

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

US INVENTOR, INC., *et al.*,

Plaintiffs,

v.

ANDREW HIRSHFELD, in his official capacity
performing the functions and duties of the Under
Secretary of Commerce for Intellectual Property and
Director, United States Patent and Trademark Office,

Defendant.

No. 2:21-cv-00047

REPLY IN SUPPORT OF DEFENDANT'S MOTION TO DISMISS

Plaintiffs' Opposition to Defendant's Motion to Dismiss ("Opposition"), ECF No. 20, fails to rebut any of the deficiencies in Plaintiffs' Amended Complaint for Declaratory and Injunctive Relief ("Amended Complaint"), ECF No. 64, identified in Defendant's Motion to Dismiss ("Motion"), ECF No. 19. The Court should therefore dismiss Plaintiffs' Administrative Procedure Act ("APA") claims challenging the factors the U.S. Patent and Trademark Office ("USPTO") has identified as relevant to the Patent Trial and Appeal Board's ("Board") discretionary denial of inter partes review ("IPR") and seeking to compel notice-and-comment rulemaking on those factors.

I. Plaintiffs Lack Standing.

A procedural injury without a resulting concrete injury is insufficient to confer standing. *Summers v. Earth Island Institute*, 555 U.S. 488, 496 (2009). Because there is no right to IPR institution or to discretionary denial of institution, Plaintiffs lack standing to challenge the USPTO's policies identifying non-exhaustive factors relevant to the institution decision. *See Mylan Labs. Ltd. v. Janssen Pharmaceutica, N.V.*, 989 F.3d 1375, 1382 (Fed. Cir. 2021). There is no merit to Plaintiffs' standing arguments as to either the Plaintiffs who own patents ("Patent Owner Plaintiffs") or Plaintiff U.S. Inventor, Inc.¹

A. The Patent Owner Plaintiffs Lack Standing.

Despite Plaintiffs' attempts to dress up their purported injury in other ways, the Patent Owner Plaintiffs lack a concrete injury that could render their alleged procedural injury sufficient for standing. *See Summers*, 555 U.S. at 496. The Patent Owner Plaintiffs cannot have such an injury because neither

¹ In their Opposition, Plaintiffs seem to imply that the Court should merely accept their *ipse dixit* that they have suffered a concrete injury sufficient to establish standing. Opp. at 4. This is not the case. Although the Court must presume for standing that the challenged conduct is unlawful, federal courts do not presume that the allegedly unlawful conduct infringes a cognizable legal interest. *See Estate of Boyland v. U.S. Dep't of Agric.*, 913 F.3d 117, 124 (D.C. Cir. 2019); *Day v. Bond*, 500 F.3d 1127, 1138 (10th Cir. 2007). Although the two inquiries frequently overlap, "[t]here are cases, such as the one before [the Court] here, where the alleged injury upon which the plaintiffs rely to establish standing is distinct from the merits of claims they assert." *Day*, 500 F.3d at 1138.

IPR petitioners nor patent owners have any rights in connection with the institution decision, which is all that is affected by the policies challenged in this case. *See Saint Regis Mohawk Tribe v. Mylan Pharm. Inc.*, 896 F.3d 1322, 1327 (Fed. Cir. 2018) (USPTO has “complete discretion” over institution).

Plaintiffs’ reliance on a purported risk to the Patent Owner Plaintiffs’ patent rights does not establish the concrete injury necessary for standing. *See* Opp. at 5-6. The USPTO cancels or amends patent claims only after the Board’s final written decision following a full IPR trial. *See* 35 U.S.C. §§ 318(a)-(b). Plaintiffs do not challenge the standards applied in those proceedings. The policies Plaintiffs challenge go only to the decision whether to institute IPR proceedings, which has no legal effect whatsoever and as to which Plaintiffs have no legal rights. Moreover, declining to institute IPR—the decision informed by the policies Plaintiffs challenge—ends the USPTO’s consideration of an IPR petition challenging a patent’s validity, meaning that the matter does not even proceed to a final written decision. *See id.* § 314(a). Although Plaintiffs attempt to reframe their purported concrete injury, they are only grieving the alleged increased chance the USPTO will institute IPR, nothing more.

