

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BIOFRONTERA INC., BIOFRONTERA BIOSCIENCE GMBH,
BIOFRONTERA PHARMA GMBH, and BIOFRONTERA AG
Petitioner,

v.

SUN PHARMACEUTICAL INDUSTRIES, INC.
Patent Owner.

Case No. IPR2025-00287
Patent 11,446,512

**PETITIONER'S RESPONSE TO PATENT OWNER'S DISCRETIONARY
DENIAL OF INSTITUTION BRIEFING**

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I. INTRODUCTION

Biofrontera Inc., Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH, and Biofrontera AG (collectively, “Petitioner”) hereby respectfully request the Board to deny Sun Pharmaceutical Industries (Patent Owner) request to discretionarily deny this *inter partes* review (IPR) of U.S. Patent No. 11,446,512 (“the ’512 Patent”). Discretionary denial of the instant IPR would not serve any purpose in light of the already instituted IPR2024-01312 challenging U.S. Patent No. 11,697,028 (“the ’028 Patent”). *See Biofrontera Inc. et. al., v Sun Pharmaceutical Industries, Inc.*, IPR2024-01312, Paper No. 9 (PTAB Feb. 24, 2025). The scope of challenged claims in this IPR of the ’512 Patent are substantially the same as those already under review by the Board in IPR2024-01312.

The analysis of *Fintiv* factors, which weighs efficiency and patent quality concerns, indicates the Director should not discretionarily deny this IPR. *See Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020) (precedential). In view of the co-pending IPR on the ’028 Patent, the most important *Fintiv* factor is the sixth factor that considers the strength of the unpatentability arguments. The Board has already instituted IPR2024-01312 challenging claims of the ’028 Patent that are substantially the same scope as those challenged here. This is strong evidence that the merits of the instant IPR are particularly strong and that there is a reasonable likelihood claims of the ’512 Patent are unpatentable just like the ’028

Patent. In addition, because the Board must issue a Final Written Decision in IPR2024-01312, there is little efficiency to be gained by discretionarily denying this IPR, which would be decided on effectively the same issues.

Moreover, as is the case for the '028 Patent, there are two co-pending proceedings involving these parties and the '512 Patent: one in District Court and one in the International Trade Commission (ITC). Patent Owner focuses exclusively on the impact of the ITC proceeding relative to this IPR, but the patent owner's analysis overlooks that trial will still be required in the District Court case it brought, regardless of the outcome of the ITC. As such, the *Fintiv* analysis must weigh the factors against both the co-pending IPR and District Court case, not just the ITC proceeding.

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 of the ITC proceeding 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).

Of particular relevance to this *Fintiv* analysis is co-pending IPR2024-01312 challenging the '028 Patent has already been instituted. The '512 and '028 Patents are within the same patent family, and their independent claims are nearly identical. Indeed, the only material phrase found in the independent claims of the '512 Patent that is not found in the independent claims of the '028 Patent is the phrase “nested hinges” used in the '512 Patent. However, the ITC has construed “nested hinges” to be encompassed by the '028 Patent’s recitation of “hinged structures on inner side surfaces.” See EX2033 at 36-37.¹ Thus, any difference in terms of patentability is *de minimis*, if any, and not material to the patentability arguments. Because the Board has already found that the IPR petition challenging the '028 Patent is reasonably likely to prevail, the merits of the instant IPR challenging the '512 Patent with nearly identical claim scope is very strong.

¹ Citations to Exhibit 2033 are to the page numbers added by Patent Owner in the Exhibit label rather than the page numbers in the original document.

Patent Owner’s sole reliance on the ITC proceeding also overlooks the currently stayed District Court proceeding involving the ’512 Patent. The ITC case cannot fully resolve the District Court proceeding like the instant IPR can because the ITC cannot invalidate a patent. The weight the Board gives to the ITC proceeding should be lessened because there is also a co-pending District Court proceeding to resolve.

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 the ITC trial may occur before the Board’s final decision in the instant IPR.

