

No. 25-570

IN THE
Supreme Court of the United States

AGILENT TECHNOLOGIES, INC.,

Petitioner,

v.

SYNTHEGO CORP.,

Respondent.

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

REPLY BRIEF

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PETITIONER'S REPLY BRIEF**I. INTRODUCTION**

This case is an excellent vehicle to address an issue that could stifle investment in crucial innovations, particularly in the biological sciences: Should a judge-made presumption override the language of 35 U.S.C. §§ 282 and 316(e), under which Congress decreed that patent challengers bear the burden of proving invalidity, to allow purely prophetic disclosures to block genuine and proven human innovation. Under the Federal Circuit's jurisprudence, every printed publication is presumed to be an enabling prior art disclosure, and the patentee must disprove that any reference cited against its patent is enabling of the challenged invention. Whether described as a shifting the burden of production or the entire burden of proof—which is what the Federal Circuit cases actually hold, as evidenced by their application here—the current framework conflicts with controlling statutes and precedent.

Contrary to Respondent's assertion, the relevant question is not whether the Board made factual findings; it is whether the evidence was evaluated under a lawful framework. Here, the Board and the Federal Circuit evaluated prior art enablement against a presumption that relieved the challenger of any obligation to come forward with proof of an element of its anticipation claim. If that framework is wrong, as Agilent contends, the appropriate remedy is the ordinary one—vacatur and remand for reconsideration under the proper standard. Agilent does not ask this Court to resolve disputed facts in the first instance; it asks the Court to correct the rules that governed the outcome below and remand.

Nor is there any reason to postpone review until a case “directly involving AI” arrives. The questions presented do not depend on artificial intelligence (“AI”). The proliferation of AI-generated technical “disclosures” merely underscores the stakes. As publication volume increases, the Federal Circuit’s presumption-driven framework encourages data-free, prophetic text to be weaponized against enabled patents—after and precisely because the patent itself demonstrated operability. But even setting AI aside, the Petition challenges settled doctrine that already affects the validity of issued patents today. This Court should grant the Petition to address this entrenched, but incorrect, framework now.

II. THE PETITION SHOULD BE GRANTED

A. The Burden to *Prove* Nonenablement (by Production and by Persuasion) Was Improperly Imposed on Agilent.

The Board’s acknowledgement that a party challenging a patent always bears the burden of persuasion (Br. at 2, 9, 13, 15-19) had no bearing on how the Board actually analyzed prior art enablement. Even though an asserted prior art reference must enable the challenged claims to prove anticipation, Synthego had no such burden. Instead, the Board presumed that Pioneer Hi-Bred was enabled, and placed the burden (of both production and persuasion) on Agilent alone to prove that it was *not enabled*:

Further, *to be anticipating, a prior art reference must be enabling*. *In re Morsa*, 803 F.3d 1374, 1377 (Fed. Cir. 2015) . . . Prior art disclosures are presumed enabling. *In re Antor*

Media Corp., 689 F.3d 1282, 1287–88 (Fed. Cir. 2012); *Apple Inc. v. Corephotonics, Ltd.*, 861 Fed. Appx. 443, 450 (Fed. Cir. 2021) (“**[R]egardless of the forum**, prior art patents and publications enjoy a presumption of enablement, and **the patentee/applicant has the burden to prove nonenablement for such prior art.**”).

App. 31a, 104a (emphasis added).

The Board then applied the presumption as a Gordian knot that Agilent urges this Court to cut.¹ Contrary to Respondent’s attempt to recast the record, the Final Written Decision speaks for itself:

Here, [IPR] Petitioner [Synthego] asserts that the RNA-based embodiments disclosed in Examples 4 and 5 of Pioneer Hi-Bred are anticipatory. **Those disclosures are presumed enabling and Patent Owner has not shown otherwise.**

App. 56a, 130a (emphasis added).² But even the PTAB’s finding that Examples 4 and 5 were, in fact, purely

1. Credit to Professor Dennis Crouch for an apt description of this judicially created conundrum. See <https://patentlyo.com/patent/2025/11/cutting-gordian-enablement.html>.

2. Because Respondent did not address enablement in its IPR Petitions, the presumption of enablement was the sole basis for establishing a prima facie case of anticipation sufficient institute the IPRs. The Board’s decisions cite Respondent’s IPR reply briefs to summarize Respondent’s position on enablement by necessity because the arguments were first advanced on reply. App. 55a-56a, 128a-129a.

prophetic did not overcome the presumption of enablement to anticipate Agilent's patent claims:

[W]hile it appears that Examples 4 and 5 in Pioneer Hi-Bred are prophetic, as opposed to working, examples, that fact alone does not undermine the presumption that Pioneer Hi-Bred is enabled.

