Case No. 25-132

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

IN RE SAP AMERICA, INC.,

Petitioner.

On Petition for a Writ of Mandamus to the
United States Patent and Trademark Office in IPR2024-01495

BRIEF OF AMICUS CURIAE PUBLIC INTEREST PATENT LAW INSTITUTE IN SUPPORT OF PETITION FOR A WRIT OF MANDAMUS

Alex H. Moss
PUBLIC INTEREST PATENT LAW INSTITUTE
79405 Hwy 111 Ste 9-414
La Quinta CA 92253
(818) 281-2191
alex@piplius.org

Counsel for Amicus Curiae

June 20, 2025

CERTIFICATE OF INTEREST

Pursuant to Federal Circuit Rules 29(a) and 47.4, counsel for the Public Interest Patent Law Institute certifies that:

1. The full name of the party that I represent is:

   Public Interest Patent Law Institute.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) I represent is: None.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party I represent are: None.

4. The names of all other law firms, partners, or associates who have not entered an appearance in this appeal and either appeared for the party I represent in the originating court or are expected to appear in this Court are: None.

5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal: None beyond those disclosed by the parties.

6. No disclosure regarding organizational victims in criminal cases or debtors or trustees in bankruptcy cases is applicable under Fed. R. App. P. 26.1(b) or (c).

June 20, 2025

/s/ Alex H. Moss
Alex H. Moss

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INTEREST OF AMICUS CURIAE[1]

The Public Interest Patent Law Institute ("PIPLI") is a nonprofit, nonpartisan public interest organization dedicated to ensuring the patent system promotes innovation and access for the public's benefit.

Many people contribute to and depend on technological advances but do not acquire or assert patents, including researchers, small businesses, and medical patients. These constituencies often have difficulty navigating the patent system and rarely find their interests adequately represented. Their absence makes it more difficult for the patent system to strike a balance that promotes innovation effectively and equitably.

PIPLI works to improve the patent system's ability to strike this balance. In service of its mission, PIPLI provides assistance, education, and counseling to people navigating the patent system; conducts policy research; and advocates for the public's interest in court and agency proceedings.

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[1] No party or party counsel wrote any part of this brief. No party or party's counsel made a monetary contribution intended to fund the preparation or submission of this brief. This brief is accompanied by a motion seeking leave to file.

PRELIMINARY STATEMENT

At stake in this case is a federal agency's disregard for the rule of law and the resulting harm to both private parties and the public at large. The United States Patent and Trademark Office (USPTO) retroactively applied a new and unexplained policy to deny an inter partes review (IPR) petition that, under its prior and well-established policy, would have proceeded. In doing so, the agency not only failed to follow the procedural requirements governing policy changes, but also violated fundamental principles of due process and administrative law.

The extraordinary circumstances here—including the USPTO's abrupt and unexplained policy reversal, its departure from precedent, and its retroactive application to pending proceedings—threaten the integrity of the IPR system and undermine public confidence in the agency's fidelity to the law. These failures carry serious consequences: IPR proceedings are essential to the public's ability to challenge invalid patents, and as research shows, they play a critical role in lowering prescription drug prices and promoting fair competition.

Extraordinary relief is warranted to correct the agency's unlawful conduct and to protect the public's interest in a stable, transparent, and lawful patent system.

ARGUMENT

I. The Extraordinary Circumstances of this Case Necessitate Extraordinary Relief.

A. The USPTO's Defiance of the Rule of Law.

The USPTO's retroactive application of its changed discretionary denial policy violates the principle of the rule of law on which our country's justice system rests. As the Supreme Court has explained: "Living under a rule of law entails various suppositions, one of which is that '(all persons) are entitled to be informed as to what the State commands or forbids.'" *Papachristou v. City of Jacksonville*, 405 U.S. 156, 162 (1972); *see also Grayned v. City of Rockford*, 408 U.S. 104, 108–09 (1972) ("[W]e insist that laws give the person of ordinary intelligence a reasonable opportunity to know what is prohibited, so that he may act accordingly.").

1. *The USPTO's Prior Discretionary Denial Policy*

SAP, and all entities with pending IPR petitions, were entitled to the application of rules that were in force when their petitions were filed. The USPTO's abrupt and unexplained departure from those rules, applied retroactively, deprived them of that right.

