

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Padagis US LLC,
Petitioner,

v.

Neurelis, Inc.

Patent Owner.

Case No. IPR2025-00466
Patent 11,793,786

**PETITIONER'S RESPONSE TO PATENT OWNER'S REQUEST TO THE
DIRECTOR FOR DISCRETIONARY DENIAL OF INSTITUTION**

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	<i>Fintiv</i> Analysis WEIGHS AGAINST DISCRETIONARY DENIAL	3
A.	Board has Long-Standing Policy that Strong Evidence of Merits Outweighs an Earlier Trial Date.....	4
1.	Board Policy Prior to Interim Procedure	4
2.	Similarity of '786 Patent Claims and the '876 Patent Claims Previously Found Unpatentable	6
B.	<i>Fintiv</i> Factors Weigh Against Discretionary Denial of this IPR	8
1.	Factor 1 - whether a stay exists or is likely to be granted if a proceeding is instituted	9
2.	Factor 2 - proximity of the court's trial date to the Board's projected statutory deadline	10
3.	Factor 3 - investment in the parallel proceeding by the court and parties	12
4.	Factor 4 - overlap between issues raised in the petition and in the parallel proceeding	14
5.	Factor 5 - whether the petitioner and the defendant in the parallel proceeding are the same party	16
6.	Factor 6 - other circumstances that impact the Board's exercise of discretion, including the merits	16
7.	Balance of Factors.....	21
III.	THE DIRECTOR SHOULD NOT DENY INSTITUTION UNDER 35 U.S.C. §325(D).....	24
IV.	THE DIRECTOR SHOULD NOT DENY INSTITUTION OF THE OBJECTIVELY STRONG PETITION	30
V.	USPTO DIRECTOR LACKS AUTHORITY TO DISCRETIONARILY DENY BASED ON THE <i>FINTIV</i> FACTORS.....	33
1.	The APA Requires Notice-And-Comment Because <i>NHK-</i> <i>Fintiv</i> is a Substantive Rule	35
2.	The Director Has No discretion to Depart From the Policy Choices Embodied in the Rule	40

3.	The AIA Reinforces that the <i>NHK-Fintiv</i> Rule Should have Been Adopted Only after Notice and Comment	41
VI.	CONCLUSION.....	43

I. INTRODUCTION

Padagis US LLC, (“Petitioner”) hereby respectfully request the Board to deny the Neurelis, Inc. (“Patent Owner”) request to discretionarily deny this *inter partes* review (IPR) of U.S. Patent No. 11,793,786 (“the ’786 Patent”).

As set forth in the Petition, the issues to be determined in this IPR are materially identical to the issues Patent Owner faced in IPR2019-00451. Petition at 8. The Board issued a final written decision in IPR2019-00451 related to U.S. Patent No. 9,763,876 (“the ’876 Patent”), which is part of the same patent family as the ’786 Patent. In the final written decision in IPR2019-00451, the PTAB determined that claims 1-16 and 24-36 are unpatentable over the combination of Gwozdz in view of Meezan, and claims 17-23 are unpatentable over the combination of Gwozdz in view of Meezan further in view of Cartt.¹ EX1040. The Board’s decision was appealed by Patent Owner but affirmed by the Federal Circuit. See EX1069 (Fed Circuit affirmance of IPR2019- 00451 decision). As such, the Board’s final decision in IPR2019-00451 provided final resolution of invalidity issues related to the

¹In IPR2019-00451 the Board refers to Meezan as “Meezan ’962.” Both Meezan in this this IPR Petition and Meezan ’962 in IPR2019-00451 are the same reference. The Board also refers to Cartt as “Cartt ’784.” Both Cartt in this IPR Petition and Cartt ’784 in IPR2019-00451 are the same reference.

Gwozdz and Meezan, and Gwozdz, Meezan, and Cartt combinations that were essential to the judgment.

As set forth in the Petition, any difference between the claims at issue herein and those found unpatentable in IPR2019-00451 do not materially alter the question of invalidity. Rather, if a method of treatment using a pharmaceutical solution is obvious, a therapeutic amount of that pharmaceutical solution must likewise be obvious for substantially the same reasons.

To avoid a similar fate, Patent Owner seeks discretionary denial to avoid having to contend with the compelling merits of the instant Petition. However, as the Director has recently explained, evidence of material error by the Office can outweigh other factors. IPR2025-00318, *Microsoft Corp. v. Partec Cluster Competence Center GMBH*, Director's Decision, Paper No. 9 at 3 ("Ordinarily, a scheduled district court trial date that precedes the date projected for a Board final written decision weighs in favor of exercising discretion to deny the Petition. Here, however, the Petitioner appears to show a material error by the Office and it is an appropriate use of Office resources to review the potential error."). In addition, the PTAB has set out in precedential decisions, that the "patent system and the public benefit from instituting challenges where there is a showing of unpatentability by compelling merits... when other considerations favor discretionary denial." *Commscope Tech. LLC, v. Dali Wireless, Inc.* IPR2022-01242 Paper 23 at 3-4

(PTAB Feb 27, 2023)(Precedential) citing *OpenSky Indus., LLC v. VLSI Tech. LLC*, IPR2021-01064, Paper 102, 49 (PTAB Oct. 4, 2022)(Precedential).

The underlying policies considerations in those cases to address facially invalid patents is exactly the case here. The Petition is built on the same prior art combinations and issues that has already been found to render obvious materially similar claims from a related patent, in a proceeding affirmed by the Federal Circuit. The legal and factual showing here easily satisfies the material error or compelling merits standard. Under the rationale of the *Microsoft* and *CommScope* decisions, that determination alone outweighs other concerns, and accordingly, institution of the present IPR is appropriate. Patent Owner should not be permitted to continue enforcing a patent whose subject matter has already been deemed unpatentable by the PTAB.

Therefore, the consideration of the underlying facts in all co-pending proceedings weighs against the Director exercising discretion to deny the instant IPR.

II. *FINTIV* ANALYSIS WEIGHS AGAINST DISCRETIONARY DENIAL

Fintiv instructs the Board to “balance considerations such as system efficiency, fairness, and patent quality.” *Fintiv* at 5. The *Fintiv* decision identifies certain non-exclusive factors that the Board looks at, and notes that “[t]hese factors relate to whether efficiency, fairness, and the merits support the exercise of authority

to deny institution in view of an earlier trial date in the parallel proceeding.” *Id.* at 6. These overarching policy considerations expressed in *Fintiv* are vitally important in the instant case because Patent Owner takes a myopic view of the *Fintiv* factors by focusing solely on the trial date instead of taking a “holistic view” that considers overall efficiency, merit, and patent quality. *Fintiv* at 6 (citing Consolidated Trial Practice Guide November 2019 at 58).

When all of the facts are looked at holistically, the Board should ***not*** exercise its discretion to deny institution of the instant IPR.

A. Board has Long-Standing Policy that Strong Evidence of Merits Outweighs an Earlier Trial Date

1. Board Policy Prior to Interim Procedure

Under the Board’s current guidance memorandum issued on March 24, 2025 (“Guidance Memo”), the Board considers discretionary denials under the policies set out in *Fintiv* and related decisions issued prior to the June 21, 2022, Interim Procedure memo (“Interim Procedure”). *See* Guidance Memo at 1 (current guidance is “to restore policy in this area to the guidance in place before the Interim Procedure”). As noted above, one of *Fintiv*’s primary policy considerations is to improve “patent quality” and thus considers if “the merits support the exercise of authority to deny institution in view of an earlier trial date in the parallel proceeding.” *Fintiv* at 6. Indeed, the Supreme Court noted that improving “patent quality” was an “important congressional objective” underlying the creation of the

IPR process. *Cuozzo Speed Techs. v. Com. for Intellectual Prop.*, 579 U.S. 261, 272 (2016) (*quoting* H.R. REP. 112- 98, pt. 1, at 45, 48 and *citing* 157 Cong. Rec. 9778 (2011)).