App. 59a, 133a. No facts could: not the need for a year of intensive testing by seven PhD scientists specialized in synthesizing and studying RNA systems; not the inherent unpredictability of the art (which, contrary to its decision here, the Federal Circuit has confirmed in other cases);³ not the evidence that Pioneer Hi-Bred was focused primarily on using guide DNA instead of RNA, which no one disputes did *not* work and was ultimately abandoned; not the fact that there is no evidence whatsoever that the few sequences in Pioneer Hi-Bred (amongst the quadrillion quadrillion disclosed possible sequences) that could potentially fall within the challenged claims have never been demonstrated to actually be functional. Contrary to Respondent's retelling, the Board and the Federal Circuit (merely repeating the Board's conclusions) simply exalted the presumption over contrary facts (including many undisputed facts).

3. See *Regents of the Univ. of California v. Broad Inst., Inc.*, 136 F.4th 1367, 1383 (Fed. Cir. 2025) (Noting "the Board's uncontested determination that the subject matter at issue is *highly unpredictable and complex*" and "[b]oth in form and in substance, the Board correctly assessed possession and thus did not commit legal error.") (emphasis added).

But even if Respondent's assertion that the Board used the presumption only to shift the burden of *production* were true, that result is also legally impermissible. Respondent failed to grasp that the party who bears the burden of persuasion "also starts out with the burden of producing evidence." *Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 107 (2011). Thus, when Section 316(e) states that "the [IPR] petitioner shall have the burden of proving a proposition of unpatentability," this statutorily assigns both the burden of production and the burden of persuasion to the patent challenger.

Respondent's cited cases are in accord. In *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, the Federal Circuit confirmed that an IPR petitioner bears both the burden of production and persuasion as to its asserted grounds:

In this case, Dynamic, as the [IPR] petitioner, had the burden of persuasion to prove unpatentability by a preponderance of the evidence, and this burden never shifted. Dynamic also had the initial burden of production, and it satisfied that burden by arguing that Raymond anticipated the asserted claims of the '196 patent under § 102(e)(2).

800 F.3d 1375, 1379 (Fed. Cir. 2015). No case cited by Respondent holds the patentee to an initial burden of any kind regarding an affirmative element of any ground raised in an IPR. To the contrary, the burden of production only shifts after a *prima facie* case of invalidity is presented and may require "producing **additional** evidence and presenting persuasive argument based on

new evidence or *evidence already of record*”—not coming forward with evidence of the other party’s claims in the first instance. *Id.* (emphasis added).

Further, in *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1375 (Fed. Cir. 2016), the Federal Circuit vacated a final written decision where the original IPR petition, on which the decision to institute the IPR was based, failed to adequately address the IPR petitioner’s motivation to combine, thereby failing to present a prima facie case of obviousness. The Federal Circuit noted that the only circumstance in which a patentee could have an affirmative burden is where a patentee “seeks to establish a proposition not relied on by the patent challenger and not a necessary predicate for the unpatentability claim asserted—effectively an affirmative defense.” *Id.* at 1376.

The Federal Circuit’s reasoning in *Magnum Oil* also undermines *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313 (Fed. Cir. 2003), where the Federal Circuit extended the presumption of prior art enablement from a procedure used by patent examiners during prosecution to all printed publications in adversarial proceedings of issued patents. Although the Federal Circuit has consistently expanded the art and forums to which burden shifting applies with regard to the presumption of enablement for prior art, it has reached a different result with regard to obviousness. *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1375 (Fed. Cir. 2016). *Magnum Oil* made clear that the burden shifting procedures used during prosecution in the Patent Office have no place in IPRs in the context of an obviousness analysis:

Indeed, “the Supreme Court has never imposed nor even contemplated a formal burden-shifting

framework in the patent litigation context.” *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1075 (Fed. Cir. 2012) **We have noted that ‘a burden-shifting framework makes sense in the prosecution context,’** where ‘[t]he prima facie case furnishes a ‘procedural tool of patent examination, allocating the burdens of going forward as between examiner and applicant.’ ***As the PTO concedes, however, that burden-shifting framework does not apply in the adjudicatory context of an IPR. . . .***

Id. (emphasis added).

