, only one PI decision was at issue, it had not yet been affirmed, and “[t]he determination underlying the grant of the [PI] d[id] not go to” the patent for which IPR was sought “at all.” *Duke*, IPR2021-00415, Paper 13 at 2, 13-14; *id.*, Ex.2019.

C. Formycon's Undue Delay

Formycon's undue delay further favors denial. Formycon asserts that only post-service delay is relevant, Reply 2, 5, but it conflates 35 U.S.C. §§ 315(b) and 314(a), *Apple Inc. v. Seven Networks, LLC*, IPR2020-00156, 2020 WL 3249313, at *4 (P.T.A.B. June 15, 2020) (“*Fintiv* considers a lack of delay in filing a petition Regarding the time-bar of § 315(b), considerations of the state of a parallel proceeding may *require petitioners to act more quickly than the maximum amount of time permitted by Congress.*” (emphasis added)). Formycon's biosimilar is substantially similar to Mylan's, Ex.2031, 13-14; Ex.2033, 13, so Formycon would have known since January 2024, *Mylan*, 714 F. Supp. 3d at 697, that Regeneron would assert the '865 patent against it; that understanding was confirmed mere weeks later when Regeneron filed its February PI motion. Instead of seeking IPR in January or February, Formycon waited until November—after a year of litigation, five months after it was enjoined, and two months after its PI appeal had been fully briefed. This unexplained delay favors denial. *Fintiv*, 2020 WL 2126495, at *5.

D. Formycon's Sotera Stipulation

Formycon's illusory *Sotera* stipulation does not “obviate[] any overlap.” Reply 3. Formycon's promise not to assert obviousness over Fraser does not remedy its Petition's substantial overlap—*e.g.*, motivation, reasonable expectation of success, and objective evidence—with its ODP arguments, which it remains free to

advance. Nor does its stipulation remedy that the Petition re-litigates obviousness over Fraser and subsidiary fact issues already resolved by *Mylan*. The stipulation thus does not “mitigate ... concern of duplication” or “outweigh the substantial investment in the district court proceeding[s]” and appeals. *Motorola Sols., Inc. v Stellar, LLC*, IPR2024-01205, Paper 19 at 4 (P.T.A.B. Mar. 28, 2025).

II. There Is No Likelihood of a Stay (*Fintiv* Factor 1)

The first *Fintiv* factor supports discretionary denial, as the parties have not sought a stay. Rather, the parties have jointly requested a status conference to determine a schedule for the remainder of the case. Ex.2035.

III. The District Court’s Trial Date (*Fintiv* Factor 2)

That the district court has not yet scheduled a trial date does not outweigh the remaining *Fintiv* factors. Formycon mischaracterizes (Reply 4) Regeneron’s recent proposal that the schedule account for—not that trial occur after—PI proceedings. Ex.1122. Formycon’s promise not to seek a trial date before the projected statutory deadline (Reply 4 n.4) is empty; the district court will likely adopt a consistent schedule for the MDL parties. Given that SB has not withdrawn its scheduling motion, nor Formycon its request that the court “not delay resolution of Regeneron’s claims against Formycon,” Ex.2034, 2, trial may still occur before the projected statutory deadline. And even were trial not to occur until September 2026, the investment in the parallel proceedings strongly favors discretionary denial. *Fintiv*,

2020 WL 2126495, at *4 (for trial date “*even significantly after* the projected statutory deadline, ... whether to institute will likely implicate other factors ... such as the *resources that have been invested* in the parallel proceeding” (emphases added)); *Arthrex, Inc. v. Medshape, Inc.*, IPR2025-00053, Paper 11 at 10, 15 (P.T.A.B. Apr. 25, 2025) (denying institution where evidence suggested trial date “*eight months after* the projected ... statutory deadline” because “considerations concerning an *uncertain trial date ... do not outweigh the more substantial reasons* identified under the other *Fintiv* Factors” (emphases added)).

IV. The Merits Strongly Favor Discretionary Denial (*Fintiv* Factor 6)

Across seven decisions, the district court and Federal Circuit have refuted the bases of Formycon’s obviousness challenge, holding that glycosylation and 98% native conformation are neither obvious nor inherent, that the prior art taught away from 40 mg/mL aflibercept, and that the ’865 patent is not obvious over Fraser. *See supra* § I.A-B. Whether different patents—all but one from different families and not reciting ophthalmic aflibercept formulations, Reply 1-2—were disclaimed or found unpatentable is irrelevant, as is IPR institution on the ’992 patent with different claims (none requiring glycosylation or 40 mg/mL) based on different prior-art grounds. Reply 1-2, 9-10. As to *this patent* and *these claims*, courts have uniformly upheld validity against obviousness and ODP challenges.

For the foregoing reasons, institution should be denied.

Date: May 7, 2025

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CERTIFICATE OF SERVICE
(37 C.F.R. § 42.6(e))

The undersigned hereby certifies that on May 7, 2025, I caused true and correct copies of the following materials:

- Patent Owner's Surreply in Support of Preliminary Response
- Patent Owner's Exhibit List
- Exhibits 2033-2035

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