No. 25-

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

PETITION FOR A WRIT OF CERTIORARI

DENISE M. DE MORY
Counsel of Record
AARON R. HAND
ABIGAIL LUBOW
KENNETH WANG
BUNSOW DE MORY LLP
701 El Camino Real
Redwood City, CA 94063
(650) 351-7248
ddemory@bdiplaw.com

Counsel for Petitioner, Agilent Technologies, Inc.

387449

COUNSEL PRESS
(800) 274-3321 • (800) 359-6859

QUESTIONS PRESENTED

A party challenging the validity of an issued patent in district court or in an *inter partes* review ("IPR") proceeding before the Patent Trial and Appeals Board ("PTAB") bears the burden of proving invalidity. 35 U.S.C. §§ 282, 316(e). To anticipate a claim of an issued patent, a prior art printed publication must disclose and enable said claim. *Seymour v. Osborne*, 78 U.S. (11 Wall.) 516, 538 (1870); *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1354 (Fed. Cir. 2003) ("a non-enabled disclosure cannot be anticipatory (because it is not truly prior art)"). The questions presented are:

1. Should printed publications be presumed to be enabling when a party challenging the validity of issued patent claims asserts that a printed publication is anticipatory prior art, such that the burden of proving that the printed publication is nonenabling lies with the patentee?

2. Should the holding in *Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318, 1326 (Fed. Cir. 2005), that "proof of efficacy is not required in order for a reference to be enabled for purposes of anticipation," be vacated or significantly narrowed?

PARTIES TO THE PROCEEDINGS BELOW

The caption of the case contains the names of all the parties to the proceedings.

RULE 29.6 CORPORATE DISCLOSURE STATEMENT

Agilent Technologies, Inc. has no parent corporations and no publicly held companies own 10% or more of its stock.

RELATED PROCEEDINGS

This petition is taken from a judgment of the Court of Appeals for the Federal Circuit entered in a consolidated proceeding involving two United States Patents, Nos. 10,337,001 and 10,900,034, assigned to Agilent Technologies, Inc.:

- *Agilent Technologies, Inc. v. Synthego Corp.*, Nos. 2023-2186 & 2023-2187, judgment dated June 11, 2025.

These Federal Circuit appeals arose from Final Written Decisions of the Patent Trial and Appeal Board entered May 17, 2023 in two corresponding *Inter Partes* Review proceedings:

- *Synthego Corporation v. Agilent Technologies, Inc.*, IPR2022-00402; and

- *Synthego Corporation v. Agilent Technologies, Inc.*, IPR2022-00403.

The patent claims found invalid by the Patent Trial and Appeal Board in the above proceedings were the subject of a declaratory judgment action for non-infringement filed by Synthego against Agilent in U.S. District Court for the Northern District of California. Agilent filed a counterclaim for infringement of the two patents. The action is stayed pending resolution of the above-referenced PTAB proceedings and the appeals therefrom:

- *Synthego Corporation v. Agilent Technologies, Inc.*, No. 3:21-cv-07801 (filed Oct. 5, 2021).

Agilent filed suit against Synthego in a patent infringement action in the U.S. District Court for the District of Delaware alleging infringement of the two patents. The case was transferred to the Northern District of California and later consolidated with the declaratory judgment case:

- *Agilent Technologies, Inc. v. Synthego Corporation*, No. 1:21-cv-01426 (filed Oct. 6, 2021).

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PETITION FOR WRIT OF CERTIORARI

Agilent Technologies, Inc. respectfully petitions for a writ of certiorari to review a judgment of the United States Court of Appeals for the Federal Circuit.

OPINIONS BELOW

The consolidated opinion of the Court of Appeals for the Federal Circuit disposing of case numbers 2023-2186 and 2023-2187 (App. 1a–24a) is reported in the Federal Reporter at 139 F.4th 1319.

The Final Written Decisions of the Patent Trial and Appeal Board for proceeding numbers IPR2022-00402 (App. 25a–96a) and IPR2022-00403 (App. 97a–177a) are not reported.

JURISDICTIONAL STATEMENT

The Federal Circuit entered judgment on June 11, 2025. This Petition is timely filed. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY AND CONSTITUTIONAL PROVISIONS INVOLVED

U.S. Const. art. I , § 8, cls. 8 & 18 provide:

> The Congress shall have power . . .
>
> * * *
>
> To promote the progress of science and useful arts, by securing for limited times to authors

> and inventors the exclusive right to their respective writings and discoveries;
>
> * * *
>
> To make all laws which shall be necessary and proper for carrying into execution the foregoing powers, and all other powers vested by this Constitution in the government of the United States, or in any department or officer thereof.

35 U.S.C. § 102(a)(1) provides:

> **(a) Novelty; Prior Art.**—A person shall be entitled to a patent unless—
>
> **(1)** the claimed invention was patented, described in a printed publication, . . . or otherwise available to the public before the effective filing date of the claimed invention; or

35 U.S.C. § 112(a) provides:

> **(a) In General.—**
>
> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

35 U.S.C § 282(a) provides:

> **(a) In General.—**
>
> A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim. The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.

35 U.S.C § 316(e) provides:

> **(e) Evidentiary Standards.—**
>
> In an inter partes review instituted under this chapter, the petitioner shall have the burden of proving a proposition of unpatentability by a preponderance of the evidence.

I. INTRODUCTION

In the decision below, the Federal Circuit held that printed publications are presumed to be enabling when asserted as prior art against issued patent claims in *inter partes* review ("IPR") proceedings. Patentees now bear the burden of proving that any printed publication asserted to anticipate their claims is not enabling. This directly conflicts with provisions of the Patent Act allocating the burden of proving invalidity to the party challenging a patent, both in IPR and district court trials. The decision below also creates conflict between the burdens of persuasion for anticipation and obviousness, since the Federal Circuit elsewhere held that for obviousness assertions in IPR and district court proceedings, the burden never rests with the patentee because the Patent Act's provisions control.

In addition to shifting the burden of proof to the patentee, the decision's additional holding that "proof of efficacy" is not required to prove enablement of a prior art printed publication renders the patentee's new burden almost impossible to meet. Even if the patentee produces actual or circumstantial evidence that the disclosure in the printed publication does not work, or likely will not work, this evidence of "lack of efficacy" will not overcome the presumption because "proof of efficacy" is not required as a matter of law. The decision below puts future investment in important technologies at risk: "Making prior-art enablement challenges infeasible with respect to non-patent prior art unnecessarily restricts the universe of inventions that can be patented and subverts achievement of the policies justifying patent law." Henry H. Perritt, Jr., *Literary Fantasies as Prior Art, Eclipsing True*

Invention, 104 J. Pat. & Trademark Off. Soc'y 453, 456 (2024).