2. Similarity of ’512 Patent and ’028 Patent Claims

As noted in the instant IPR petition challenging the ’512 Patent, there is substantial overlap between this proceeding and IPR2024-01312 challenging the ’028 Patent. First, the ’512 and ’028 share a specification as the ’028 Patent is a continuation of the ’512 Patent. In addition, the scope of the independent claims is strikingly similar, with the ’512 Patent independent claims being *broad*er than the ’028 Patent independent claims.

As an example, claim 1 of each patent is shown below with the only additional limitations in the ’512 Patent reciting “nested hinges” and “at least” five panels being highlighted, neither of which material impacts the patentability of the claims (the ’028 Patent recites an additional limitation not found in the ’512 Patent):

’512 Patent, Claim 1	’028 Patent, Claim 1
1. A system for photodynamically diagnosing or treating a patient, comprising: an illuminator comprising at least five panels connected by nested hinges on inner side surfaces of adjacent panels , light sources disposed on surfaces of the at least five panels , the illuminator being configured to uniformly	1. A system for photodynamically diagnosing or treating a patient, comprising: an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels ; and light sources disposed on surfaces of the five panels , the illuminator being configured to uniformly illuminate a

illuminate a treatment surface of the patient via the light sources, one of the at least five panels positioned as a center panel configured to face the treatment surface, and two or more of the at least five panels being configured to be angled relative to the center panel, wherein each of the at least five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.	treatment surface of the patient via the light sources, one of the five panels being positioned as a center panel configured to face the treatment surface, and two or more of the five panels being configured to be angled relative to the center panel, wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface, and wherein each of the five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.
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Compare EX1001 at 10:22-40 with EX1036 at 10:24-44.

The difference between “nested hinges on inner side surfaces” of the ’512 Patent and “hinged structures on inner side surfaces” of the ’028 Patent (highlighted in green) is immaterial in view of Patent Owner’s construction of “nested hinged on inner side surfaces,” which was adopted by the ITC. *See* EX2033 at 31-37. As found in the ITC, “the term ‘nested hinges on inner side surfaces of adjacent panels’ will be construed as ‘hinges that fit on inner side surfaces of adjacent panels.’” *Id.* at 37. According to the ITC Judge, the word “nested” can be ignored since it is redundant

to “on inner side surfaces of adjacent panels” despite Petitioner’s argument that doing so would violate the doctrine of claim differentiation:

Accordingly, for these reasons I find that the intrinsic evidence demonstrates that the terms “nested” and “on inner side surfaces of adjacent panels” are redundant....Even assuming that claim differentiation applies here, as noted above “the presumption of differentiation in claim scope is not a hard and fast rule.” I have already found that the intrinsic evidence demonstrates that there is redundancy between “nested” and “on inner side surfaces of adjacent panels.” It is thus not problematic that one patent uses the term “nested hinges,” while the other patent recites “hinged structures.” Rather, this difference demonstrates that the ’512 patent includes redundant language, while the ’028 patent does not.

Id. at 36-37 (internal citations omitted).

As such, under Patent Owner’s and the ITC’s construction, there is no material difference between “nested hinges on inner side surfaces of adjacent panels” (’512 Patent) and “hinged structures on inner side surfaces of adjacent panels” (’028 Patent) since a nested hinge is simply a redundant way to recite hinge on an inner side surface of an adjacent panel.

That leaves the only other additional language in ’512 Patent claim 1 as the phrase “at least five panels.” However, the ’028 Patent claims “five panels,” which is encompassed by “at least five panels.” Thus, this difference is likewise immaterial in terms of patentability since prior art teaching of five panels found to render

obvious the '028 Patent claims would likewise render obvious “at least five panels” reciting in the '512 Patent claims.

