

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 OPPOSITION TO PATENT OWNER'S
REQUEST FOR DISCRETIONARY DENIAL**

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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

Pursuant to the Director’s Memorandum issued on March 26, 2025, Petitioner Fresenius Kabi SwissBioSim GmbH (“Fresenius” or “Petitioner”) files this Opposition to Patent Owner’s Discretionary Denial Brief (Paper 6, hereinafter “Brief” or “Br.”), setting forth reasons why the Director should not exercise discretion to deny the Petition for *inter partes review* (“Petition”) of claims 1-5, 7-30, and 32-50 (the “challenged claims”) of U.S. Patent No. 11,084,865 B2 (the “’865 Patent”) (Ex. 1001), as asserted by Regeneron Pharmaceuticals, Inc. (“Regeneron” or “Patent Owner”).

I. INTRODUCTION

Petitioner respectfully requests that the Board not exercise its discretion to deny institution of Fresenius’s Petition under *Fintiv* or any other discretionary factors. Patent Owner’s reliance on the multidistrict litigation, *In re Aflibercept Patent Litigation*, No. 1:24-md-3103 (N.D. W.Va.) (the “MDL proceeding”), to analyze the *Fintiv* factors rests on the flawed premise that the MDL proceeding should influence the *Fintiv* analysis of Fresenius’s Petition when Fresenius is not a party to the MDL proceeding. Patent Owner’s reliance on preliminary injunction decisions and *inter partes review* (“IPR”) petitions in which Petitioner is not a party is equally misplaced. It would be unduly prejudicial for the Board to discretionarily deny Fresenius’s Petition based upon decisions in other litigations, when Fresenius was not a party to those litigations. *See Taylor v. Sturgell*, 553 U.S. 880, 892 (2008)

(“A person who was not a party to a suit generally has not had a ‘full and fair opportunity to litigate’ the claims and issues settled in that suit.”)

II. BACKGROUND

Fresenius’ Petition includes a single anticipation ground challenging claims 1-5, 7-30 and 32-50 of the ’865 Patent based on U.S. Patent No.: 10,406,226 (“Dix ’226”) (Ex. 1005). Dix ’226 has not been evaluated on the merits in any *instituted* IPR proceeding related to the ’865 Patent. While the ’865 Patent was challenged in *Samsung Bioepis Co. Ltd. v. Regeneron Pharmaceuticals, Inc.*, IPR2025-00176 (P.T.A.B.) (“*Samsung*”), *Formycon Inc. v. Regeneron Pharmaceuticals, Inc.*, IPR2025-00233 (P.T.A.B.) (“*Formycon*”), and *Celltrion, Inc. v. Regeneron Pharmaceuticals, Inc.*, IPR2025-00456 (P.T.A.B.) (“*Celltrion*”), the Board denied institution on discretionary grounds in each petition.

Moreover, the patent has not been evaluated since the Federal Circuit seemed likely to invalidate the ’865 Patent in the *Mylan* litigation in view of Dix ’226, as Regeneron settled that pending litigation before any decision could issue. For example, the panel noted that Regeneron relied on using 40 mg/ml despite the prior art range of 10-50 mg/ml for which “the claimed invention is critical only if it can be shown that the claimed invention works for 40 mg and not for others.” (Ex.1008 at 38:2-20). So while Patent Owner refers to the *Mylan* appeal (No. 24-2002, ECF No. 58 (Fed. Cir. 2025)), the Petition demonstrated that the appeal was likely to

invalidate the claims of the '865 Patent, but for Regeneron's settlement with Mylan and the ensuing dismissal, before the opportunity for any written decision on the merits. As to earlier rulings on preliminary injunction issues, the Federal Circuit affirmed *Regeneron Pharm., Inc. v. Mylan Pharm. Inc.*, 127 F.4th 896 (Fed. Cir. 2025), *Regeneron Pharm., Inc. v. Mylan Pharm. Inc.*, 2025 WL 324288 (Fed. Cir. Jan. 29, 2025), and *Regeneron Pharm., Inc. v. Mylan Pharm. Inc.*, 2025 WL 706079 (Fed. Cir. Mar. 5, 2025) (collectively the "PI affirmances") by an obviously preliminary decision given the posture of those cases. *See Abbott Lab'ys. v. Sandoz, Inc.*, 544 F.3d 1341, 1361 (Fed. Cir. 2008) (representing that a preliminary injunction decision is not a final adjudication on the merits).