Two Agilent patents that claim improvements to synthetic guide RNAs ("gRNA") that are a core component of the CRISPR-Cas genome-editing system, and recognized in the industry as "seminal" and "landmark," were found invalid because Agilent could not overcome the presumption that a prophetic, abandoned patent application enabled the challenged claims. Agilent's patents claim specific chemical modifications that can be applied to gRNA to resist degradation; the claims also require that the modified gRNA remain functional in the CRISPR-Cas system. Using Agilent's patent claims as a guide, four sequences having the recited modifications were identified in that prior publication—but it was undisputed that those sequences had not been tested or otherwise determined to function as claimed by Agilent. It was the hindsight matching of sequences alone, without regard to whether they met the express functionality requirements of the claims, that shifted the burden to Agilent to prove nonenablement of the asserted prior art. But the exclusion of "efficacy" as a relevant enablement factor made this an impossible task. The absurdity is highlighted by the PTAB's reasoning, as affirmed by the Federal Circuit:

> Thus, while 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. *See Antor Media*, 689 F.3d at 1289–90.

App. 59a, 133a. The decision below effectively rules that prior public disclosure of a genetic sequence or chemical compound alone is anticipatory, without regard for whether it will work for a claimed purpose.

The framework established in the opinion below directly conflicts with this Court's precedent in *Seymour v. Osborne*, 78 U.S. (11 Wall.) 516, 555 (1870), which requires that a printed publication must describe and enable the challenged invention to anticipate it. And the Federal Circuit's burden shifting stands in reckless disregard of the statutory evidentiary burdens governing challenges to patent validity in district court and *inter partes* review proceedings set forth in 35 U.S.C. §§ 282 and 316(e), respectively, which the court below did not address when adopting its rule.

The implications of the lower court's decision are of paramount concern. Consider the ability of Artificial Intelligence ("AI") tools to generate an exhaustive list of chemical compounds that can currently be manufactured and that have ever been contemplated in any academic research to be "cancer-curing chemical compounds." Publishing that list is trivial. Under the decision below, a pharmaceutical company that expended considerable resources in not only the discovery and synthesis of a drug compound, but also the testing necessary to demonstrate efficacy in curing cancer, would be foreclosed from protecting that innovation if its drug compound appeared in that prior published list. Had it secured a patent, its issued claims would be easily lost when an accused infringer used the patent as a guide to identify the allegedly anticipatory compound in that list. After all, it was expressly disclosed and could be manufactured.

And not only would the publication be presumed enabling of the later-claimed drug for the purpose of anticipation, but the pharmaceutical company would be hard-pressed to rebut that presumption absent a proof of efficacy requirement for a prior art enablement. Indeed, this hypothetical played out in real life—albeit absent AI—in the proceedings here.

This is of serious concern for industry. A recent Patent and Trademark Office request for comment ("RFC") regarding the impacts of AI received a robust response.[1] America's innovators loudly and uniformly identified the presumption of prior art enablement during prosecution as a significant legal issue with public and economic implications so compelling that they urged a revisiting of the rule to avoid subversion of our patent system's principles.[2] And although the RFC solicited

1. *See* Request for Comments Regarding the Impact of the Proliferation of Artificial Intelligence on Prior Art, the Knowledge of a Person Having Ordinary Skill in the Art, and Determinations of Patentability Made in View of the Foregoing, 89 F.R. 34217 (Apr. 30, 2024), *at* https://www.regulations.gov/docket/PTO-P-2023-0044.

2. *See* Corey Salsberg, Novartis, *Comment Letter on Impact of AI on Prior Art and PHOSITA* (July 26, 2024), at 2–3, *at* https://www.regulations.gov/comment/PTO-P-2023-0044-0037 ("[M]aterials—which, in our field, could perhaps include large, autonomously generated lists of *theoretical compounds, genetic sequences or antibodies—should not be treated as invalidating prior art if they are speculative, inoperable, non-enabling*, or do not exhibit practical utility. Treating such references as prior art would conflict with the policy aims of the patent system, destroying the enabling role of patents as an incentive to not only invent new subject matter that is actually useful and operable, but to invest in developing and commercializing it to advance human

feedback regarding impacts of AI generated art and inventions, IBM's response was not so limited: "[G]iven that enablement concerns have been expressed for both AI-generated and human-authored disclosures, neither should be entitled to a presumption of enablement if cited by an Examiner as a prior art printed publication."[3] These expressed policy concerns regarding presumptive enablement of prior art *during prosecution* ring even louder when the presumption is applied to *issued patents*, especially given Congress's express directives regarding the party that must bear the evidentiary burden.

The framework applied in the proceedings below is contrary to the statutory burdens imposed by Congress, and this Court's long-established precedent in *Seymour* that alleged prior art must enable the challenged claims in order to anticipate them. That framework also places

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progress.") (emphasis added); Ann M. Mueting, President, American Intellectual Property Law Association, *Comment Letter on AI and Inventorship RFC*, at 4 (July 29, 2024), *at* https://www.regulations.gov/document/PTO-P-2023-0044-0048 ("[T]he sheer number of these publications, and the resultant burden on a patent applicant to prove lack of enablement for large numbers of references, may have significant negative impact on the patent system."); *see also* Keith Moore, President, IEEE-USA, *Comment Letter on AI and Inventorship RFC* (July 22, 2024), *at* https://www.regulations.gov/document/PTO-P-2023-0044-0025 ("[T]he issue is whether 'prior art flooding' with 'wholly' automatically generated, edited, and published combinations and permutations should qualify as section 102 disclosure ...."); BSA Software Alliance, *Response to USPTO Solicitation of Comments on AI and Patentability* (July 26, 2024), at 5, *at* https://www.regulations.gov/comment/PTO-P-2023-0044-0034).

3. Mark Valone & Lisa Ulrich, IBM Corp., *Comment Letter on Proliferation of AI* (July 29, 2024), at 5, *at* https://www.regulations.gov/document/PTO-P-2023-0044-0042 (footnotes omitted).

the patent system at risk of failing its constitutional purpose by improperly affording more societal weight to a non-enabling publication than to inventors that bring "new designs and technologies into the public domain through disclosure" for the benefit of all. *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 151 (1989). Companies will be loath to invest in identifying and proving that new compounds work for their intended purpose if they cannot secure patent protection for their endeavors.

This petition should be granted.

II. STATEMENT OF THE CASE

A. Seven Ph.D. Scientists from Agilent invented fundamental improvements for the CRISPR-Cas System.

The Agilent patents at issue here claim improvements to the synthetic guide RNAs that are a core component of the CRISPR-Cas gene-editing system. Those improvements were recognized in the industry as "seminal" and "landmark."