While the above analysis focuses on claim 1 of each patent, the same is true of the remaining independent claims 8 and 20 of the '512 Patent, which similarly correspond to claims 5 and 20 in the '028 Patent. *Compare* EX1001 at 10:61-11:9 (Claim 8) and 12:17-37 (Claim 20) *with* EX1036 at 10:54-11:3 (Claim 5) and 12:18-41 (Claim 20). Like with claim 1, the only added limitations of claims 8 and 20 of the '512 Patent relative to claims 5 and 20 of the '028 Patent are “nested hinges” and “at least five panels.” *Id.*

Therefore, the Board’s findings regarding the '028 Patent independent claims 1, 5 and 20 in IPR2024-01312 will likewise be determinative of all three independent claims—claims 1, 8 and 20 of the '512 Patent—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.

The '512 Patent is subject to two other concurrent proceedings, one in District Court and one in the ITC. The Patent Owner’s *Fintiv* analysis focuses solely on the

ITC proceeding while ignoring the District Court proceeding. While the recent Guidance Memo states that co-pending ITC proceedings will now be considered in the overall *Fintiv* analysis, it does not suggest that the Board should ignore the co-pending District Court proceeding as Patent Owner's arguments imply.

Rather, as *Fintiv* recognized, “[o]ne particular situation in which stays arise frequently is during a parallel district court *and* ITC investigation involving the challenged patent.” *Fintiv* at 8 (emphasis in original). In these situations, *Fintiv* indicates that “an earlier ITC trial date may favor exercising authority to deny institution” because “as a practical matter, it is difficult to maintain a district court proceeding on patent claims *determined to be invalid at the ITC.*” *Id.* at 8-9 (emphasis added). However, unaddressed by *Fintiv* is the other potential scenario where patent claims are determined to be not invalid at the ITC. Under this scenario, there will necessarily be a continuation of the District Court litigation here because Patent Owner's complaint in the District Court requests relief that cannot be granted by the ITC, including monetary damages. EX1018 at 30-31 (Patent Owner requesting “an award of damages...including reasonable royalties and/or Sun Pharma's lost profits”); *see* 19 U.S.C. § 1337(d) (ITC remedies do not include monetary damages).

District courts have original jurisdiction over patent issues and are thus obligated “to reach an independent conclusion regarding validity” of a patent.

DynaEnergetics Europe GmbH v. Hunting Titan, Inc., 629 F. Supp. 3d 548, 570 (S.D. Tex. 2022) (citing *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1139 (Fed. Cir. 1985)); 28 USC § 1338. In contrast, the ITC “has the authority to determine the patent validity issue *only for the limited purposes of its administration of section 1337*,” which is to determine “whether the Fair Trade Practices Act had been violated.” *In re Convertible Rowing Exerciser Patent Litigation*, 814 F. Supp. 1197, 1200, 1207 (D. Del. 1993) (emphasis added).

Decisions on patent invalidity by the ITC “do not have preclusive effect on district court litigation.” *INVT SPE LLC v. Int’l. Trade Comm.*, 46 F.4th 1361, 1370 (Fed. Cir. 2022). While “persuasive value” may be attributed to prior ITC decisions, these decisions “are not binding on district courts in subsequent cases brought before them.” *Motorola Solutions, Inc. v. Hytera Communications Corp. Ltd.*, 402 F. Supp. 3d 450, 457, 459 (N.D. Ill. 2019) (quoting *Texas Instruments Inc. v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1569 (Fed. Cir. 1996)). Therefore, contrary to the Patent Owner’s assertion in its request to discretionarily deny the instant IPR, the validity of the ’512 Patent **cannot** be decided at the ITC as a matter of law. See Patent Owner’s Motion for Discretionary Denial at 3 (wrongly stating “the validity of the ’512 patent will be decided at the ITC”).

Thus, even though the ITC action is presently scheduled to resolve before this IPR, validity needs to be re-tried as a matter of law for the District Court to resolve

all of the issues. Unlike the ITC decision, a decision by the Board in this matter will have a legal preclusive effect on validity by cancelling claims as unpatentable or application of statutory estoppel under 35 U.S.C. § 315(e).

