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

US INVENTOR INC., TINNUS ENTERPRISES, LLC, 10TALES, INC., STRAGENT, LLC, 360 HEROS, INC., RAMZI MAALOUF, LARRY GOLDEN, WORLD SOURCE ENTERPRISES, LLC and E-WATCH, INC.,	§	
Plaintiffs,	§	
v.	§	**Civil Action No. 2:21-cv-00047**
DREW 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.	§	

PLAINTIFFS' OPPOSITION TO DEFENDANT'S MOTION TO DISMISS

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PLAINTIFFS' OPPOSITION TO DEFENDANT'S MOTION TO DISMISS

The Director's motion to dismiss lacks merit. This Administrative Procedure Act (APA) case arises because Congress ordered the USPTO Director to do something, but he hasn't done it yet. Meanwhile, the incomplete measures he did take did not observe lawful procedures required under the APA. Plaintiffs have standing and have pleaded a meritorious APA cause of action.

News reports suggest that the Director will soon be barred by issue preclusion from presenting most of his motion. (Exhibit A, "Tech Titans Strike Chord With Judge on PTAB Denials Suit" (Law360, March 11, 2021)). The Northern District of California held oral argument in March on the Director's motion to dismiss in *Apple v. Hirshfeld*, 5:20-cv-06128. Judge Davila appeared inclined to grant the *Apple* plaintiffs' claim that *Fintiv* discretionary standards are unlawful for lack of notice-and-comment rulemaking, which will moot the Director's arguments here about lack of standing and the allegedly non-substantive nature of the relevant rules. *Id.*

I. BACKGROUND

In 2011, Congress fashioned two agency post-grant tribunals (inter partes review and post grant review—IPR and PGR) to adjudicate patent validity. These tribunals proceed in two phases: first, the USPTO Director decides if there are sufficient grounds to institute a review, and second, the agency holds a "trial" if the Director has answered the first question "yes." The Patent Trial and Appeal Board (PTAB) conducts the trials, which result in patent invalidity 84% of the time, compared to 29% invalidity rates in federal district court trials. (Malone Decl., ECF#8-1 ¶ 11).

The issues in this case focus on the first phase. Part of the Director's "sufficient grounds" institution decision (which he has delegated the PTAB) centers on whether he will apply his broad discretion to deny review. Discretionary denial has become one of the most important "off-ramps" for patent owners, permitting them to escape a procedure that shuns juries and lacks the due process

and legal protections available in Article III courts. The Director has developed standards to guide this discretion and has bestowed "precedential" and "binding" effect on those standards. (ECF#13-3, at 11). But this happened without notice-and-comment rulemaking.

This was unlawful because 35 U.S.C. § 316(a)(2) requires the Director to perform proper rulemaking on this topic. In Section 316(a)(2), Congress commanded the Director to "prescribe regulations." The plain text of Section 316(a)(2) indicates that such regulations must "set[] forth the standards for the showing of sufficient grounds to institute a review under section 314(a)." Section 314(a), in turn, is the basis for the Director's discretion to deny review in the first place. *See Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2140 (2016).

The Federal Circuit recently confirmed that "precedential" designations by the Director on ad hoc adjudication decisions (which can be withdrawn any time without notice on a whim, ECF#13-3, at 11) do not constitute notice-and-comment rulemaking. *See Facebook, Inc. v. Windy City Innovations, LLC*, 973 F.3d 1321, 1347-54 (Fed. Cir. 2020) (*reinstated on rehearing in relevant part*). Even so, the Director has used such designations to make "binding" several groups of standards that apply to particular situations. For example, the *Fintiv* standards concern discretionary denial in view of parallel district court litigation. (ECF#13-3, at 64-81). The *Advanced Bionics* standards concern discretionary denial in view of the same or substantially the same prior art or arguments having been considered in prior USPTO proceedings. (ECF#13-3, at 40-62). And the *General Plastics* standards concern discretionary denial in view of multiple or serial PTAB petitions. (ECF#13-3, at 16-39). Under the Director's "SOP 2," he does not need to consult with the public or stakeholders before either bestowing or removing the "precedential" label that makes such standards binding on PTAB panels. (ECF#13-3, at 11).

Even though the APA provides a private right of action so that this Court might compel agency action unlawfully withheld (5 U.S.C. § 706(1)) or hold unlawful agency action without observance of procedure required by law (5 U.S.C. § 706(2)(D)), the Director has moved to dismiss under Fed. R. Civ. P. 12. The Director makes two basic arguments: lack of standing, and failure to state a claim. The Director is incorrect in both regards.

The Director presents inaccurate statements of the issues presented by his motion. The actual issues presented are:

1. Do Plaintiffs have Article III standing, where federal agency action and inaction addressed by the Amended Complaint caused patent owner Plaintiffs increased risk to their concrete property interests, and caused the nonprofit Plaintiff to divert resources and efforts in furtherance of its organizational mission?
2. Do the Director's discretionary standards for deciding whether to institute IPR and PGR petitions under 35 U.S.C. § 314(a) (*e.g.*, the *Fintiv*, *Advanced Bionics* and *General Plastics* standards) qualify as "standards for the showing of sufficient grounds to institute a review under section 314(a)," such that 35 U.S.C. § 316(a)(2) requires the Director to "prescribe regulations . . . setting forth" those standards?
3. Is the Director's declaring sets of standards "binding" on PTAB panels a final agency action, where no panel has discretion to reach alternate outcomes on facts "similar" to those in the ad hoc decisions that gave rise to those standards, and where those "binding" decisions determine whether property rights become subject to an 84% invalidation risk versus 29% in federal court (or 0% where no parallel litigation exists)?
4. Are the "binding" and "precedential" discretionary standards for the Director's "sufficient grounds to institute" decision substantive rules requiring notice-and-

comment, where they determine whether property rights become subject to an 84% invalidation risk versus 29% in federal court (or 0% where no parallel litigation exists)?

