

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

**PATENT OWNER'S RESPONSE TO
PETITIONER'S REQUEST FOR DIRECTOR REVIEW**

TABLE OF CONTENTS

TABLE OF AUTHORITIES	ii
TABLE OF EXHIBITS	iv
I. Introduction.....	1
II. Argument	2
A. Fresenius Does Not Dispute That <i>Fintiv</i> Strongly Supports Denial	2
B. Fresenius’s Through-the-Looking-Glass Version of “Settled Expectations” Does Not Support Institution.....	5
C. Fresenius’s Selective Quotations from the <i>Mylan</i> Oral Argument Do Not Support Institution.....	7
D. Fresenius’s Constitutional and APA Arguments Are Meritless	10
III. Conclusion	14

TABLE OF AUTHORITIES

CASES

<i>Apple Inc. v. Fintiv, Inc.</i> , IPR2020-00019, 2020 WL 2126495 (P.T.A.B. Mar. 20, 2020).....	passim
<i>Apple Inc. v. Samsung Elec. Co.</i> , 809 F.3d 633 (Fed. Cir. 2015)	10
<i>Bloch v. Powell</i> , 348 F.3d 1060 (D.C. Cir. 2003).....	14
<i>Cerini v. Warrior Energy Servs., Inc.</i> , 2014 WL 7015992 (W.D. Pa. Dec. 11, 2014)	8
<i>Cuozzo Speed Techs. v. Lee</i> , 579 U.S. 261 (2016).....	6
<i>Douglas Dynamics, LLC v. Buyer Prods. Co.</i> , 717 F.3d 1336 (Fed. Cir. 2013)	10
<i>In re Cambridge Indus. USA Inc.</i> , 2025 WL 3526129 (Fed. Cir. Dec. 9, 2025).....	12
<i>In re Killian</i> , 45 F.4th 1373 (Fed. Cir. 2022)	11
<i>In re Motorola Sols., Inc.</i> , 159 F.4th 30 (Fed. Cir. 2025)	14
<i>Lincoln v. Vigil</i> , 508 U.S. 182 (1993).....	13
<i>NHK Spring Co. v. Intri-Plex Tech., Inc.</i> , IPR2018-00752, 2018 WL 4373643 (P.T.A.B. Sept. 12, 2018)	7
<i>Sandoz, Inc. v. Amgen, Inc.</i> , 773 F.3d 1274 (Fed. Cir. 2014)	6
<i>United States v. Arthrex, Inc.</i> , 594 U.S. 1 (2021).....	12, 13, 14

<i>Valve Corp. v. Elec. Scripting Prods., Inc.</i> , IPR2019-00064, Paper 10 (P.T.A.B. May 1, 2019)	6
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OTHER AUTHORITIES

5 U.S.C. § 553(b)	13
35 U.S.C. § 314(a)	12
37 C.F.R. § 42.75	1
37 C.F.R. § 42.101	6
Interim Processes for PTAB Workload Management (Mar. 26, 2025).....	11, 13
USPTO, Director Review Process, https://www.uspto.gov/patents/ptab/decisions/director-review-process (Dec. 15, 2025)	4, 5, 11