This Court is well-aware of both the substance and history of the rules that were in effect at that time. *See, e.g.*, *Apple Inc. v. Vidal*, 63 F.4th 1 (Fed. Cir. 2023). In *Apple v. Vidal*, this Court recounted in detail the USPTO's prior policy, as promulgated in the Memorandum from PTO Director to PTAB, Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation (June 21, 2022) ("June 2022 Mem.").

The USPTO's policy, reiterated in the *Apple* litigation, was crystal clear with respect to the effect of stipulations to forego potentially duplicative claims in district court litigation: "no *Fintiv*-based institution denial would occur 'where a petitioner presents a stipulation not to pursue in a parallel proceeding the same grounds or any grounds that could have reasonably been raised before the [Board].'" *Apple*, 63 F.4th at 9 (quoting June 2022 Mem. at 3.).

Nevertheless, a *Fintiv*-based institution denial where a petitioner had made such a stipulation is exactly what occurred in this case.

2. *The USPTO's Unlawful Change in Policy*

Of course, agencies have authority to change their policies. But they do not have unfettered freedom to do so when and how they please. As the Supreme Court recently re-affirmed, agencies must follow specific rules when changing policies. Specifically, an agency must (1) "provide a

reasoned explanation for the change," (2) "display awareness that [it is] changing position," and (3) "consider serious reliance interests." *Food & Drug Admin. v. Wages & White Lion Invs., L.L.C.*, 145 S. Ct. 898, 917 (2025) (quoting *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221–222 (2016) (quoting *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009)) (internal quotation marks omitted). When the USPTO changed its discretionary denial policy, it defied all three.

The USPTO notified the public that it had "rescinded" the June 2022 Memo in a three-sentence statement in a "News and Updates" section of its website. Appx81. Beyond announcing the rescission, the statement referred parties to precedential PTAB decisions (*Apple Inc. v. Fintiv Inc.* and *Sotera Wireless Inc. v. Massimo Corp.)* that were in effect before and after the June 2022 Memo. The statement concluded by noting that "[t]o the extent any PTAB or Director Review decisions rely on the [June 2022] Memorandum, the portions of those decisions relying on [it] shall not be binding or persuasive on the PTAB." *Id.*

This statement did not include any explanation for the change in policy or reflect any consideration of existing or prospective petitioners' reliance interests. Nor did it acknowledge the fact or significance of the policy change the rescission effected. By implying that PTAB decisions

had not relied on the June 2022 Memo (except, perhaps, in severable portions), it ignored the fact that "the June 2022 instructions [we]re part of the . . . operative instruction set regarding institution decisions by the Board as delegatee of the Director." *Apple*, 63 F.4th at 10. Completely overlooked were the consequences of eviscerating that instruction set for existing and prospective petitioners as well as the public.

A month after the recission, the USPTO released a memorandum from Chief Administrative Patent Judge Scott Boalick, stating that the June 2022 Memo was rescinded "[i]n the absence of rulemaking, . . . to restore policy in this area to the guidance in place before the Interim Procedure, including the Board's precedential decisions in *Apple Inc. v. Fintiv, Inc.* . . . and *Sotera Wireless, Inc. v. Masimo Corp.*" Appx82 ("Boalick Memo"). But it did not end there. The Boalick Memo "set[] forth *additional* guidance" that was entirely new. Appx82 (emphasis added).

This additional guidance began with the retroactive application of the recission to all pending proceedings. Appx83. Going further, it authorized requests for reconsideration of institution decisions after the time for Director Review had passed.[2] Appx83. Then, it mandated the

[2] Although the Boalick Memo stated that reconsideration would require "extraordinary circumstances," the USPTO's Acting Director has granted

application of *Fintiv*'s rubric in all cases involving parallel proceedings at the International Trade Commission, despite the non-preclusive nature of that tribunal's invalidity determinations. *Id.*

The Boalick Memo further asserted that, going forward, the "Board is more likely to deny institution where the ITC's projected final determination date is earlier than the Board's deadline to issue a final written decision." Appx83. This policy extends far beyond *Fintiv*, which merely instructed parties to indicate whether district court stays were ordered because of parallel ITC proceedings, and if so, whether the patentability issues would be resolved therein. *Apple Inc. v. Fintiv, Inc. v. Apple,* 2020 WL 2126495 (P.T.A.B. Mar. 20, 2020) at *4 (explaining that "parties should indicate whether there is a parallel district court case that is ongoing or stayed . . . pending the resolution of the ITC investigation," and if so "whether the patentability disputes before the ITC will resolve all or substantially all of the patentability disputes between the parties").

