

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FRESENIUS KABI SWISSBIOSIM GMBH,
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

Case IPR2025-01268
U.S. Patent No. 11,084,865 B2

**PETITIONER'S SUR-REPLY IN OPPOSITION TO PATENT OWNER'S
REQUEST FOR DISCRETIONARY DENIAL**

TABLE OF CONTENTS

I.	THE <i>FINTIV</i> FACTORS DO NOT SUPPORT DISCRETIONARY DENIAL.....	1
II.	THE INTERIM GUIDANCE FACTORS DO NOT SUPPORT DISCRETIONARY DENIAL	4
III.	THE APPLICATION OF THE INTERIM MEMORANDA IS UNCONSTITUTIONAL.....	5

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>In re Aflibercept Patent Litigation</i> , No. 1:24-md-3103 (N.D. W.Va.).....	2, 3
<i>Apple Inc. v. FinTiv, Inc.</i> , IPR2020-00019, Paper 11 (P.T.A.B. Mar. 20, 2020)	1
<i>ClearValue, Inc. v. Pearl River Polymers, Inc.</i> 668 F.3d 1340 (Fed. Cir. 2012)	2
<i>Pfaff v. Wells Elecs., Inc.</i> , 525 U.S. 55 (1998).....	4
<i>POSCO Co. Ltd. v. ArcelorMittal</i> , IPR2025-00370, Paper 10 (P.T.A.B. June 25, 2025)	3
<i>Sand Revolution II, LLC v. Cont’l Intermodal Grp.–Trucking LLC</i> , IPR2019-01393, Paper 24 (P.T.A.B. June 16, 2020)	3
<i>Valve Corp. v. Elec. Scripting Prods., Inc.</i> , IPR2019-00064, Paper 10 (P.T.A.B. May 1, 2019)	4

LIST OF EXHIBITS

Exhibit	Document
1001	U.S. Patent No. 11,084,865 (“the ’865 Patent”)
1002	Expert Declaration of Dr. Joshua Ramsey in Support of Petition for <i>Inter Partes</i> Review of Patent No. 11,084,865 (“Ramsey”)
1003	<i>Curriculum Vitae of Dr. Joshua Ramsey</i>
1004	File History of U.S. Application No. 16/739,559
1005	U.S. Patent No. 10,406,226 to Dix et al. (“Dix ’226”)
1006	Jocelyn Holash et al., <i>VEGF-Trap: A VEGF Blocker with Potent Antitumor Effects</i> , 99 PROC. NAT’L ACAD. SCI. 11393 (2002) (“Holash”)
1007	<i>Regeneron v. Mylan</i> , Memorandum Opinion and Order Following Bench Trial, C.A. No. 1:22-cv-0061 (W. Va. Dec. 27, 2023)
1008	Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc., Transcript from Oral Argument, Case No. 24-2002 (CAFC Feb. 7, 2025) (“Transcript”)
1009	U.S. Patent No. 10,464,992 (“The ’992 Patent”)
1010	Executive Order titled “Lowering Drug Prices by Once Again Putting Americans First” dated April 15, 2025
1011	From the Office of Amy Klobuchar, U.S. Senator of Minnesota, “Klobuchar, Grassley Introduce Bipartisan Bills to Reduce Drug Prices by Promoting Competition and Taking on Big Pharma” dated March 26, 2025
1012	Fresenius Kabi Press Release “Fresenius to Expand Biopharma Portfolio with a New Licensing Agreement to Commercialize a Proposed Aflibercept Biosimilar” dated December 19, 2024

Regeneron's Reply in Support of Discretionary Denial (Paper 9, hereinafter "Reply") still fails to justify discretionary denial. Regeneron's arguments rely on proceedings to which Fresenius is not a party and on claims that are different from those challenged here. Regeneron misstates the *Fintiv* framework, mischaracterizes prior district court and preliminary-injunction rulings, and downplays the merits of Fresenius's anticipation ground in view of U.S. Patent No.: 10,406,226 ("Dix '226") and the Federal Circuit's oral argument.

I. THE *FINTIV* FACTORS DO NOT SUPPORT DISCRETIONARY DENIAL

Factor Six. Factor six of the *Fintiv* analysis weighs against discretionary denial. Where "the merits of a ground raised in the petition seem particularly strong on the preliminary record," the Board favors institution. *Apple Inc. v. FinTiv, Inc.*, IPR2020-00019, Paper 11 (P.T.A.B. Mar. 20, 2020), at 14-15 (discussing the "merits"). In addition to the fact that Regeneron's Reply relies on a district court record addressing a *different claim set* and *different theories*, rather than the set of challenged claims and single anticipation ground mapped in the Petition, Regeneron's Reply fails to dispute that (1) Dix '226 disclosed every element of the challenged claims, arranged as in the claims; (2) Dix '226 explicitly disclosed stability data showing $\geq 98-99\%$ native conformation and inherently disclosed claimed stability limitations; (3) Dix '226 disclosed a 10–50 mg/mL range for liquid

aflibercept; (4) there is no criticality for the claimed 40 mg/mL concentration; and (5) *In re Aflibercept Patent Litigation*, No. 1:24-md-3103 (N.D. W.Va.) (the “MDL proceeding”) failed to properly apply *ClearValue, Inc. v. Pearl River Polymers, Inc.* 668 F.3d 1340, 1344-45 (Fed. Cir. 2012); Petitioner’s Opposition to Patent Owner’s Request for Discretionary Denial (Paper 7, hereinafter “Opp.”), 5-9. Regeneron’s Reply completely ignores *ClearValue* and the Federal Circuit’s oral argument demonstrating the strength of the Dix ’226 anticipation argument—that claims are anticipated if they fall within prior art ranges, unless the *patentee* can show criticality. *See ClearValue*, 668 F.3d at 1344-45; Ex. 1008 at 36:6-9; 38:7-10. The core efficiency-based values of *Fintiv* will be abused in this case if Regeneron is permitted to escape Board review despite the Federal Circuit’s oral argument analysis already on the record.