TABLE OF EXHIBITS

Exhibit	Description
2001	Mylan Redacted Trial Decision, 22-cv-61, Dkt. 692 (N.D.W. Va.)
2002	SB Redacted PI Decision, 24-md-3103, Dkt. 194 (N.D.W. Va.)
2003	Formycon Redacted PI Decision, 24-md-3103, Dkt. 247 (N.D.W. Va.)
2004	Celltrion Redacted PI Decision, 24-md-3103, Dkt. 248 (N.D.W. Va.)
2005	SB Appeal Decision, 24-1965, Dkt. 76 (Fed. Cir.)
2006	Formycon Appeal Decision, 24-2009, Dkt. 67 (Fed. Cir.)
2007	Celltrion Appeal Decision, 24-2058, Dkt. 62 (Fed. Cir.)
2008	Fresenius, Fresenius to Expand Biopharma Portfolio with a New Licensing Agreement to Commercialize a Proposed Aflibercept Biosimilar (Dec. 20, 2024), https://www.fresenius.com/node/6982
2009	Email from D. Berl to S. Gibson re Scheduling Conference (Sept. 12, 2025)
2010	Zaltrap® Label
2011	Regeneron v. Mylan, 22-cv-61, Trial Transcript (Public Excerpts) (N.D.W. Va.)
2012	J.L. Fast et al., Physical Instability of a Therapeutic Fc Fusion Protein: Domain Contributions to Conformational and Colloidal Stability, 48 BIOCHEM. 11724 (2009) (“Fast”)
2013	Regeneron v. Mylan, 22-cv-61, Trial Ex. DTX-3619A, Fusion Proteins Disclosed in Papadopoulos
2014	International Publication No. WO 00/75319 (“WO 00/75319”)
2015	U.S. Patent Application Pub. No. 2006/0058234 A1 (“Daly”)
2016	W. Wang, Protein Aggregation and Its Inhibition in Biopharmaceutics, 289 INT. J. PHARM. 1 (2005) (“Wang 2005”)
2017	J. Gaudreault et al., Preclinical pharmacokinetics of Ranibizumab (rhuFabV2) after a single intravitreal administration, 46(2) INVEST OPHTHALMOL VIS SCI. 726 (2005) (“Gaudreault”)

Exhibit	Description
2018	Thomas et al., Comparative Effectiveness of Aflibercept for the Treatment of Patients with Neovascular Age-Related Macular Degeneration, 7 CLINICAL OPHTHALMOLOGY 495 (2013) (“Thomas”)
2019	International Publication No. WO 2005/102303 A2 (“Peyman”)
2020	M.R. Marmour, Retinal detachment from hyperosmotic intravitreal injection, 18(12) INVEST OPHTHALMOL VIS SCI. 1237 (1979) (“Marmour ”)
2021	Declaration of Kenneth S. Graham, dated April 18, 2024
2022	Excerpts of File History of U.S. Patent No. 11,084,865
2023	Scheduling Order, Case No. MDL 24-md-3103, ECF No. 663

I. Introduction

Fresenius's Request (Paper 12, "Req.") comes nowhere close to making out the requisite showing under 37 C.F.R. § 42.75 and the associated Office guidance. To the contrary, Fresenius, its head buried firmly in the sand, quadruples down on the myriad deficiencies in its Petition that rendered it especially well-suited for discretionary denial—as the Director correctly concluded. *See* Paper 11.

First, Fresenius seeks reversal due to a supposed "mistake" in the Director's discretionary-denial decision, Req. 1, but Fresenius fails even to cite *Fintiv*, let alone dispute that the *Fintiv* factors strongly support discretionary denial. Fresenius's failure to address *Fintiv* dooms its Request. Second, Fresenius continues to advance its nonsensical conception of settled expectations according to which successfully defeating *ten* validity challenges somehow favors institution of an *eleventh*. Third, Fresenius persists in transparently cherry-picking questions from the *Mylan* oral argument to suggest that the Federal Circuit panel "was about to resolve invalidity" while studiously refusing to acknowledge (let alone substantively address) any of the panel's remarks (repeatedly cited in Regeneron's briefing) that expose the deficiencies in Fresenius's anticipation position. Req. 3. Finally, Fresenius's constitutional and APA arguments are largely copy-pasted from its Discretionary Denial Opposition (Paper 7, at 18-20), and they are just as meritless as before. Req. 6-9. The Director should deny Fresenius's Request.