II. PLAINTIFFS HAVE STANDING

Plaintiffs have standing to bring this action. This is true both for patent owner Plaintiffs, and for nonprofit US Inventor. Only one Plaintiff needs legal standing for the Court to reject the Director's motion in this regard. *Texas v. Rettig*, 987 F.3d 518, 528 (5th Cir. 2021). Here, all Plaintiffs have standing.

A. Patent Owner Standing

The Director overlooks the most crucial aspect of the standing analysis. In a case seeking review of an agency's rulemaking activities, when assessing whether there is "concrete injury" among the plaintiffs, the Court is required to assume that the plaintiffs win on the merits. *NRDC v. Wheeler*, 955 F.3d 68, 77 (D.C. Cir. 2020) (in "determining standing, we must assume that petitioners will prevail on the merits of their argument."); *Texas v. United States*, 945 F.3d 355, 383 (5th Cir. 2020) (same). Put differently, the Court must assume for purposes of the standing analysis that the Director has, in fact, acted unlawfully to evade notice-and-comment rulemaking on discretionary standards for the institution of trial, and that lawful rulemaking would provide better discretionary off-ramps for patentees so they can more often avoid institution of IPR or PGR. *Id.* Likewise, the Court must assume the truth of the Complaint's allegations related to concrete injury. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992) (at the pleading stage, "general factual allegations of injury resulting from the defendant's conduct may suffice"). Under this framework, the Director's motion fails.

In *Lujan*, the Supreme Court considered the issue of standing in the context of a "procedural right." 504 U.S. at 572. The Court observed that

> "procedural rights" are special: The person who has been accorded a procedural right to protect his concrete interest can assert that right without meeting all the normal standards for redressability and immediacy. Thus, under our case law, one living adjacent to the site for proposed construction of a federally licensed dam has standing to challenge the licensing agency's failure to prepare an environmental impact statement, even though he cannot establish with any certainty that the statement will cause the license to be withheld or altered, and even though the dam will not be completed for many years.

Id. n.7. When a procedural deprivation creates a risk to an existing legal right or interest, that alone suffices to establish "concrete injury." The government causes concrete injury in depriving litigants of notice and comment rights from added *risk* to protectible interests. *Sierra Club v. Marsh*, 872 F.2d 497, 503 (1st Cir. 1989) (Breyer, J.) (holding a harm to the environment included "the added *risk* to the environment that takes place when governmental decisionmakers make up their minds without having before them an analysis (with prior public comment) of the likely effects of their decision . . . .") (emphasis in original); *Capitol Area Immigrants' Rights Coalition v. Trump*, 471 F. Supp. 3d 25, 38-39 (D.D.C. 2020) ("increased risk" to concrete interests shown).

Patents are property rights, and those rights are at greater risk when validity disputes get decided in IPR or PGR rather than Article III court proceedings (84% invalidity rate versus 29%). (Malone Decl., ECF#8-1 ¶ 11). Under *Lujan*, even though plaintiffs "cannot establish with any certainty" that the outcome of notice-and-comment rulemaking will lead to more frequent discretionary denials, that does not matter for standing. *Lujan*, 504 U.S. 572 n.7; *accord Summers v. Earth Island Institute*, 555 U.S. 488, 129 S. Ct. 1142, 1149-51 (2009) (before a settlement, forest enthusiasts had standing to bring action for notice-and-comment rulemaking on disposition of fire-damaged timber on government lands, even though they could not guarantee their viewpoints would prevail); *United States v. Johnson*, 632 F.3d 912, 921 (5th Cir. 2011) (for standing based on procedural injury from lack of notice and comment, plaintiff "need not establish that a favorable decision by this court would result in a different rulemaking by the Attorney General.").

Patentees analogize to *Lujan*'s property holders living adjacent to a site for a federally licensed dam. They have a legal interest (a property right) that might be placed at risk in the absence of their lawfully-required viewpoint on upcoming government action. Patentees also analogize to the forest enthusiasts in *Summers* who provably frequented the forest area subject to the regulations. Patentee property rights and prospective injury are at least as substantial and concrete as those belonging to the *Summers* enthusiasts, who merely asserted recreational interests in a particular forest's plants and animals. 129 S. Ct. at 1151.

The Director does not argue otherwise. Rather, the Director relies on the inapposite point that particular institution decisions are discretionary and not appealable. (Mot. 7-9). Ironically, the lack of appealability bolsters the "concrete injury" conclusion. It underscores that patentees suffer when deprived of a "seat at the table" during the creation of any discretionary denial framework, *i.e.*, denied notice-and-comment, because patentees have no right of review for individual decisions. The discretionary nature of individual decisions does not alter this conclusion. *See, e.g., Nat'l Venture Capital Ass'n v. Duke*, 291 F. Supp. 3d 5, 13-15 (D.D.C. 2017) ("lost opportunity" for discretionary relief caused by rule promulgated without notice-and-comment procedures conferred standing). Government agencies who start out with broad discretion regularly channel and constrict that discretion through rulemaking. *Graham v. Ashcroft*, 358 F.3d 931, 932 (D.C. Cir. 2004) ("In *Vitarelli* [*v. Seaton*, 359 U.S. 535, 539-40 (1959)], the Supreme Court held that even agencies with broad discretion must adhere to internally promulgated regulations limiting the exercise of that discretion."); *see also Watkins v. United States Bureau of Customs*, 643 F.3d 1189, 1198 (9th Cir. 2011) ("It is a familiar rule of administrative law that an agency must abide by its own regulations.") (citation omitted); *Am. Acad. of Pediatrics v. FDA*, 379 F. Supp. 3d 461, 481-85 (D. Md. 2019) ("*AAP*") (enforcement guidelines that amount to substantive rulemaking are for

that reason within an exception to agency's broad enforcement discretion). In this case, Congress required rulemaking, under 35 U.S.C. § 316(a)(2). For that, the Director possesses no discretion.