There is no merit to Plaintiffs’ contention that a supposedly increased chance of IPR institution is a concrete harm because the IPR proceedings could affect the patentability of their patent claims. In any adjudication there is a chance that a litigant could lose. If that chance amounted to a concrete injury, then the institution of an adjudicative process would always be a concrete injury sufficient for an injury in fact. However, an adjudication is just a procedure, and procedural injuries alone are not concrete injuries. *Summers*, 555 U.S. at 496. The mere institution of an adjudication has “no legal force or practical effect . . . other than the disruptions that accompany any major litigation,” which are “part of the social burden of living under government.” *FTC v. Standard Oil Co. of Cal.*, 449 U.S. 232, 243-444 (1980) (citation omitted). Thus, it cannot suffice to establish a concrete injury.

Plaintiffs do not cite a single case in which a court found a concrete injury based on the possibility a plaintiff might lose an administrative or judicial proceeding. Instead, Plaintiffs rely on

inapposite case law finding standing when there is a risk from events outside the adjudicative process. *See* Opp. at 5 (citing *Sierra Club v. Marsh*, 872 F.2d 497, 503 (1st Cir. 1989) (standing based on risk of environmental harm from construction project)). A risk that a plaintiff will suffer an unlawful harm can in some circumstances convey standing. *See, e.g., Cole v. Gen. Motors Corp.*, 484 F.3d 717, 722-23 (5th Cir. 2007) (risk from defective product malfunctioning); *Baur v. Veneman*, 352 F.3d 625, 634 (2d Cir. 2003) (risk from unhygienic food causing illness). Here, Plaintiffs do not predicate their alleged standing on the possibility of an unlawful injury occurring outside the adjudicative process. Rather, they rely on the possibility that there will be a legal determination that harms them. In other words, Plaintiffs base their supposed standing on the risk of a lawful harm to their interests. To the extent there is any legal error in that determination, the only permissible avenue for relief is by appeal to the Federal Circuit. *See* 35 U.S.C. § 319. Plaintiffs thus fail to allege a cognizable concrete injury that could convert their alleged procedural injury into an injury in fact.²

Furthermore, even if the institution of administrative proceedings were a cognizable concrete injury, Plaintiffs have not shown a sufficiently increased risk to establish standing. Because “there is a powerful argument that ‘increased-risk-of-harm’ claims . . . fail to meet the constitutional requirement that a plaintiff demonstrate harm that is ‘actual or imminent, not conjectural or hypothetical,’” courts will “allow[] standing [on this basis only] when there was at least both (i) a *substantially* increased risk of harm and (ii) a *substantial* probability of harm with that increase taken into account.” *Pub. Citizen, Inc. v. Nat’l Highway Traffic Safety Admin.*, 489 F.3d 1279, 1293-95 (D.C. Cir. 2007). Plaintiffs persist in asserting that they can establish standing on this basis because, they assert, there is “a 29% invalidation rate [in a judicial] proceeding” and “an 84% invalidation rate [in an IPR]

² At one point Plaintiffs suggest that the loss of an opportunity to present one’s views to an agency is alone sufficient to establish a concrete injury. *See* Opp. at 6. However, the Supreme Court explicitly rejected this argument. *Summers*, 555 U.S. at 494, 496-97.

proceeding.” Opp. at 7. As discussed in the Motion, any direct comparison between the two is logically flawed, and Plaintiffs’ proffered statistics are demonstrably false. Mot. at 10-11.