Consistent with this policy goal to improve patent quality, prior to the Interim Procedure the Board had a history of refusing to discretionarily deny under *Fintiv* when the merits were particularly strong. *See, e.g., Illumina Inc. v. Trs. of Columbia Univ.*, IPR2020-00988, Paper 20 (PTAB Dec. 8, 2020) (declining to deny under *Fintiv* in light of strong evidence on the merits even though four factors weighed in favor of denial and remaining factor was neutral); *Synthego Corp. v. Agilent Techs., Inc.*, IPR2022-00402, Paper 11 (PTAB May 31, 2022) (granting institution as efficiency and integrity of the system would not be served by denying institution of petition with particularly strong evidence on the merits); *Samsung Elecs. Co. v. Scramoge Tech., Ltd.*, IPR2022-00241, Paper 10 (PTAB June 13, 2022) (*Fintiv* analysis concluded that “very strong” evidence on the merits outweighs concurrent litigation involving earlier scheduled trial date and significant overlap in proceedings).

The Guidance Memo states that the Board should restore policy to the guidance in place before the June, 21 2022 Interim Procedure, so the Board now should adopt the reasoning of these prior decisions and refuse to discretionarily deny

based on the strong evidence of the merits even if other factors weigh in favor of denial.

2. Similarity of '786 Patent Claims and the '876 Patent Claims Previously Found Unpatentable

As noted above and in the instant IPR petition challenging the '786 Patent, there is substantial overlap between this proceeding and IPR2019-00451 against the '876 Patent.

The '876 Patent and '786 Patents both claim priority back to U.S. patent application no. 12/413,439 ("439 Application") through continuation or continuation-in-part priority claims. The '876 Patent recites substantially the same limitations as claims 1-9 and 11-25 of the '786 Patent. The primary difference between the '876 Patent claims found to be unpatentable in IPR2019-00451 and the aforementioned claims of the '786 Patent is that the former are directed to a method of treatment using a specific pharmaceutical solution while the latter are to the pharmaceutical solution itself. To illustrate, a comparison of claim 1 of the '786 Patent and claim 1, 4, 7 and 26 of the '876 Patent (collectively reciting the same limitations found in claim 1 of the '786 Patent) is provided below:

<u>Claims 1, 4, 7 and 26 of 9,763,876 Found Unpatentable in IPR 2019-00451</u>	<u>Claim 1 of 11,793,786</u>
1. A method of treating a patient with a disorder which is treatable with a benzodiazepine drug, comprising: administering to one or more nasal mucosal membranes of a patient a pharmaceutical solution for nasal administration consisting of a benzodiazepine drug, one or more natural or synthetic tocopherols or tocotrienols, or any combinations thereof, in an amount from about 30% to about 95% (w/w); ethanol and benzyl alcohol in a combined amount from about 10% to about 70% (w/w); and an alkyl glycoside. 4. The method of claim 3, wherein the benzodiazepine drug is diazepam, or a pharmaceutically-acceptable salt thereof. 7. The method of claim 1, wherein the one or more natural or synthetic tocopherols or tocotrienols are selected from the group consisting of: α-tocopherol, β-tocopherol, γ-tocopherol, δ-tocopherol, α-tocotrienol, β-tocotrienol, γ-tocotrienol, δ-tocotrienol, tocophersolan, any isomers thereof, any esters thereof, any analogs or derivatives thereof, and any combinations thereof. 26. The method of claim 25, wherein the solution contains about 0.01% to 1% (w/w) of dodecyl maltoside.	1. A pharmaceutical solution for nasal administration consisting of: a therapeutically effective amount of diazepam or a pharmaceutically acceptable salt thereof; one or more natural or synthetic tocopherols or tocotrienols selected from the group consisting of α-tocopherol, β-tocopherol, γ-tocopherol, δ-tocopherol, α-tocotrienol, β-tocotrienol, γ-tocotrienol, δ-tocotrienol, tocophersolan, any isomers thereof, any esters thereof, and any combinations thereof, in an amount from 30% to 95% (w/w); one or more alcohols in an amount from 10% to 70% (w/w), wherein the one or more alcohols comprises benzyl alcohol; and n-dodecyl beta-D-maltoside

See EX1069 (comparing claims 1-9 and 11-25 of the '786 Patent to claims 1-36 of the '876 Patent).

The present IPR relies on the same prior art and substantially same arguments that the Board considered already in IPR2019-00451 to find the claims there were

unpatentable. The Board having already found a method of treatment using the claimed pharmaceutical formulation being obvious, there is no patentable distinction in claiming the pharmaceutical formulation itself. As such, Neurelis, Inc. (“Patent Owner”) is collaterally estopped from contesting the issues previously addressed in IPR2019-00451. Even assuming Patent Owner is not collaterally estopped from contesting the patentability of the claims over the prior art cited in this Petition, the reasoning and analysis of the Board’s decision in IPR2019-00451 why the claim pharmaceutical compound is obvious would apply equally in the instant IPR. The only claims in the ’786 Patent that present new invalidity issues for the Board to consider are claims 10, 26 and 27. However, these claims are likewise unpatentable over the prior art cited in this Petition. For the reasons provided by the Board in IPR2019-00451 and as explained in detail below, there is a reasonable likelihood that claims 1-27 of the ’786 Patent are unpatentable, and the Board should institute IPR based on this Petition.

Therefore, the Board’s findings regarding the ’876 Patent are likewise determinative of the issues in the instant IPR. As such, there is little, if any, efficiency gained by denying the instant IPR.

B. *Fintiv* Factors Weigh Against Discretionary Denial of this IPR

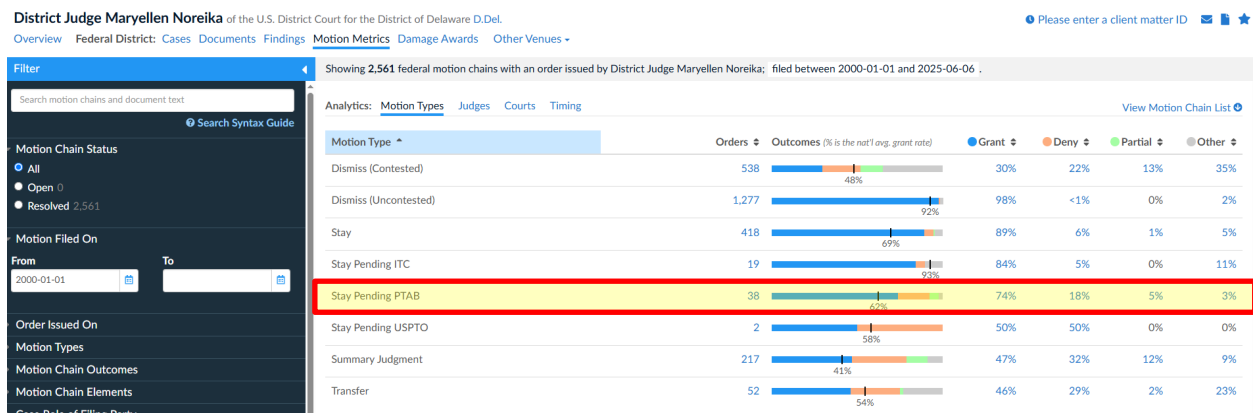
As discussed above, *Fintiv* factor 6 weighs heavily against discretionary denial in this matter given that the Board has already weighed in favorably on the

merits. Moreover, *Fintiv* factors 1-5 collectively are neutral with regards to discretionary denial and thus would not overcome factor 6.

1. Factor 1 - whether a stay exists or is likely to be granted if a proceeding is instituted

The Patent Owner is correct; the District Court has not granted a stay of proceedings pending resolution of the IPR proceeding, as Padagis has not yet moved for a stay. Such a motion would not be ripe until the IPR is instituted.

