

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 REQUEST FOR DIRECTOR'S REVIEW

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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

Petitioner respectfully requests Direct review of the Decision Denying Institution of *Inter Partes* Review (“IPR”) (“Decision”) of U.S. Patent No. 11,084,865 (the “’865 patent”). The Decision provided no findings or reasoning supporting discretionary denial. Petitioner is left guessing as to why the petition was not referred to a panel for a decision on institution. Patent Owner’s submission relied on settled expectations and prior litigation, but both of those favor Petitioner so a mistake appears to have been made in the review process.

First, “settled expectations” does not weigh in favor of discretionary denial. To the contrary, the ’865 patent was promptly and repeatedly challenged, and the Federal Circuit—particularly anticipation in light of the Dix ’226 patent on which this petition relies—discussed at oral argument its likely anticipated status. In addition, based on the procedural posture of concurrent litigation challenging the ’865 patent, maintaining the discretionary denial would incentivize patent owners to litigate weak patents and engage in carefully timed strategic settlements to avoid unfavorable decisions so Patent Owner can engage in a rear-guard action, delaying the inevitable determination of invalidity, to the detriment of petitioners and the public. Permitting this approach, in the context of this case, means preserving weak patents—which should not be encouraged.

I. LEGAL STANDARD

Pursuant to 37 CFR § 42.75 and the USPTO’s guidance on Director Review, a party may seek review of “any decision on institution under 35 U.S.C. § [314].” *See* 37 CFR § 42.75: “Guidance on Director Review Process.” Review is appropriate where the decision reflects “(a) an abuse of discretion, (b) important issue of law or policy, (c) erroneous findings of material fact, or (d) erroneous conclusions of law.” *Id.* Review of discretionary issues is specifically allowed. *See* “Guidance on Director Review Process” at 2B.

II. ARGUMENT

A. “Settled Expectations” Rule Does Not Justify Discretionary Denial

The Decision provides no reasoning or findings but presumably the Board applied the interim memoranda, announcements, and processes issued earlier this year (*see* Section III) establishing a new procedure for considering discretionary denial, which Patent Owner relied upon including focus on the “settled expectations” factor.

The “settled expectations” here weigh *against* discretionary denial. The only legitimate “settled expectation” Patent Owner could have regarding the ’865 patent is that the patent will be subject to challenge. The ’865 patent was challenged numerous times before this petition: three IPR petitions (the Board denied institution on discretionary grounds in each petition); the *Mylan* litigation; and the

MDL litigation. *See* Petitioner’s Opposition to PO’s Request for Discretionary Denial (Paper No. 7) at 2-4. Patent Owner itself invited challenges by using this very patent to attempt to block biosimilar from reaching the market.

Furthermore, applying “settled expectations” is particularly problematic in the biosimilars technology area, because of issued related to standing to appeal. Under *Sandoz*, a biosimilar applicant cannot challenge a patent “too soon” because then it would lack standing to appeal. *Sandoz, Inc. v. Amgen, Inc.*, 773 F.3d 1274 (Fed. Cir. 2014). Biosimilars companies challenge IPRs years into a patent’s term, not because of any settled expectations related to the patent, but because of the built-in process issues limiting earlier challenges, as parties await the biosimilar application process. Therefore, the challenges to the ’865 patent so far have been as early as practical, and that includes the Petition. In this context, using settled expectations to deny review undercuts the President’s goal for affordable drugs, by severely handicapping IPR petitions even for weak patents.

There is also no reasonable “settled expectation” regarding the validity of the ’865 patent given that the Federal Circuit was about to resolve invalidity, but Patent Owner settled before a decision was issued. The ’865 patent has only been subject to preliminary-injunction rulings and discretionary denial of PTAB petitions, neither or which are final decisions on the merits. *See* Petitioner’s Opposition to PO’s Request for Discretionary Denial (Paper No. 7) at 2-3.

Patent Owner made sure there was no final determination by quickly settling after an argument before a skeptical Federal Circuit panel. The '865 patent was included in litigation filed by Patent Owner against Mylan and Biocon, with a finding after trial in favor of Patent Owner, but then appealed to the Federal Circuit in the matter *Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc.*, Nos. 24-1965, 24-1966, 24-2002, 24-2009, 24-2019, 24-2058, 24-2082, 24-2083, 24-2147, 24-2156, 24-2351 (Fed. Cir.). The parties to that appeal completed briefing and the Federal Circuit held oral argument. The Court called into question several of the district court's findings in favor of the Patent Owner, with a persistent focus on the Dix '226 reference that is the subject of this Petition.

Specifically, the panel in the Mylan/Biocon appeal repeatedly placed a particular emphasis on the invalidity analysis based on the '865 patent purporting to cover an individual drug concentration point (40 mg/ml) within a range that Dix '226 already disclosed (10-50 mg/ml). The Court pressed the point that Patent Owner—not the patent challenger—had the burden to show criticality, and that no such evidence had been shown. *E.g.* Ex. 1008 at 32:19-33:2 (“would you agree that putting this one factor to the side that when we have something like this 40 mg per milliliter inside the range in the prior art of 10 to 50, then it’s incumbent upon the patent owner to show or demonstrate some kind of criticality?”). This theme was

repeated throughout the oral argument. (Ex. 1008 at 9:9-11, 14:9-16:2, 27:5-28:6, 32:19-36:15, 37:21-38:20, 41:9-44:4 discussing lack of criticality.)