In the CRISPR-Cas system, bacteria store a "library" of encountered pathogens as a series of DNA base sequences within their own DNA, from which CRISPR gets its name (**C***lustered* **R***egularly* **I***nterspaced* **S***hort* **P***alindromic* **R***epeats*). CRISPR-associated ("Cas") proteins are used to read and write into the library, and to carry out immunological response; the Cas9 protein functions to cleave pathogenic DNA. App. 2a. In 2012, U.C. Berkeley and Broad Institute researchers demonstrated

how the natural Cas proteins could be reimagined as tools for altering targeted DNA sequences.[4] The approach involved synthesizing a guide RNA—a short RNA molecule designed to pair at a specific section of target DNA—and then binding it to a Cas9 protein to form a "complex" essential for targeting and then cutting DNA. Once the gRNA-Cas9 complex pairs with DNA at the target site, the Cas9 protein functions to precisely cleave the target. App. 27a.

Because Cas proteins do not naturally occur in humans or many other organisms, their cells can treat Cas proteins as invaders. Cells are also naturally hostile to foreign RNA; anti-RNA proteins called nucleases rapidly degrade unprotected RNA—having the potential effect of preventing the targeting or editing process entirely. App. 27a–28a. Scientists suggested that guide RNAs might be able to be modified to resist such attack. But any modifications to the guide could impact its ability to perform the functions critical to the CRISPR system, including the ability to complex with the Cas protein and/or accurately target the desired genomic sequence. Determining whether, where, and how to apply chemical modifications to gRNAs to resist degradation while preserving the desired CRISPR functionality was arduous—and the technology for doing so was nascent in 2012. App. 54a. But Agilent's inventors took on this task.

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4. In June 2012, Jennifer Doudna and Emmanuelle Charpentier published a paper in the journal *Science* demonstrating that CRISPR technology could be used for *in vitro* gene editing, for which they were later granted the Nobel Prize in Chemistry. Martin Jinek et al., *A Programmable Dual-RNA–Guided DNA Endonuclease in Adaptive Bacterial Immunity*, 337 Science 816 (2012), *at* https://doi.org/10.1126/science.1225829.

While chemical modifications had been tested in other biological systems to varying success, no successful predictive model existed. To determine whether a particular chemical modification would remain functional in the CRISPR-Cas system, empirical testing using synthesized modified gRNA candidates was necessary. Between 2012 and 2014, Agilent scientists conducted exhaustive assays to determine which modifications conferred the desired nuclease resistance without impacting guide RNA functionality (Cas association, gRNA structure, or DNA targeting). Their work resulted in U.S. Patent Nos. 10,337,001 and 10,900,034. The patents describe and enable the claimed inventions, supported by synthesis, testing, and validation—the hallmarks of true experimentation and invention.

Each claim of the Agilent patents recites a gRNA with specific modifications that is functional to (1) associate with a Cas protein, and (2) target that Cas-complex to a target polynucleotide—the prerequisites for cleavage and editing. For example, claim 1 of the '001 patent recites:

> A synthetic CRISPR guide RNA having at least one 5′-end and at least one 3′-end, the synthetic guide RNA comprising:
>
> (a) one or more modified nucleotides within five nucleotides from said 5′-end, or
>
> (b) one or more modified nucleotides within five nucleotides from said 3′-end, or
>
> (c) both (a) and (b);

> wherein said guide RNA comprises one or more RNA molecules, and has *gRNA functionality comprising associating with a Cas protein and targeting the gRNA:Cas protein complex to a target polynucleotide*, wherein the modified nucleotide has a modification to a phosphodiester linkage, a sugar, or both.

App. 3a–4a (emphasis added).

B. The Agilent inventions were recognized as "landmark" and "seminal," and copied by Synthego.

Shortly after the patents were filed, the Agilent inventors reported their inventions, and the success of their chemically modified gRNA in editing human cells in collaborative research with Stanford researchers, in a 2015 paper published in *Nature Biotechnology*.[5] Their work was hailed as "landmark" and "seminal." Statistics provided by its publisher rank the paper in the top one-percentile by citation—over 1,000 in the decade since its publication.[6] App. 80a.

Notwithstanding the positions taken in its IPRs, Synthego, too, recognized the importance of Agilent's

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5. Ayal Hendel et al., *Chemically Modified Guide RNAs Enhance CRISPR-Cas Genome Editing in Human Primary Cells*, 33 Nature Biotechnology 985 (2015), *at* https://doi.org/10.1038/nbt.3290.

6. Nature Biotechnology Metrics for *Chemically Modified Guide RNAs Enhance CRISPR-Cas Genome Editing in Human Primary Cells*, *at* https://www.nature.com/articles/nbt.3290/metrics (last visited Nov. 2, 2025.)

research and inventions. Synthego copied the chemical modifications reported by Agilent's inventors, and its website called them "the method of choice" for CRISPR-Cas9 editing in primary human cells. App. 83a. Agilent's inventions were the foundation on which Synthego built its business and through which Synthego directly competed against Agilent—bragging about its "very disruptive price."

After licensing discussions failed, patent infringement litigation ensued, and Synthego filed two IPR petitions.

C. Synthego's IPRs rely on a prophetic printed publication.

Synthego's petitions relied primarily on a reference that Synthego called "Pioneer Hi-Bred," an international patent application published under the Patent Cooperation Treaty. It never issued as a patent because it was abandoned.

In lieu of RNA guides, Pioneer Hi-Bred proposed DNA or "DNA-RNA combination sequences" as CRISPR guides. App. 18a–19a, 38a–39a. Unlike RNA—which is single-stranded, chemically reactive, and unstable *in vivo*—DNA's double-stranded, deoxyribose backbone confers greater stability. This fundamental difference makes RNA more difficult to synthesize and employ as a guide.

The 146-page Pioneer Hi-Bred publication is, at best, a test plan. The authors propose every known type of potential chemical modification, in every possible position in the guide, for every known purpose. In the

IPR proceedings it was undisputed that Pioneer Hi-Bred disclosed 6^{39}—over a quadrillion quadrillion—possible combinations, with no way to choose among them. App. 18a. Pioneer Hi-Bred provides the results of a single test. Its results show that the authors' preferred approach of using DNA as the guide did not work. App. 45a.

Synthego asserted that Pioneer Hi-Bred anticipated Agilent's patent claims via express disclosure.[7] App. 29a; App. 101a–102a. Working backward from Agilent's claims, Synthego identified four RNA sequences in Pioneer Hi-Bred with modifications that matched modifications required by Agilent's claim limitations. These sequences were in a list in a section that described "methods for evaluating" how proposed modifications would impact functionality.