Likewise, the Director misidentifies patent owner Plaintiffs' injury as the expense and annoyance of litigation. (Mot. 8). That is a caricature. The concrete injury of the patent owner Plaintiffs is the risk to property rights (84% versus 29% invalidation rates), through deprivation of notice-and-comment-rights. This is also why it is beside the point for the Director to argue that the institution decision (viewed in a vacuum) does not alter a patentee's rights. (Mot. 10). This myopic statement ignores what the decision signifies: shunting of a patent dispute from a 29% invalidation rate proceeding (if litigation is pending at all) into an 84% invalidation rate proceeding. The Director ignores that discretionary denial is an important mechanism for patentees to avoid near-certain risk of destruction of their property rights.

The Director offers no true counterweight to legal standing in view of these statistics. Instead, the Director resorts to arguing that Plaintiffs' statistics are "untrue and misleading" (Mot. 10). Even if the Court could entertain this argument at the pleading stage, the Director has it backwards. It is the Director, not Plaintiffs, who offers misleading apples-to-oranges comparisons.

The Director points to statistics on the percentages of final written decisions as a percentage of "all petitions." (Mot. 10 n.9 and 10-11). That is the wrong baseline for comparison. In point of fact, Plaintiffs' 29% district court figure correctly refers to ***final determination*** outcomes on the litigated question of patent validity in Article III courts, which is ***not*** comparable to using "all petitions" at the PTAB in the PTAB denominator, as the Director would do. Using "all petitions" in the PTAB denominator would include matters that settle, as well as petitions deemed to present invalidity grounds not worthy of being litigated in Article III courts (*i.e.*, do not have a "reasonable" chance of being proved under the lower-than-Article III "preponderance" standard).

(Mot. 11). This latter category of validity challenges would not be brought in federal litigation at all by attorneys who comply with Fed. R. Civ. P. 11, since those attorneys are duty-bound only to bring "reasonable" invalidity claims under the higher "clear-and-convincing" standard. By contrast to the Director, Plaintiffs' apples-to-apples methodology compares actual ***final*** determinations in ***both*** Article III litigation ***and*** at the PTAB. This undisputedly results in a methodologically sound 84% to 29% comparison. The Director's factual attack fails at every level. It does not refute the severe risk to important property rights that the PTAB institution decision represents, especially since the Director applies standards developed without giving patent owners their "seat at the table" through notice-and-comment rulemaking

For these reasons, the Director's challenge to patent owner standing fails. Patent owner Plaintiffs clearly show concrete injury sufficient to convey Article III standing.

B. US Inventor Standing

US Inventor also has organizational standing. To meet this threshold, US Inventor's injury in fact does not even need to be "substantial," as it need not measure more than an "identifiable trifle." *OCA-Greater Houston v. Texas*, 867 F.3d 604, 612 (5th Cir. 2017) (describing the measure as "qualitative," not "quantitative"). For an organization like US Inventor, it is enough that the complained-of government action has caused the organization to take steps to counteract its effect by trying to mitigate its real-world impact on its members and the public. *Id.* (consumption of time and resources on education that would not otherwise be spent absent the challenged action). As long as the present litigation "is germane to the purposes of [the] organization," US Inventor has organizational standing. *Gulf Restoration Network, Inc. v. Salazar*, 683 F.3d 158, 168 (5th Cir. 2012). This comports with the law in other circuits, like the D.C. Circuit, which has held that an agency's failure to enact standards that impairs an organization's interests by depriving it of key

information relied upon to fulfill its mission suffices to demonstrate the organization's legal standing. *Am. Anti-Vivisection Soc'y v. USDA*, 946 F.3d 615, 619 (D.C. Cir. 2020) ("*AAVS*").

US Inventor amply meets the threshold for legal standing. It has needed to consume time and resources that would not otherwise be spent had there been lawful promulgation of notice and comment regulations. As pleaded in the Amended Complaint at paragraph 12:

> One of the primary ways in which US Inventor accomplishes its mission is to educate the public by providing information about the factors that will lead to a grant, versus a denial, of institution of AIA trials, particularly on discretionary factors. To do so, US Inventor relies (or would rely) on issued regulations published in the Federal Register for notice and comment, ultimately appearing in the Code of Federal Regulations. But the USPTO and its past and current Directors never promulgated any such notice-and-comment regulations on the topic of how discretionary considerations impact "sufficient grounds" for institution decisions. Because the Director's and the USPTO's inaction denied US Inventor access to authoritative and clear key information it wishes to use in its routine information dispensing activities and to fulfill its mission, the USPTO and the Director have inhibited its daily operations. This constitutes organizational injury to US Inventor.

(ECF#6, ¶ 12). And as explained in even greater detail in the previously-filed Declaration of Josh Malone:

> Without rules, US Inventor is temporarily forced to advise its members that not participating in the U.S. patent system, reducing investments in inventing, and/or to keeping their inventions secret may now (solely because of AIA trial reviews) be the best way forward for their situation. These mitigation measures undermine our core mission of fostering innovation and helping inventors to achieve the American Dream, build businesses, and create jobs.

(ECF#8-1 ¶ 26). Other facts also support standing. Specific activities of US Inventor became necessary in support of its inventor-rights mission ***only because of the absence*** of notice-and-comment rules on discretionary standards. This is like the *AAVS* nonprofits who had to undertake additional work for their mission because the USDA snubbed Congress by not regulating birds.