There is no logical basis for making a direct comparison between final written decisions in IPR proceedings and judicial decisions. As noted in the Motion, the Board can reach a final written decision only after it has already conducted an initial merits screening. 35 U.S.C. § 314(a); Mot. at 10-11. Plaintiffs claim their comparison is valid because Federal Rule of Civil Procedure 11 serves a comparable function in judicial proceedings. Opp. at 8. This claim is risible. In contrast to § 314(a), which requires “a reasonable likelihood that the petitioner would prevail with respect to at least [one] of the claims challenged in the petition,” Rule 11 requires only a good faith basis for factual contentions and “a nonfrivolous argument” for legal contentions. *See also Smith v. Nat’l Health Care Servs. of Peoria*, 934 F.2d 95, 97 (7th Cir. 1991); *Soto v. Bushmaster Firearms Int’l, LLC*, 139 F. Supp. 3d 560, 563 (D. Conn. 2015) (“The analysis under . . . Rule 11 . . . turns not on how likely a claim is to succeed, but rather on whether the claim is objectively frivolous.”). The two standards are vastly different, so there is no merit to Plaintiffs’ claim that they have the same effect.

Indeed, even accepting Plaintiffs’ points of comparison, Plaintiffs’ statistics are inaccurate. Publicly available USPTO data shows that Plaintiffs exaggerate the proportion of claims found unpatentable in final written decisions.³ Even more telling, Plaintiffs’ grossly overstate the rate which courts find patents to be invalid. Academic studies that control for bad data show that the courts find about half of challenged patents to be invalid, not 29% as Plaintiffs assert. *See* Jonathan H. Ashtor, *Does Patented Information Promote the Progress of Technology?*, 113 Nw. 1 U. L. Rev. 943, 965 (2019) (54.7% invalidated); John R. Allison, *et al*, 82 U. Chi. L. Rev. 1073, 2 1100 (2015) (42.6% invalidated). Thus,

³ PTAB Trial Statistics FY20 End of Year Outcome Roundup, IPR, PGR, CBM, https://www.uspto.gov/sites/default/files/documents/ptab_aia_fy2020_roundup.pdf, slide 15 (less than 74% of claims found unpatentable in final written decisions).

even ignoring the merits screening that makes any comparison between the two processes inapposite, the actual difference in invalidation rates would be less than half what Plaintiffs claim.

Using the valid comparison between unpatentability challenges asserted in IPR petitions and invalidity challenges asserted in judicial proceedings, the rates of success are comparable.⁴ Accounting for Plaintiffs' empirical and methodological errors, IPR may even be more favorable to patent owners.

B. US Inventor Has Not Met Its Burden to Establish Organizational Standing.

US Inventor has also not established standing in its own right to assert the claims in the Amended Complaint because it has not shown that it was forced to divert such significant resources to combatting the USPTO's allegedly wrongful conduct that there was a significant impairment to the services it provides. *See NAACP v. City of Kyle, Tex.*, 626 F.3d 233, 238 (5th Cir. 2010). Moreover, US Inventor's newly asserted informational injury fails as well.

The Opposition identifies two types of activities that allegedly establish US Inventor's organizational standing. First, as part of "its mission to educate the public," US Inventor now allegedly recommends that its members "not participat[e] in the U.S. patent system." Opp. at 9 (citations omitted). However, "an organization . . . expend[ing] resources to educate its members" is not an injury in fact "unless doing so subjects the organization to 'operational costs beyond those normally expended.'" *Food & Water Watch, Inc. v. Vilsack*, 808 F.3d 905, 920 (D.C. Cir. 1995) (citation omitted). US Inventor has not averred that it expends more resources advising its members not to file patents than it would advising them otherwise if the USPTO had engaged in notice-and-comment rulemaking on discretionary denial of IPR petitions. Thus, US Inventor cannot have standing on this basis.