On balance, *Fintiv* factors 1-5 are neutral when considering both co-pending proceedings (District Court and ITC) for the reasons explained below. However, with regards to *Fintiv* factor 6, the Board has already found a likelihood that some claims will be found unpatentable, thus supporting a strong case on the merits. As such, *Fintiv* factor 6 tilts the weight of the *Fintiv* analysis against discretionary denial.

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

The District Court has granted a stay of proceedings pending resolution of the ITC proceeding. *See* EX2032 at 1. The ITC proceeding is not stayed.

Thus, factor 1 is neutral since one co-pending proceeding is stayed while the other co-pending proceeding is not stayed.

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

The District Court action is stayed pending resolution of the ITC matter with no trial date set. The ITC proceeding has set a target date of February 2, 2026 to issue its final determination. The Board's anticipated statutory deadline to issue a Final Written Decision for the instant IPR is August 12, 2026.

Thus, the District Court trial date would not occur until well after the Board's projected statutory deadline, while the ITC target date is before the Board's projected statutory deadline. As discussed above, the ITC cannot provide the relief sought by Patent Owner in the District Court, so a District Court trial is a necessity that must occur to resolve Patent Owner's complaint, rather than being some hypothetical occurrence. EX1018 at 30-31 (Patent Owner requesting "an award of damages...including reasonable royalties and/or Sun Pharma's lost profits"); see 19 U.S.C. § 1337(d) (ITC remedies do not include monetary damages). Since the ITC validity decisions "do not have preclusive effect on district court litigation.", the validity of the '512 Patent would need to be re-tried in the District Court action. *INVT*, 46 F.4th at 1370.

Therefore, factor 2 is also neutral since the Board decision falls between the expected final determination dates of the two co-pending proceedings.

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

The District Court was stayed near inception, and there has been little to no investment in that proceeding by the Court or the parties. The parties and the ITC have invested resources into the ITC proceeding, but the prior art invalidity portion of the ITC investment is largely based on the work product the parties prepared for the Petition and Preliminary Response in IPR2024-01312 challenging the '028 Patent (which are substantially the same issues in the instant IPR challenging the

'512 Patent). Thus, the parties' ITC investment is in part cumulative to the investment first made in an IPR before the Board.

As discussed above, regardless of the conclusion in the ITC, further investment in the District Court action will be required since a District Court must "reach an independent conclusion regarding validity." *DynaEnergetics*, 629 F. Supp. 3d at 570 (*citing Interconnect Planning*, 774 F.2d at 1139). In addition, the District Court action will require additional investment in issues that are not addressed by the ITC, including monetary damages. As such, the Board cannot dismiss the future investment of resources that will be required by Court and parties in the District Court action. Resources that may never need to be expended if the Board institutes this IPR.

Therefore, factor 3 is also neutral since the investment in the co-pending District Court proceeding is *de minimis* while there has been investment in the ITC proceeding. However, the District Court proceeding will require substantial investment in the future regardless of the outcome of the ITC proceeding.

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

The District Court action was stayed near inception and has not progressed to the point where the issues have been developed in comparison to the instant IPR proceeding. However, because of that stay, it is highly unlikely that the same issues will be raised in the District Court if this IPR is instituted since the Board would

issue a Final Written Decision before the same issues could be tried in District Court resulting in cancelled claims or estoppel under 35 U.S.C. § 315(e).

Nonetheless, to avoid any doubt that there would be no overlap in issues between the instant IPR and subsequent District Court litigation, Petitioner hereby stipulates in accordance with *Sotera* that, if the Board institutes this IPR, Petitioner will not pursue in the co-pending District Court proceeding the same grounds as in this Petition or any grounds that could have reasonably been raised in this Petition. *See Sotera Wireless, Inc. v. Masimo Corp.*, IPR2020-01019, Paper 12 at 17 (PTAB Dec. 1, 2020) (precedential).

The ITC proceeding involves overlapping invalidity issues that were first raised in the instant IPR. *Compare* EX1002 (Dr. Grove's IPR expert declaration submitted on Dec. 24, 2024) *with* EX2034 (Dr. Grove's ITC expert report submitted a month later on January 22, 2025). The Board has already determined that there is a reasonable likelihood that Petitioner will prevail on these issues, as discussed above, while the ITC has not yet made any such determination.