For example, in 2020, US Inventor dedicated website resources and personnel time to creating a portal for inventors to deliver their opinions to the Director on their yearning for

certainty in institution phase discretionary decisions, and for notice-and-comment rules. *See* https://usinventor.org/ptabcomments/. This would have been unnecessary if those rules already existed. Likewise, also in 2020, US Inventor fellow Josh Malone (in his US Inventor capacity) published commentary to inventors on topics germane to the currently-defective "precedential" rule sets: the environment for discretionary denial in view of parallel litigation (*Fintiv* issues) and serial and parallel petitions (*General Plastics* issues). *See* https://www.ipwatchdog.com/2020/11/10/give-inventors-chance-ptab-must-regulated/id=127182/. This too would have been unnecessary if lawful rules already existed. Third, also in 2020, US Inventor filed a full-blown petition for rulemaking at the agency, in an attempt to persuade the agency to act legally. (Malone Decl., ECF#8-1). This as well would have been unnecessary if lawful rules already existed.[1] The Director cannot seriously contend that US Inventor has been unaffected by the agency action and inaction surrounding the mishandling of discretionary denial standards. It has had to divert resources in ways that it otherwise would not have if the Director had acted lawfully.

Also ignored by the Director, US Inventor has shown "informational injury." This is a type of injury that gives rise to standing for organizations when a plaintiff has been deprived of information that a statute requires the government to disclose, and it suffers (through such denial) the type of harm Congress intended to prevent by requiring disclosure. *FEC v. Akins*, 524 U.S. 11, 21-23 (1998). The D.C. Circuit has specifically found organizational standing in the context of an agency's inaction over many years in promulgating required regulations, because of the absence

[1] The Director might argue that spending resources on the present litigation does not count for standing purposes. The August 2020 petition, however, involved resources diverted to an effort that is *not* the present litigation. For example, the present suit does not seek review of any action or inaction on that intra-agency petition for rulemaking. That petition was a pure mitigation step completed before any litigation began, and demonstrates US Inventor standing.

of required and Congressionally-mandated information that would be published in the form of agency regulations. *AAVS*, 946 F.3d at 619. For example, in *AAVS*, the USDA caused informational injury to animal welfare organizations interested in the care and welfare of birds, by failing to promulgate required regulations on the appropriate handling of birds. *Id.* The "failure to issue standards" alone caused sufficient concrete injury based on that being inaction depriving the organization of key information it relied on to fulfill its mission. *Id.* The same is true here. Just like bird regulations at the USDA, lawful regulations on the subject of standards for discretionary denial have not yet issued. This has harmed US Inventor as an organization, forcing it to divert resources to collecting and disseminating information it would otherwise never have done.

The District of Maryland rejected arguments similar to those presented by the Director here. In *AAP*, the FDA issued "Guidance" that delayed the time period otherwise set by regulation for e-cigarette manufacturers to file authorization applications. This extension delayed discretionary enforcement actions by the FDA. 379 F. Supp. 3d at 472. It also delayed plaintiffs' receipt of e-cigarette information to support their anti-addiction mission. *Id.* at 475-77. The FDA argued lack of standing, but the court rejected that challenge. *Id.* at 474-78. The court reasoned that the FDA's "Guidance" prevented information from getting to the plaintiffs, causing the organizations to divert resources to identify and counteract the government's unlawful practices, and therefore impeded and frustrated their core mission. *Id.* at 478. The same has occurred here.

For these reasons, the Director's challenge to US Inventor's organizational standing fails.

III. NO EXHAUSTION ISSUE EXISTS

In a first Rule 12(b)(6) challenge specific to Count I, the Director contends that Count I should be dismissed for failure to exhaust administrative remedies. The Director misapprehends the nature of this count. It does not seek review of action or inaction on any specific petition

brought within an agency decision process. It is rather an action under Section 706(1) of the APA to compel agency action unlawfully withheld. Such an action does not depend on adjudication of a rulemaking petition, nor on a plaintiff even having brought an intra-agency petition for rulemaking at all. *See AAVS*, 946 F.3d at 619-21 (vacating dismissal of Section 706(1) complaint alleging many years of the USDA's failure to conduct Congressionally-required rulemaking about birds, without mention of plaintiffs ever having brought an intra-agency rulemaking petition at all). As *AAVS* shows, a Section 706(1) action may stand alone (with or without a companion agency petition), and is meritorious where (as here) there was a Congressional mandate to promulgate regulations but the agency did not completely fulfil it. *Id.* (regulations complete for other animals, but not "birds").

The Director's cited authorities do not say otherwise. Those decisions do not interpret a district court's authority under Section 706(1) in view of an agency's failure to conduct Congressionally-mandated rulemaking in the first instance, where no statute channels a petitioner to address the omission to the agency first. *See Auer v. Robbins*, 519 U.S. 452, 459 (1997) (argument *under Section 706(2)(A)* that failure to amend a *complete and lawful* rule in light of an intervening court decision was arbitrary and capricious better presented as a petition to the agency); *Gulf Restoration Network v. McCarthy*, 783 F.3d 227, 235 (5th Cir. 2015) (agency petition actually filed, deemed final when denied); *In re Howard*, 570 F.3d 752, 757-58 (6th Cir. 2009) (Mine Act provision expressly required initial presentation of "objection" to enactment or nonenactment of regulation to the Secretary); *In re City of Fall River, Mass.*, 470 F.3d 30, 33 (1st Cir. 2006) (denying mandamus in the court of appeals, in view of availability of APA injunctive relief in a district court); *Weight Watchers Int'l, Inc. v.* FTC, 47 F.3d 990, 992 (9th Cir. 1995) (agency petition actually filed, deemed final when denied); *Clark v. Busey*, 959 F.2d 808, 812-13 (9th Cir.