It is undisputed that Pioneer Hi-Bred lacked test data or other express confirmation that the four sequences that allegedly expressly disclosed Agilent's claims—or any of the quadrillions of modified guides proposed—have "gRNA functionality" as required by the claims. App. 18a–19a & n.11. In contrast, for two of the four identified sequences, Agilent established that the opposite was true. App. 46a; App. 120a. Agilent pointed to test data in its own patents demonstrating that two of these four sequences were not functional. *Id.*

7. Synthego did not assert that Pioneer Hi-Bred alone rendered the claims obvious, nor did Synthego allege that the functionality of the identified sequences was inherent. Synthego's IPRs do include obviousness grounds for some dependent claims, but they are all predicated on the same Pioneer Hi-Bred disclosures. App. 7a–8a; *see also* App. 29a–30a, 101a–103a. Thus, the issues presented here are outcome determinative as to all claims.

As to the other two, Agilent submitted evidence suggesting that a POSITA would not have expected them to work. Dr. Doudna's seminal paper reported that the CRISPR guide region was about 20 nucleotides long. The identified Pioneer Hi-Bred sequences were only 17 nucleotides long. Agilent submitted uncontested evidence that 16-nucleotide guides were nonfunctional, and that 17 nucleotides was the minimum-length guide that could work, but for only *unmodified* guides. App. 50a, 124a. Because there is no evidence that Pioneer Hi-Bred or anyone else tested the prophetic modified 17-nucleotide guides, it is unknown, even today, if they would be functional.[8]

Agilent also submitted extensive expert testimony regarding the nascent state of CRISPR, the unpredictability of the art, and how and why a POSITA would understand that the mechanisms of CRISPR were unique from other systems in which chemical modifications had been identified (through testing) to resist degradation and remain functional. *See Regents of the Univ. of Cal. v. Broad Inst., Inc.*, 903 F. 3d 1286, 1292–93 (Fed. Cir. 2018); App. 14a–15a, 74a–75a, 154a–155a.

D. The PTAB invalidated all claims.

To meet the functionality limitation required to find express disclosure, the PTAB ultimately relied on a theory not advanced by Synthego—that because the

8. The Board ultimately dismissed this evidence because it did not prove nonenablement, and instead used *Agilent's* specifications to conclude that Pioneer Hi-Bred's sequences might work, thereby negating nonenablement. App. 48a–51a; App. 122a–125a.

Pioneer Hi-Bred authors called their proposals "guide polynucleotides," that was sufficient to disclose actual functionality as guides.[9] App. 44a–45a.

As to enablement, the PTAB relied on Federal Circuit precedent to conclude that Pioneer Hi-Bred is "presumed to be enabled," citing *In re Antor Media Corp.*, 689 F.3d 1282, 1287–88 (Fed. Cir. 2012), and quoting from *Apple Inc. v. Corephotonics, Ltd.*, 861 Fed. App'x 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."). The PTAB considered, and waved away, Agilent's evidence (including the test data in Agilent's patents that refuted functionality) by casting doubt on the results. The PTAB found the disclosures in Pioneer Hi-Bred enabled based on a myriad of justifications—none of which showed efficacy of the relied-upon synthesized gRNAs. App. 45a–54a, 56a–61a, 118a–128a, 129a–135a. The PTAB concluded:

> Here, Petitioner 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). The Board did so even though it acknowledged that Examples 4 and 5 were prophetic, determining that this did not undermine the presumption that they were functional:

9. Agilent maintains that this is not express disclosure of the claimed functionality, and that it was a violation of the Administrative Procedure Act, which the Federal Circuit rejected. App. 12a n.8.

> Thus, while 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. *See Antor Media*, 689 F.3d at 1289–90 ("[T]he mere use of forward-looking language (such as terms like 'should') does not show one way or another whether a person of ordinary skill in the art would have to engage in undue experimentation to perform the claimed invention.").

App. 59a, 133a.

E. The Federal Circuit affirmed and issued a published opinion confirming that printed publications are presumed enabled.

Citing the "substantial evidence standard," the Federal Circuit accepted the PTAB's findings that Pioneer Hi-Bred's definitional say-so constituted "express disclosures of functionality." App. 11a–12a. Agilent maintains that this decision was in error because no modified guides with the claimed functionality were disclosed or enabled.

As to enablement, the court held that the asserted prior art was presumed enabled, placing the burden on Agilent to demonstrate *non*enablement. App. 14a. The court also relied on its jurisprudence that "proof of efficacy is not required in order for a reference to be enabled for purposes of anticipation." App. 13a (citing *Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318, 1326 (Fed. Cir. 2005)). This combined prior art enablement jurisprudence amounts to a Sisyphean task: a patentee bears the burden

of proving that functional claims are not enabled by the prior art, but functionality (i.e., efficacy) is not required for prior art to be enabled.

III. THE PETITION SHOULD BE GRANTED

A. The decision below results in an unprecedented and improper expansion of what qualifies as invalidating prior art that threatens innovation.

1. The decision below is wrong because the Patent Act provides that the burden of proving invalidity always rests with the patent challenger.

To anticipate a patent claim, a printed publication must both disclose and enable the claimed invention:

> Patented inventions cannot be superseded by the mere introduction of a foreign publication of the kind, though of prior date, *unless the description and drawings contain and exhibit a substantial representation of the patented improvement, in such full, clear, and exact terms as to enable any person skilled in the art or science to which it appertains, to make, construct, and practice the invention* to the same practical extent as they would be enabled to do if the information was derived from a prior patent. . . . [T]he knowledge supposed to be derived from the publication must be *sufficient to enable those skilled in the art or science to understand the nature and operation of the invention, and to carry it into practical*

> *use*. . . . [T]he account published, to be of any effect to support such a defense, *must be an account of a complete and operative invention capable of being put into practical operation*.

Seymour, 78 U.S. at 555 (emphasis added). The holding in *Seymour* remains the law today:

> A claimed invention cannot be anticipated by a prior art reference if the allegedly anticipatory disclosures cited as prior art are not enabled. Long ago our predecessor court recognized that a non-enabled disclosure cannot be anticipatory (because it is not truly prior art) if that disclosure fails to "enable one of skill in the art to reduce the disclosed invention to practice."

Amgen, 314 F.3d at 1354 (citations omitted). Thus, disclosure and enablement are both affirmative elements of an anticipation defense. Indeed, enablement is so central to anticipation that a non-enabled disclosure "is not truly prior art." *Id.*

Section 282, which applies to district court proceedings, provides: "The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity." 35 U.S.C. § 282. "[B]y its express terms, § 282 establishes a presumption of patent validity, and it provides that a challenger must overcome that presumption to prevail on an invalidity defense." *Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 100 (2011). In patent infringement proceedings, this presumption of validity cannot be overcome "except by clear and cogent evidence." *Id.* at 101.

