

**IN THE
SUPREME COURT OF THE UNITED STATES**

AUDIO EVOLUTION DIAGNOSTICS, INC., PETITIONER

v.

UNITED STATES, ET AL.

**ON PETITION FOR WRIT OF CERTIORARI TO
THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

**REPLY TO BRIEF FOR THE UNITED STATES IN
OPPOSITION TO PETITION FOR WRIT OF CERTIORARI
OF AUDIO EVOLUTION DIAGNOSTICS, INC.**

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ARGUMENT

I. Petitioner is Entitled to *Certiorari* in View of the Government’s Confession of Error.

It took almost five years but the government finally agreed that AED’s patents are valid when it announced in response to the petition that it “will not defend” the dismissal by the Claims Court below determining the patents-in-suit are invalid under *Alice Corp. v. CLS Bank International*, 573 U.S. 208 (2014), and will instead “argue that the relevant claims are patent-eligible under Section 101.” (SG Br. 9). Under similar circumstances, confessions of error may result in grant, vacatur, and remand by this Court with direction to the lower court to reconsider its judgment in view of an intervening decision or a change in the law. But there is no intervening decision or change in the law to direct the lower courts to consider on remand here. As a result, the government’s stated commitment to petitioner to “argue that the relevant claims are patent-eligible under Section 101” and permit petitioner’s claims to proceed will never happen unless the petition is granted.

AED is entitled to a measure of justice here. The government agrees. AED’s patents were wrongly invalidated. The government agrees. The patents-in-suit describe “a new and useful machine with a claimed specific ordered combination of physical electronic components that capture, transform, analyze,

display with a customizable display, and transmit physiologic sounds for diagnosing medical issues with the human body.” (Pet. 2). AED’s invention “falls within the traditional bailiwick of [patentable] scientific, technological, and industrial arts.” (SG Br. 11). The government agrees that AED invented “a quintessentially technological innovation [that] should be patent-eligible, even if it relies on the use of conventional components.” (SG Br. 11).

The government’s brief cites three separate amicus briefs filed by the United States in support of prior petitions seeking review of the application of *Alice/Mayo* that this Court denied.¹ (SG Br. 11). Because *this Court* refused to grant those petitions, the government blames *this Court* for the state of uncertainty that reigns below over the application of *Alice*. (SG Br. 9). Those amicus briefs were cited to the Federal Circuit in AED’s briefs, at oral argument, and on reconsideration *en banc*. In the Federal Circuit when the government was confronted with the prior positions it took as amicus before this Court—positions

¹ U.S. Amicus Br., *Interactive Wearables, LLC v. Polar Electro Oy*, and *Tropp v. Travel Sentry, Inc.*, 143 S. Ct. 2482 and 2483 (2023) (Nos. 21-1281 and 22–22); U.S. Amicus Br., *American Axle & Manufacturing, Inc. v. Neapco Holdings LLC*, 141 S. Ct. 2594 (2021) (No. 20-891); U.S. Amicus Br., *Hikma Pharmaceuticals USA Inc. v. Vanda Pharmaceuticals Inc.*, 140 S. Ct. 911 (2020) (No. 18-817).

consistent with the one it is taking now—the government acknowledged in a footnote that “the outcome of the abstract-idea analysis in this case” would have been impacted had this Court granted review in those other cases, but blamed this Court’s failure to grant those other petitions for the reigning lack of clarity over the application of *Alice*. (Gov’t C.A. Br. 18 n.6.)

At oral argument below, the panel’s first question referred to the government’s footnote six and asked “If we affirm and the other side files either an *en banc* petition or a *cert* petition, what are you going to say?” The government demurred. “I’m not sure what position we would take.” (CA 23-1096, May 10, 2024, Oral Arg. File “23-1096_05102024.mp3” at 11:55, located at <https://www.cafc.uscourts.gov/home/oral-argument/listen-to-oral-arguments/>) (last visited May 12, 2025). The panel pressed the SG:

Why aren’t you waiving any rights that a defendant has here under any aspect of our 101 law that goes beyond what you think is correct?” A litigant can say there is some point I could have invoked but I am not going to invoke, and the government of all parties—with an interest in getting the law right—why don’t you waive the overbroad aspect as you see it about 101?

Id. The government responded that it was “not sure” if the AED patents would be eligible under *Interactive*

Wearables and *Tropp*. The government also agreed that it did not have to move to dismiss under 101 in the first instance at all. *Id.*

The government abandoned its role to defend the public interest instead of itself, and its “opposition” to certiorari here is indefensible. “A patent by its very nature is affected with a public interest.” *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 816 (1945). “The [government] has both an obligation not to unjustly issue patents and an obligation not to unjustly deny patents. Innovation and technological advancement are best served when an inventor is issued a patent with the scope of protection that is deserved.” Manual for Patent Examining Procedure, § 2001.04 (9th Ed., rev. 01.2024).