1992) (intermediate agency step of publishing a summary of a petition for rulemaking not a final agency action subject to judicial review). Unlike *AAVS*, these authorities are not on point about this Court's authority under Section 706(1) in view of the Director's Section 316(a)(2) obligation.

Though largely irrelevant, the Director urges that he has requested comment on issues surrounding discretionary denial, and 822 comments have poured in. (Mot. 13-14). The Director's admission that "[t]he diversity of views among the 822 comments demonstrates the complexity and importance" of discretionary factors (*id*. at 14) underscores the fact that ad hoc precedential designations are no substitute for formal rulemaking, illustrating the vast concern of those who have been left out of the rulemaking process. In any event, the Director does not claim (nor could he) that this comment-request procedure is the same thing as an actual rulemaking process under APA Section 553 (it is not). Moreover, the Director misstates the significance of his taking this less-than-half-measure. That request for comment process only began ***after*** substantially the same plaintiffs attempted intervention to bring the identical Section 706(1) claims in the Northern District of California, in *Apple v. Hirshfeld*. Rather than show agency alacrity, the Director's strangely-timed comment-request procedure only highlights his noncompliance with proper APA rulemaking procedures. His unilateral action certainly has no bearing on whether Count I states a cause of action. *See AAP*, 379 F. Supp. 3d at 470 (over 15,000 comments about agency's proposed alteration to challenged "guidance" did not obviate reviewability of guidance).

IV. "STANDARDS" FOR THE SHOWING OF SUFFICIENT GROUNDS TO INSTITUTE UNDER SECTION 314(a) INCLUDE DISCRETIONARY STANDARDS

In a second and final challenge specific to Count I, the Director argues that Plaintiffs have misinterpreted the Director's obligations to promulgate regulations under Section 316(a)(2). The Director argues that discretionary standards are implicitly excluded. The Director is incorrect. The

"standards" for determining "sufficient grounds" under Section 314(a) include "standards" governing discretionary denial.

First, no statutory text supports the Director's novel argument about Section 314(a), that it cleaves a difference between "minimum requirements" for grant of institution, versus "discretion to deny IPR petitions that meet those requirements." (Mot. 15). The institution decision is lumped into one.[2] *General Plastics*, *Advanced Bionics* and *NHK* all discretionarily denied without addressing the "reasonable likelihood" factor. (ECF#13-3). Section 314(a) is the undisputed source of the Director's authority to apply discretionary standards in the first place, thus meeting the Section 316(a)(2) definition of "standards . . . under section 314(a)." *See Cuozzo*, 136 S. Ct. at 2140; *see also SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1356 (2018) ("§ 314(a) invests the Director with discretion on the question *whether* to institute review . . . ," emphasis in original); *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016) (citing Section 314(a), holding "the PTO is permitted, but never compelled, to institute an IPR proceeding"). Consequently, Section 314(a) is not bifurcated into "sufficient grounds" versus "discretion" as the Director argues, because "standards for the showing of sufficient grounds to institute a review under section 314(a)" ***include*** factors that relate to discretion.

Second, the standards themselves all place a burden of proof on a petitioner. This means, as a matter of logic, that these standards are within petitioner's "showing . . . under section 314(a)." Under *General Plastics*, a petitioner must provide an "adequate explanation" of delay between serial petitions. (ECF#13-3, at 24). Under *Advanced Bionics*, a petitioner must make "a showing" to "demonstrate error" in the handling of the same or similar prior art during USPTO examination.

[2] As additional proof of this, the petitions recently filed against 10Tales and Stragent each seek institution (*i.e.*, each try to advance "sufficient grounds") by arguing against *discretionary* denial in the *opening* paper. *See, e.g.*, Petitions in IPR2021-00417, IPR2021-00476.

(ECF#13-3, at 47). And under *Fintiv*, a petitioner has to explain its delay during parallel litigation in the filing of its petition, and must explain why "the merits" might be "particularly strong" so as to favor institution. (ECF#13-3, at 75-79).

Finally, the Director in his brief tries not to describe his discretionary standards as "standards" at all. (Mot. 1-2 (calling them "factors"), 12, 16 (calling them "policies")). This is presumably to distance "factors" and "policies" from the statutory language that brings them into the Director's obligations under Section 316(a)(2) (mentioning "standards . . . under section 314(a)"). Such cosmetic word choice will not work. The Federal Circuit itself calls these "standards." *Mylan Labs. Ltd. V. Janssen Pharma., N.V.*, 989 F.3d 1375, _ (Fed. Cir. 2021) ("In exercising its discretion, the Board applied its six-factor ***standard*** for evaluating whether to deny institution in view of an earlier trial date in a co-pending district court proceeding." Emphasis added). The Federal Circuit has already doomed the Director's word-play strategy.

Since the statutory argument is so weak, the Director lobs an undeveloped argument in footnote 13 that there is a 6-year limitations problem. But the statute of limitations is not at issue in this case. An APA claim accrues on the ***later*** of final adoption of an agency action, ***or*** the adverse application of the action against the claimant. *Hyatt v. U.S. Patent & Trademark Office*, 904 F.3d 1361, 1372 (Fed. Cir. 2018). "Rules" for discretionary standards did not exist until the Defendant began making the insufficient and unlawful "precedential" designations, which first occurred on October 17, 2017. https://www.law360.com/articles/975848. Thus, the earliest "final" adoption of an agency action at issue here occurred on October 17, 2017, making the limitations period irrelevant. In addition, adverse application of the failure to promulgate notice-and-comment rules renews each time a US Inventor member is served with an AIA trial petition. The record shows at least two examples, each from this year. *See* Russek and Gordon Declarations (ECF##8-2, 8-3).

For the foregoing reasons, the Director has failed to present any meritorious argument that this Court should dismiss Count I.