The MDL proceeding is further unavailing. As conceded by the Patent Owner, the MDL proceeding's anticipation inquiry into Dix '226 encompasses claims that differ in scope from the challenged claims. Br. 7. For example, claims 4, 7, 9, 11, and 14-17 were at issue in the *Mylan* litigation, while those claims and claims 29, 32, 34, 36, 39-42, and 55 were collectively asserted in the *Samsung Bioepis*, *Formycon*, and *Celltrion* litigations. *See In re Aflibercept*, No. 1:24-md-03103 (N.D.W. Va.), Dkt. Nos. 194, 247, 248; *Regeneron Pharm., Inc. v. Mylan Pharm. Inc.*, Memorandum Opinion and Order Following Bench Trial, C.A. No. 1:22-cv-0061 (W. Va. Dec. 27, 2023). These claims do not include challenged claims 1-3, 5, 8, 10, 12-13, 18-28, 30, 33, 35, 37, 38, and 43-50, which present different limitations

and invalidity theories in view of Dix '226. Thus, the claims at issue in the MDL proceeding do not substantially overlap and are not similar to the challenged claims included in Fresenius' petition. *See Edwards Lifesciences Corp. v. Colibri Heart Valve LLC*, IPR2020-01649, 2021 WL 1158197, at *5–6 (P.T.A.B. Mar. 26, 2021) (finding that differences in claim posture weighed against denial).

As a result, Fresenius' Petition should be instituted. In addition to the fact that Petitioner has not been afforded any chance to litigate its anticipation ground relating to the '865 Patent because Petitioner is *not a party* to the MDL proceeding, there are no set trial dates in the MDL proceeding, and any trial will occur *after* the Board's final written decision (FWD), as discussed *infra*. Moreover, Fresenius' Petition and strong anticipation ground in view of Dix '226 represent a compelling case on the “merits.” *See Apple Inc. v. FinTiv, Inc.*, IPR2020-00019, Paper 11 (P.T.A.B. Mar. 20, 2020), at 14-15 (discussing the “merits”).

III. DISCRETIONARY DENIAL UNDER *FINTIV* IS NOT WARRANTED

All of the *Fintiv* factors, as addressed by Patent Owner in its Request for Discretionary Denial, support instituting the Petition.

In the context of Fresenius's Petition, it is critical to assess the sixth *Fintiv* factor, which Patent Owner has all but overlooked, and sheds light on the other factors. It is critical because the Federal Circuit's oral argument demonstrated the strength of the Dix '226 anticipation argument for the '865 Patent. The Federal

Circuit’s stated reasoning for likely finding anticipation was firmly rooted in *ClearValue, Inc. v. Pearl River aPolymers, Inc.* 668 F.3d 1340, 1344-45 (Fed. Cir. 2012), about claimed values within prior art ranges, which are not patentable without showing criticality. Patent Owner failed to address any of these points. So while in some cases other litigation may provide a reason to deny institution, here the other litigation provides a reason to institute: otherwise the PTAB will be endorsing patent holders in doomed litigations to settle on the eve of a decision and then forever claim in IPRs that discretionary denials should prevent any further review.

A. Factor Six (Merits) Weighs Against Discretionary Denial

Factor six of the *Fintiv* analysis **weighs heavily against** discretionary denial. This factor accounts for other relevant circumstances, including whether “the merits of a ground raised in the petition seem particularly strong on the preliminary record,” which favors institution. *Fintiv*, Paper 11 at 14-15; *OpenSky Indus., LLC v. VLSI Tech. LLC*, IPR2021-01064, Paper 102 at 49–50 (P.T.A.B. Oct. 4, 2022) (deciding the Board will not discretionarily deny institution under *Fintiv* when the petition presents evidence of unpatentability related to compelling merits).