Section 316(e), which applies to *inter partes* review proceedings, states that "the petitioner shall have the burden of proving a proposition of unpatentability" by a preponderance of the evidence. 35 U.S.C. § 316(e). In *Cuozzo Speed Technologies, LLC v. Lee*, this Court held that "[t]he challenger bears the burden of proving unpatentability." 579 U.S. 261, 278–79 (2016).

The decision below impermissibly shifted the burden to Agilent, the patentee, to prove nonenablement of the alleged prior art publication. That decision cannot stand and should be vacated on this basis alone.

2. The decision below should be vacated because it is not supported by precedent.

The decision below should be vacated for the additional reason that the cases on which it rests do not support its holding. The Federal Circuit relied on *Impax Laboratories, Inc. v. Aventis Pharmaceuticals, Inc.*, 545 F.3d 1312, 1316 (Fed. Cir. 2008) (reaffirming that an anticipating prior art patent is presumptively enabled), and *Antor Media*, 689 F.3d at 1288 (extending the presumption to printed publications), in support of its holding that Agilent bore the burden of proving nonenablement. Neither case supports that result.

Impax is inapposite. In *Impax*, a prior art *patent* was asserted—not a printed publication. Whether a patent challenger can rely on a presumption of enablement when a prior art patent is asserted as anticipatory art is not at issue here.

Antor Media, involving an appeal of a reexamination proceeding, is also inapposite.[10] The appeal here involved an *inter partes* review. "In an *inter partes* review, the burden of persuasion is on the petitioner to prove 'unpatentability by a preponderance of the evidence,' 35 U.S.C. § 316(e), and that burden never shifts to the patentee." *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364 (Fed. Cir. 2016) (quoting *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015)).[11]

But even if *Impax* and *Antor Media* applied, the decision should still be vacated because neither is supported by sound precedent. *Impax* and *Antor Media* both trace their origin to *Amgen*, 314 F.3d at 1354–55, which provides no reasoned or sound basis for the result here. *See Impax Labs.*, 545 F.3d at 1316; *Antor Media*, 689 F.3d at 1288.

In *Amgen*, the defendant asserted that certain unclaimed subject matter in a prior art patent anticipated Amgen's patent claims. 314 F.3d at 1354–55. Amgen countered that the defendant had not proven that the

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10. 35 U.S.C. § 132 governs the content of communications from the examiner in reexamination proceedings and during patent prosecution. It does not establish any burden of proof, but specifies the level of notice that must be provided to the applicant to allow for consideration and response.

11. The same is true in patent infringement cases in district court. The burden of proof never shifts to the patentee. *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1075 (Fed. Cir. 2012) (reversing obviousness determination because "the court imposed a burden-shifting framework in a context in which none exists").

unclaimed subject matter in the patent was enabling and therefore had not established anticipation because enablement is a required element of the defense. The question before the Federal Circuit was which party had the burden of establishing whether the *unclaimed* subject matter was enabling. *Id.* at 1355–56.

Although issued patents are entitled to a presumption of enablement under 35 U.S.C. § 282, Amgen argued that the presumption was not operative in its case because the presumption extended only to claimed subject matter in issued patents. *Amgen*, 314 F.3d at 1355. Thus, Amgen contended that the defendant bore the burden of establishing enablement, which it had failed to do. *Id.*

The Federal Circuit disagreed, holding that the unclaimed subject matter was entitled to a presumption, and that Amgen, the patentee, had the burden of proving that it was not enabling. *Id.* The Federal Circuit was explicit that its ruling was not premised on the prior art patent also having a presumption of validity pursuant to Section 282. *Id.* at 1354 ("We agree that prior art patents are presumed enabled, but under authority going beyond § 282.").

Instead, the Federal Circuit purported to base its decision on its own jurisprudence. *Id.* at 1355. Specifically, the Federal Circuit relied on a proposition from *In re Sasse*, 629 F.2d 675, 681 (C.C.P.A. 1980), describing patent office procedure during the application process: "[W]hen the PTO cited a disclosure which expressly anticipated the present invention . . . the burden was shifted to the applicant. He had to rebut the presumption of the operability of [the prior art patent] by a preponderance of

the evidence." (citation omitted). The applicant, however, can then overcome that rejection by proving that the relevant disclosures of the prior art patent are not enabled. *Id.* Citing *In re Sasse*, the court noted: "In patent prosecution the examiner is entitled to reject application claims as anticipated by a prior art patent without conducting an inquiry into whether or not that patent is enabled or whether or not it is the claimed material (as opposed to the unclaimed disclosures) in that patent that are at issue." After making this observation, the Federal Circuit made the following leap:

> We hold that an accused infringer should be similarly entitled to have the district court presume the enablement of unclaimed (and claimed) material in a prior art patent defendant asserts against a plaintiff. *Thus, a court cannot ignore an asserted prior art patent in evaluating a defense of invalidity for anticipation, just because the accused infringer has not proven it enabled.*

Amgen, 314 F.3d at 1355 (emphasis added). But this is remarkably wrong. Indeed, just a page earlier in the same decision, the Federal Circuit confirmed that proof of enablement is a requirement to qualify as prior art: "Long ago our predecessor court recognized that a non-enabled disclosure cannot be anticipatory (because it is not truly prior art)." *Id.* at 1354. Thus, a court can and must ignore prior art "just because the accused infringer has not proven it enabled," because that means it *is not* prior art.

The Federal Circuit then proposed a procedure to determine whether a *patentee* met its burden of proving nonenablement:

> Like the applicant in *ex parte* prosecution, however, the patentee may argue that the relevant claimed or unclaimed disclosures of a prior art patent are not enabled and therefore are not pertinent prior art. If a patentee presents evidence of nonenablement that a trial court finds persuasive, the trial court must then exclude that particular prior art patent in any anticipation inquiry, for then the presumption has been overcome.

Id. at 1355. Given that there is no back-and-forth in district court proceedings (unlike in prosecution practice), it is unclear under what procedural rules or mechanisms this would even occur in district court. But regardless, as noted above with regard to *Antor Media*, reexamination procedures have no bearing on the statutory burden of proof in IPR proceedings.

The only other rationale the court offered is in a footnote:

> Additionally, we think it unwise as a matter of policy to force district courts to conduct a mini-trial on the proper claim construction of a prior art patent every time an allegedly anticipating patent is challenged for lack of enablement. As we frequently revisit district courts determinations in matters of claim construction and validity, we are certainly aware that *such a task can occupy a great deal of a court's resources*. In any event, because the presumption outlined here does not rely on § 282, we see no reason to impose these burdens on litigants and the district courts.