II. Argument

Fresenius professes ignorance as to “why the petition was not referred to a panel for a decision on institution,” speculating that institution was denied based “on settled expectations and prior litigation,” each of which Fresenius asserts “favor[s] Petitioner so a mistake appears to have been made in the review process.” Req. 1. Fresenius maintains that “‘settled expectations’ does not weigh in favor of discretionary denial” because “the ’865 patent was promptly and repeatedly challenged, and the Federal Circuit ... discussed at oral argument its likely anticipated status,” and it argues that the “concurrent litigation challenging the ’865 patent” does not favor institution because it would permit Regeneron to “preserv[e] weak patents.” *Id.* Moreover, it recycles its argument that the Office’s discretionary-denial process is unconstitutional and violates the APA. Req. 6-9. None of Fresenius’s arguments merits the Director reaching a different outcome on institution. As discussed below, *infra* §§ II.B, II.D, Fresenius’s upside-down interpretation of the settled-expectations factor does not support institution, and its constitutional and APA arguments are meritless. But at the outset, Fresenius’s arguments are foreclosed by its failure even to cite *Fintiv*, much less contest that the *Fintiv* factors overwhelmingly favor discretionary denial.

A. Fresenius Does Not Dispute That *Fintiv* Strongly Supports Denial

The Director and Board repeatedly have held—and Regeneron repeatedly has

explained—how the *Fintiv* factors foreclose institution of challenges like Fresenius’s. *See* Paper 6, at 4-20; Paper 9, at 1-3. Fresenius’s Request, however, neither addresses nor contests any of those points.

Relying on *Fintiv*, the Director and Board have denied institution of multiple petitions nearly identically situated to Fresenius’s. The Board and Director denied institution of three petitions (from Samsung Bioepis, Formycon, and Celltrion) challenging U.S. Patent 11,084,865 (the “’865 patent”) based on the considerable overlap in claims and issues between those petitions and the parallel litigation before the District Court for the Northern District of West Virginia (“District Court”) and Federal Circuit; the substantial investment in the parallel litigation (*e.g.*, the *Mylan* bench-trial decision, as well as multiple preliminary-injunction decisions and affirmances thereof); and the fact that numerous decisions had upheld the validity of the ’865 patent’s claims. IPR2025-00456, Paper 14, at 2; IPR2025-00176, Paper 12, at 11-23; IPR2025-00233, Paper 15, at 12-23. In each decision, the Board and Director necessarily found discretionary denial appropriate under *Fintiv*. *Id.*

As Regeneron has explained, moreover, Fresenius’s Petition—like Samsung’s, Formycon’s, and Celltrion’s—raises claims and issues that significantly overlap not only with the *Mylan* litigation but also the preliminary-injunction proceedings and appeals. *See* Paper 6, at 4-20; Paper 9, at 1-3. Accordingly, institution of Fresenius’s Petition would be manifestly inefficient given the

enormous investment in parallel litigation and the numerous decisions upholding the '865 patent. *Id.* And the fact that Fresenius has not yet joined the parallel litigation as a defendant is of no moment. *See, e.g., Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, 2020 WL 2126495, at *6 (P.T.A.B. Mar. 20, 2020) (precedential) (“Even when a petitioner is unrelated to a defendant, however, if the issues are the same as, or substantially similar to, those already or about to be litigated, or other circumstances weigh against redoing the work of another tribunal, the Board may, nonetheless, exercise the authority to deny institution.”). The *Fintiv* factors therefore require discretionary denial here, just as with the other three petitions.

Fresenius’s Request makes no argument to the contrary, thus conceding that consideration of the *Fintiv* factors compels discretionary denial. *See* USPTO, Director Review Process, <https://www.uspto.gov/patents/ptab/decisions/director-review-process> (Dec. 15, 2025) (“Director Review Process”) (“Any argument not made within the request may be deemed waived.”). In other words: (1) the Director and Board repeatedly have determined that discretionary denial is appropriate for challenges like Fresenius’s to the '865 patent; (2) the *Fintiv* factors weigh just as strongly in favor of discretionary denial here as they did with the three prior petitions; and (3) Fresenius makes no argument otherwise. As a result, discretionary denial of Fresenius’s Petition is mandated irrespective of its spurious arguments about settled expectations and meritless constitutionality and APA challenges.