First, Dix ’226 discloses every element of the challenged claims, “arranged as in the claims,” as required by *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1370–71 (Fed. Cir. 2008); Br. 10. As discussed in the Petition, Dix ’226 clearly discloses formulations for aflibercept in particular, and specifically formulations

with an organic co-solvent (polysorbate 20), a buffer (a phosphate buffer), and a stabilizing agent (sucrose). *See* Pet. 2-5. These formulation components are shown below, including these exact same excipients recited in the challenged claims:

Dix '226 Formulation	Challenged Claims Active Ingredients and Excipients
aflibercept	aflibercept
polysorbate 20	an organic co-solvent, with polysorbate 20 in dependent claims
phosphate buffer	a buffer, with phosphate in dependent claims
sucrose	a stabilizing agent, with sucrose in dependent claims

Dix '226 expressly discloses stability data showing $\geq 98-99\%$ native conformation at 2–24 months at 5°C in disclosed formulations. *See* Pet. 1, 4, 28-29, 39-41. In addition to these explicit disclosures, Dix '226 also inherently discloses the claimed stability limitations related to the disclosed formulation. *See* Pet. 1, 4, 28-29, 39-41; *Hospira, Inc. v. Fresenius Kabi USA, LLC*, 946 F.3d 1322, 1329–32 (Fed. Cir. 2020) (noting extrinsic evidence can show what is necessarily present in a prior-art embodiment, even if not itself prior art); *Atlas Powder Co. v. IRECO Inc.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999) (finding that recognition of an unappreciated property or mechanism of a prior-art composition does not confer patentability); *In re Best*, 562 F.2d 1252, 1255 (C.C.P.A. 1977) (finding the burden shifts to the patent owner to show a meaningful compositional difference).

Second, Patent Owner failed to meet its burden to demonstrate otherwise. Patent Owner's reliance on the "SS195" formulation at the preliminary injunction stage (which showed less than 98% native conformation at time zero) is unavailing. Br. 15. S195 represents a different formulation than the embodiments described in Fresenius' Petition which explicitly disclose materially identical compositions to the claimed stability limitations. *See* Pet. 22-24, 39-41.

Patent Owner's arguments that Dix '226 failed to disclose a 10–50 mg/mL range for liquid aflibercept or a pre-lyophilized 40 mg/mL are also defective. Dix '226 clearly discloses a 10–50 mg/mL range and Fresenius' Petition demonstrates that Patent Owner failed to show criticality for the 40 mg/mL concentration or that the remainder of the 10–50 mg/mL range is inoperable for the claimed use. *See* Pet. 29–33. Likewise, Dix '226's "pre-lyophilized 40 mg/mL" disclosure, lyophilized and altered to 80 mg/mL is entirely sufficient for anticipation, whether or not the claim preambles are deemed limiting. *See* Pet. 18–19, 32–33; *see also Catalina Mktg. Int'l v. Coolsavings.com*, 289 F.3d 801, 809–10 (Fed. Cir. 2002) ("Preambles describing the use of an invention generally do not limit patent claims, because the patentability of apparatus or composition claims depends on the claimed structure, not on the use or purpose of that structure.").

Even though the preamble phrase "suitable for intravitreal administration" is non-limiting, Dix '226 clearly disclosed the same ophthalmically accepted

excipients the '865 Patent itself lists as “suitable.” *See* Pet. 4; *Catalina*, 289 F.3d at 809–10. Thus, district court discussion cited by Patent Owner fails because the excipients are “suitable” for claimed use and because no proof of actual administration is required for composition claims. *See In re Spada*, 911 F.2d 705, 708 (Fed Cir. 1990) (discussing analogous compositions confer the same properties).