Id. n.21 (emphasis added). But work avoidance cannot justify ignoring controlling law. *Amgen* is not sound precedent to support the decision below, which must be vacated.[12]

3. The decision below is at odds with Federal Circuit decisions regarding the burden of proof for obviousness.

Magnum Oil Tools addressed the question of whether the patentee ever bears the burden of persuasion in an IPR proceeding concerning obviousness. *Magnum Oil Tools*, 829 F.3d at 1375. The patentee asserted that the PTAB improperly shifted the burden to him in its obviousness analysis, and that the decision had to be vacated because the challenger never established by a preponderance of the evidence that the patent was invalid. *Id.* The Federal Circuit held that the burden of persuasion never shifts to the patentee as to the elements of an invalidity claim. *Id.*

Moreover, *Magnum Oil Tools* expressly rejects the notion that the burden-shifting patent office procedure proposed in *Amgen* has any relevance to district court proceedings:

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12. Relying on *Antor Media*, *Impax*, and *Amgen*, in *Apple Inc. v. Corephotonics, Ltd.*, 861 F. App'x at 450, the Court reversed a PTAB decision for requiring that Apple, the petitioner, establish the pedigree of its proffered prior art. The Court held: "We do not see a principled distinction between our cases holding that this presumption [of enablement] and burden apply during patent examination and in district court litigation, and AIA trial proceedings." But *Corephotonics* is not sound precedent for the same reasons as *Amgen*.

> 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.'" *Id.* at 1080 n. 7 (citing *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992)). As the PTO concedes, however, that burden-shifting framework does not apply in the adjudicatory context of an IPR. Intervenor Br. at 30 (citing *In re Jung*, 637 F.3d 1356, 1362 (Fed. Cir. 2011) (holding the prima facie case during patent examination "is merely a procedural device that enables an appropriate shift of the burden of production" from the PTO to the patent applicant)).

Id. Ultimately, the Federal Circuit held that the patent challenger always has the burden to prove obviousness by a preponderance of the evidence pursuant to Section 316(e), and reversed the outcome in the IPR. *Id.* at 1378–79. The burden never shifts to the patentee.

In addition to *Magnum Oil Tools*, many other Federal Circuit decisions confirm that the burden never shifts to patentee for obviousness. *See, e.g., Sanofi-Aventis Deutschland GmbH v. Mylan Pharms. Inc.*, 66 F.4th 1373, 1378 (Fed. Cir. 2023) ("We have routinely held that the petitioner has the burden of proving unpatentability."); *E.I. du Pont de Nemours & Co. v. Synvina C.V.*, 904 F.3d 996, 1007 (Fed. Cir. 2018) ("[T]here was no dispute that the burden of persuasion remained with the patent challenger."); *FanDuel, Inc. v. Interactive Games LLC*, 966 F.3d 1334, 1341 (Fed. Cir. 2020) ("[T]he burden of

proving invalidity in an IPR remains on the petitioner throughout the proceeding."); *Aqua Prods., Inc. v. Matal*, 872 F.3d 1290, 1306 (Fed. Cir. 2017).

The decision below is in conflict, and cannot be reconciled with these obviousness cases that correctly apply the burdens of proof established by the Patent Act. The decision must be reversed for this reason as well.

B. The decision below should be vacated because *Rasmusson* is either inapplicable and its narrow application should be clarified, or it conflicts with *Seymour* and should be overruled.

After applying Federal Circuit law to shift the burden to Agilent, the PTAB relied on the Federal Circuit's pronouncements in *Rasmusson*, 413 F.3d at 1326, to summarily dismiss the vast majority of evidence that Agilent brought forth to meet its burden. It did so by classifying Aligent's evidence as relating to "proof of efficacy," while also holding that proof of efficacy was not a necessary element of prior art enablement.

The opinion below cites *Rasmusson* to support its finding of "no error in the Board's conclusion that Pioneer Hi-Bred is enabling," because "[p]roof of efficacy is not required in order for a reference to be enabled for purposes of anticipation." App. 13a. This essentially negated *any* requirement for utility in an enabling prior art disclosure. It justified the finding that Pioneer Hi-Bred's disclosure was enabled without undue experimentation, because all that was required was the ability to make one guide that had the claimed modifications. The PTAB and Federal Circuit used this bright-line rule to dismiss Agilent's

evidence as irrelevant to the inquiry of whether a prior art reference is enabled for purposes of anticipation. App. 13a (citing *Rasmusson,* 413 F.3d at 1326).

The decision below should be vacated in view of its reliance on unsound precedent, or inapposite precedent. *Rasmusson*'s broad proclamation that "proof of efficacy is not required to enable a prior art reference for purposes of anticipation" is unsound, or inapposite. At a minimum, *Rasmusson*'s holding should be expressly confined to "failure to establish enablement due to a failure to demonstrate sufficient utility of a chemical or therapeutic compound pursuant to Section 101." *Rasmusson*, 413 F.3d at 1323. The decision should also be vacated because it conflicts with *Seymour v. Osbourne*, which requires a patent challenged to prove that a printed publication discloses "an operative invention capable of being put into practical operation."

Rasmusson arose from an appeal of an interference proceeding related to patents for treating prostate cancer. The misapplication and confusion that has resulted from the overstated holdings of *Rasmusson* is a matter of semantics and the Federal Circuit's contortion of the Board's results to affirm them. In *Rasmusson*, the Board determined that certain of Rasmusson's applications were not enabled, and hence, he was not entitled to priority of those applications. As the Federal Circuit explained the enablement rejection:

> With respect to enablement, the Board found that none of the applications filed before the ninth application "would have enabled a person of ordinary skill in the art as of

> each of the respective filing date[s] to treat human prostate cancer by administering a therapeutically effective amount of finasteride to a human in need thereof without undue experimentation." The Board based that finding on its determination that a person of ordinary skill in the art *would have had no basis as of the filing date of the eighth application for believing that finasteride could be used to treat prostate cancer in light of the state of the art* and *in light of Rasmusson's failure to provide any data to demonstrate the effects of finasteride in treating prostate cancer.*

Rasmusson, 413 F.3d at 1322 (emphasis added). In response, Rasmusson argued that the lack of efficacy was only related to Section 101 (i.e., utility), and that because the rejection was not based on Section 101, the Board erred.

The Federal Circuit disagreed, explaining that utility under Section 101 is incorporated by reference into the "use" part of Section 112. "As this court has explained, 'the how to use prong of section 112 incorporates as a matter of law the requirement of 35 U.S.C. § 101 that the specification disclose as a matter of fact a practical utility for the invention.'" Thus, "efficacy," which was really "utility," now became associated with "enablement," because "utility" is incorporated into "enablement."