Because Fresenius cannot show “an abuse of discretion,” “erroneous findings of material fact,” or “erroneous conclusions of law,” *see id.*, its Request must be denied.

B. Fresenius’s Through-the-Looking-Glass Version of “Settled Expectations” Does Not Support Institution

Fresenius fundamentally misapprehends the settled-expectations factor, which decisively favors denial here. First, Fresenius re-treads its argument that Regeneron could have no settled expectations regarding the validity of the ’865 patent because it has been challenged in three previous IPR petitions, the *Mylan* District Court trial, and in the preliminary-injunction proceedings and ensuing appeals. Req. 2-3. Fresenius, however, again ignores that the validity of the ’865 patent was *confirmed* in each of these proceedings. This consistency across challenges and tribunals creates—rather than undermines—settled expectations in the validity of the ’865 patent.

Second, Fresenius suggests that “Patent Owner itself invited challenges by using this very patent to attempt to block biosimilar [sic] form [sic] reaching the market.” Req. 3. In other words, Fresenius maintains that *whenever* a patent is asserted against a putative generic or biosimilar drug product, settled expectations favor institution, because the patent owner is “invit[ing] challenges” to its patent. *Id.* Fresenius’s notion that merely asserting a patent automatically favors institution of serial, meritless IPRs is as absurd as it is unsupported. To the contrary, “serial and repetitive attacks ... favor denying institution,” and this rule does not change

even “[w]hen different petitioners challenge the same patent,” *Valve Corp. v. Elec. Scripting Prods., Inc.*, IPR2019-00064, Paper 10, at 2, 16-17 (P.T.A.B. May 1, 2019), *contra* Fresenius, *see* Req. 6 (“Here, unlike *Valve*, there is no gamesmanship and no serial filing by the same party.”). Fresenius’s upside-down conception of settled expectations would subject patent owners to “frivolous and duplicative proceedings,” the avoidance of which Fresenius concedes is “the point of ‘settled expectations.’” Req. 6.

Third, Fresenius complains that this consideration “is particularly problematic in the biosimilars technology area, because of issued [sic] related to standing to appeal,” *i.e.*, “a biosimilar applicant cannot challenge a patent ‘too soon’ because then it would lack standing to appeal.” Req. 3 (quoting *Sandoz, Inc. v. Amgen, Inc.*, 773 F.3d 1274 (Fed. Cir. 2014)). According to Fresenius, then, “the challenges to the ’865 patent so far have been as early as practical, and that includes the Petition.” *Id.* Not so. Even if Fresenius had to “await the biosimilar application process” before challenging the ’865 patent in court, *id.*, Fresenius could have filed its Petition challenging the ’865 patent at any time since it issued. *See* 37 C.F.R. § 42.101; *Cuozzo Speed Techs. v. Lee*, 579 U.S. 261, 279 (2016) (IPR petitioners do not need constitutional standing). Mylan asserted anticipation by Dix at trial in June 2023, but rather than promptly filing its copycat Petition then, Fresenius chose to wait *several years*, by which point the validity of the ’865 patent had been upheld *ten*

times, with the District Court and Federal Circuit having *repeatedly* addressed, for instance, the '865 patent's non-anticipation by Dix and the non-inherency of the "native conformation" claim limitation—findings that dispose of Fresenius's Petition. *See* Paper 6, at 8-15, 19-20; Paper 8, at 15-45; Paper 9, at 1-3. The AIA's basic objective is "to provide an effective and efficient alternative to district court litigation." *NHK Spring Co. v. Intrix-Plex Tech., Inc.*, IPR2018-00752, 2018 WL 4373643, at *7 (P.T.A.B. Sept. 12, 2018) (precedential). That Fresenius's "only option to challenge the '865 patent is district court litigation," Req. 6, is the product of its decision to wait to file its Petition until well past the point that institution of IPR could have provided an effective and efficient alternative to such litigation.