Petitioner notes, using data from Lex Machina, that District Judge Maryellen Noreika, who is presiding over the underlying litigation, has a high propensity for granting stays once IPR is instituted (e.g., 74% grant rate).



Of the 7 denied motions to stay pending PTAB, District Judge Maryellen Noreika rationale for denial is as follows:

Case Citation	Rationale for Denial
<i>Best Medical International, Inc. v. Varian Medical Systems, Inc.</i> , No. 1:18-cv-01599 (D. Del.)	No detailed rationale provided; motion denied orally following Markman and motion hearing.
<i>PayRange Inc. v. CSC ServiceWorks, Inc.</i> , No. 1:23-cv-00278 (D. Del.)	Denied as premature; court permitted refiling after PTAB institution decision.

Case Citation	Rationale for Denial
<i>Intuitive Surgical, Inc. et al v. Auris Health, Inc.</i> , No. 1:18-cv-01359 (D. Del.)	Denied with leave to renew; issued following Markman hearing.
<i>Exact Sciences Corp. v. Geneoscopy, Inc.</i> , No. 1:23-cv-01319 (D. Del.)	Denied with leave to refile if PTAB institutes review of second patent.
<i>PureWick Corp. v. Sage Products, LLC</i> , No. 1:19-cv-01508 (D. Del.)	Denied; parties required to update court after PTAB final written decision.
<i>Omega Flex, Inc. v. Ward Mfg., LLC</i> , No. 1:18-cv-01004 (D. Del.)	Denied without prejudice; court allowed renewal if PTAB institutes review.
<i>Rex Computing, Inc. v. Cerebras Systems Inc.</i> , No. 1:21-cv-00525 (D. Del.)	Denied; parties instructed to inform court upon issuance of PTAB's final written opinion.

As can be seen in the data above, District Judge Maryellen Noreika frequently denies motions to stay pending PTAB review where the PTAB has not yet instituted review, consistently requiring institution as a threshold before considering any stay. Thus, the Patent Owner has not yet moved for a stay in view of Judge Norieka's preferences. Patent Owner intends to move for a stay if this IPR is instituted, which based on objective statistics has a greater than 74% chance of being granted (since the grant rate would increase when excluding the denials involving pre-institution stay motions).

Thus, factor 1 is weighs against denial since objective evidence shows that a stay is likely to be granted (if the Board institutes this IPR).

2. Factor 2 - proximity of the court's trial date to the Board's projected statutory deadline

Patent Owner's argument under *Fintiv* Factor 2 misrepresents both the timing of this proceeding and the procedural realities of the district court litigation.

First, the timeline Patent Owner advances is artificially skewed. Although the Petition was filed on January 17, 2025, the Board did not issue a notice of accorded filing date until March 17, 2025, a full two months later. This internal processing delay materially impacts the *Fintiv* analysis.

Second, the litigation schedule itself is far from certain. Patent Owner is actively prosecuting, and in some cases, has already secured, additional patents claiming similar subject matter. These include:

- U.S. Patent No. 12,268,664 (listed in the Orange Book)
- U.S. Application No. 2022/0117887 (status changed to “Patented Case” as of May 28, 2025)
- U.S. Application No. 2022/0241187 (Notice of Allowance issued May 15, 2025; issue fee paid May 19, 2025)
- As well as at least three pending U.S. applications that could mature into issued patents during this litigation.

Patent Owner has not disclaimed the possibility of asserting these additional assets. Their inclusion would necessitate a significant shift in the current trial posture. Given this, the trial date is speculative at best, and the risk of duplicative or overlapping adjudication is overstated.

Finally, even if the district court trial was scheduled before the projected final written decision, institution would still be appropriate where the petitioner filed a

broad stipulation and the merits were compelling as the Director determined in a group of related IPRs. *See* IPR2025-00217, IPR2025-00217, IPR2025-00219, IPR2025-00220, IPR2025-00221, IPR2025-00222, and IPR2025-00339 *Tesla Inc. v. Intellectual Ventures II LLC*, Director’s Decision, Paper No. 10 at 2-3, The same rationale applies here, as the Petitioner has provided a broad Sotera stipulation (discussed for Factor 4) and the Board has already invalidated substantially similar claims in prior proceedings (discussed for Factor 6).

Therefore, factor 2 is neutral since the delay in issuing a filing date in this IPR was not caused by Petitioner and the trial date remains speculative.

3. Factor 3 - investment in the parallel proceeding by the court and parties

Patent Owner’s narrative of “delay” by Padagis is unsupported by the actual record. The complaint in this case was filed on May 8, 2024. Padagis filed three IPR on January 17, 2025, barely eight months later and well before any substantive orders had issued on the ’786 Patent.

Patent Owner’s claim that the district court will have substantially progressed on the merits by the institution decision deadline is not supported by the litigation calendar. In reality, the timeline reflects ongoing procedural steps, not meaningful adjudication of the ’786 Patent’s validity. Moreover, and as discussed above, the timeline Patent Owner advances is artificially skewed. Although the Petition was

filed on January 17, 2025, the Board did not issue a notice of accorded filing date until March 17, 2025, a full two months later.

The key dates are as follows:

- Petition Filed: January 17, 2025
- Scheduling Order (Revised): March 11, 2025
- Close of Fact Discovery: May 30, 2025
- Claim Construction Opening Brief: June 27, 2025
- Claim Construction Answering Brief: July 11, 2025
- Claim Construction Reply Brief: July 25, 2025
- Surreply Brief: August 8, 2025
- Joint Claim Construction Brief: August 15, 2025
- Markman Hearing: September 12, 2025
- Institution Decision Deadline: September 17, 2025

This chronology confirms that, as of the date the Board must decide institution:

- Expert discovery will not yet have begun; the first expert reports are not due until September 26, 2025 (after institution).²

² **Opening Expert Reports:** September 26, 2025; **Rebuttal Expert Reports:** October 17, 2025; **Reply Expert Reports:** November 7, 2025; **Expert**

- Claim construction may not yet be fully resolved; the Markman hearing is scheduled just five days before the institution deadline. The institution decision may occur before Markman depending on when the Board issues the decision. In addition, the institution decision would have statutorily occurred before the Markman hearing but for the two-month delay in issuing a notice of filing date in this IPR.

Contrary to Patent Owner's assertion, the PTAB has not treated claim construction briefing or scheduled hearings as determinative under *Fintiv* Factor 3. Instead, the relevant inquiry is whether the district court has invested in adjudicating the merits. Here, the answer is clearly no.

Moreover, the timing of Padagis's three IPR Petitions, just eight months after the complaint was filed on May 8, 2024, confirms diligence, not delay.

Therefore, factor 3 is also neutral since some investment in the co-pending District Court proceeding has occurred but there is still a substantial investment that remains to be incurred by both parties.

4. Factor 4 - overlap between issues raised in the petition and in the parallel proceeding

Discovery: November 21, 2025; **Daubert Motions:** November 25, 2025;

Answering Brief: December 9, 2025; **Reply Brief:** December 16, 2025

Patent Owner's attempt to diminish the effect of Padagis's *Sotera* stipulation under *Fintiv* Factor 4 is directly contradicted by the record.

Contrary to Patent Owner's assertion, Padagis's stipulation is neither hypothetical nor delayed. It appears in the Petition itself and states unambiguously:

"Petitioner stipulates that if the Board institutes this IPR then Petitioner will not pursue in a parallel district court proceeding the same grounds as in this Petition or any grounds that could have reasonably been raised in this Petition." Petition at 69, citing *Sotera Wireless, Inc. v. Masimo Corp.*, IPR2020-01019, Paper 12 at 17 (PTAB Dec. 1, 2020) (Precedential).

Petitioner's stipulation eliminates any concern about duplicative litigation, conserving both judicial and Board resources. There is no ambiguity and no delay. Patent Owner's mischaracterization of the stipulation should be disregarded.