Therefore, factor 4 is also neutral since, if the instant IPR is instituted, there will be no overlap of issues with the District Court while there are overlap of issues with the ITC proceeding.

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

In IPR2024-01312, the Board has already determined that the prior art and arguments presented by Petitioner show a reasonable likelihood to prevail against the claims of the '028 Patent. *Biofrontera Inc. et. al., v Sun Pharmaceutical Industries, Inc.*, IPR2024-01312, Paper No. 9 at 2 and 23 (PTAB Feb. 24, 2025); *see also id.* at 22 (“we have already determined that Petitioner has demonstrated a reasonable likelihood that it would prevail in showing the unpatentability of each of

the challenged claims based upon the combined teachings of Lundahl and Larsen.”). The same Lundahl and Larsen combination asserted against independent claims 1, 5 and 20 of the ’028 Patent in IPR2024-01312 is being asserted against independent claims 1, 8 and 20 of the ’512 Patent in the instant IPR. *See* Petition at 24.

As explained above, there is substantial overlap between this proceeding challenging the ’512 Patent and IPR2024-01312 challenging the ’028 Patent. *See supra* Section II(A)(2). The challenged independent claims of the ’512 Patent in the instant IPR have nearly identical issues to consider as the challenged independent claims of the ’028 Patent that the Board is already reviewing in IPR2024-01312. Thus, the Board’s finding that at least some claims of the ’028 Patent are likely to be found unpatentable likewise means that at least some claims of the ’512 Patent are likely to be found unpatentable.

Indeed, the only difference between “nested hinges on inner side surfaces” (recited in the ’512 Patent independent claims) and “hinged structures on inner side surfaces” (recited in the ’028 Patent independent claims) is immaterial, particularly in view of Patent Owner’s construction of “nested hinged on inner side surfaces,” which was adopted by the ITC. *See* EX2033 at 31-37. As found in the ITC, “the term ‘nested hinges on inner side surfaces of adjacent panels’ will be construed as ‘hinges that fit on inner side surfaces of adjacent panels.’” *Id.* at 37. According to the ITC Judge, the word “nested” can be ignored since it is redundant to “on inner side

surfaces of adjacent panels.” *Id.* at 37. As such, under Patent Owner’s and the ITC’s construction, there is no material difference between “nested hinges on inner side surfaces of adjacent panels” (’512 Patent) and “hinged structures on inner side surfaces of adjacent panels” (’028 Patent).

The only other additional language in the ’512 Patent independent claims is the phrase “at least five panels” instead of the ’028 Patent’s independent claims recitation of “five panels.” However, “five panels” is encompassed by “at least five panels.” Thus, this difference in the ’512 and ’028 independent claims is likewise immaterial in terms of validity since disclosure of five panels meets the limitations of both the ’512 Patent and the ’028 Patent.

It is difficult to imagine a fact pattern that shows stronger evidence of merit than here given that the Board has effectively concluded the strength of the merits in the instant IPR via its Institution Decision in IPR2024-01312. 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 Board will issue a Final Written Decision in IPR2024-01312 challenging claims of the ’028 Patent, which have substantially similar scope as the claims at issue in the instant IPR. Should the Board discretionarily deny the instant IPR, the outcome may be a finding by the Board that the claims of the ’028 Patent are unpatentable while the ITC or District Court find claims of the broader claims of the ’512 Patent as not invalid due to the higher evidentiary burden in those forums.