Third, Patent Owner ignored the fact that the MDL proceeding failed to properly apply *ClearValue*, which was precisely the issue the Federal Circuit hammered home in the oral argument that resulted in Regeneron settling with Mylan before the Federal Circuit could issue a decision. Pet. 30–31. In particular, the panel noted that “it seems like the thrust of the thinking of -- for criticality is comparing what you’ve claimed against other embodiments that come within the prior art range.” (Ex. 1008 at 36:6-9). Importantly, the panel explained during questioning that “the claimed invention is critical only if it can be shown that the claimed invention only works for 40 mg and not for others.” *Id.* at 38:7-10. In *ClearValue*, the Federal Circuit confirmed that claims are anticipated if they fall within prior art ranges, unless the *patentee* can show criticality. *See* 668 F.3d at 1344-45; *see also UCB, Inc. v. Actavis Lab’ys. UT, Inc.*, 65 F.4th 679, 687 (Fed. Cir. 2023) (correcting the *Genentech, Inc. v. Hospira, Inc.* framework cited by Patent Owner and underscoring that *ClearValue*’s criticality requirement governs anticipation in overlapping-range cases); *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 782 (Fed.

Cir. 1985) (deciding anticipation where the prior art disclosed a range encompassing a claimed figure). Patent Owner's silence here is fatal.

For at least the foregoing reasons, Petitioner has established the merits of the Dix '226 ground as *particularly strong* on the preliminary record, as the prior litigation proceedings favor institution in view of the Federal Circuit's oral argument assessment and *ClearValue* and its progeny. Given there is a reasonable likelihood that claims 1-5, 7-30 and 32-50 are unpatentable as anticipated by Dix '226, Factor six of the *Fintiv* analysis **weighs heavily against** discretionary denial.

B. Factor Five (Same Party) Weighs Against Discretionary Denial

Factor five of the *Fintiv* analysis **weighs against** discretionary denial. Petitioner is not a party to the MDL proceeding or any ongoing litigation.

Petitioner is not the same party as any of Mylan, Formycon, SB, Celltrion, Amgen, or Sandoz. Patent Owner fails to make any credible assertion or provide any analysis as to why Mylan, Formycon, SB, Celltrion, Amgen, or Sandoz should be effectively treated as a co-petitioner, and for that reason alone the Director should reject Patent Owner's assertion.

As the Board has repeatedly held, *Fintiv* Factor five weighs against denial when the petitioner is unrelated to the defendant in the earlier court proceeding. *Fintiv*, Paper 11 at 6; *Samsung Bioepis Co., Ltd v. Regeneron Pharms., Inc.*, IPR2023-00884, Paper 13 at 71 (Nov. 17, 2023) ("It is undisputed that Petitioner is

not a party to the district court action, which we determine weighs very heavily against exercising our discretion to deny institution.”); *see also POSCO Co. Ltd. v. ArcelorMittal*, IPR2025-00370, Paper 10 at 2 (P.T.A.B. June 25, 2025) (“Petitioner is not a party in the ITC investigation. Rather, Petitioner’s customer, listed as a real party-in-interest in the petition, is a party in the ITC proceeding.”). While Petitioner and defendants in the MDL proceeding have “a common desire” to see the ’865 Patent invalidated, that does not mean that Petitioner and defendants in the MDL or any other proceeding should be treated as the same or related party for the purposes of the *Fintiv* analysis. *See WesternGeco LLC v. ION Geophysical Corp.*, 889 F.3d 1308, 1321 (Fed. Cir. 2018).

This clear distinction is not only dispositive as to the fifth *Fintiv* factor, but also fundamentally undermines any Patent Owner argument alleging any commercial relationship between Petitioner and any of Mylan, Formycon, SB, Celltrion, Amgen, or Sandoz that could support discretionary denial under any other factor. Patent Owner’s allegations are baseless, much less sufficient to show a commercial relationship that is “sufficiently close that both should be bound” by the MDL proceeding. *Id.* To the contrary, Patent Owner’s own evidence proves Fresenius’s point: a prospective licensing agreement between Petitioner and South Korea’s SamChunDang Pharm (SCD), Br. 18, but SCD is not a party to the MDL

proceeding either. Accordingly, *Fintiv* Factor five **weighs heavily against discretionary denial** and should be dispositive of the *Fintiv* analysis.