C. Fresenius's Selective Quotations from the *Mylan* Oral Argument Do Not Support Institution

Fresenius asserts that "[t]here is also no reasonable 'settled expectation' regarding the validity of the '865 patent given that the Federal Circuit was about to resolve invalidity" Req. 3. But Fresenius, as in its Petition and subsequent submissions, is once again cherry-picking quotes from the *Mylan* oral argument to advance its unsupported narrative that the Federal Circuit would have overturned the District Court's *Mylan* decision if it had not been stymied by settlement. Req. 4-5. Fresenius's fanciful theory is unavailing.

First, as explained in Regeneron's Preliminary Response, *oral argument questions are not evidence*. "Experience teaches that questions asked by a Judge at

oral argument are a rather poor predictor of a decision yet to be made.” Paper 8, at 20 (quoting *Cerini v. Warrior Energy Servs., Inc.*, 2014 WL 7015992, at *3 n.3 (W.D. Pa. Dec. 11, 2014)). Fresenius’s reliance on oral argument questions as proof “that the Federal Circuit was about to resolve invalidity,” Req. 3, is thus baseless.

Second, Fresenius’s myopic view of the oral argument transcript misrepresents the entirety of the argument. *See, e.g.*, Paper 8, at 20-21. Fresenius again single-mindedly fixates on the issue of the criticality of the concentration claimed in the ’865 patent in light of Dix’s range of concentrations. Req. 4-5. Fresenius ignores, however, that the members of the Federal Circuit panel repeatedly acknowledged that the criticality issue was not dispositive—rather, Mylan’s (and thus Fresenius’s) anticipation argument is littered with roadblocks that preclude a finding of anticipation regardless of criticality. As the panel recognized, the District Court’s non-anticipation finding could be affirmed on the bases that: (1) Dix’s generic disclosure of concentrations applies to a class of VEGF antagonists and not aflibercept specifically; (2) Dix’s disclosed concentration range is too broad to invoke any presumption of anticipation; (3) there was no evidence that Dix’s formulations would inherently have 98% native conformation as recited by the ’865 patent’s claims; and (4) all but two claims recited a specific concentration (40 mg/ml), whereas Dix disclosed a range of concentrations. *See, e.g.*, Ex.1008 at 35:4-9 (“[A]s I understand your argument, you’ve got roadblocks that’s setting up before

we have to worry about criticality. One is we're dealing with, as you would call it, a class of VEGF antagonists and two, the size of the prior art ... range is just too big."); *id.* at 17:6-20:22 ("What about the 98 percent stability limitation? I think there was a finding that ... even if Dix discloses the 40 mg [concentration] ... there is nothing in Dix that necessarily leads to that particular formulation that would get you this ... particularized stability."); *id.* at 45:22-46:7 (similar); *id.* at 7:11-13 ("I haven't found a case, which is our case, which is the prior art has the range [of values] and the patent has just one [value]."). Across its Petition, Discretionary-Denial Opposition, Discretionary-Denial Sur-reply, and now its Request, Fresenius has not once acknowledged these remarks from the panel, nor has it meaningfully attempted to show that the District Court's findings on these points were erroneous. Accordingly, even if attempting to read tea leaves from an oral argument were a valid means of assessing a patent's strength and thus the propriety of instituting an IPR challenging that patent, Fresenius has utterly failed to substantiate its surmise "that the Federal Circuit was about to resolve invalidity" Req. 3. Instead, if anything, the panel's remarks underscore the correctness of the District Court's conclusion of non-anticipation.