The government—whose interest is in getting patent law right for the public—always had the power to fix the problem in this case. The government could have asked the Federal Circuit panel to reverse based on the plain language of § 101 at the outset, on reconsideration, or on reconsideration *en banc*. The government could have answered the complaints in the Claims Court and not moved to dismiss under § 101. It is simply unfair to AED and the public for the government—only now in 2025, four and a half years after this case was filed at the point when denial of the petition inures to the government’s pecuniary benefit—to confess error while simultaneously throwing

up its hands that “this case does not present any better vehicle.” (SG Br. 9).

The Solicitor General offered no valid reason why this case is not the right vehicle. The SG faults the CFC’s “factbound inquiry” and its “analysis under *Alice* step two,” (SG Br. 13), even though (1) the SG and AED admit that the patents survive *Alice* step one and need not reach step two, and (2) AED’s pleadings and briefing provided multiple tables and extensive explanation linking the claim language to the patents’ inventive concepts satisfying step two. The SG’s contention that AED’s claims are “unpatentable under other applicable requirements” (SG Br. 14) is false, speculative, was not decided below, and raise arguments under §§ 102, 103, and 112 that are separate from the § 101 inquiry. Granting certiorari will solve the problem that the Solicitor General identified when it three times before requested that this Court grant certiorari on the application of § 101. The only difference here is that the government is the defendant.

No case is more cert-worthy than this one. *The record is limited*; we are here on a motion to dismiss addressed to the pleadings alone. *The technology is not complicated*; the invention is a machine that is used for telemedicine and is not a complicated biotechnology treatment or similar complex technology. *The patents claim an apparatus*; they are not method

claims that cause the most abstract idea problems.² The passage of eleven years’ time since this Court’s *Alice* decision in 2014 and the government’s interest in clarifying the law for agencies and the public compels the grant of *certiorari*.

II. The Court Should Grant the Petition to Refocus the Lower Courts on the Plain Language of § 101

Section 101 is clear. It covers a “machine” like plaintiff’s invention. Therefore, in answer to the first question in the *Alice/Mayo* framework—“whether the claims at issue are directed to one of those patent-ineligible concepts”—the answer should have been “no” because the claims recite a machine as listed in the plain language of § 101. The cause of the disarray in the lower courts was not only this Court’s “repeated[] den[ial of] petitions seeking review of Federal Circuit

² Contrary to the SG’s arguments (SG Br. 11, 15), the asserted claims of the AED patents are not at all “similar” to the ones in *University of Florida Research Found., Inc. v. General Electric Co.*, 916 F.3d 1363 (Fed. Cir. 2019). The claims in *University of Florida* are *method* claims that recite a method of processing information about patient treatment, not a machine that treats patients. AED’s patent claims recite a machine with hardware components to treat and diagnose patients by capturing body sounds (like heartbeats and bowel sounds), processing the sounds collected by the machine, transmitting the sounds to remote locations, and presenting the collected and processed sounds to a medical professional on a customizable display.

Section 101 decisions, including in cases where the government has recommended review.” (SG Br. 9). The lower courts have strayed from applying the plain statutory language of § 101—which defines patent eligible inventions as “any new and useful process, machine, manufacture, or composition of matter”—and instead have expanded the definition of “abstract idea” to include the very same inventions already determined to be patent eligible in the statute. In other words, the exception has swallowed the rule.³

This Court warned the lower courts “that too broad an interpretation of this exclusionary principle could eviscerate patent law.” *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 71 (2012). It also

³ As this Court knows, without appropriate vigilance, an exception can easily devour a rule whole. See, e.g., *SEC v. Jarkesy*, 603 U.S. 109, 131 (2024) (observing that since *Murray’s Lessee v. Hoboken Land & Improvement Co.*, 59 U.S. 272 (1855) this Court has “evaluated the legal basis for the assertion of the [public rights] doctrine with care” because “[w]ithout such close attention . . . the exception would swallow the rule.”) This is especially true where, as here, the lower courts stray from the application of the plain language of a statute. See, e.g., *Fourth Estate Pub. Ben. Corp. v. Wall-Street.com, LLC*, 586 U.S. 296, 302–03 (2019) (rejecting a statutory construction of the Copyright Act’s registration provision followed in the Ninth Circuit where the exception contained in the second sentence of § 411(a) of the Act swallowed the plain language rule in the first sentence requiring registration before filing suit.)

warned that “a process is not unpatentable simply because it contains a law of nature or a mathematical algorithm.” *Diamond v. Diehr*, 450 U.S. 175, 187 (1981) (quoting *Parker v. Flook*, 437 U.S. 584, 590 (1978)). In *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, this Court instructed that “[i]f there is to be invention from [a discovery of a law of nature], it must come from the application of the law of nature to a new and useful end.” 333 U.S. 127, 130 (1948). And in *MacKay Radio & Telegraph Co. v. Radio Corp. of America*, this Court stressed that “[w]hile a scientific truth, or the mathematical expression of it, is not a patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be.” 306 U.S. 86, 94 (1939). But the lower courts failed to heed this Court’s warnings time and again, strayed from the plain language of § 101, and invalidated “quintessentially scientific or technological inventions” like AED’s. (SG Br. 12).