Moreover, as Patent Owner notes, the Boalick Memorandum provides that a *Sotera* stipulation is not dispositive on its own, it also confirms that such stipulations are "highly relevant" and can weigh strongly in favor of institution. When the Board has strong merits before it, as is the case here with a compelling showing of unpatentability and collateral estoppel support from related claims being invalidated, the unambiguous stipulation neutralizes concerns under *Fintiv* Factor 4.

Therefore, factor 4 strongly favors institution, if the instant IPR is instituted, there will be no overlap of issues with the District Court.

5. Factor 5 - whether the petitioner and the defendant in the parallel proceeding are the same party

There is no dispute that the same parties are involved in all three co-pending proceedings. However, there is no indication in *Fintiv*, and little policy reason, why the same parties should weigh in favor of discretionary denial as Patent Owner suggests. Rather, as *Fintiv* itself indicates, “[i]f a petitioner is unrelated to a defendant in an earlier court proceeding, the Board has weighed this fact *against* exercising discretion.” *Fintiv* at 13-14 (emphasis added). As such, this factor is one that can weigh against denial if it exists but not one that can meaningfully weigh in favor of denial.

Thus, the Board should weigh this factor as neutral as it has in other cases where the parties are the same. *See Snap, Inc. v. SRK Technology, LLC*, IPR2020-00820, Paper 15 at 16 (PTAB Oct. 21, 2020) (precedential) (where parties were the same “we regard the consideration of the fifth *Fintiv* factor as neutral or, at most, weighing slightly in favor of exercising discretion to deny institution”).

6. Factor 6 - other circumstances that impact the Board's exercise of discretion, including the merits

Factor 6 weighs heavily in favor of institution due to recent issuance of the '786 Patent and the compelling nature of the unpatentability showing, which is not only well-supported but also previously adjudicated by the Board in a related proceeding.

First, the '786 Patent issued recently in 2023. The Director has previously found that institution of IPR is favored when patents have issued recently. IPR2025-00289, *Imperative Care, Inc. v. Inari Medical, Inc.*, Director's Decision, Paper No. 9 at 2 ("In addition, the challenged patent issued recently, in 2023. Early challenges to patents favor robust, predictable patent rights and weigh against discretionary denial.").

Second, as set forth in detail above and in the Petition, the challenged claims of the '786 Patent are materially the same as those from those of the '876 Patent, which the Board previously held unpatentable in IPR2019-00451. Both patents stem from the same priority chain and recite substantively identical formulation limitations. The only difference is that the '876 claims were directed to methods of treatment, while the '786 claims are drawn to the pharmaceutical composition itself. That distinction does not confer patentability. The Board has already determined that administration of the claimed formulation was obvious over the very same prior art references and combinations advanced here.

As the Director has considered in a prior decision, a material error by the Office in issuing a patent can outweigh a trial date that precedes the final written decision date. See IPR2025-00318, *Microsoft Corp. v. Partec Cluster Competence Center GMBH*, Director's Decision, Paper No. 9 at 3 ("Ordinarily, a scheduled district court trial date that precedes the date projected for a Board final written

decision weighs in favor of exercising discretion to deny the Petition. Here, however, the Petitioner appears to show a material error by the Office and it is an appropriate use of Office resources to review the potential error.”) Here the case for material error by the Office in issuing the ’786 Patent is indisputable

This is not a borderline case. The arguments and evidence have already survived Board scrutiny and led to a final written decision canceling claims directed to the same formulation, which was upheld on appeal. As outlined in the Petition, that prior adjudication not only supports institution under a compelling merits framework but also raises collateral estoppel concerns. Namely, Patent Owner is precluded from contesting the following findings made by the Board in IPR2019-00451:

- U.S. Prov. App. No. 61/040,558 (“the ’558 provisional”) “does not provide adequate written description support for the ‘alkyl glycoside’ limitation.” *See* EX1040 at p. 23 (finding that “after reviewing all of the evidence, we find that the ’558 provisional does not provide adequate written description support for the ‘alkyl glycoside’ limitation. Therefore, the claims of the ’876 patent are not entitled to the benefit of priority to the ’558 provisional.”)
- Gwozdz is entitled to the filing date of the ’281 Provisional. *See* EX1040 at p. 14 (finding “Petitioner has shown that the claims of

Gwozdz are supported by the Gwozdz provisional, ‘at least because Gwozdz’s claims are literally identical to the claims filed in [the] Gwozdz provisional.’”.)

- “a person of ordinary skill in the art would have had reason to add alkyl glycoside as a penetration enhancer, as disclosed in Meezan ’962, with a formulation of benzodiazepine, tocopherol, ethanol, and benzyl alcohol, as disclosed in Gwozdz.” EX1040 at p 47.
- “each limitation of claims 1–16 and 24–36 [of the ’876 Patent] are taught or suggested by the combination of Gwozdz and Meezan ’962 and further that the skilled artisan would have had reason to make the suggested combination with a reasonable expectation of success.” EX1040 at p. 51 (emphasis added); *see also id.* at p. 54 (“On this record, we also find that the evidence of secondary considerations of non-obviousness is weak, at best. As discussed above, we find that Patent Owner has not established the requisite nexus between the challenged claims and any of the asserted secondary considerations”) (emphasis added); *see also* EX1065 (comparing claims of the ’546 Patent and the ’876 Patent).
- “a person of ordinary skill in the art would have been motivated to combine the disclosures of Gwozdz and Meezan ’962 with Cartt

'784...one of ordinary skill in the art would have looked to Cartt '784's disclosure when seeking dosing regimens for the compositions disclosed in Gwozdz and Meezan '962, and would have had a reasonable expectation of success in achieving the claimed invention. Petitioner also sufficiently explains how the combined disclosures of Gwozdz, Meezan '962, and Cartt '784 would have taught or suggested the subject matter of claims 17–23. As discussed supra, we also find that the evidence of secondary considerations of nonobviousness is weak, at best.” EX1040 at 58-59.

The findings in IPR2019-00451 above are materially identical to issues to be determined in this IPR.

In similar cases with particularly strong merits, the Board has found that *Fintiv* factor 6 outweighs other factors that may support discretionary denial, such as an earlier trial date. *See, e.g., Illumina Inc. v. Trs. of Columbia Univ.*, IPR2020-00988, Paper 20 (PTAB Dec. 8, 2020) (declining to deny under *Fintiv* in light of strong evidence on the merits even though four factors weighed in favor of denial and remaining factor was neutral); *Synthego Corp. v. Agilent Techs., Inc.*, IPR2022-00402, Paper 11 (PTAB May 31, 2022) (granting institution as efficiency and integrity of the system would not be served by denying institution of petition with particularly strong evidence on the merits); *Samsung Elecs. Co. v. Scramoge Tech.*,

Ltd., IPR2022-00241, Paper 10 (PTAB June 13, 2022) (*Fintiv* analysis concluded that “very strong” evidence on the merits outweigh concurrent litigation involving earlier scheduled trial date and significant overlap in proceedings).

In addition, another basis for the Board to decline discretionary denial of the instant IPR is to avoid inconsistent outcomes. The PTAB issued a Final Written Decision, affirmed by the Federal Circuit, in IPR2019-00451 invalidating the claims of the ’876 Patent, which have substantially similar scope as the claims at issue in the instant IPR. Should the PTAB discretionarily deny the instant IPR, the Patent Owner will be afforded the opportunity to assert subject matter that has already been determined as unpatentable. Such an outcome risks different outcomes based on the same or similar facts.

Therefore, factor 6 strongly favors institution to correct the Office’s error in issuing the ’786 Patent.

7. Balance of Factors

Patent Owner contends that the *Fintiv* factors, when weighed collectively, favor discretionary denial. That assertion fails under both the facts of this case and applicable PTAB precedent.