"Efficacy" in *Rasmusson*, in each instance that the term is used, is about "utility" or usefulness (i.e., Section 101), whether it is incorporated into the "use" prong of the enablement requirements or not. The

Federal Circuit ultimately sustained the use/enablement rejection, and found the Board's enablement rejection incorporated utility, and the utility requirement was not met because of the lack of proof of efficacy. Efficacy in *Rasmusson* is shorthand for utility or usefulness only in the context of chemical compounds and therapeutics, and the only relationship between efficacy and enablement is the *Rasmusson* court's holding that Section 101 is incorporated by reference into enablement.

Rasmusson then turned to consideration of whether the Rasmusson applications, that had just been determined to be not enabled because they failed to show utility/efficacy, could nonetheless anticipate the SmithKline applications that were the subject of the interference proceeding. And, citing *Hafner*, the court determined that they could.

> [A] disclosure lacking a teaching of how to use a fully disclosed compound for a specific, substantial utility or of how to use for such purpose a compound produced by a fully disclosed process is, under the present state of the law, *entirely adequate to anticipate a claim to either the product or the process and, at the same time, entirely inadequate to support the allowance of such a claim*.

Rasmusson, 413 F.3d at 1325 (citing *In re Hafner*, 410 F.2d 1403, 1405 (C.C.P.A. 1969)). The court noted that since *Hafner*, also cited in the decision below, the Federal Circuit "has continued to recognize that a prior art reference need not demonstrate utility in order to serve as an anticipating reference under section 102." *Id.* at 1326.

The final reference to efficacy in the case relates to the parties' debate about the breadth of *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368 (Fed. Cir. 2001). It is here that the Federal Circuit agrees with *Rasmusson* that "proof of efficacy is not required in order for a reference to be enabled for purposes of anticipation." *Rasmusson*, 413 F.3d at 1326. And efficacy means the same thing here: utility.

Rasmusson, and the cases cited therein, are interference proceedings, involving chemical compounds or therapeutics, where the question of efficacy or effectiveness is a question of utility. They have no application outside of this realm, and should be limited to such.

To the extent that these cases, including *Rasmusson*, have applicability outside the scope of interference proceedings, then at least *Rasmusson* was wrongly decided because it conflicts with *Seymour*, discussed above in Sections III.A.1 and III.A.3. In *Seymour*, this Court set forth the test for test for enablement of a printed publication for purposes of anticipation. To anticipate, a publication must "*enable those skilled in the art or science to understand the nature and operation of the invention, and to carry it into practical use*. . . . [T]he account published, to be of any effect to support such a defense, *must be an account of a complete and operative invention capable of being put into practical operation*." 78 U.S. at 555 (emphasis added). To the extent *Rasmusson* is interpreted to state that functionality (which is an express element of the Agilent claims, in any event) is not required for purposes of establishing that a publication is enabled for purposes of anticipation, it conflicts with *Seymour* and must be overruled.

IV. THIS CASE IS AN IDEAL VEHICLE.

This case is an ideal vehicle for resolving a recurring and outcome-determinative question of patent law: whether printed publications are presumed enabling when asserted as anticipatory prior art, and further, whether excluding "efficacy" as an enablement factor is good law or policy.

The dispute below turned on whether the key prior art reference (*a printed publication*) was enabling. Both the Patent Trial and Appeal Board and the Federal Circuit addressed that issue directly, with the Federal Circuit devoting substantial analysis to affirming a distinct standard of enablement for § 102, complete with citations to the factual record and some accounting as to the legal reasoning of the Federal Circuit. App. 17a–20a. There are no factual or procedural obstacles that might prevent this Court from reaching the core legal question. The record contains the prior art reference itself and extensive expert testimony on what it taught (or failed to teach) concerning functional guide RNAs, and the standards applied by the Federal Circuit.

Moreover, Petitioner consistently argued that Pioneer Hi-Bred lacked a practical enabling disclosure—even invoking this Court's recent decision in *Amgen Inc. v. Sanofi,* 598 U.S. 594 (2023), by analogy, preserving this issue for review. Repudiating this Court's recent jurisprudence on § 112 enablement, the Federal Circuit squarely rejected Agilent's arguments because they turned on § 112 rather than § 102, ignoring what may be this Court's attempted harmonization of the law of enablement in adversarial proceedings.

Importantly, the outcome of this case hinges on the presumption of enablement for printed publications that should be applied by the Federal Circuit and the PTAB. If *Seymour*'s standard had been applied, the primary reference (which merely proposed guides without any data showing their CRISPR efficacy) would be deemed not enabling under § 112 standards and thus not prior art. Petitioner's patents would have survived, as no *truly enabling* disclosure predated the inventions claimed therein. But, under the Federal Circuit's enablement standard, the same reference was found sufficient to anticipate because a skilled artisan could *theoretically* find "at least one embodiment" that works by routine experimentation. Thus, the legal presumption of enabled anticipatory prior art was outcome determinative here. A Supreme Court ruling that the correct standard is the one articulated in *Seymour* would require reversal in the present case. There is no doubt that the issue is squarely presented and material to the judgment, satisfying the Court's ideal vehicle criteria.

Finally, the question carries exceptional national importance. Notwithstanding the *significant* concerns voiced by tech, biotech, and industry regarding the presumption of enablement for printed publications, the ruling below threatens to undermine American innovation fundamentally, especially in the unpredictable arts. Clarifying that the burden falls on the petitioner in litigation would restore coherence to patent law, ensure fairness in adversarial proceedings, and reaffirm the patent system's constitutional balance between public disclosure and genuine innovation. Moreover, given the nature of review in patent law, there is unlikely to be any meaningful circuit split forthcoming. Therefore this case,

where a pioneering CRISPR invention was invalidated by an abandoned prophetic application, offers the ideal vehicle for this Court to restore coherence and integrity to the law of enablement.

V. THIS CASE IS OF SIGNIFICANT IMPORTANCE AND SHOULD BE REVIEWED.

This petition presents a question of exceptional importance concerning a foundational bargain in the U.S. patent system. The Federal Circuit has reaffirmed the presumption that printed publications are enabling, shifting the burden to patent owners—and moreover, obviated "efficacy" as a dispositive factor when patent owners try to rebut. The result is a doctrinal double standard: patent applicants must disclose enough to teach the public how to practice the invention, yet alleged prior art may invalidate those same claims on the basis of speculative or prophetic disclosure with no supporting data. In this case, the functional gRNA limitations recited in Agilent's issued patents were deemed anticipated by an abandoned patent application, which included no evidence that the sequences recited therein (which contained unpredictable modifications), were in fact functional.