V. DISCRETIONARY STANDARDS ARE SUBSTANTIVE RULES REQUIRING NOTICE-AND-COMMENT RULEMAKING

The Director's specific arguments against Count II also fail. For this count, Plaintiffs allege that precedential designations of ad hoc adjudication decisions, which establish discretionary denial standards, amount to unlawful promulgation of rules—*i.e.*, without notice and comment under APA Section 553. Thus the Court may grant relief under APA Section 706(2)(D) to set aside such agency action that was without proper procedure required by law. The Director contends that Plaintiffs fail to state a claim because the rules are not "substantive." The Director is wrong.

First, the Director argues that the rule sets in question (going by labels such as *Fintiv*, *Advanced Bionics* and *General Plastics*) are not final agency actions. The Director claims that they do not mark the culmination of the agency's decisionmaking process, and no rights or obligations have been determined from which legal consequences will flow. (Mot. 16-17). But the Director's position rests entirely on his characterization of these rules as "internal agency policy." (Mot. 16). The Federal Circuit has already held otherwise. They are "standards." *Mylan*, *supra*. But regardless of label, they are substantive rules that embody a "final agency action."

A final agency action is one (1) that "mark[s] the consummation of the agency's decisionmaking process" and (2) "by which rights or obligations have been determined, or from which legal consequences will flow." *Bennett v. Spear*, 520 U.S. 154, 177-178 (1997) (quotation marks omitted). "The core question is whether the agency has completed its decisionmaking process, and whether the result of that process is one that will directly affect the parties." *Or. Nat'l Desert Ass'n v. U.S. Forest Serv.*, 465 F.3d 977, 982 (9th Cir. 2006) (quotation marks omitted). Courts consider "both the practical and legal effects of the agency action," defining the finality

requirement "in a pragmatic and flexible manner." *Havasupai Tribe v. Provencio*, 906 F.3d 1155, 1163 (9th Cir. 2018) (citation and quotation marks omitted), *cert. denied*, 139 S. Ct. 2621 (2019). The Director's discretionary rules satisfy both elements of the *Bennett* test because they set forth standards that the PTAB is ***required*** to apply in making institution decisions and whose application determines whether sufficient grounds to institute exist. *See AAP*, 379 F. Supp. 3d at 489-90 (enforcement guidelines that extended e-cigarette application deadlines deemed "final" as agency's definitive legal position regarding its statutory authority, causing immediate burdens on nonprofits). These "practical and legal effects" are markers of final agency action.

These discretionary rules are neither "tentative [nor] interlocutory," and "mark[s] the consummation of the agency's decisionmaking process." *Bennett*, 520 U.S. at 178. Thus the first *Bennett* prong is satisfied. The Director decided to adopt these rules by designating ad hoc decisions containing them as precedential. *See POET Biorefining, LLC v. EPA*, 970 F.3d 392, 404 (D.C. Cir. 2020) (guidance at issue satisfied the first *Bennett* prong because it "consistently speaks in the [agency's] voice" and was issued by an Assistant Administrator who was the agency head's "principal advisor" on the issue at hand). The PTAB applies the rules to decide whether there are sufficient grounds to grant IPR and PGR petitions because the Director "has designated [these decisions] precedential." *See, e.g.*, *Apple Inc. v. Maxell, Ltd.*, No. IPR2020-00407, Paper 12 (P.T.A.B. Aug. 11, 2020), at 14-15. The PTAB's implementation of the rules is "further proof that [the USPTO] ha[s] reached a final decision." *Pub. Util. Dist. No. 1 of Snohomish Cty. v. Bonneville Power Admin.*, 506 F.3d 1145, 1152 (9th Cir. 2007) (agency's implementation of its decision showed the first *Bennett* prong was met).

These discretionary rules also satisfy the second *Bennett* prong. The rules are those "by which rights or obligations have been determined, or from which legal consequences will flow,"

Bennett, 520 U.S. at 178, because they "impose[] obligations on the agency" to consider certain standards in making its institution decisions, and rule a certain way if the material facts are identical to those in the precedential decisions. *Sierra Club v. Trump*, 929 F.3d 670, 698 n.23 (9th Cir. 2019). The challenged rules meet this test because they govern the PTAB's decisions on IPR and PGR petitions by setting out standards that the PTAB must consider in making institution decisions. For example, in *POET Biorefining*, the D.C. Circuit held that the challenged guidance "carries legal consequences because it withdraws ***some*** of the discretion . . . afforded" the agency in evaluating applications for regulatory approval. 970 F.3d at 405 (emphasis added).

Moreover, the discretionary rules obligate parties to make a particular showing to the agency—*i.e.*, whether the *Fintiv*, *Advanced Bionics* or *General Plastics* standards weigh for or against institution. "[O]bligations have been determined" by agency action, and the second *Bennett* prong has been met because the agency requires a party to make a particular showing under a regulatory scheme. *Bennett*, 520 U.S. at 178. Thus, in *POET Biorefining*, the court determined that challenged guidance met the second *Bennett* prong because it "impose[d] obligations" on regulated parties to "demonstrate to [the agency] the reliability of their methods" for measuring the contents of their fuel as a condition of obtaining regulatory approval of the fuel. 970 F.3d at 405.

Finally, the "practical and legal effects" of the discretionary rules for petitioners and patent owners are large. As explained, the PTAB must apply the rules as they are written, and that has resulted and will result in the inappropriate grant of IPR and PGR petitions filed against Plaintiffs, depriving them of the benefits Congress intended from an institution regime that was designed to have input from stakeholders incorporated into that rulemaking.