Indeed, the Supreme Court noted that “different evidentiary burdens mean that the possibility of inconsistent results is inherent to Congress’ regulatory design.” *Cuozzo*, 579 U.S. at 283. The Federal Circuit has likewise held that “the PTAB properly may reach a different conclusion based on the same evidence” due to differences between the clear and convincing evidence standard and the preponderance of the evidence standard. *Novartis AG v. Noven Pharms. Inc.*, 853 F.3d 1289, 1294 (Fed. Cir. 2017). Thus, by discretionarily denying the instant IPR,

it is entirely possible that a patent with claim scope that the Board believes is unpatentable (via its findings in IPR2024-01312) is nonetheless allowed to be legally enforced by Patent Owner. This result is the exact opposite of what *Fintiv* espouses for its policy goal to improve “patent quality.” *Fintiv* at 5; *see also* *Cuozzo*, 579 U.S. at 272 (improving “patent quality” was an “important congressional objective” underlying the creation of the IPR process).

Finally, the Board should also consider that *Fintiv*’s goal of “efficiency” would not be further achieved by a discretionary denial of the instant IPR. *Fintiv* at 6. That is because the Board has already instituted IPR2024-01312, which will require the Board to address most of the exact same issues that would be addressed in the instant IPR. As such, any efficiency savings resulting from denial of the instant IPR would be small, if any. The benefit of such efficiency savings obtained via discretionary denial pales in comparison to the detriment of allowing a patent of questionable patentability to continue being enforced.

Therefore, *Fintiv* factor 6 weighs strongly against discretionary denial in view of the strong merits and avoidance of inconsistent results. In addition, any efficiency gained due to discretionary denial would be minimal at best given that the Board is required by statute to issue a Final Written Decision in IPR2024-01312 addressing the same issues that would be addressed in the instant IPR.

III. 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”).² *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 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

² 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.

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). The notice-and-comment process reflects Congress’s “judgment that notions of fairness and informed administrative decision making require” agency decisions to be made “only after affording interested persons notice and an opportunity to comment.” *Chrysler Corp. v. Brown*, 441 U.S. 281, 316 (1979).

“[N]otice and the opportunity to be heard are an essential component of fairness to affected parties.” *Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 547 (D.C. Cir. 1983) (quotation marks omitted); *see also Ivy Sports Med., LLC v. Burwell*, 767 F.3d 81, 87-88 (D.C. Cir. 2014). Moreover, notice and comment “ensur[es] that agency regulations will be tested by exposure to diverse public comment,” *Small Refiner*, 705 F.2d at 547 (quotation marks omitted), thereby “afford[ing] the agency a chance to avoid errors and make a more informed decision,” *Azar v. Allina Health Servs.*, 587 U.S. 566, 582 (2019). Public feedback thus yields an “improved” final rule, *Veterans Justice Grp., LLC v. Sec’y of Veterans Affairs.*, 818 F.3d 1336, 1344 (Fed. Cir. 2016), by ensuring that “the agency has all pertinent information before it,” *Elec. Privacy Info. Ctr. v. DHS*, 653 F.3d 1, 6 (D.C.

Cir. 2011). 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.* As the D.C. Circuit later explained, the rule altering the parole board’s standards was subject to notice and comment not because inmates had an “existing right” to parole— they did not—but because the rule was “calculated to have a substantial effect on ultimate parole decisions.” *Am. Hosp. Ass’n*, 834 F.2d at 1046. Similarly, in *W.C. v. Bowen*, 807 F.2d 1502 (9th Cir. 1987), *amended on denial of reh’g*, 819 F.2d 237 (9th Cir. 1987), the Ninth Circuit considered a program that subjected Administrative Law Judges’ decisions to an additional level of review by an agency appellate tribunal if those decisions were favorable to Social Security claimants. 807 F.2d at 1505. Previously, those decisions would not have been subject to further review. *Id.* The court held that the revised program was a substantive rule “affect[ing] existing rights” because it was “designed to alter ALJ decisions,” causing the agency “to deny benefits in close cases where benefits might previously have been granted.” *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.