As addressed in detail above, multiple *Fintiv* factors either favor institution or are, at most, neutral:

- **Factor 1 (Stay):** As discussed above, District Judge Maryellen Noreika, who is presiding over the underlying litigation, has a high propensity for granting stays (e.g., 74% grant rate). While no stay has been entered, a stay motion in Noreika's court is not ripe until the IPR is instituted. If a stay motion is filed, the objective statistics indicate a high chance of success for such a stay motion. Accordingly, this factor favors institution .
- **Factor 2 (Trial Timing):** Patent Owner's reliance on the February 2026 trial date ignores the USPTO's two-month delay in issuing the Notice of Filing Date, which artificially widened the timeline gap. Moreover, that trial date remains speculative considering Patent Owner's ongoing prosecution strategy. This evolving landscape undermines any assumption that the current schedule is fixed. Accordingly, this factor is at most neutral.
- **Factor 3 (Court Investment):** As of the Petition's filing date in January 2025, the Court had issued no claim construction orders and had not ruled substantively on the '786 Patent. Discovery and expert exchanges are ongoing and are scheduled to continue well past the PTAB's institution decision date (September 17, 2025). Thus, some investment in the litigation has occurred but much will remain at the time of the institution decision. Accordingly, this factor is at most neutral.

- **Factor 4 (Overlap of Issues):** Padagis expressly included a *Sotera* stipulation in the Petition (p. 69), precluding it from pursuing in district court any grounds raised or that could reasonably have been raised in this IPR. This directly addresses and neutralizes any concern of duplicative litigation or inefficient overlap. Accordingly, this factor strongly favors institution.
- **Factor 5 (Identity of Parties):** This is not disputed and does not weigh heavily under PTAB precedent when other procedural safeguards (like a *Sotera* stipulation) are in place. Accordingly, this factor is neutral.
- **Factor 6 (Other Circumstances):** This factor overwhelmingly supports institution. The '786 Patent is recently issued. In addition, the challenged claims are materially indistinct from those invalidated in IPR2019-00451. The Board's prior analysis directly applies. Denial in this context would prevent correction of the Office's error in issuing this patent, promote inconsistent outcomes and undermine confidence in the AIA review system.

Patent Owner's "balance of factors" argument fails because it overweights speculative trial timelines and mischaracterizes the status of the district court litigation. Where compelling merits are present, as they are here, the Board should institute the present IPR to ensure consistent application of the law and to protect the public interest in invalidating improperly granted patents.

Institution is warranted under the totality of circumstances.

III. THE DIRECTOR SHOULD NOT DENY INSTITUTION UNDER 35 U.S.C. §325(D)

Patent Owner argues that the Director should dismiss this IPR under 35 U.S.C. §315(D) in view of the framework set out in *Advanced Bionics LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 20 (PTAB Feb. 13, 2020) (precedential). *Advanced Bionics* step one is if the same art or arguments were presented to previously presented to the office. While the same prior art cited in this IPR was submitted in an IDS, Patent Owner admits that the Examiner did not address the prior art or arguments raised in this IPR because the Examiner determined that “Gwozdz...does not qualify as prior art” based on the mistaken belief that the claims of the ’786 Patent had priority to the provisional application. *See* PO Request for Denial at 37-38 (citing Ex. 1004 at 27-29).

Assuming this satisfies step one of *Advanced Bionics*, Patent Owner acknowledges that Petitioner set out a material error by the Examiner in finding priority to the provisional application. PO Request for Denial at 9 (“Padagis contends the Office erred in finding that the ’558 Provisional supports n-dodecyl beta-D-maltoside”); *see* Petition at 12-16. Indeed, without this error in the priority determination, the Examiner indicated that he would have rejected the claims over Gwozdz and Meezan. Ex. 1004 at 29 (“In any case where priority to the provisional did not exist, the obviousness rejections presented by the BPAI in the IPR of 14/527,613 (USP 9,763,876) would be included.”). As explained in the Petition, the

Examiner's error in granting priority to the '558 Provisional is clear and indisputable based on the findings by the PTAB in IPR2019-00451. *See Microsoft Corp. v. Partec Cluster Competence Center GMBH*, Director's Decision, Paper No. 9 at 3 (correcting examiner's error is basis to deny discretionary denial of an IPR).

This Examiner's priority determination is based on the finding that the '558 "provisional Application **incorporates** a listing of n-dodecyl β -D-maltoside **by reference to a Sigma Catalog.**" Ex. 1004 at 28 (emphasis added). There are multiple errors in that finding. As discussed below, the PTAB previously determined based on the same relevant disclosure as the '786 Patent specification that [1] there was no incorporation by reference to the Sigma Catalog and [2] even if there were incorporation by reference the Sigma Catalog's listing of 150 compounds did not provide support to claim individual compounds. In addition, Dr. Donovan provides additional testimony why the Sigma Catalog does not provide sufficient support for the claims of the '786 Patent, which was not previously considered by the Examiner. Ex. 1062 at ¶¶44-53.

First, the PTAB determined that incorporation of essential material from the Sigma Catalog was an improper incorporation by reference:

Although Patent Owner contends that the disclosure of alkyl glycosides from the SIGMA catalog was incorporated by reference into the '558 provisional, our Rules do not permit the incorporation by reference of

essential material from non-patent publications. See 37 C.F.R. § 1.57(d)... The “alkyl glycoside” limitation appears to be essential material. Therefore, reliance on the disclosure of the SIGMA catalog for adequate support for the “alkyl glycoside” limitation recited in the challenged claims is improper.

IPR2019-00451, Institution Decision, Paper No. 8 at 9-10 (PTAB Aug. 13, 2019). Patent Owner even requested rehearing on this issue which the PTAB denied. *See* IPR2019-00451, Rehearing Decision, Paper No. 14 (PTAB Sept. 27, 2019).

Like the alkyl glycoside limitation in the '876 Patent, the “n-dodecyl beta-D-maltoside” limitation in the '786 Patent is essential material since it is necessary to provide “a written description of the claimed invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same.” *See* 37 C.F.R. §1.57(d) (defining essential material).

Second, even assuming that incorporation by reference to the Sigma Catalog were proper, the PTAB previously determined the Sigma Catalog’s listing of approximately 150 biological detergents did not provide sufficient written description support for the claims to recite the “particular species or subgenuses” disclosed in the Sigma Catalog:

We do not find that the '558 provisional's incorporation by reference to six pages of the SIGMA catalog, which includes about 12 alkyl glycosides in a list of about 150 biological detergents, is sufficient to provide written description support for the claim. Furthermore, the listing of biological detergents in the SIGMA catalog is just a subset of the numerous possible "enhancing agents" that are discussed in the '558 provisional. There is nothing in the disclosure of the '558 provisional that directs one of skill in the art to the relatively small number of alkyl glycosides disclosed in the SIGMA catalog. *Purdue Pharma*, 230 F.3d at 1326-27 ("[O]ne cannot disclose a forest in the original application and then later pick a tree out of the forest and say here is my invention. In order to satisfy the written description requirement, the blaze marks directing the skilled artisan to that tree must be in the originally filed disclosure."); *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571 (Fed. Cir. 1996) ("In the absence of such blazemarks, simply describing a large genus of compounds is not sufficient to satisfy the written description requirement as to particular species or subgenuses.").

IPR2019-00451, Final Written Decision, Paper No. 44 at 19-20 (PTAB Aug. 6, 2020) (internal citations and footnotes omitted).