Second, for the first time in the Opposition, Plaintiffs identify actions US Inventor took to advocate for the USPTO to issue regulations on the IPR institution decision, including discretionary denial of institution. Opp. at 9-10. Specifically, Plaintiffs allege that US Inventor encouraged the

⁴ *Id.* (29% of challenged claims found unpatentable in final written decisions in fiscal year 2020).

public to submit comments to the USPTO on the factors for IPR institution, facilitated such comments by creating a website, and filed a petition for rulemaking proposing rules for IPR institution. *Id.* However, “the expenditure of resources on advocacy is not a cognizable Article III injury.” *Turlock Irr. Dist. v. FERC*, 786 F.3d 18, 24 (D.C. Cir. 2015). As a result, “‘associational resources’ . . . spent commenting on and responding to” challenged agency actions are insufficient to confer organizational standing. *Ass’n of Home Builders v. U.S. Army Corps of Eng’rs*, 663 F.3d 470, 475 (D.C. Cir. 2011); *see Nat’l Ass’n of Home Builders v. EPA*, 667 F.3d 6, 12 (D.C. Cir. 2011) (“considerable staff time and resources” spent on, *inter alia*, “submitting comments to” federal agencies insufficient for standing). Even if US Inventor could identify some harm to its other activities from its advocacy—and it has not even alleged such a harm—it would not have demonstrated organizational standing.

Third, Plaintiffs advance an entirely new theory, contending that US Inventor suffered an informational injury from the absence of “lawful regulations on the subject of standards for discretionary denial” of IPR petitions. *Opp.* at 10-11. To show an informational injury, a plaintiff must show: “(1) it has been deprived of information that, on its interpretation, a statute requires the government or a third party to disclose to it, and (2) it suffers, by being denied access to that information, the type of harm Congress sought to prevent by requiring disclosure.” *Friends of Animals v. Jewell*, 828 F.3d 989, 992 (D.C. Cir. 2016). Plaintiffs cannot meet the first prong of this test because the Amended Complaint alleges that the USPTO was required to enact policies on discretionary denial by notice-and-comment regulation, not that the USPTO has failed to comply with an obligation to disclose information. *Cf. Wilderness Soc’y, Inc. v. Rey*, 622 F.3d 1251, 1260 (9th Cir. 2010) (no informational injury from violation of non-APA statute requiring public participation in agency decision-making); *Bensman v. U.S. Forest Serv.*, 408 F.3d 945, 960 (7th Cir. 2005) (same). Plaintiffs cannot meet the second prong because the USPTO has disclosed the relevant factors for the discretionary denial through publicly available precedential decisions, so no information has been

withheld. Plaintiffs' conclusory and belated assertion of informational injury therefore fails. *See Ctr. for Biological Diversity v. Bernhardt*, 442 F. Supp. 3d 97, 111–13 (D.D.C. 2020) (bare assertion of information injury from lack of notice-and-comment rulemaking insufficient for individual or organizational standing).

Plaintiffs' sole authority for their purported informational injury is unavailing. *See* Opp. at 10-11 (citing *Am. Anti-Vivisection Soc'y & Avian Welfare Coal. v. U.S. Dep't of Agric.* (“*AAVS*”), 946 F.3d 61 (D.C. Cir. 2020)). The plaintiff organization in that case sued to compel an agency to issue certain standards—as it was purportedly required to do by statute—and alleged a cognizable informational injury because it was “compelled to fill the void by developing the guidance . . . that [the] federal standards would otherwise provide.” *AAVS*, 946 F.3d. at 619. Here, the USPTO has identified the factors it takes into account when exercising its discretion to deny IPR—just not in the manner Plaintiffs would prefer—and US Inventor has not expended any resources to supply the factors itself. *AAVS* is therefore inapposite and does not support US Inventor's standing here.

II. Plaintiffs' Claims Lack Merit.

Neither Plaintiffs' Count I, seeking to compel notice-and-comment rulemaking on the factors for discretionary denial of IPR petitions, nor Count II, seeking to set aside the factors adopted pursuant to precedential Board decisions, states a claim upon which relief could be granted.

A. Count I Should Be Dismissed.

Plaintiffs claim to compel notice-and-comment rulemaking fails because (1) Plaintiffs did not exhaust their administrative remedies and (2) Plaintiffs' legal theory relies on a false conflation of the USPTO's obligation to enact a regulation concerning the minimum threshold for a petition to be eligible for institution and the factors relevant to the discretionary denial of institution.