Factor Five. Factor five of the *Fintiv* analysis weighs against discretionary denial. Fresenius was not a party to the *Mylan* litigation and is not a party to the MDL or any proceeding, and if anything the *Mylan* litigation helps because of the Federal Circuit status that led to settlement just before a decision could be reached. Opp., 2-4 (discussing other proceedings involving the ’865 Patent); *id.*, 9-11, and generally. The Board routinely accords significant weight to the petitioner’s non-party status under Factor five, particularly where, as here, the petitioner neither

controlled nor participated in the earlier proceedings. *See id.*; *POSCO Co. Ltd. v. ArcelorMittal*, IPR2025-00370, Paper 10 at 2 (P.T.A.B. June 25, 2025).

Factor Two. Regeneron points to a case-management schedule it says is “consistent with trial in early 2027.” Reply 2-3. But the case schedule cites *no set trial date* whatsoever. Ex. 2023. Moreover, the trial court has not committed to any date for issuing an opinion, and it is highly likely that accepting Regeneron’s view will mean it gets to “run out the clock” for the ’865 Patent, which expires June 2027. A Final Written Decision here will come sooner. Opp., 12-13. Therefore, Factor two weighs against discretionary denial.

Factors Three and Four. Regeneron ignores the Board’s determination that “investment in proceedings” where merits have not been fully adjudicated do not weigh against institution. *See Sand Revolution II, LLC v. Cont’l Intermodal Grp.–Trucking LLC*, IPR2019-01393, Paper 24 at 10–12 (P.T.A.B. June 16, 2020) (deciding to institute where merits were not fully developed). Opp., 13. Regeneron’s reliance on numerous proceedings without a decision on the merits is thus unavailing. Reply, 1-3. So too is its reliance on claims challenged here by Fresenius not previously addressed in *Mylan* nor the MDL proceeding. Opp., 13-14. This ’865 patent was already considered by the Federal Circuit, and Fresenius only seeks to implement that which the panel already observed about Dix ’226 when Regeneron settled before an opinion could issue.

II. THE INTERIM GUIDANCE FACTORS DO NOT SUPPORT DISCRETIONARY DENIAL

Settled Expectations. Regeneron’s “settled expectations” theory appears to constitute nothing more than relying on preliminary injunctions and discretionary denials of others’ petitions to foreclose PTAB review by an “unrelated petitioner.” Reply, 3-4. Regeneron’s assertion that the ’865 Patent was “repeatedly upheld” is wrong, because preliminary-injunction rulings are not final decisions on the merits because prior PTAB petitions by other parties were denied on discretionary grounds, and because Regeneron ignores the Federal Circuit’s on-the-record assessment. *Id.*; Opp., 2-4. The point of “settled expectations” is to avoid frivolous and duplicative proceedings—which in this context means permitting the Petition based on Federal Circuit oral argument analysis regarding the one anticipation ground based on Dix ’226, rather than requiring Fresenius to start from scratch only to get to the same result. *Valve Corp. v. Elec. Scripting Prods., Inc.*, IPR2019-00064, Paper 10 at 17 (P.T.A.B. May 1, 2019). Here, unlike *Valve*, there is no gamesmanship and no serial filing by the same party.

Economic and Public Health Factors. Rather than dispute Petitioner’s contention that biosimilar competition “foster[s] innovation and decreas[es] drug prices” (Opp., 16-17), Regeneron merely alleges the public interest is simply served by “protecting property rights.” Reply, 4-5. Not so. See *Pfaff v. Wells Elecs., Inc.*,

525 U.S. 55, 63 (1998) (discussing the patent system is a balance between competing public interests). Protecting patent rights is only legitimate where the patents are not repeats of old patents, extending the patent monopoly without any basis. That is the situation here, challenged claims are anticipated in view of Dix '226.

Expert Testimony. Regeneron dedicates a few lines to merely allege that “reliance on expert testimony ... may suggest that the questions are better resolved in an Article III court.” Reply, 5. However, Regeneron ignores the March 26, 2025 Memorandum of Acting Director Coke Morgan Stewart (the “Director Memorandum”) which explicitly lists “petition's reliance on expert testimony” as an interim factor for consideration before the Board. Petition’s reliance on expert testimony parties weighs against discretionary denial. Opp., 17-18.

III. THE APPLICATION OF THE INTERIM MEMORANDA IS UNCONSTITUTIONAL

Regeneron’s Reply fails to address any due process or administrative arguments promulgated in Fresenius’ Opposition. Reply, 5. Regeneron merely recites broad statements about “established property rights” without addressing any of the detailed arguments regarding 35 U.S.C. § 316(a) and the Administrative Procedure Act (“APA”). *Id.*; Opp., 18-20. If anything, Regeneron calls for abandoning IPRs, despite Congress having established them.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

Pursuant to 37 CFR §§ 42.6(e)(4)(i) *et seq.* and 42.105(b), the undersigned certifies that on November 5, 2025, a complete and entire copy of Petitioner's Sur-Reply in Opposition to Patent Owner's Request for Discretionary Denial, and Exhibit 1012 were provided by electronic email on the following counsel of record:

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