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such reconsideration without any reference to, let alone application of, this standard. *Semiconductor Components Industries v. Greenthread*, IPR2023-01242–44, Paper No. 94 (P.T.A.B. April 24, 2025).

The effect of this new policy goes further than its wording suggests: practically, it guarantees IPR petitions will be denied when ITC proceedings are underway. That is so because the ITC's rules prescribe a projected final determination date within 16 months[3]—two months earlier than PTAB's 18-month deadline for final written decisions.[4]

The Boalick Memo took a similar approach to *Sotera*—paying lip service to the decision before announcing policies beyond its bounds. In *Sotera*, the stipulation to forego invalidity grounds in district court that could have been raised at the PTAB was the *only* factor that weighed strongly for or against institution, and therefore was dispositive of its holistic analysis. *See Sotera Wireless, Inc. v. Masimo Corp.*, 2020 WL

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[3] The ITC is statutorily required to conclude investigations "at the earliest practicable time" after the publication of notice, 19 U.S.C. § 1337(b)(1). Pursuant to this requirement, the ITC's policy is to set target dates for completion of "16 months or less" by default. The U.S. ITC, *Section 337 Investigations: Frequently Asked Questions*, Publication No. 4105 (March 2009), https://www.usitc.gov/intellectual_property/documents/337_faqs.pdf, at 20 n.16. ("Target dates of 16 months or less are set by the Judge's order. If the Judge seeks to establish a longer target date, the Judge must issue an Initial Determination that is subject to review by the Commission.").

[4] 37 C.F.R. § 42.107(b) (3-month deadline for preliminary response to IPR petition); 35 U.S.C. §§ 314(b) (3-month deadline for institution decision) & § 316(a)(11) (1-year deadline for final written decision).

7049373 (P.T.A.B. Dec. 1, 2020), at *5–8 (assessing the *Fintiv* factors). Nevertheless, the Boalick Memo declared that such stipulations "will not be dispositive." Appx84. This definitive statement of policy contradicted the June 2022 Memorandum and went beyond any guidance the agency had previously provided.

As with the website statement, the Boalick Memo did not give any explanation for the USPTO's drastic change in policy. *See* Appx82–84. For example, it did not suggest the prior policy had negatively affected the patent system or that any evidence to that effect existed. The agency did not give any indication that it had considered the reliance interests of existing or prospective petitioners. Nor did it make any attempt to address these interests, for example, by offering refunds of fees paid to file petitioners that were denied on newly announced grounds. And by purporting to "restore" guidance while announcing entirely new policies, the USPTO did not evince any awareness of the changes being made.

Changing policy in this manner clearly and indisputably violated the law. *See FDA*, 145 S. Ct. at 917. The USPTO defied the Supreme Court's warning that "an agency should not mislead regulated entities," *id.*, and caused the very problem the change in position doctrine is supposed to prevent. In so doing, the agency infringed a core constitutional principle: that people have a right to know what the law is in advance of

its application so that they can choose to conform their conduct to it. *See, e.g.*, *Papachristou*, 405 U.S. at 162.

If a government agency falters in its fidelity to this principle, individual liberty in this country falters with it. The USPTO's extraordinary disregard for the law necessitates extraordinary relief.

B. The Public's Stake in the Lawful Administration of IPR Proceedings.

The USPTO's fidelity to the rule of law in administering IPR proceedings is an issue of paramount importance to the public. Empirical studies show that IPR proceedings can have concrete and far-reaching effects on the public. For example, research by Professor Charles Duan reveals that IPR proceedings leading to the cancellation of drug patents lead to significant reductions in drug prices.[5] To highlight a few examples:

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[5] Charles Duan, *On the Appeal of Drug Patent Challenges*, 2 AM. U. L. REV. 1177 (2023). For research showing that "AIA proceedings are [also] an effective way of correcting erroneously granted biologic patents that can be used to delay biosimilar entry," *see* V.L. Van de Wiele, A.S. Kesselheim, & SS. Tu, *Biologic patent challenges under the America Invents Act.,* NATURE BIOTECHNOLOGY 42, 374–377 (2024).