The Director contends that the discretionary rules "cannot effect a certain legal change" for patentees because "the Board can nonetheless decide that those factors are outweighed by other

considerations." (Mot. 17-18). This faulty logic ignores how "binding" and "precedential" standards work. The mere fact that other standards might creep into decisionmaking in individual cases on top of existing standards does not negate that the standards the Director requires the PTAB to apply in precedential decisions are "binding" on all future PTAB panels. If the material facts line up with those decisions marked "precedential," individual panels have ***no*** discretion.

The Director also urges that the "institution decision" is not a final agency action (Mot. 18), but again, this sidesteps the relevant considerations. It is the precedential designation of ad hoc adjudication decisions that created the discretionary standards in the first place that Count II addresses. It is undisputed that the Director has made "final" precedential designations on those respective sets of standards. Whether a given institution decision amounts to a final agency action is not the question before the Court. In any case, as discussed before, such institution decisions do affect substantial rights, insofar as the discretionary standards embody crucial off-ramps for patentees to avoid near certain (84%) patent invalidation.

Finally, the Director also argues that the discretionary rules are simply unreviewable "general statements of policy" (Mot. 18-20). This is incorrect given the rules' undeniably binding force and the fact that they are dispositive of IPR and PGR petitions. The relevant inquiry is the text of SOP 2, not the content of the rule sets. SOP 2 dispositively describes precedential decisions as "binding" on future AIA panels. (ECF#13-3, at 11).

Indeed the "critical question in distinguishing between legislative rules and general statements of policy is whether the statement 'is of ***present*** binding effect; if it is, then the APA calls for notice and comment.'" *Casa de Md. v. United States Dep't of Homeland Security*, 924 F.3d 684, 702 (4th Cir. 2019) (emphasis added, also referring to "binding norms"); *see also Colwell v. Dep't of Health Human Servs.*, 558 F.3d 1112, 1124 (9th Cir. 2009) ("critical factor" is

"extent to which 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." (alterations omitted)). Attempting to counter this foundational legal principle, the Director cites *Professionals & Patients for Customized Care v. Shalala*, 56 F.3d 592, 593-594 (5th Cir. 1995), for the proposition that non-exhaustive and non-exclusive discretionary factors are somehow inherently non-substantive and exempt from the notice-and-comment process. (Mot. at 19-20.) But the enforcement guidelines at issue in *Professionals & Patients* involved "nothing new or changed about the law that [the challenged regulation] clarifies." 56 F.3d at 602. They "merely restate[] a long-standing [agency] position" as the district court had found. *Id*. at 597. And unlike here, the *Professionals & Patients* list of enforcement guidelines, on its face, included text about its non-binding nature: *i.e.*, presence of all factors did not require FDA enforcement, and absence of all factors did not bar FDA enforcement. By contrast, the "precedential" designation under SOP 2 links a particular collection of facts with a particular adjudicative outcome, making named standards "binding Board authority in subsequent matters involving similar facts or issues." (SOP 2, ECF#13-3, at 11). The rules at issue here are prospective and binding on IPR panels; they are not clarifications of a "long-standing [agency] position," and a convergence of "similar facts" in a future case compared to those in the designated decisions leaves ***no*** discretion on the part of future PTAB panels to reach a different outcome. *Professionals & Patients* is inapposite.

While "binding" tests emerged as multi-factor, "non-exclusive" or "non-exhaustive," it is improper bootstrapping to say this makes resulting rules "nonsubstantive" or "nonlegislative." The fact that the Director has made what should have been notice-and-comment rules nonpredictive of some future outcomes speaks to injury, not a justification to sidestep notice-and-comment and escape mandates in Section 316(a)(2) and the APA Section 706(2)(D). Plus, the rules are

"substantive" inasmuch as they define how to exit an 84% invalidation rate proceeding. Moreover, the Director's decision to promulgate the rules through a procedural shortcut (precedential designation) rather than through notice-and-comment rulemaking (as he was required to do) does not change the binding nature of the rules or their impact on the parties. "[I]t is well established that . . . guidance issued without formal notice and comment rulemaking can qualify as final agency action." *Arizona v. Shalala*, 121 F. Supp. 2d 40, 48 (D.D.C. 2000); *see also POET Biorefining*, 970 F.3d at 404-406 (agency "Guidance" issued without notice and comment was reviewable final action). The Director cannot insulate improper promulgation of rules from judicial review by choosing to disregard notice-and-comment requirements.

For the foregoing reasons, the Director's challenges to Count II all fail, just like the challenges to Count I. The "binding" rules are substantive and not "general statements of policy." Their existence as rules (albeit promulgated through improper procedures) cannot be disputed, nor the Federal Circuit's holding that they are rules that sidestepped "notice-and-comment." *See Facebook*, 973 F.3d at 1347-54. The Court should deny the motion to dismiss as to Count II.

VI. CONCLUSION

For the foregoing reasons, Plaintiffs have standing and they have properly stated a claim, for both Count I and Count II. The Court should deny the Director's motion to dismiss in its entirety. At the very least, any dismissal should be without prejudice to permit Plaintiffs to cure any alleged defect.

Dated: April 26, 2021

Respectfully submitted,
/s/ Michael C. Smith

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EXHIBIT A

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Tech Titans Strike Chord With Judge On PTAB Denials Suit

By **Britain Eakin**

Law360 (March 11, 2021, 10:19 PM EST) -- A California federal judge seemed persuaded at times on Thursday by an argument from Apple and other tech giants that the Patent Trial and Appeal Board's practice of denying patent reviews due to looming trials in parallel district court litigation is unlawful.

In considering their motion for summary judgment to strike down the practice of denials and bar the U.S. Patent and Trademark Office from further relying on it, U.S. District Judge Edward J. Davila said that he had some concerns about how the USPTO director implemented the practice. During the roughly 90-minute Zoom hearing, he questioned whether it should have gone through notice-and-comment rulemaking under the Administrative Procedure Act, as the tech companies have alleged in their **August suit challenging the practice**.