The Federal Circuit did not have the opportunity to issue a ruling on invalidity in view of Dix '226, however, as the oral argument was held on February 7, 2025, and the parties reported they settled the matter by April 15, 2025. To the best of our understanding, no other appeals to the Federal Circuit involving the '865 patent and no other Petitions involving the '865 patent argued invalidity based on Dix '226. And no other cases resulted in settlement, either. Accordingly, Patent Owner cannot reasonably have a “settled expectation” related to the validity of the '865 patent and Director Review of discretionary denial is warranted.

B. Discretionary Denial Incentivizes Strategic Litigation and Settlement of Weak Patents

Allowing the Decision to stand provides incentives that are contrary to the public health and economic policies of fostering innovation and decreasing drug prices through competition, particularly in view of the unpatentable claims present in the '865 Patent. *See* Petitioner’s Opposition to PO’s Request for Discretionary Denial (Paper No. 7) at 16-17. Discretionary denial here rewards Patent Owner’s strategy of litigating and strategically settling cases involving weak patents and then weaponizing that litigation before the Board in its requests for discretionary denial.

Allowing discretionary denial here is also contrary to the point of “settled expectations” which is to avoid frivolous and duplicative proceedings. Discretionary denial leaves Petitioner (or any similarly situated party) without a viable pathway to challenge the ’865 patent before the Board. As a result, Petitioner’s only option to challenge the ’865 patent is district court litigation. In other words, rather than the Board addressing the one anticipation ground based on Dix ’226, Fresenius would be required to start from scratch in the courts and re-do the litigation that resulted in the skeptical Federal Circuit panel in the *Mylan* appeal. *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. Therefore, Director Review is necessary at least because the Decision is misaligned with policy objectives.

III. THE USPTO’S GUIDANCE LEADING TO DISCRETIONARY DENIAL IS UNCONSTITUTIONAL

The unconstitutionality of interim memoranda, announcements, and processes weigh heavily against discretionary denial. Significant changes were made to required standards, beginning with the March 24, 2025 Memorandum of Chief Administrative Patent Judge Scott Boalick (the “Boalick Memorandum”) and the March 26, 2025 Memorandum of Acting Director Coke Morgan Stewart (the “Director Memorandum”). Three weeks after the Director Memorandum issued, the

USPTO held an oral webcast setting forth additional substantive details of the new interim procedure not found in the Director Memorandum. Shortly thereafter, the USPTO posted on its website “FAQs for Interim Processes for PTAB Workload Management” with additional new details (“FAQs”). Petitioner submits that the Boalick Memorandum, Director Memorandum, oral webcast, and FAQs (collectively, the “interim memoranda and announcements”) contravene statutory and due process obligations.

Statute dictates the standards for implementing IPRs without regard to the time since a patent issued. 35 U.S.C. § 314(a). Unlike PGRs, which have a time limit and are limited to challenge patents with months of issuance, IPRs have no such statutory limit. Creating and imposing such a limit to deny IPRs based on this separate factor therefore exceeds statutory authority, and does not address the merits of any particular patent.

In addition, the interim memorandum and announcements fail to satisfy 35 U.S.C. § 316(a) and the Administrative Procedure Act (“APA”) at least because changes were made—including establishing the “settled expectations” rule—without going through notice-and-comment rulemaking. Notice-and-comment “assure[s] fairness and mature consideration of rules of general application.” *NLRB v. Wyman-Gordon Co.*, 394 U.S. 759, 764 (1969). Agency action disregarding that procedural requirement must be set aside. *See, e.g., Coal. for Common Sense in Gov’t*

Procurement v. Sec’y of Veterans Affs., 464 F.3d 1306, 1317 (Fed. Cir. 2006). The Steward memo, in particular the “settled expectations” rule, imposed without notice-and-comment procedures, violates the APA and should be set aside.

The APA requires notice-and-comment rulemaking for substantive rules. 5 U.S.C. §553. The APA defines as a “rule” any “agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy.” §551(4). Substantive rules, but not “interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice,” require notice and comment. §553(b). Rules are “substantive” if they “effect a change in existing law or policy” or “affect individual rights and obligations.” *Paralyzed Veterans of Am. v. West*, 138 F.3d 1434, 1436 (Fed. Cir. 1998).

The USPTO’s “settled expectations” rule in the Steward Memo is a “rule” under the APA. It applies generally and prospectively to any IPR petition, and it implements and prescribes a concrete limit on IPR. The “settled expectations” rule “change[s] existing law and policy,” *id.*, by introducing a never-seen-before IPR precondition. The “settled expectations” rule affects patent challengers’ rights by creating a new ground for depriving opportunities to seek patent cancellation through IPR. It substantively affects patent owners and the public by establishing a category of “old” patents that are protected against IPR, and affects challengers’

rights and obligations by requiring premature IPR challenges early in a patent's life, or forfeiture of IPR rights.

Therefore, Director Review is necessary to correct any reliance on the improper interim memorandum and announcements.

IV. CONCLUSION

For all the foregoing reasons, petitioner respectfully requests that the Director grant review, vacate the Decision, and refer the Petition to the Board.

Dated: December 19, 2025

Respectfully submitted,

/Imron T. Aly/

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CERTIFICATE UNDER 37 C.F.R. § 42.24

Pursuant to 37 C.F.R. § 42.24(d), the undersigned certifies that this Request for Director Review complies with the 15-page limit exclusive of the parts exempted as provided in 37 C.R.F. § 42.24(a).

/s/ Imron T. Aly
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Lead Counsel

CERTIFICATE OF SERVICE

Pursuant to 37 CFR §§ 42.6(e)(4)(i) *et seq.* and 42.105(b), the undersigned certifies that on December 19, 2025, a complete and entire copy of Petitioner's Sur-Reply in Opposition to Patent Owner's Request for Director's Review were provided by electronic mail on the following counsel of record:

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