Moreover, the purpose of notice-and-comment rulemaking is to ensure that those who will be affected have an opportunity to be heard and that the agency benefits from their perspective and any information they can offer. *See Small Refiner*, 705 F.2d at 547. These considerations plainly apply when a standard is changed in a way that makes it harder to obtain a benefit, even when the affected parties have no entitlement to the benefit. IPR petitioners have precisely the type of stake in institution standards that the notice-and-comment process is intended to accommodate. Importantly, nothing in *W.C.*'s holding turned in any way on whether the benefits at issue were discretionary or certain; what mattered was that the rule altered the agency's decisions, causing the agency "to deny benefits in close cases where benefits might previously have been granted." *Id.* at 1505. The same is true here.

Finally, the *NHK-Fintiv* Rule requires petitioners seeking to avoid denial of institution under the Rule to file IPR petitions sooner than the AIA allows or to stipulate that they will not pursue overlapping invalidity arguments in both the

District Court litigation and the IPR, even though the AIA permits them to do so in many circumstances. In any event, the relevant question under the APA is whether it “significant[ly] [a]ffects ... private interests.” *Batterton*, 648 F.2d at 701-702; see *Chestek*, 92 F.4th at 1110. And here, the *NHK-Fintiv* Rule harms the “legally protected interest” of infringement defendants by “caus[ing] more denials of institution than might otherwise occur,” thereby denying infringement defendants the benefits of IPR. *Apple*, 63 F.4th at 16-17.

In short, *NHK-Fintiv* deprives infringement defendants of opportunities to challenge asserted patent claims through the efficient and specialized alternative to litigation that Congress created. Indeed, the purpose of IPR was to protect the rights of parties opposing questionable patents by making it easier and faster to vindicate those rights. *NHK-Fintiv* was thus a substantive rule that required notice-and-comment rulemaking.

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.

Courts have found rules that bind agencies in a manner similar to *NHK-Fintiv* to be substantive rules subject to notice-and-comment requirements. *See, e.g., Syncor*, 127 F.3d at 95-96 (notice-and-comment required where FDA rule bound the agency to a particular regulatory position); *Pickus*, 507 F.2d at 1113 (parole standards requiring board to consider several categories of factors were substantive rules because they “narrow[ed]” the board’s “field of vision” to encourage “decisive reliance” on the factors and “define[d] a fairly tight framework to circumscribe the [parole board]’s statutorily broad power”); *W.C.*, 807 F.2d at 1505 (rule that “substantially limit[ed]” the decisionmaker’s discretion whether to review ALJ decisions is a substantive rule).

Moreover, a rule that changes the substantive standards by which an agency evaluates individual applications is subject to notice-and-comment requirements even if there is no single dispositive criterion. *See JEM Broad.*, 22 F.3d at 327 (distinguishing *Reeder*, 865 F.2d at 1305). Indeed, the Rule is designed to be outcome-determinative, or else it would not effectuate the Director’s policy choices for when IPR should be instituted. *See Apple*, 63 F.4th at 13.

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.

4. The *NHK-Fintiv* Rule’s Flaws Demonstrate Why It Should Have Been Adopted Through Notice-And-Comment Rulemaking

The Director’s failure to follow notice-and-comment requirements directly contributed to the Director’s adoption of a deeply flawed rule, and the resulting harms illustrate why *NHK-Fintiv* is precisely the type of rule that should have undergone notice-and-comment rulemaking. As explained, notice-and-comment

procedures are intended to promote fairness and improve agency decision making by ensuring that parties whose interests would be harmed by a proposed rule have an opportunity to be heard before those harms are imposed and ensuring that agencies have the full picture of the wisdom and likely consequences of a proposed rule.

Here, following notice-and-comment procedures would have afforded affected parties an opportunity to identify numerous defects in the *NHK-Fintiv* Rule before the Director adopted it. For example, several provisions of the AIA make clear that IPR may proceed alongside overlapping infringement litigation, *see Apple*, 63 F.4th at 8 n.3 (noting “Congress’s expectation that the same patent claims might well be at issue in both an IPR proceeding and a court case”), and the Director cannot exercise institution discretion in a manner that violates those provisions and thwarts their purposes. Had the Director followed notice-and-comment procedures, Petitioner and other affected parties could have presented their arguments regarding the Rule’s conflict with AIA, and the Director would have been obligated to consider those arguments and address the statutory violation, which it has now effectively shielded from judicial review. *See* 5 U.S.C. § 553(c); *Overton Park*, 401 U.S. at 416. Similarly, notice-and-comment rulemaking would have given Petitioner and others an opportunity to explain the *NHK-Fintiv* Rule’s irrationality and the arbitrary consequences it would produce.