With regard to exhaustion, Plaintiffs claim that they do not need to exhaust their remedies because they are seeking to compel issuance of a regulation and not to compel action on a specific

proposed regulation. Opp. at 11-13. Plaintiffs, however, provide no support for such a distinction. Indeed, federal courts have specifically rejected the proposition that plaintiffs “are not required to exhaust claims that can be characterized as arising under 5 U.S.C. § 706(1),” the section of the APA concerning “agency action unlawfully withheld or unreasonably delayed.” *Gilmore v. Weatherford*, 694 F.3d 1160, 1169 (10th. Cir 2012). Plaintiffs’ admitted failure to exhaust therefore bars Count I.

Plaintiffs’ Count I fails on the merits as well. Plaintiffs posit three reasons that there is purportedly no distinction between an IPR petition’s eligibility for institution and the USPTO’s discretion to nonetheless deny institution. None of the three has merit.

First, Plaintiffs claim that § 316(a)(2) obligates the USPTO to promulgate regulations on discretionary denial because “the institution decision is lumped into one” and the precedential Board decisions laying out the factors for discretionary denial of IPR petitions address only that aspect of § 314(a), not the petitions’ threshold eligibility for IPR. Opp. at 14. This argument is unpersuasive on its face because nothing requires an adjudicating body to address issues in a particular order or to address every possible basis for its decision. *Cf. Pearson v. Callaban*, 555 U.S. 223, 236 (2009) (overruling earlier decision requiring courts to address two prongs of qualified immunity analysis sequentially). If the Board denies an IPR petition as a matter of discretion, then there is no need for the Board to also address whether the petition was actually eligible for institution. Additionally, Plaintiff is factually wrong. The Board has specifically acknowledged that the two aspects of § 314(a) are distinct, noting that, “if a petitioner fails to present a reasonable likelihood of prevailing[,] . . . the Board may deny the petitions on the merits and may choose not to reach a patent owner’s discretionary denial arguments.” *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11, 15 n.32 (P.T.A.B. Mar. 20, 2020).

Second, Plaintiffs argue that the threshold for granting IPR petitions and the discretion to deny eligible petitions are the same because the burden for both is on the petitioner. Opp. at 14-15. Even if it were true, the fact that a party bears two burdens does not make those burdens one and the

same. For example, the burdens of persuasion and production virtually always fall on the same party, but they are “two separate burdens.” *Microsoft Corp. v. i4i Ltd. P’ship*, 564 U.S. 91, 100 n. 4 (2011). Further, neither party to an IPR proceeding bears an exclusive burden. *See* 35 U.S.C. § 314(a) (determining likelihood of success based on both the IPR petition and the response to it); *Fintiv*, Paper 11 at 11, 16 (stating that “the parties should explain” factors relevant to discretionary denial).

Third, Plaintiffs quibble with Defendant’s use of the term “policies” or “factors” to describe the holdings of precedential Board decisions explaining the relevant considerations for discretionary denial of IPR petitions. *Opp.* at 15. While admitting that the terminology used is irrelevant to the obligations imposed by 35 U.S.C. § 316(a)(2), Plaintiffs prefer the term “standards” because it is the term used in that statutory provision. *Opp.* at 15. What Plaintiffs omit from this argument is that § 316(a)(2) specifies that the required regulation provide “standards for the showing of sufficient grounds to institute a review under section 314(a),” not standards to deny a review as a matter of discretion. (emphasis added) The interpretation of § 316(a)(2) that underlies Count I is thus refuted by the plain language of the statute, regardless of the terminology either party uses in its briefs.

B. Count II Should Be Dismissed.

Plaintiffs’ claim to set aside the precedential decisions laying out the factors relevant to the discretionary denial of IPR petitions is non-justiciable, and regardless, lacks merit.