Fresenius also falsely characterizes the '865 patent as "weak." Req. 1, 3, 5. For instance, it argues that "using settled expectations to deny review undercuts the President's goal for affordable drugs, by severely handicapping IPR petitions even

for weak patents,” Req. 3, and that “[d]iscretionary denial here rewards Patent Owner’s strategy of litigating and strategically settling cases involving weak patents,” Req. 5. But the sole basis for its ludicrous characterization of the ’865 patent—which has *withstood ten validity challenges*—as “weak” is the *Mylan* oral argument, which, as described above, by no means suggests “weakness” in the ’865 patent’s validity. To the contrary, the strength of the ’865 patent, evidenced by the many decisions confirming its validity, undermines Fresenius’s policy arguments that discretionary denial here somehow undermines the affordability of drugs or leads to perverse incentives by patent owners. Indeed, the public interest “nearly always weighs in favor of protecting property rights in the absence of countervailing factors, especially when the patentee practices his inventions,” as is undisputedly the case here. *Apple Inc. v. Samsung Elec. Co.*, 809 F.3d 633, 647 (Fed. Cir. 2015). This public interest, especially given the numerous decisions consistently upholding the ’865 patent’s validity, *see Douglas Dynamics, LLC v. Buyer Prods. Co.*, 717 F.3d 1336, 1346 (Fed. Cir. 2013), outweighs whatever value purportedly would arise from “competition” from Fresenius’s Eylea[®] copycat, Req. 5.

D. Fresenius’s Constitutional and APA Arguments Are Meritless

Finally, Fresenius maintains that the Office’s “interim memoranda, announcements, and processes” are unconstitutional, exceed statutory authority, and violate the APA. Req. 6. Fresenius’s arguments, which are at best retreads of—and

at worst literally copy-pasted from—arguments in its previous submissions, do not justify the Director reaching a different conclusion as to institution here.

First, Fresenius offers no basis to find that the discretionary-denial processes are unconstitutional or “exceed[] statutory authority.” Req. 6-7. Indeed, Fresenius sets forth those arguments in two paragraphs that are literally copied and pasted from its Discretionary-Denial Opposition. *Compare id.* (first two paragraphs in § III), *with* Paper 7, at 18-19 (first two paragraphs in § IV.D). As before, these arguments cite ***not one constitutional or statutory provision***, aside from a passing reference to “statutory and due process obligations.” Req. 7. Fresenius’s “conclusory, skeletal” arguments alleging unspecified violations of unspecified “obligations” fail even to preserve these issues, *In re Killian*, 45 F.4th 1373, 1385-86 (Fed. Cir. 2022), let alone show “an abuse of discretion,” “erroneous findings of material fact,” or “erroneous conclusions of law,” *see* Director Review Process.

Moreover, Fresenius’s contention that “[c]reating and imposing ... a limit to deny IPRs based on this [settled-expectations] factor therefore exceeds statutory authority,” Req. 7, completely misses the mark. That the “[s]ettled expectations of the parties, such as the length of time the claims have been in force,” are one among many ***“relevant considerations,”*** Interim Processes for PTAB Workload Management at 2 (Mar. 26, 2025) (“Stewart Memo”) (emphasis added), does not mean that the Office has somehow created a hard-and-fast “time limit” for IPRs.

Req. 7. In other words, the Office’s consideration of settled expectations as one “**factor**” affecting whether discretionary denial is, as a whole, appropriate does not support Fresenius’s charge that the Office improperly created a new “statutory limit.” *Id.* (emphasis added). Rather, Fresenius is once more tilting at windmills.

For similar reasons, Fresenius’s APA arguments are unavailing. Fresenius complains that “[t]he USPTO’s ‘settled expectations’ rule in the Steward [sic] Memo ... implements and prescribes **a concrete limit** on IPR” and “introduc[es] a never-seen-before IPR **precondition**.” Req. 8 (emphases added). But the settled-expectations factor is neither “a concrete limit” nor a “precondition,” *id.*; rather, it is simply one additional factor among many¹ that the Director may consider in the exercise of his statutory discretion regarding whether IPR should be instituted, *see* 35 U.S.C. § 314(a); *United States v. Arthrex, Inc.*, 594 U.S. 1, 8-9 (2021); *In re*

¹ What is more, as described above, it is a factor that no previous decision by the Board or Director denying institution of IPRs challenging the ’865 patent relied upon, and one that need not be relied upon here to deny institution given how overwhelmingly the *Fintiv* factors favor discretionary denial. *See supra* § II.A. Accordingly, the alleged impropriety of a “rule” that has not previously been applied to petitions identically situated to Fresenius’s and that, even if applied, would not change the outcome (in light of the *Fintiv* factors as a whole) is simply irrelevant.