Lastly, as explained in the Petition, Dr. Donovan provides testimony that a POSITA would not consider the Sigma Catalog to provide sufficient support for the claims of the '786 Patent reciting n-dodecyl β -D-maltoside. The '558 Provisional discloses “enhancers” (i.e., “any material which acts to increase absorption across the mucosa and/or increases bioavailability”) but only generally and does not provide any guidance that would lead a POSITA to the use of alkyl glycosides. EX1062, ¶¶47-52. Specifically, the '558 Provisional discloses at least fifteen different chemical classes of enhancers, one of which are the biological detergents listed in the 1998 SIGMA Catalog. *Id.*, ¶48 (citing ¶¶ [150]-[152] of the '558 Provisional). However, the SIGMA Catalog includes over 100 biological detergents on the pages cited of which only a very small percentage (i.e., only about a dozen) are alkyl glycosides. *Id.*, ¶49.

The '558 Provisional application does not identify with detail and particularity that it is incorporating the alkyl glycosides referred to in the Sigma Catalog, and a POSITA looking at the more than 100 ionic and non-ionic compounds listed in the Sigma Catalog would have no reason to select alkyl glycoside(s) (in particular n-dodecyl beta-D-maltoside) over other compounds disclosed in the Sigma Catalog to be used as the “enhancer” compound. See *id.*, ¶¶49-50. Based on this lack of guidance in the '558 Provisional, a POSITA would be forced to undergo undue experimentation to determine whether any of the alkyl glycosides are useful or

preferred over any of the other hundreds of biological detergent candidates disclosed. *Id.*, ¶50-52.

Even considering the disclosure of the Sigma Catalog as a potential basis for support of the claimed “n-dodecyl beta-D-maltoside” (which is not appropriate under 37 C.F.R. §1.57(d)), the ’558 Provisional does not provide an enabling disclosure for the support of “n-dodecyl beta-D-maltoside.” *Id.*, ¶50-51. Consequently, the ’786 Patent is entitled to a priority date no earlier than the March 27, 2009, filing date of the ’439 Application.

Therefore, the claims of the ’786 Patent have the same priority defect the PTAB already determined with respect to the ’876 Patent. First, the Sigma Catalog is an improper incorporation of reference since it contains essential material for either the ’768 or ’876 Patent claims. Second, the ’786 Patent claims a particular species (n-dodecyl β -D-maltoside) listed in the Sigma Catalog while the ’876 Patent claimed a specific subgenus (alkyl glycosides) listed in the Sigma Catalog. Consistent with controlling Federal Circuit law and the PTAB decision in IPR2019-00451, the mere listing of n-dodecyl β -D-maltoside in the Sigma Catalogue does not provide sufficient written description for a priority claim to that specific species given the absence of any blazemarks directing a skilled artisan to that particular species from the hundreds of other compounds listed. *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1326-27 (Fed. Cir. 2000); *Fujikawa* 93 F.3d at 1571

(“In the absence of such blazemarks, simply describing a large genus of compounds is not sufficient to satisfy the written description requirement as to particular species or subgenuses.”).

Given the above, there can be no dispute that the Examiner erred when stating the claims of the '786 Patent have priority to the '558 Provisional because the “provisional Application incorporates a listing of n-dodecyl β -D-maltoside by reference to a Sigma Catalog.” Ex. 1004 at 28. There is also no dispute that this error was material given the Examiner’s statements that he would have rejected the claims based on the prior art cited in this IPR if the '786 Patent did not have priority to the '558 Application. Ex. 1004 at 29.

IV. THE DIRECTOR SHOULD NOT DENY INSTITUTION OF THE OBJECTIVELY STRONG PETITION

The Patent Owner raises as an additional reason for discretionary denial being the merits of the petitions and the expert testimony. PO Request for Denial at 41-50. Patent Owner allegation that the “Petition is weak” is demonstrably false in light of the PTAB’s decision in IPR2019-00451 that found all claims of the '876 Patent unpatentable after full consideration of Patent Owner’s arguments, which was then upheld on appeal to the Federal Circuit.

As explained in the Petition, the issues to be decided in the instant IPR are the same as those already decided in IPR2019-00451 and Patent Owner is precluded from even contesting the patentability of the claims due to collateral estoppel. Even

if collateral estoppel does not apply, the PTAB has already considered Patent Owner's arguments on priority and motivation to combine and found none of them persuasive to overcome obviousness. There is little reason to believe Patent Owner would be successful in overcoming the obviousness rejections set out in this IPR based on those same arguments that failed in IPR2019-00451. *See* PO Request for Denial at 42-43 (PO intending to argue priority) and 44-45 (PO intending to argue motivation to combine).

Patent Owner paradoxically argues that the expert testimony submitted to support the instant IPR Petition is "compromised" because it uses some of the same language from the expert declaration submitted in IPR2019-00451 and thus should be given little weight. PO Request for Denial at 47-50. The fact that Dr. Donovan agrees with certain testimony submitted in Dr. Peppas and Dr. Wermeling's declarations should not be surprising as they provide the perspective of a person of skill in the art as to why the claimed subject matter is obvious – just as Dr. Donovan's declaration provides.

Patent Owner's suggestion that two experts cannot share the same opinion defies common sense. Unsurprisingly, Patent Owner provides no case, PTAB decision, or regulation that would suggest two experts cannot share the same opinions. Moreover, as Patent Owner notes, Dr. Donovan provided new and original testimony as well. PO Request for Denial at 47 ("While it certainly is true that other

portions of the Donovan Declaration were written anew,...”). This illustrates that Dr. Donovan did not simply accept the prior declaration testimony as correct without consideration but performed her own independent analysis as to the correctness of the statements. Most importantly, Dr. Donovan signed under penalty of perjury that all the statements in her declaration are “believed to be true.” Ex. 1062 at ¶269.

Finally, Patent Owner’s argument that some of Dr. Donovan’s testimony is unsupported by evidence is facially false. PO Request for Denial at 48-50. For example, Patent Owner criticizes Dr. Donovan’s statement about organic solvents being used for nasal delivery as unsupported. *Id.* Yet, this statement appears in the context of Dr. Donovan’s description of the state of the art and the subsection it is located in cites at least four background references supporting her analysis. See Ex. 1062 at ¶¶63-72 (citing Exs. 1019, 1027, 1053 and 1054). Inexplicably, Patent Owner also criticizes Dr. Donovan’s opinion on the expectation of success in combining Gwozdz with Meezen despite the fact that the PTAB has already determined a POSITA would have a reasonable expectation of success in combining these references. IPR2019-00451, Final Written Decision, Paper No. 44 at 50 (“one of ordinary skill in the art would have had a reasonable likelihood of success in combining the disclosures of Gwozdz and Meezan ’962 to achieve the claimed invention.”). Patent Owner’s argument merely highlights the reason that collateral

estoppel should apply to this proceeding. Patent Owner already made these same arguments and lost – it does not get a second bite at the appeal.

In any event, Patent Owner’s argument that the declaration is compromised or unsupported is belied by the evidence of record and the Board’s prior findings in IPR2019-00451.

V. USPTO DIRECTOR LACKS AUTHORITY TO DISCRETIONARILY DENY BASED ON THE *FINTIV* FACTORS

Although the Director should find that applying the *Fintiv* factors weighs against denial, for the reasons provided above, the Director also lacks authority to deny an otherwise meritorious IPR petition based on the *Fintiv* factors, including co-pending District Court and ITC proceedings. Specifically, the Director’s discretionary denial via the *Fintiv* factors is unlawful because it is based on a rule the Director adopted without notice-and-comment rulemaking required under the Administrative Procedure Act, 5 U.S.C. §§ 701–706 (“APA”).³ *Fintiv* and related decisions like *NHK* (collectively *NHK-Fintiv*) establish a binding standard governing whether an IPR will be instituted when parallel District Court litigation exists. See *NHK Spring Co., Ltd., v. Intri-Plex Techs., Inc.*, IPR2018-00752, Paper

³ Petitioner notes that a case currently pending before the Federal Circuit challenges the Director’s authority to deny IPRs based on *Fintiv*. See *Apple Inc., et. al. v. Stewart*, Fed. Circ. Appeal No. 2024-1864. The Federal Circuit has not yet issued a ruling in this appeal.