C. Factor One (Likelihood of Stay) Weighs Against Discretionary Denial

Factor one of the *Fintiv* analysis **weighs against** discretionary denial. As indicated above in discussing Factor five, Fresenius is not any of the parties in the MDL proceeding, and there is no parallel district court proceeding for Fresenius involving the '865 Patent, so there is no district case to be stayed. Notwithstanding Fresenius' non-party status, no party in the MDL proceeding has requested a stay, and there is no indication that a stay is likely to be granted. The Board has repeatedly held that the absence of a stay request or likelihood of a stay for a party in a parallel proceeding renders this factor neutral or favors institution. *See Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, 2020 WL 2126495, at *3 (P.T.A.B. Mar. 20, 2020).

Since Fresenius is not a party to a parallel court proceeding involving the '865 Patent, *Fintiv* Factor one **weighs against** discretionary denial.

D. Factor Two (Timing of Trial) Weighs Against Discretionary Denial

Factor two of the *Fintiv* analysis **weighs against** discretionary denial for the reason that the '865 Patent is not asserted in any litigation to which Petitioner is a party, and therefore there is no set trial date at which Petitioner will have the opportunity to challenge the '865 Patent. Even if a litigation were to be filed later, it

would not be timely resolved, both in view of anticipated litigation timelines, and the anticipated expiration of the '865 Patent in June 2027.

Nonetheless, even if Patent Owner's reliance on the MDL proceeding were given any credence, the MDL proceeding is still in its early stages, and Patent Owner acknowledges there is *no* trial date nor do the parties have any indication the district court will set a trial date any time soon. Br. 19. Despite the parties' requests for a status and scheduling order since May 2024, the court only recently responded. *See Formycon*, IPR2025-00233, Paper 12, at 3-4. On September 29, 2025, the MDL court finally issued a scheduling order with pretrial deadlines for the parties that extend from now through February 17, 2027. *See In re Aflibercept*, No. 1:24-md-3103, Dkt. 663. Notably, the scheduling order fails to include *any trial date*, and the 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 (P.T.A.B. Sept. 25, 2024) (other *Fintiv* factors do not outweigh lack of trial date). Even if a trial date had been set, it would be after February 2027, so it is highly improbable to expect a trial court decision by the '865 Patent expiration in June 2027, much less Federal Circuit review. The timing factor favors institution so as to prevent Patent Owners from "running out the clock" for weak patents that are blocking biosimilar drug approval. Even where the timing of trial is uncertain or likely to be contemporaneous with the Board's Final Written Decision, this factor favors institution. *See Samsung Elecs.*

Co. v. Clear Imaging Rsch., LLC, IPR2020-01551, 2021 WL 628829, at *7–9 (P.T.A.B. Feb. 17, 2021). In this case, therefore, Factor two **weighs heavily against** discretionary denial and should be dispositive of the *FinTiv* analysis.

E. Factors Three and Four (Investment in Parallel Proceedings, Overlap of Issues) Weigh Against Discretionary Denial

Factors three and four of the *FinTiv* analysis **weigh against** discretionary denial because Petitioner is not a party to the MDL or any other proceeding, and the only investment and overlap with issues in the earlier litigation—the *Mylan* pending appeal—is favorable to Petitioner.

The Board has held that investment in proceedings where the merits have not been fully adjudicated does not weigh heavily against institution. *See Edwards Lifesciences Corp. v. Evalve, Inc.*, IPR2019-01479, 2020 WL 927867, at *4–5 (P.T.A.B. Feb. 26, 2020) (finding the investment in a preliminary injunction proceeding is not the same as the investment in a full trial on the merits.). As discussed above, Fresenius’ single-reference anticipation ground including challenged claims based on Dix ’226 was not raised in any prior instituted IPR. *See supra* Section II. The *Mylan* appeal was dismissed because of settlement before any written decision on the merits, and *Samsung*, *Formycon*, and *Celltrion* were denied on discretionary grounds without reaching the merits. *Id.* Further, the PI affirmances at the Federal Circuit merely evaluated preliminary injunction arguments. *Id.*