B. Proof of Efficacy Should Be Required.

Respondents agree that *Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318 (Fed. Cir. 2005), is limited to the discrete issue of whether a prior art reference must meet the standard for utility under 35 U.S.C. § 101. Br. at 20-21. It follows then that *Rasmusson* should have played no role in Board’s disclosure or enablement analysis or determinations. But that is exactly what happened here, further compounding the Board’s improper shifting of the burden of proof to Agilent.

All claims at issue here have express limitations requiring that the modified guide-RNA are functional in a Cas9 system, and can associate with a Cas protein and target the intended sequence. Yet, *Rasmussen* was used by the Board to effectively eliminate the need to prove that the disclosed sequences in Pioneer Hi-Bred, including the ones that putatively fall in the scope of Agilent’s claims,

would work and were enabled. Respondent’s only retort is that Agilent focused only on DNA embodiments (which is not correct), or that it was undisputed that the RNA embodiments in Pioneer Hi-Bred did work (which is also not correct). *Compare* Br. at 20-21, *with* App. 45a-54a, 119a-128a. Ultimately, the Board knew that particular sequences in Pioneer Hi-Bred worked only because Agilent discovered and demonstrated that they did. This hindsight bias is exactly why prophetic disclosure should not be favored over true innovation.

III. THE PETITION PRESENTS AN IDEAL VEHICLE FOR REVIEW

A. The Questions Presented Were Properly Passed Upon.

Agilent raised the substance of the questions presented below, at various stages of the proceeding. *See* Opening Brief for Appellant, *Agilent Techs., Inc. v. Synthego Corp.*, No. 23-2186 (Fed. Cir. filed Nov. 20, 2023) (Dkt. 14), at 1 (“*Did the Board err in finding that the claims were anticipated by and obvious over a prior art reference that never worked...*”); *see also* Oral Arg. at 11:01-11:20 (“[T]he legal question here is if a prior art reference says ‘try anything,’ throw things at the wall and see what sticks [...] would a person of ordinary skill in the art know ‘let me pick out the one thing that the patentee later found out worked right’ . . .”).⁴ Respondent’s characterization of the record is incorrect. Br. 21-22.

4. https://www.cafc.uscourts.gov/oral-arguments/23-2186_03072025.mp3

In any event, consideration of the issues presented is proper under *United States v. Williams*, 504 U.S. 36, 41 (1992). *Williams* holds that the Court is permitted to review questions “pressed *or* passed upon below;” this is a rule that “operates [...] in the disjunctive, permitting review of an issue not pressed so long as it has been passed upon....” *Id.* (emphasis added). If either condition has been satisfied, a party is free to make its arguments in support of the issues. *See Yee v. City of Escondido*, 503 U.S. 519, 534 (1992).

The Federal Circuit passed upon the issues presented in the Petition. *See* App. 14a (“Prior art disclosures are presumed enabling. *Impax Labs., Inc. v. Aventis Pharms., Inc.*, 545 F.3d 1312, 1316 (Fed. Cir. 2008) (reaffirming that an anticipating prior art patent is presumptively enabled); *In re Antor Media Corp.*, 689 F.3d 1282, 1288 (Fed. Cir. 2012) (extending the presumption to printed publications).”). Indeed, the Federal Circuit opinion assesses the propriety of the Board’s decision from the perspective of whether the Board appropriately rejected Agilent’s efforts to prove non-enablement. *See id.* (repeatedly noting “The Board rejected Agilent’s argument that ...”).

In affirming the Board’s enablement analysis, the Federal Circuit necessarily passed upon the legal framework that the Board applied, including the presumption of prior-art enablement and the burden placed on Patent Owner to come forward with evidence of non-enablement.⁵ *Id.* That inquiry also encompasses the sub-question of *who bears the burden* of proving

5. A tribunal cannot decide whether prior-art disclosures are “enabling” without deciding, implicitly, who bears the ultimate burden of persuasion.

or disproving enablement. Both (1) the correct burden-shifting framework, and (2) the correct prior art enablement standard are therefore properly before this Court for review.