Two Federal Circuit errors require this Court's review. First, the Federal Circuit's adoption of a presumption of enablement for printed publications contravenes the burden on patent challengers established by this Court in *Seymour*, and is contrary to §§ 282 and 316(e), which assign the burden of proof to the challenger.

Second, the Federal Circuit's holding articulated in *Rasmusson* that "proof of efficacy is not required

in order for a reference to be enabled for anticipation" fundamentally misapprehends the appropriate boundaries of the holding in *Rasmusson*, which should be vacated or limited, and ignores long-standing interpretations of operative language surrounding the correct enablement standard for § 102.

This error by the Federal Circuit invites the publication of "paper" disclosures—speculative, inoperative disclosures that could never support patentability but may later be weaponized to invalidate genuine, working inventions. Left uncorrected, this approach undermines congressional intent, distorts prosecution practice, and erodes confidence in the patent system.

The Federal Circuit's error originated in a demonstrable misreading of this Court's precedent and has become entrenched in the nation's sole appellate court for patent law, precluding any possibility of correction without this Court's intervention. As the Federal Circuit is, for many patent law topics, the court of both first and last resort, the institutional reality makes this Court's review not merely important, but essential.

A. The Federal Circuit's doctrine ignores federal statutory directives designed to fulfill the Intellectual Property Clause.

The Federal Circuit's inconsistent logic and legally unsupportable enablement presumption fails on multiple independent grounds.

First, the Federal Circuit's insistence on shifting the burden to Patent Owners to disprove enablement during

adversarial proceedings stands contrary to statutory language in Sections 282 and 316(e)—mandating that the patent challenger bears the burden of proof, and must be addressed by the Court.

Second, this Court must untangle the complex web of exceptions built by the Federal Circuit in maintaining that "no efficacy is required" for a reference to be enabled—and re-establish a standard of prior art enablement in accord with this Court's holding in *Seymour* for challenges in district court and PTAB trials.

Without the guidance of this Court, the Federal Circuit's entrenched self-made presumption will continue to reward thin, hypothetical "paper" disclosures to the detriment of true innovators.

B. The Federal Circuit's prior art enablement framework forecloses practical application of this Court's precedent to counter anticipation challenges premised on non-enabled publications.

This Court's ruling in *Seymour* should serve as the blueprint for prior art enablement under Sections 102 and 103 of the Patent Act. *Seymour* held that a prior publication can defeat a patent only if it discloses the challenged invention "in such full, clear, and exact terms as to enable any person skilled in the art … to make, construct, and practice the invention." 78 U.S. at 555. Stated differently, prior art must be enabling to the same degree that § 112 requires of a patent specification.

As discussed in Section III.B above, the Federal Circuit departed from *Seymour*, relying instead on *Rasmusson* and *Hafner* to justify dismissing the vast majority of evidence that Agilent brought to meet the burden imposed upon it, reasoning that the distinction between Sections 112 and 102/103 was warranted because "§ 112 'provides that the specification must enable one skilled in the art to "use" the invention whereas 35 U.S.C. §102 makes no such requirement as to an anticipatory disclosure.'" App. 17a (quoting *Rasmusson*, 413 F.3d at 1325). But in *Hafner*, the CCPA justified the split standard through a superficial textual analysis of the Patent Act and ignored this Court's established precedent in *Seymour*. Thus, the Federal Circuit's ruling in the below case rests on foundational textual and historical error and should be reversed.

Reaffirming the principles established in *Seymour* will correct a decades-old judicial distortion and realign patent law with the statutory text. Crucially, it will protect genuine, operative inventions from being undone by incomplete and inoperative disclosures. In an era where artificial intelligence can generate vast volumes of technical material at unprecedented speed, the issue of invalidating "paper" disclosures (presumed to be enabled) will undoubtedly predominate unless addressed by this Court now. This Court, by clarifying that non-enabling disclosures are insufficient to anticipate, can restore the constitutional bargain and ensure that the patent system rewards innovators like Agilent who place truly useful knowledge into the public domain.

C. The Federal Circuit's doctrine perverts the incentives that our patent laws were designed to foster.

Congress designed the Patent Act to promote efficient examination and reward genuine innovation. But the Federal Circuit's ruling threatens both objectives. By improperly shifting the burden of proof and adopting a dismissive "proof of efficacy is not required" enablement standard for printed publications, the Federal Circuit created a doctrinal gulf that distorts patent incentives and undermines advancement of the useful arts.

Section 112 defines the baseline for the enablement inquiry during prosecution: a patent may issue only when the specification teaches those skilled in the art to "make and use" the invention in "full, clear, concise, and exact terms." 35 U.S.C. § 112(a); *Amgen*, 598 U.S. at 605 ("So today, just as in 1790, the law secures for the public its benefit of the patent bargain by ensuring that, 'upon the expiration of [the patent], the knowledge of the invention [i]nures to the people, who are thus enabled without restriction to practice it.'") (quoting *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 187 (1933)). Properly applied, that standard discourages speculative or prophetic filings and ensures that patents correspond to operable, demonstrated inventions. It also guards against "omnibus" applications that attempt to claim every conceivable variation of a concept without teaching how to realize it—a concern magnified now that AI can generate vast pseudo-technical disclosures in seconds.

The Federal Circuit's presumption of enablement for printed publications invites the very behavior § 112

was designed to prevent. If a minimally described and non-enabled disclosure can later serve as fully "enabled" prior art, entities seeking to clear a particular field could simply flood the patent office with sprawling, speculative publications. These "paper patents," even if abandoned, are prior-art landmines, capable of invalidating genuine, fully enabled inventions years later.

The Federal Circuit's presumption has far-reaching consequences for all stages of the patent process. At the beginning, this doctrine threatens to overwhelm already overburdened examiners, frustrate efficient prosecution, and reward bad-faith actors who weaponize untested disclosures as presumptively enabled prior art. By the end, accused infringers will seek outcomes like in the below case that threaten to forestall American invention. The result is a less innovative patent landscape—one in which volume and speculation replace substance and proof.

Only this Court's intervention can restore the correct standard within the statutory framework of the Patent Act. Reaffirming that prior art must meet the same enablement standard that governs patent applicants under § 112 would realign the statutory balance between disclosure and innovation, deter strategic abuse, and preserve the efficiency and integrity of the patent system that Congress envisioned.

VI. CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

Denise M. De Mory
Counsel of Record
Aaron R. Hand
Abigail Lubow
Kenneth Wang
Bunsow De Mory LLP
701 El Camino Real
Redwood City, CA 94063
(650) 351-7248
ddemory@bdiplaw.com

Counsel for Petitioner,
Agilent Technologies, Inc.

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