1. *Announcing Non-Exhaustive, Non-Dispositive Factors for Discretionary Denial of IPR Petitions is Not a Final Agency Action Subject to APA Review.*

Count II is non-justiciable because adopting an internal agency policy that the Board must consider a set of non-exhaustive, non-dispositive factors before exercising its delegated discretion to deny an IPR petition eligible for institution has no direct legal consequences. *See Bennett v. Spear*, 520 U.S. 154, 178 (1997) (establishing the test for final agency action).

As an initial matter, even if the USPTO had adopted an outcome determinative rule concerning IPR institution, that would not be a final agency action because the institution decision

lacks any direct legal effect on the parties. “Although th[e] burden [of participating in an administrative proceeding] certainly is substantial, it is different in kind and legal effect from the burdens attending what heretofore has been considered to be final agency action.” *Standard Oil*, 449 U.S. at 242. Plaintiffs attempt to rebut this point by asserting that the lack of legal consequences is irrelevant because they are challenging the adoption of the policies governing the institution decision, not the institution decision itself. Opp. at 19. But if the institution decision lacks legal consequences, then a policy governing it also lacks the requisite consequences. As an alternative argument, Plaintiffs assert that the institution decision has legal consequences due to the supposedly increased chance of patent invalidation from the outcome of IPR proceedings. Opp. at 19. This assertion fails for the same reasons that it failed in the standing context. See § I.A, *supra*. Plaintiffs thus lack a justiciable claim because they are not challenging a final agency action.

Further, assuming *arguendo* that IPR institution had the requisite legal effect, the USPTO adopting non-exhaustive, non-dispositive factors to guide the IPR institution decision would not be a final agency action. Plaintiffs make two arguments in response to this point, but neither has merit.

Plaintiffs first argue that the challenged policies are final agency actions because they require the Board to “rule a certain way if the material facts are identical to those in the precedential decisions,” thereby limiting the Board’s discretion. Opp. at 18. However, merely imposing a requirement on an entity within an agency will not constitute a final agency action unless it “directly affect[s] the parties.” *Franklin v. Massachusetts*, 505 U.S. 788, 797 (1992). The challenged precedential decisions do not meet this test because the factors they set forth are non-dispositive and non-exhaustive and do not instruct adjudicators how to weigh these factors in any particular case. See, e.g., *Fintiv*, Paper 11 at 6 (requiring consideration of “other circumstances that impact the Board’s exercise of discretion, including the merits”). In other words, the Board could find in any given case that, despite the factors favoring one outcome, outside considerations warrant a contrary institution decision.

Courts have concluded that there has not yet been a final agency action in parallel circumstances. For example, the Fifth Circuit held that there was no final agency action from the issuance of a policy enumerating factors the agency “will consider” when making a decision whether to institute an administrative proceeding, despite the policy’s “mandatory tone,” because the factors were non-exhaustive and non-dispositive (*i.e.*, the agency “retain[ed] discretion whether to” initiate the proceeding). *Profls & Patents for Customized Care v. Shalala*, 56 F.3d 592, 597-98 (5th Cir. 1995). Likewise, in *Planned Parenthood of Wisconsin v. Azar*, the court held that there was no final agency action from a policy “govern[ing] how [agency grant] review panels will score applicants” when the ultimate decision-maker could consider factors other than the scoring criteria. 316 F. Supp. 3d 291, 300-01 (D.D.C. 2018), *vacated as moot*, 942 F.3d 512 (D.C. Cir. 2019). Even if an institution decision had the requisite legal effect—and, as discussed below, it cannot—it is the application of the factors for discretionary denial that would be a final agency action, not the enumeration of those factors in the abstract. *See id.* at 300 (no final agency action until non-exhaustive criteria were applied). Congress’s decision to foreclose review of such actions does not expand the scope of review under the APA.