Moreover, the scope of the Petition includes claims not involved in the earlier litigations, so it cannot be said that the efficiency reasoning applies for discretionary denial. If anything, the opposite is true here, because the Petition cites to and shows the benefit of Federal Circuit analysis that supports Petitioner's IPR argument. Claims 4, 7, 9, 11, and 14-17 were directly at issue at the Mylan litigation. *Mylan*, 714 F. Supp. 3d at 677. Likewise, claims 29, 32, 34, 36, 39-42, and 55 were collectively asserted in the *SB*, *Formycon*, and *Celltrion* litigations. *Mylan*, 714 F. Supp. 3d at 677; *SB PI Decision*, 2024 WL 3422971, at *3; *Formycon PI Decision*, 2024 WL 3423047, at *3. The existence of non-overlapping claims (e.g. claims 1-3, 5, 8, 10, 12-13, 18-28, 30, 33, 35, 37, 38, and 43-50 included in Fresenius' Petition) demonstrates that issues remain, and that the public will benefit from invalidating the entire set of challenged claims in the Petition. See *Edwards Lifesciences*, IPR2020-01649, 2021 WL 1158197, at *5.

Ultimately, because Petitioner is not a party to the MDL or any other proceeding and in view of the lack of significant investment and overlap of numerous claims, Factors three and four of *Fintiv* **weigh strongly against** discretionary denial.

IV. DISCRETIONARY DENIAL UNDER INTERIM GUIDANCE FACTORS IS NOT WARRANTED

On March 26, 2025, the United States Patent and Trademark Office (U.S.P.T.O.) issued a memorandum on interim processes for PTAB workload

management, which introduced several factors that the Director will consider in determining whether to discretionarily deny an IPR petition. The oft-cited factor discussing settled expectations weighs against denying institution.

A. Settled Expectations of the Parties Weighs Against Discretionary Denial

Settled expectations of the parties **weighs against** discretionary denial.

Patent Owner's assertion that it has settled expectations should be disregarded, especially where the '865 Patent has been challenged so many times already. *See* Section II. The only expectation is to see continued challenges, because Patent Owner itself has so far used this very patent to block biosimilars from reaching the market. Thus, Patent Owner itself set the expectation that the '865 patent will be challenged. Patents are a limited monopoly, with the public expecting that they are free to use the invention once its claims are invalidated. *Singer Mfg. Co. v. June Mfg. Co.*, 163 U.S. 169, 185 (1896). And because of the Federal Circuit *Mylan* oral argument posture that led to settlement before likely invalidation, the Petition justifies use of resources to increase efficiency. Patent Owner's view would require relitigating a patent that was nearly invalidated at the Federal Circuit, and likely would have been invalidated but for Patent Owner's settlement with Mylan.

Applying settled expectations is particularly problematic in the biosimilars technology area, because of issues related to standing. Under *Sandoz*, a biosimilar

sponsor generally lacks standing to pre-clear patent issues in litigation without an application before the FDA. *Sandoz, Inc. v. Amgen, Inc.*, 773 F.3d 1274 (Fed. Cir. 2014). Similar issues may apply to preserving the right to appeal an IPR petition. 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 issues limiting earlier challenges. The settled expectations practice undercuts the President's goal for affordable drugs, by severely handicapping IPR petitions even for weak patents.

B. Compelling Economic and Public Health Factors Weigh Against Discretionary Denial

Compelling economic and public health factors **weigh against** discretionary denial. The public and economic policies of fostering innovation and decreasing drug prices through competition, particularly in view of the unpatentable claims present in the '865 Patent, strongly weighs against the Director exercising its discretion to deny institution.

“[T]he patent system represents a carefully crafted bargain that encourages both the creation and the public disclosure of new and useful advances in technology, in return for an exclusive monopoly for a limited period of time.” *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 63 (1998). The Challenged Claims of the '865 Patent do not adhere to said patent bargain. Patent Owner made the choice to seek claims that the Dix '226 had already disclosed. It should not be allowed to extend its own prior

monopoly with more claims to the same old technology, for which it has already benefited, including with patent protection.