Cambridge Indus. USA Inc., 2025 WL 3526129, at *2-3 (Fed. Cir. Dec. 9, 2025) (recognizing that arguments that the Office improperly “created what amounts to a ‘maximum-patent-age cap on IPR’” are ultimately “about what factors the Director may consider when deciding whether to institute IPR”).

Nor is Fresenius correct that the “‘settled expectations’ rule ... is a ‘rule’ under the APA.” Req. 8. As Fresenius itself acknowledges, “[s]ubstantive rules, but not ‘interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice,’ require notice and comment.” *Id.* (quoting 5 U.S.C. § 553(b)). “[G]eneral statements of policy” are “statements issued by an agency to *advise the public prospectively of the manner in which the agency proposes to exercise a discretionary power.*” *Lincoln v. Vigil*, 508 U.S. 182, 197 (1993) (emphasis added) (citation omitted). Such is the case here. The Director has “unreviewable discretion” over IPR institution, *Arthrex*, 594 U.S. at 8-9, and the Stewart Memo merely advised the public that, going forward, the “considerations bearing on the Director’s discretion” may include the “[s]ettled expectations of the parties,” Stewart Memo at 2-3. The Stewart Memo, including the settled-expectations factor, is therefore a “general statement[] of policy,” and “[t]he notice-and-comment requirements ... do not apply.” *Lincoln*, 508 U.S. at 196.

Fresenius also erroneously characterizes the settled-expectations factor as a rule because it “affects patent challengers’ *rights* by creating a new ground for

depriving opportunities to seek patent cancellation through IPR” and “by requiring premature IPR challenges early in a patent’s life, or forfeiture of IPR *rights*.” Req. 8-9 (emphases added). But as before, the Director has “unreviewable discretion” over whether to institute IPR, *Arthrex*, 594 U.S. at 8-9, so Fresenius cannot claim any “right” to institution, *see In re Motorola Sols., Inc.*, 159 F.4th 30, 36 (Fed. Cir. 2025) (“Motorola *does not claim any rights in institution of IPR ... , nor could it*: ‘[W]hen a statute *leaves a benefit to the discretion of a government official, no protected property interest in that benefit can arise.*’” (alteration in original; emphases added) (quoting *Bloch v. Powell*, 348 F.3d 1060, 1069 (D.C. Cir. 2003))).

In sum, Fresenius identifies no support for its notion that the Stewart Memo was a “substantive rule” requiring notice-and-comment rulemaking under the APA. Req. 8. Accordingly, Fresenius has failed to justify its request for “Director Review ... to correct any reliance on the improper interim memorandum and announcements.” Req. 9. The Director should reject Fresenius’s baseless argument.

III. Conclusion

Fresenius’s Request merely rehashes the same arguments previously considered and properly rejected by the Director in exercising his discretion to deny institution—and thus provides no basis for the Director to reach a different decision. The Director therefore should deny Fresenius’s Request for Review.

Date: January 6, 2026

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CERTIFICATION AS TO LENGTH

The undersigned certifies that this Response to Fresenius's Director Review Request complies with the 15-page limit provided in the Director's December 19, 2025 authorization to file a Response.

Date: January 6, 2026

/David I. Berl/

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Lead Counsel for Patent Owner

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

The undersigned hereby certifies that on January 6, 2026, I caused true and correct copies of the following materials:

- Patent Owner's Response to Petitioner's Request for Director Review

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