B. The Federal Circuit’s Framework Dispositively Influenced the Result.

Respondent Synthego argues that the questions presented are “immaterial” because the Board’s decision supposedly rested on “findings, not a presumption” (Br. 24) with the Federal Circuit only discussing the presumption “in passing” (Br. 26). But as described above, the presumption of enablement is itself foundational to how the entire record was developed. By starting with the presumption that Pioneer Hi-Bred was enabled, the Board placed an extra-statutory burden on Agilent to prove a negative—that a skilled artisan could not make and use the invention. Under 35 U.S.C. § 316(e), it should be that the IPR petitioner alone must bear the burden of proving unpatentability. A decision premised on relieving an IPR petitioner of its obligation to produce any evidence as to an affirmative element of its claim cannot be deemed immaterial, particularly when the Federal Circuit reviews the Board’s fact finding for substantial evidence, affirming the Board’s IPR results about 75-85 percent of the time.⁶

6. <https://www.finnegan.com/en/insights/blogs/at-the-ptab-blog/federal-circuit-ptab-appeal-statistics-for-september-november-2025.html>; <https://perkinscoie.com/sites/default/files/2025-01/Law360Review.pdf>.

**IV. THE FEDERAL CIRCUIT’S FRAMEWORK
POSES A THREAT TO INNOVATION AND IS
UNLIKELY TO BE CORRECTED ABSENT THIS
COURT’S REVIEW.**

Respondent tries to recast the petition as a request for error correction, while dismissing discussion of artificial intelligence as speculative and irrelevant. That perspective is mistaken. This petition challenges the Federal Circuit’s unsupported legal framework that determines when printed publications may invalidate issued patent claims. Those rules are not confined to the facts of this case, and their importance does not depend on artificial intelligence. Generative disclosure merely illustrates why the questions presented are increasingly consequential now, as the Patent Office has itself recognized. Vast technical disclosures can be “drafted,” disseminated, and invoked as prior art with unprecedented ease, and any disclosure in them can later be proclaimed to be enabling by citing the hard work that a patentee undertook to discover, prove and disclose what actually works. A patentee’s own success should not retroactively validate a data-free, prophetic “guess.” The Federal Circuit created a circular rule that shields speculative text from the rigorous enablement standards required of true innovation.

Respondent further urges this Court to wait and see when a future vehicle directly involving artificial intelligence arises, hoping that the AI-subject matter posed “may be resolved before they reach this Court,” pointing to potential political-branch activity addressing the issue, and invoking prior denials of certiorari. Br. 28-29. But those are not reasons to deny review. Denials of certiorari express no view on the merits. *See, e.g., State*

of *Md. v. Baltimore Radio Show*, 338 U.S. 912, 919 (1950). Whatever future guidance an agency might consider cannot resolve the statutory questions of burden allocation and enablement standards that the Federal Circuit applies in adjudicating invalidity. Nor do the questions presented depend on AI; they concern an improper and prejudicial legal framework now being applied in *inter partes* review and district court invalidity proceedings.

Finally, the cases Respondent relies on do not reflect merits consideration of the questions presented here, but instead involve summary dispositions without full opinions (e.g., *Converter Mfg., LLC v. Tekni-Plex, Inc.*, No. 24-866; *Queen's Univ. at Kingston v. Samsung Elecs. Co.*, No. 18-190), or address materially different factual circumstances (*In re Finjan, Inc.*, No. 12-1245)—such as USPTO reexamination-stage burden rules—outside the scope of this petition.

Respondent also speculates that the Federal Circuit might be open to correct its own jurisprudence. *See* Br. 30. This is no reason to deny review, especially where the Federal Circuit has greatly expanded this improper framework over time (and over adversarial objection), from applying it to the claims of issued prior art patents, to unclaimed subject matter in prior art patents, to any publication—and from applying it in patent prosecution to post-issuance invalidity challenges in any forum. *See* Pet. 20-25. Under these circumstances, there is no reason to believe that *en banc* proceedings will be fruitful. Mandating a future litigant to succeed in *en banc* review of a rule that the Federal Circuit continually justified and expanded invites legal error, particularly when a large percentage of IPR appeals are resolved via Federal

Circuit Rule 36 affirmances without written opinions.⁷ Only this Court can resolve the conflict between the Federal Circuit's judge-made presumptions and the statutory requirements of the Patent Act. *See* 35 U.S.C. §§ 282, 316(e).

V. CONCLUSION

For the foregoing reasons, the Court should grant the petition.

Respectfully submitted.

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7. For example, in 2024, almost 45% of IPR affirmances were summary affirmances. *See* <https://perkinscoie.com/sites/default/files/2025-01/Law360Review.pdf>.