Judge Davila simultaneously considered the USPTO's motion to dismiss the case, with the agency arguing during the hearing that the tech titans haven't been able to show any concrete injury, and therefore don't have the ability to sue for an APA violation.

The issue at the heart of Thursday's hearing stems from two precedential PTAB decisions known as NHK Spring and Fintiv, the latter of which laid out six factors for the board to consider when weighing whether to exercise its discretion to deny patent reviews if parallel district court litigation is at an advanced stage.

The tech companies, including Apple, Cisco, Intel, Google and Edwards Lifesciences, contend that the NHK Spring and Fintiv framework not only violates the APA but also goes against the America Invents Act because its "vague factors lead to speculative, unpredictable, and unfair outcomes" that can have the effect of essentially shutting some petitioners out from being able to challenge patents at the PTAB.

Judge Davila took particular interest in whether the board's application of the precedential decisions amounts to a substantive rule that required formal agency rulemaking.

During the hearing, U.S. Department of Justice attorney Gary Feldon argued that the PTAB's practice of discretionarily denying patent reviews isn't a substantive rule because the outcome isn't predetermined. To support that assertion, he said that the board has instituted 292 patent reviews and denied 119 petitions in a survey of institution decisions in which the board applied the NHK Spring and Fintiv factors.

But Judge Davila appeared skeptical, suggesting that the application of the precedential decisions

changed the landscape so sufficiently that it should have gone through notice-and-comment rulemaking.

"It just seems to have changed the whole procedural aspect of IP practice, and to such an extent that it's not something that is in the purview of the director's unilateral decision," the judge said.

Arguing on behalf of Apple, Cisco and Intel, Catherine M.A. Carroll of WilmerHale said that the PTAB's practice of discretionarily denying patent reviews is a substantive rule because the NHK and Fintiv decisions are binding on the board since administrative patent judges can't not apply them.

Judge Davila asked the attorney about the genesis of the Fintiv factors, noting that they don't appear anywhere in the America Invents Act. Carroll said the board surveyed its decisions after NHK Spring, which was the first PTAB decision to hold that a district court case set to go to trial before the PTAB's final decision is due weighs in favor of denying review.

The board noticed in its survey that the same factors came up again and again in those decisions, leading them to become the six factors laid out in the Fintiv decision, Carroll said. But she called those factors arbitrary, saying they often lead to "absurd results" when, for example, a looming trial date that the board relied on to deny a patent review gets pushed back.

Feldon contested that argument, claiming that the framework "makes perfect sense" from an administrative perspective. If the board had unlimited resources and could implement every single patent review, that would be one thing, he said. But the reality is that the board has limited resources and must choose wisely which petitions to institute on. If a district court will likely resolve the validity issue first, he said that constitutes a valid reason to deny a petition.

Feldon said that the APA carves out internal rules of agency procedure, organization and policy that are binding on members of the agency. Just because the board has to follow the precedential decisions doesn't mean that it's going to be a substantive rule as applied to the regulated parties — in this case, patent owners and the petitioners challenging patents.

He said that the USPTO director has authority without going through notice-and-comment rulemaking to tell its employees how to act, and it's only when that outcome has a determinative effect on the regulated parties that it becomes a substantive rule.

"We don't have that here, that's not present here?" Judge Davila asked in response.

"Absolutely not," Feldon responded. He went on to say that the factors are simply a set of criteria that the board must consider when deciding whether to exercise its discretion. Given that nearly two-thirds of petitions still get instituted, the attorney said that there is no guaranteed or predetermined outcome.

But Judge Davila expressed concern that application of the NHK Spring and Fintiv framework is like assigning decisions "to a moving target," in that trial dates often change. "How can you assign a decision to that?" he asked. "That seems to be arbitrary and inappropriate."

The USPTO undertook official rulemaking on discretionary denials, but it didn't start until after this suit was filed. **It drew in more than 800 comments**.

At the end of Thursday's hearing, Judge Davila said that he would take the matter under submission, noting that he'd like to do some careful reading before making a decision.

Apple, Cisco and Intel are represented by Mark D. Selwyn, Catherine M.A. Carroll, David M. Lehn, Rebecca Lee and Alyson Zureick of WilmerHale.

Google is represented by Daniel T. Shvodian, Theresa Nguyen and Andrew T. Dufresne of Perkins Coie LLP.

Edwards Lifesciences is represented by John B. Sganga and Christy G. Lea of Knobbe Martens.

The USPTO is represented by Michael D. Granston, Lesley Farby and Gary Feldon of the U.S. Department of Justice's Civil Division.

The case is Apple Inc. et al. v. Hirshfeld, case number 5:20-cv-06128, in the U.S. District Court for the Northern District of California.

--Additional reporting by Dani Kass and Tiffany Hu. Editing by Steven Edelstone.

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

US INVENTOR INC., TINNUS ENTERPRISES, LLC, 10TALES, INC., STRAGENT, LLC, 360 HEROS, INC., RAMZI MAALOUF, LARRY GOLDEN, WORLD SOURCE ENTERPRISES, LLC and E-WATCH, INC.,	§	
Plaintiffs,	§	
v.	§	**Civil Action No. 2:21-cv-00047**
DREW 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.	§	

ORDER DENYING DEFENDANT'S MOTION TO DISMISS

Pending before the Court is the Motion to Dismiss filed by Defendant Drew Hirshfeld ("the Director") (Docket #19) and Plaintiffs' response to same. Having considered the motion and response thereto, the Court finds that the Director's motion to dismiss should be denied in its entirety.

IT IS THEFEFORE ORDERED that Defendant's Motion to Dismiss be and hereby is DENIED in its entirety.