Again, if notice-and-comment rulemaking had properly been followed, the Director would have had to alter the rule to address those defects or else provide a reasoned explanation for refusing to do so. *See* 5 U.S.C. § 553(c); *Overton Park*, 401 U.S. at 416. Instead, the Director acted without warning and entirely failed to grapple with serious questions regarding the Rule's validity and its arbitrary consequences. As adopted by the Director without notice and comment, the *NHK-Fintiv* Rule has harmed infringement defendants seeking the benefits of IPR, and it has undermined the patent system as a whole.

As things stand, a defendant accused of infringement would understand from the AIA that it has one year to file an IPR petition after being served with a complaint. 35 U.S.C. § 315(b). The PTO regulations regarding who may file a petition contain similar language regarding the one-year period. 37 C.F.R. § 42.101(b). Yet, there is nothing in the PTO regulations about the significance of co-pending litigation, nor anything about factors related to the timing of parallel litigation.. *See id.* § 42.102, 42.104. Only by consulting the list of Board decisions that the Director has designated as precedential, and by reviewing the *NHK* and *Fintiv* decisions, would the defendant learn that, despite the statutory one-year period for filing an IPR petition, time was of the essence and the de facto deadline was far sooner (but how much sooner would depend upon the circumstances of the case). Nor would the petitioner be aware of the possibility that the Director's policies

embodied in the *NHK-Fintiv* Rule could change without notice at any time as they have in this case. See Guidance memo at 2 (changing policy so that co-pending ITC cases will now be considered in the *Fintiv* analysis). “Agency rulemaking is not supposed to be a scavenger hunt.” *Aqua Prods., Inc. v. Matal*, 872 F.3d 1290, 1322 (Fed. Cir. 2017). Conducting notice-and-comment rulemaking, as the APA and AIA require, would have exposed these problems and hopefully averted them.

The notice-and-comment process is now even more crucial to ensuring fairness and sound decision-making in the Director’s adoption of binding institution standards. The Federal Circuit has established that binding rules that change the standards for institution and make institution less likely will be difficult, if not impossible, to challenge as contrary to law or arbitrary and capricious. *Apple*, 63 F.4th at 11-14. Those rules cannot be challenged in the context of individual institution decisions and courts lack jurisdiction to intervene, *see, e.g., Mylan Labs. Ltd. v. Janssen Pharmaceutica, N.V.*, 989 F.3d 1375, 1378 (Fed. Cir. 2021), *cert. denied*, 142 S. Ct. 874 (Jan. 18, 2022) (Mem.). As a result, notice-and-comment procedures provide the last remaining check for affected parties against the Director’s adoption of unlawful or irrational institution standards that harm parties’ legally protected interests. It is all the more necessary, then, to enforce Congress’s command that “the interested public should have an opportunity to participate, and

the agency should be fully informed, before rules having such substantial impact are promulgated.” *Pickus*, 507 F.2d at 1112.

IV. CONCLUSION

For the reasons provided above, Petitioner requests the Director finds the *Fintiv* factors weigh against discretionarily denying the instant IPR petition and to pass this IPR petition onto the Board panel for review on the merits. Even if the Director finds the *NHK* and *Fintiv* factors favor discretionarily denying the instant IPR petition, the Director’s reliance on the *NHK-Fintiv* factors to deny institution here is improper since those factors constitute substantive rule making without any notice-and-comment period. Thus, any denial based on the *NHK-Fintiv* Rule is improper and contrary to the statute implementing IPR proceedings.

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Respectfully submitted,
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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 and all accompanying exhibits are being served via electronic mail on May 12, 2025 upon the following:

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