- The price of abiraterone acetate (marketed as Zytiga), a prostate cancer drug, dropped by up to 98% after IPR proceedings;
- Prasugrel (marketed as Effiant), a cardiovascular disease treatment, became 97% cheaper after IPR proceedings;
- IPR proceedings led to a 75% decrease in the price of glatirimer acetate (marketed as Copaxone), a multiple sclerosis treatment; and
- Rivastigmine (marketed as Exolon patch), a dementia treatment, saw a 75% price reduction following IPR proceedings.

While these exemplary IPR-driven price reductions are staggering, they do not fully capture the benefits the public receives from such proceedings. For some patients, a 75% price reduction makes it possible to afford treatment that is otherwise out of reach. For others, it brings an end to rationing medication or forgoing other life essentials, like food. For all, the elimination of invalid patents creates space for research and development that may lead to new or better treatments altogether.

These considerations merely buttress what this Court and the Supreme Court have long recognized: "the far-reaching social and economic consequences of a patent give the public a paramount interest in seeing

that patent monopolies are kept within their legitimate scope." *Id.* (quoting *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 816 (1945) (internal quotation marks removed) (alteration in original omitted). Because IPR proceedings "help protect" this public interest, their significance to the public is especially great. *Cuozzo Speed Techs., LLC v. Lee*, 579 U.S. 261, 272 (2016) (quoting *Precision,* 324 U.S. at 816); *see also CUPP Computing AS v. Trend Micro Inc.*, 53 F.4th 1376, 1383 (Fed. Cir. 2022) (quoting *id.*); *Arista Networks, Inc. v. Cisco Sys., Inc.*, 908 F.3d 792, 804 (Fed. Cir. 2018) (quoting *id.*). Accordingly, the impact of the USPTO's change in policy on members of the public beyond the parties should receive due consideration and weight.

This impact includes long-term harm resulting from the deterrent effect of the USPTO's approach on prospective petitioners and its corrosive effect on public trust. After witnessing the USPTO abruptly abandon established policies without explanation and retroactively apply entirely new ones, neither petitioners nor the public will be able to trust the agency to provide fair notice of its own rules or faithfully apply those of other branches. The erosion of certainty, transparency, and fairness will deter parties from making the substantial investments of time and

money required to mount meritorious patent challenges. Deterring these challenges will, in turn, prolong the harm that invalid patents inflict on the public by inflating drug prices to unjustifiable heights. Some patent owners may prosper, but many more patients will suffer.

Given the cascade of extraordinary and irreparable harm threatening the public, this Court's immediate intervention is imperative.

CONCLUSION

For the foregoing reasons, amicus respectfully urges this Court to grant the petition for a writ of mandamus.

Respectfully submitted,

/s/ Alex H. Moss

Alex H. Moss
PUBLIC INTEREST PATENT LAW INSTITUTE
79405 Hwy 111 Ste 9-414
La Quinta CA 92253
(818) 281-2191
alex@piplius.org

Counsel for Amicus Curiae

Dated: June 20, 2025

CERTIFICATE OF COMPLIANCE

I hereby certify as follows:

1. This brief complies with the type-volume limitation of Federal Circuit Rule 21(e). There are 2,520 words in the motion according to the word count of the word-processing system used to prepare the brief (excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f) and Federal Circuit Rule 32(b)).

2. This brief complies with the typeface and style requirements of Federal Rule of Appellate Procedure 32(a)(5) and (a)(6). This document has been prepared using Microsoft Office Word in a proportionally spaced typeface in 14-point Century Schoolbook font.

Dated: June 20, 2025

/s/ Alex H. Moss
Alex H. Moss

CERTIFICATE OF SERVICE

I hereby certify that on June 20, 2025, I caused the foregoing to be served by electronic means via the Court's CM/ECF system on all counsel registered to receive electronic notices.

/s/ Alex H. Moss
Alex H. Moss