This Court offers the last resort for guidance on its prior decisions. Only this Court can repair the “substantial uncertainty” surrounding the application of *Alice/Mayo*. (U.S.-Axle-Br. 9–10). The SG agrees that the Federal Circuit cannot fix the problem because it “has repeatedly divided in recent years over the content of the abstract-idea exception and the proper application of the two-step methodology under Section

101.” (U.S.-*IW*-Br. 11; *accord id.* at 19) (“Recent Federal Circuit precedent reflects significant confusion over the application of this Court’s Section 101 decisions.”).

This case also provides this Court with an opportunity to refocus the analysis where it belongs: on the patent claims in view of the language of § 101. The government incorrectly trains its focus on the specifications asserting that they acknowledge “that the claims’ elements by and large existed in the prior art.” (SG Br. 14). That is not only untrue,⁴ it is also irrelevant to the § 101 analysis versus analysis under §§ 102 and 103. The proper focus is on the claims. See *Mayo*, 566 U.S. at 72–73, citing *Flook*, 437 U.S. at 593 (the validity determination “rests upon an examination of the particular claims . . . in light of the Court’s precedents [that] . . . warn us against interpreting patent statutes in ways that make patent eligibility ‘depend simply on the draftsman’s art’ without reference to the ‘principles underlying the prohibition against patents for [natural laws].’”)

⁴ Nowhere in the government’s citations is there an admission of any kind that “the claims’ elements by and large existed in the prior art.” (SG Br. 14). For example, the government’s citation to “Pet. App. 45a–47a” (Sg. Br. 14) is not a citation to the “specifications of the relevant patents” at all, let alone any type of acknowledgement that “the claims’ elements by and large existed in the prior art.”

Oddly, despite agreeing that the claims are § 101 eligible, the government continues to argue issues of preemption, novelty, obviousness, written description, and enablement under §§ 102, 103, and 112. (SG Br. 14). *First*, the lower courts never decided those issues. *Second*, novelty, obviousness, written description, and enablement are separate statutory questions that the government itself argues should not “bleed into” the § 101 analysis. (SG Br. 10).

III. The Federal Circuit’s Application of Rule 36 Runs Afoul of Normative Rules of Decision-Making.

Rule 36 embodies the appellate court bestowing upon itself a quixotic power to affirm even when the conditions exist for it to reverse or remand. That was the precise situation before the Federal Circuit below. Instead of reversing or remanding, the pervasive use of Federal Circuit Rule 36—a use that wrongly and systematically biases appellate outcomes in favor of affirmance—caused the Circuit to affirm instead.

“The law in this area is clear. This Court has supervisory authority over the federal courts, and we may use that authority to prescribe rules of evidence and procedure that are binding in those tribunals.” *Dickerson v. United States*, 530 U.S. 428, 437 (2000). This Court should exercise that authority here to review Federal Circuit Rule 36, particularly since the Solicitor General has confessed that the result below

was erroneous but will defend the use of Rule 36 regardless.

Rule 36 undermines the Federal Circuit's requirement to provide constitutional due process. Implicit in the requirement of an unbiased decision-maker is the notion that cases should receive the disposition that they deserve. Rule 36 permits the Federal Circuit to dispose of cases in the opposite manner: with an affirmance when it should vacate or reverse because of erroneous legal findings. The very existence of the rule justifies "undue" outcomes.

This danger is not theoretical. Petitioner raised the government's prior amicus briefs in cases supporting inventors whose inventions were equally valid under § 101 as petitioner's invention. Paradoxically, Rule 36 permitted the Federal Circuit panel to question the legal merits of the government's position at oral argument, yet affirm without opinion anyway. This Court should intervene to review the validity of this unneeded, unjust, and disruptive power that the intermediate appellate court bestows upon itself.

A Rule 36 affirmance also sidesteps the judicial process and systematically biases appellate outcomes in favor of affirmance, since it eliminates all possibility of "vote fluidity." Chief Justice Rehnquist recounted in *The Supreme Court: How it Was, How It Is* (1987) that Chief Justice Douglas, "a very rapid

worker,” would finish up in early June and leave for his summer home in the mountains. His house lacked a telephone. Consequently, none of the other justices could reach the Chief Justice to discuss the decisions they were still writing. “I remember his once telling Lewis Powell that if he had only seen the latter’s dissent in a case that was handed down in the latter part of June he would have joined the dissent rather than the majority opinion!” *Id.* at 255.

Rule 36 is the functional equivalent of judges issuing rulings from isolated mountain retreats. There is no “vote fluidity” with Rule 36 affirmances. A panel member’s (or the whole panel’s) thoughts may change on further reflection after oral argument, after conference but before final decision. Rule 36 thus unnecessarily biases outcomes through a rush to judgment, needlessly causing the Federal Circuit to affirm where it might otherwise vacate or reverse.

CONCLUSION

This Court should grant certiorari.

Respectfully submitted.

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