Granting the Petition will also encourage biosimilar applicants to develop more affordable pharmaceutical products for the American public. On April 15, 2025, the White House issued Executive Order 14273 titled “Lowering Drug Prices by Once Again Putting Americans First.” Ex. 1010. The Executive Order states that “[i]t is the policy of the United States that Federal health care programs, intellectual property protections, and safety regulations are optimized to provide access to prescription drugs at lower costs to American patients and taxpayers.” *Id.* at Section 2. Similarly, Senators Amy Klobuchar (D-MN) and Chuck Grassley (R-IA), Chairman of the Senate Judiciary Committee, introduced two bipartisan bills to reduce drug prices by promoting competition. Ex. 1011.

Accordingly, the compelling economic and public health factors of the parties **weighs strongly against discretionary denial.**

C. **The Extent of the Petition’s Reliance on Expert Testimony Weighs Against Discretionary Denial**

The extent of the Petition’s reliance on expert testimony **weighs against** discretionary denial. Petitioner submitted an expert declaration from Dr. Joshua Ramsey, a highly accomplished expert in the field of biomedical/bioengineering. There is no defect in his declaration, and not even Patent Owner suggests otherwise.

Had Petitioners used an expert that provided mere *ipse dixit*, Patent Owner would have complained. *See Xerox Corp. v. Bytemark, Inc.*, IPR2022-00624, 2022 WL 3648989, Paper 9, at *6 (P.T.A.B. Aug. 24, 2022) (faulting expert that did “not cite to any additional supporting evidence or provide any technical reasoning to support his statement”). Dr. Ramsey’s testimony “is merely complying with regulations requiring disclosure of ‘underlying facts or data,’” such as 37 C.F.R. § 42.65(a). *See GD Energy Prods., LLC v. Kerr Mach. Co.*, PGR2025-00031, Paper 11 at 2 (P.T.A.B. June 25, 2025). Thus, “Patent Owner does not identify any portions of the expert testimony that suggest Petitioner is using its expert to fill gaps in the prior art.” *Cambridge Indus. USA, Inc. v. Applied Optoelectronics, Inc.*, IPR2025-00434, Paper 11 at 2 (P.T.A.B. June 26, 2025). Therefore, the extent of the Petition’s reliance on expert testimony parties **weighs strongly against** discretionary denial.

D. The Application of the Interim Memoranda 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 memoranda and announcements fail to satisfy 35 U.S.C. § 316(a) and the Administrative Procedure Act (“APA”) because (1) changes were made without going through notice-and-comment rulemaking; (2) the memoranda and announcements do not set “forth the standards for the showing of sufficient grounds to institute review”; (3) the memoranda and announcements lack a sufficiently reasoned explanation for the changes in the factors relevant to institution; (4) the oral webcast and FAQs were retroactively applied to some petitions filed prior to issuance of the new policies; (5) the new process created a

perception of a lack of transparency with regard to discretionary denial; and (6) applying self-created discretionary denial criteria effectively ignores and rewrites the IPR statute, violating statutory authority, APA, and separation of powers.

Accordingly, the unconstitutionality of the interim memoranda and announcements **weighs heavily against** discretionary denial.

V. CONCLUSION

Petitioner respectfully requests that the Director reject Patent Owner's request for discretionary denial and refer Petitioner's Petition to a panel for an institution decision on the merits.

Dated: October 23, 2025

Respectfully submitted,

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CERTIFICATE OF PAGE LIMIT

The undersigned certifies that Petitioner's Opposition to Patent Owner's Request for Discretionary Denial complies with the 20-page limit provided in Section III.C.iii of the Interim Director Discretionary Process guidance available at <https://www.uspto.gov/patents/ptab/interim-director-discretionary-process>.

Dated: October 23, 2025

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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 October 23, 2025, a complete and entire copy of Petitioner's Opposition to Patent Owner's Request for Discretionary Denial, and all supporting exhibits were provided by electronic email on the following counsel of record:

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