Plaintiffs next claim that the challenged policies have a legal effect because they “obligate parties to make a particular showing to the agency.” *Opp.* at 18. However, “alter[ing] the manner in which the parties present themselves or their viewpoints to the agency” is the hallmark of a non-substantive policy, *JEM Broad. Co., Inc. v. FCC*, 22 F.3d 320, 326 (D.C. Cir. 1994) (citation omitted), which “generally do not qualify [as final agency actions] because they are not ‘finally determinative of the issues or rights to which [they are] addressed,’” *Am. Tort Reform Ass’n v. OSHA*, 738 F.3d 387, 395 (D.C. Cir. 2013) (citation omitted) (second alteration in original). *See also Valero Energy Corp. v. EPA*, 927 F.3d 532, 538 (D.C. Cir. 2019). Announcing the factors relevant to the USPTO’s discretionary denial of IPR only informs parties how best to present their viewpoints on institution, nothing more.

POET Biorefining, LLC v. EPA, 970 F.3d 392 (D.C. Cir. 2020), cited by Plaintiffs, is not to the contrary. *See* Opp. at 18. That case concerned agency guidance issued without notice-and-comment that effectively modified a regulation setting forth the showing required for regulated entities to meet their statutory obligations. *POET Biorefining*, 970 F.3d at 397-398, 405-06. When a new policy “effectively amends” a substantive rule, rather than merely interpreting it, the new policy is typically itself a substantive rule, the issuance of which will be a final agency action. *U.S. Telecom Ass’n v. FCC*, 400 F.3d 29, 34 (D.C. Cir. 2005). Here, by contrast, there were no preexisting rules governing the showings required for discretionary denial of IPR petitions. Thus, this case is governed by the general rule that a policy altering the way a party presents its views to an agency is not a final agency action. As such, Plaintiffs’ Count II should be dismissed.

2. *The USPTO Identifying Factors It Deems Relevant When Exercising Its Unfettered Authority to Decline to Institute IPR Proceedings Is a General Statement of Policy, Not a Substantive Rule.*

Notice-and-comment rulemaking is not required for general statements of policy, which are “statements issued by an agency to advise the public prospectively of the manner in which the agency proposes to exercise a discretionary power.” *Lincoln v. Vigil*, 508 U.S. 182, 196-97 (1993) (citation omitted). The USPTO has “complete discretion” to deny IPR petitions and, through the challenged precedential decisions, has announced how it will exercise that discretion. *Saint Regis Mohawk Tribe*, 896 F.3d at 1327.

Plaintiffs offer no reason that the challenged policies would constitute substantive rules that must be issued through notice-and-comment other than an unavailing attempt to distinguish this case from *Professionals and Patients*. *See* Opp. at 19-21. Plaintiff argues that *Professionals and Patients* differs from this case because the non-dispositive, non-exhaustive list of factors found not to be a substantive rule in that case only “clarifie[d]” existing law by codifying agency practice, rather than changing the law. Opp. at 20. However, the challenged precedential decisions have not changed existing law either. The USPTO has complete statutory discretion, and the challenged precedential decisions permit the

Board to consider any factors (enumerated or not) and to find those factors be determinative when exercising that discretion. Rather, like in *Professionals and Patients*, the precedential factors are ones that “[t]he Board consistently . . . considered” in earlier cases. *Gen. Plastic Indus. Co. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19, at 15 (P.T.A.B. Sept. 6, 2017).⁵ Plaintiffs therefore fail to distinguish this case from *Professionals and Patients*, and the Court should dismiss Count II for this reason as well.

CONCLUSION

For the reasons set forth in the Motion and herein, the Court should dismiss the Amended Complaint.

Dated: May 3, 2021

Respectfully submitted,

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⁵ See also *Fintiv*, Paper 11 at 5-7 & nn. 7-12 (collecting cases where “the Board’s decisions ha[d] balanced the” enumerated factors); *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6, at 7 (P.T.A.B. Feb. 13, 2020) (adopting factors identified in earlier *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 (Dec. 15, 2017)); *Becton, Dickinson*, Paper 8 at 17-18 (listing “common *non-exclusive* factors” the Board “ha[d] weighed” in previous cases).