8 (PTAB Sept. 12, 2018) (precedential). The APA, however, requires notice-and-comment rulemaking for any substantive rule that affects parties' legal rights and interests and binds agency decisionmakers, like the *NHK-Fintiv* rule. *See* 5 U.S.C. §§ 553.

It changes the institution standards to implement the Director's policy judgments by making institution less likely when there is parallel litigation, depriving infringement defendants of the opportunity to seek cancellation of patents through IPR. *NHK-Fintiv* thus is not a "general statement [] of policy" exempt from notice-and-comment. *See* 5 U.S.C. § 553(b). Notice-and-comment requirements are thus vital to ensure that affected parties, like Petitioner, are heard and that the agency confronts the legal and policy flaws in its approach. Moreover, IPR denial decisions are generally not reviewable by the Federal Circuit. As a result, notice-and-comment rulemaking provides the only opportunity for affected parties to challenge the wisdom and legality of the Rule. *See* 35 U.S.C. § 314(d) ("The determination by the Director whether to institute an inter partes review under this section shall be final and nonappealable.").

Finally, the *NHK-Fintiv* Rule's flaws illustrate why the Rule should have been subject to notice and comment. If stakeholders had been able to comment on the Rule before its adoption, they would have pointed out the Rule's many legal and policy defects. Instead, the Director imposed a binding rule without warning that it

would harm IPR petitioners and thwart the purposes of the AIA. Particularly where every other possible avenue for obtaining judicial review of the Rule has seemingly been foreclosed, the Director should not be permitted to evade statutory notice-and-comment requirements intended to ensure a measure of public accountability.

1. The APA Requires Notice-And-Comment Because *NHK-Fintiv* is a Substantive Rule

Under the APA, an agency may adopt rules—other than policy, interpretative, or procedural rules—only through notice-and-comment rulemaking. 5 U.S.C. § 553. This procedure requires an agency to “give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments” before the rule is adopted, and to consider and respond to significant comments received during the comment period. *Id.* § 553(c); *see also Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971). Here, the Director did not follow required notice and comment procedures before adopting the *NHK-Fintiv* Rule.

The APA defines a “rule” as an “agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy.” 5 U.S.C. § 551(4). *NHK-Fintiv* applies generally to any IPR petition when parallel litigation involving the same patent is pending in District Court; *NHK-Fintiv* applies prospectively; and *NHK-Fintiv* “implements” and “prescribe[s] ... policy” by

instructing how the Directors will exercise discretion to deny institution. *See Apple Inc. v. Vidal*, 63 F.4th 1, 8 (Fed. Cir. 2023).

The APA requires all “rules” to be adopted through notice-and-comment procedures, except for “interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice.” 5 U.S.C. § 553(b). To distinguish between those exceptions and the rules subject to notice-and-comment requirements, courts “generally refer [] to the category of rules to which the notice and comment requirements ... apply” as “substantive” or “legislative” rules. *Mendoza v. Perez*, 754 F.3d 1002, 1021 (D.C. Cir. 2014).

Two characteristics are especially relevant in identifying “substantive” rules and distinguishing them from general statements of policy. First, courts consider the rule’s impact on affected parties. A “substantive” rule is “one that effects a change in existing law or policy which affects individual rights and obligations.” *In re Chestek PLLC*, 92 F.4th 1105, 1109 (Fed. Cir. 2024) (quotation marks omitted); *see also Chrysler*, 441 U.S. at 302 (a substantive rule “affect[s] individual rights and obligations”). A substantive rule, in other words, “grant[s] rights, impose[s] obligations, or produce[s] other significant effects on private interests.” *Batterton v. Marshall*, 648 F.2d 694, 701-02 (D.C. Cir. 1980). That consideration is relevant to the notice-and-comment requirement because fairness demands notice and an

opportunity to be heard when a rule affects private rights and interests. *See Chrysler*, 441 U.S. at 316.

Second, courts ask whether “the challenged [directive] leaves the agency, or its implementing official, free to exercise discretion to follow, or not to follow, the [announced] policy in an individual case.” *Mada-Luna v. Fitzpatrick*, 813 F.2d 1006, 1013 (9th Cir. 1987) (alterations in *Mada-Luna*). A substantive rule is “binding” on implementing officials. *Id.*; *see also Coal. for Common Sense in Gov’t Procurement v. Secretary of Veterans Affairs.*, 464 F.3d 1306, 1317 (Fed. Cir. 2006) (a substantive rule is “binding ... within the agency”). That consideration is relevant because, when implementing officials are bound to follow the policy judgments embodied in a rule, the notice-and-comment process will be the only opportunity for affected parties to challenge the policy determinations underlying the rule. *Mada-Luna*, 813 F.2d at 1013. Applying these considerations firmly supports the conclusion that *NHK-Fintiv* is a substantive rule that should have been adopted through notice-and-comment procedures.

First, the *NHK-Fintiv* Rule is a substantive rule because it “produce[s] ... significant effects on private interests.” *See Batterton*, 648 F.2d at 702. In rejecting the Director’s challenge to Apple’s Article III standing to challenge the *NHK-Fintiv* Rule, the Federal Circuit already held that the Rule harms IPR petitioners. *Apple*, 63 F.4th at 16-17. A standard that reduces the likelihood that IPR will be instituted

deprives infringement defendants of IPR's benefits and thus qualifies as a harm to a legally protected interest. *Id.* The Federal Circuit so held even though institution decisions are subject to the Directors "discretion." *Id.* at 7.

In addition, the Federal Circuit and other appellate courts have repeatedly recognized that rules "affecting the substantive ... standards by which [an agency] examines a party's application" for a benefit have the requisite effect on rights and interests and are therefore subject to notice-and-comment if they are binding. *Chestek*, 92 F.4th at 1109-110 (PTO was not required to conduct notice-and-comment rulemaking where the challenged rule did "not alter the substantive standards by which the USPTO evaluates trademark applications"). Among rules held subject to notice-and-comment requirements are: a rule changing the "substantive criteria" used by the FCC to allot radio stations (*Reeder v. FCC*, 865 F.2d 1298, 1305 (D.C. Cir. 1989)); a guidance document governing how the EPA would assess applications to use non-standard waste-disposal methods (*General Elec. Co. v. EPA*, 290 F.3d 377, 379 (D.C. Cir. 2002)); and a rule changing the criteria for selecting union election observers that limited unions' ability to select whomever they wanted (*AFL-CIO v. NLRB*, 57 F.4th 1023, 1041 (D.C. Cir. 2023)); *cf. JEM Broad. Co. v. FCC*, 22 F.3d 320, 327, 507 (D.C. Cir. 1994) (distinguishing *Reeder* and finding no notice-and-comment was required for a challenged rule that

“did not change the *substantive standards* by which the FCC evaluate[s] license applications” (emphasis in original)).

The same analysis applies to agency rules that make it harder to obtain a benefit even if the benefit is discretionary or uncertain. For example, rules that alter the standards a parole board must apply in a manner that makes it harder to obtain parole have long been described as the “classic example” of a substantive rule subject to notice and comment, even though parole decisions are imbued with discretion. *Am. Hosp. Ass’n v. Bowen*, 834 F.2d 1037, 1046 (D.C. Cir. 1987) (citing *Pickus v. U.S. Bd. of Parole*, 507 F.2d 1107, 1113 (D.C. Cir. 1974)). In *Pickus*, the D.C. Circuit held that guidelines establishing factors for the United States Board of Parole to consider in the “exercise of its discretion to parole eligible federal prisoners,” 507 F.2d at 1108, ranked as “substantive agency action” subject to notice-and-comment requirements, *id.* at 1113-1114. That was so despite the parole board’s discretion because the guidelines had “great [] impact on an inmate’s chances for parole” and were “likely to produce parole decisions different from those which alternatives would be likely to produce.” *Id.*

Here, too, the *NHK-Fintiv* Rule has a “substantial effect on ultimate” institution decisions and makes it less likely an infringement defendant’s IPR petition will be granted. *Am. Hosp. Ass’n*, 834 F.2d at 1046. The Rule is designed to alter Board decisions by aligning them with the Director’s policy choice that access

to the benefits of IPR should be denied based on the pendency of parallel litigation in many cases in which an IPR might previously have been instituted. And in cases where parallel litigation is pending in a jurisdiction with fast-moving dockets, the Rule effectively truncates the one-year filing window Congress intended to allow. *See* 35 U.S.C. § 315(b). Such a rule affects IPR petitioners' private interests even though petitioners have no entitlement to IPR, and notice-and-comment rulemaking is thus required.

2. The Director Has No discretion to Depart From the Policy Choices Embodied in the Rule

The “critical factor” distinguishing a substantive rule from a general statement of policy is whether “the challenged [directive] leaves the agency, or its implementing official, free to exercise discretion to follow, or not to follow, the [announced] policy in an individual case.” *Mada-Luna*, 813 F.2d at 1013 (alterations in *Mada-Luna*); *see also Syncor Int’l Corp. v. Shalala*, 127 F.3d 90, 94 (D.C. Cir. 1997). A general statement of policy “advise[s] the public prospectively of the manner in which [an] agency proposes to exercise a discretionary power,” *Lincoln v. Vigil*, 508 U.S. 182, 197 (1993) (quotation marks omitted)—for example, an announcement of how the agency intends to allocate funds from a lump-sum appropriation, *id.*—but leaves implementing officials free to decide whether to follow that announced policy in individual cases, *Mada-Luna*, 813 F.2d at 1013-1014. The agency retains “the discretion and the authority to change its position—

even abruptly—in any specific case.” *Syncor*, 127 F.3d at 94. A substantive rule, in contrast, binds implementing officials to follow the policy determination embodied in the rule. *Id.*; see also *Mada-Luna*, 813 F.2d at 1014. Notice-and-comment procedures are required for such rules because the rulemaking proceeding “represent[s] the only opportunity for parties to challenge the policy determinations upon which the new rule is based.” *Id.*

Here, the *NHK-Fintiv* Rule leaves the Director and/or the Board members that assist the Director in making discretionary denial determinations with no “discretion to follow, or not to follow” it in a particular case. *Mada-Luna*, 813 F.2d at 1013. Under the Rule, when parallel litigation involving the same patent is pending in a District Court, the Director and Board panel members deciding discretionary denial must (1) consider the Rule’s factors, (2) treat each factor as weighing for or against institution in the specific manner dictated by the Rule, and (3) conclude that IPR would be “inefficient” and deny the petition when the factors on balance point against institution. The Rule thus embodies not just a list of factors but a binding policy judgment by the Director that, when certain facts about the parallel litigation are present, conducting an IPR would be inefficient, and institution should be denied.

3. The AIA Reinforces that the *NHK-Fintiv* Rule Should have Been Adopted Only after Notice and Comment

The AIA expressly incorporates the APA’s notice-and-comment requirements by providing that the Director adopt certain types of generally applicable rules governing IPR, if at all, by “prescrib[ing] regulations.” 35 U.S.C. § 316(a). Congress’s use of the term “regulations” generally denotes “legislative [i.e., substantive] rules” rules issued after notice and comment. *U.S. Telecom Ass’n v. FCC*, 400 F.3d 29, 38 (D.C. Cir. 2005). The requirement to proceed by “prescrib[ing] regulations” applies specifically to rules “setting forth the standards for the showing of sufficient grounds to institute a review under section 314(a),” 35 U.S.C. § 316(a)(2), and rules “establishing and governing [IPR] ... and the relationship of [IPR] to other proceedings” under the relevant statutory title, *id.* § 316(a)(4). With its reference to Title 35 of the U.S. Code, the latter provision encompasses patent-infringement actions brought in a District Court under 35 U.S.C. § 281. *See Apple*, 63 F.4th at 8 n.3. Together, these provisions evidence Congress’s understanding that rules setting institution standards and coordinating the relationship between IPR and parallel litigation are substantive rules beyond the scope of the PTO’s pre-existing procedural rulemaking authority. *See SoftView LLC v. Apple Inc.*, 108 F.4th 1366, 1373 (holding that, unlike 35 U.S.C. § 2(b)(2)(A), § 316(a)(4) is a source of rulemaking authority for the PTO to issue “‘substantive’ rules”).

NHK-Fintiv is exactly such a rule. The *NHK-Fintiv* Rule modifies the standards for the showing of sufficient grounds to institute [an IPR] under section 314(a), 35 U.S.C. § 316(a)(2), by dictating that an IPR will not be instituted when the Director would find the IPR inefficient in light of parallel litigation in a District Court. Moreover, the *NHK-Fintiv* Rule “establish[es] and govern[s] ... the relationship” between an IPR and a District Court infringement litigation, 35 U.S.C. § 316(a)(4), by instructing the Board whether and when to institute an IPR when a related infringement action is pending in a District Court. The PTO itself has thus invoked the rulemaking considerations laid out in Section 316 in purporting to justify the *NHK-Fintiv* Rule. *See* 88 Fed. Reg. 24,503, 24,505 (Apr. 21, 2023). The AIA thus independently demonstrates that Congress would have expected a rule like the *NHK-Fintiv* Rule to be adopted only through notice-and-comment rulemaking. The Director has no discretion to forgo notice-and-comment procedures when they are required by statute. *Apple*, 63 F.4th at 15.

VI. CONCLUSION

The material issues in this proceeding have already been resolved against Patent Owner in IPR2019-00451. The PTAB previously considered Patent Owner’s argument on priority and motivation to combine and found they were unpersuasive to overcome the strong obviousness of the claimed subject matter. The only reason the ’414 Patent was allowed to issue is the Examiner’s error in refusing to follow the

PTAB and Federal Circuit's guidance on priority determinations. This IPR should be instituted so that the Office can correct that error and prevent the unjust enforcement of a patent that claims subject matter the PTAB has already determined is unpatentable.

For the reasons provided above, Petitioner requests the Director finds consideration of all factors weigh against discretionarily denying the instant IPR petition and to pass this IPR petition onto the Board panel for review on the merits.

Dated: June 16, 2025,

Respectfully submitted,

/James P. Murphy/

James P. Murphy

Reg. No. 55,474

Polsinelli PC

1000 Louisiana Street

Suite 6400

Houston, Texas 77002

Tel: (713) 374-1600

Corey Casey

Reg. No. 66,950

Polsinelli PC

900 West 48th Place

Suite 900

Kansas City, Missouri 64112

Tel: (816) 572-4439

CERTIFICATE OF WORD COUNT

Pursuant to 37 C.F.R. §42.24(d), the undersigned hereby certifies that this paper contains 9,464 words, excluding the portions exempted under 37 C.F.R. §42.24(a)(1), according to the word count feature of the word-processing system used to prepare this paper.

Dated: June 16, 2025,

Respectfully,

/James P. Murphy/

James P. Murphy (Reg. No. 55,474)

POLSINELLI PC

1000 Louisiana, Suite 6400

Houston, Texas 77002

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the accompanying Petitioner's Response to Patent Owner's Discretionary Denial of Institution Briefing is being served via electronic mail on June 16, 2025, upon the following:

Michael Sitzman
msitzman@mwe.com

Timothy P. Best
tbest@mwe.com

Raymond Miller
raymond.miller@us.dlapiper.com

N. Nicole Endejann
nicole.endejann@us.dlapiper.com

/Ericka McNeil/
Ericka McNeil

Polsinelli, PC
1000 Louisiana Street, Suite 6400
Houston, Texas 77002
Tele: (713) 374-1600