No. 21-757

In the Supreme Court of the United States

AMGEN, INC., ET AL.,
PETITIONERS,
v.
SANOFI, ET AL., RESPONDENTS.

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

BRIEF OF THE INTELLECTUAL PROPERTY LAW ASSOCIATION OF CHICAGO AS AMICUS CURIAE IN SUPPORT OF NO PARTY

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E. Wyndham Hulme, "The History of the Patent System Under the Prerogative and at Common Law" (1826), 12 LQ Rev 141 13

Gary Hoffman & Robert Kinder, *Supreme Court Review of Federal Circuit Patent Cases: Placing the Recent Scrutiny in Context and Determining If it Will Continue*, 20 DePaul J. Art, Tech. & Intell. Prop. L. 227 (2010), https://via.library.depaul.edu/jatip/vol20/iss2/2 ..30

Hulme, "On the History of Patent Law in the 17th and 18th Centuries" (1902) 18 LQ Rev 280 13

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INTEREST OF AMICUS CURIAE[1]

The Intellectual Property Law Association of Chicago ("IPLAC") suggests that this Court vacate and remand.[2] Choice (a) of the two choices (a) or (b) presented by the issue is the right choice.

Founded in 1884 in Chicago, a principal forum for innovation, and intellectual property law representation, IPLAC is the country's oldest bar association devoted exclusively to intellectual property matters. IPLAC has as its governing objects, *inter alia,* to aid the development of intellectual property laws, their administration, and the procedures of the U.S. Patent and Trademark Office, the U.S. Copyright Office, and the U.S. courts and other offices and tribunals charged with administration. IPLAC's about 900 voluntary members include attorneys in private and corporate practices in the areas of copyrights, patents, trademarks, trade secrets, and the legal issues they present before federal courts throughout the United States, as well as before the U.S. Patent and Trademark Office and the U.S. Copyright Office.[3] In

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[1] Pursuant to Rule 37.6, no counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person or entity other than the amicus curiae, its members, or its counsel, made such a monetary contribution.

[2] Pursuant to Rule 37.3(a), Petitioners and Respondents have provided blanket consents to amicus briefs.

[3] In addition to footnote 1, after reasonable investigation, IPLAC believes that (a) no member of its Executive or Amicus

patent litigation, IPLAC's members represent inventors and accused infringers in roughly equal measure, split roughly equally between plaintiffs and defendants.[4]

STATEMENT OF THE CASE[5]

"An 'antibody' is a species of an antigen binding protein." U.S. Pat. 8,829,165 ("the '165 Patent"), column 32 lines 44-45. "An 'antigen binding protein' … means any protein that binds [to] a specific target protein." *Id.* 29:58-59.

Backing up, "[t]he body's immune system helps prevent or limit infection. One way the body fights foreign invaders, like bacteria and viruses, is by making antibodies against them." Tianna Hicklin, *Decoding the Variety of Human Antibodies*, NIH Research Matters (Feb. 12, 2019)("Hicklin"), https://www.nih.gov/news-events/nih-research-matters/decoding-variety-human-antibodies. "An antibody is ... produced by white blood cells." *Id.*

Committees who voted to prepare this brief, or any attorney in the law firm or corporation of such a member, represents a party to the litigation in this matter; (b) no representative of any party to this litigation participated in the authorship of this brief; and (c) no one other than IPLAC, or its members who authored this brief and their law firms or employers, made a monetary contribution to the preparation or submission of it.

[4] Although over 30 federal judges are honorary members of IPLAC, none were consulted on, or participated in, this brief.

[5] Amicus believes the case could use a Statement of the Case from amicus.

Where something, called an "antigen," including another protein different than the antibody, enters and causes an immune system response, antibody "arms" and "chains" "create specificity" for the antigen." *Id.* That is, they focus the antibody on the antigen so that it binds—attaches—to the antigen. "Antibodies are protective proteins produced by your immune system. They attach to antigens (foreign substances)—such as bacteria, fungi, viruses and toxins—and remove them from your body." Cleveland Clinic, Antibodies. https://my.clevelandclinic.org/health/body/22971-antibodies.

Here, "the specified target antigen is the PCSK9 protein." '165 Patent 29:59-61. Petitioners have obtained more than a dozen patents drawn to their R&D in production of antibodies that bind to the target PCSK9 antigen/protein.[6] *E.g.*, '165 Patent. For a short, easily understood audiovisual tutorial, see "See How Repatha Works Differently," https://www.repatha.com/what-is-repatha#video. While it is Petitioners', it appears objective, and is helpful. It states LDL cholesterol, "bad cholesterol" (and itself part protein), can cause heart attacks and strokes. LDL is removed from blood by the liver. Receptors on the liver help it capture and take away LDL—but the liver also makes the protein PCSK9, which can cause the liver to destroy its own receptors.

By binding to PCSK9, *i.e.*, "the target antigen," in a specific region of it, antibodies block the target

[6] Amicus is unaware of any recognized pronunciation of "PCSK9," other than "P-C-S-K-9," so has replaced PCSK9 with the term "target antigen" insofar as considered appropriate.

antigen from binding to LDL liver receptors, "like a false key jamming a lock," because otherwise, target-antigen-to-liver-receptor binding would cause a lowered ability to reduce cholesterol. *Amgen Inc. v. Sanofi*, No. 14-1317, ECF 10 ¶¶ 23-38 (D. Del. Nov. 17, 2014) (quotation lifted from Siddhartha Mukherjee, *The Emperor of All Maladies: a Biography of Cancer*, 31, Simon & Schuster (2010)).

For example, the '165 patent asserts it discloses

> [a]ntigen binding proteins … that bind to PCSK9 … and prevent PCSK9 from functioning … [and] block or reduce the ability of PCSK9 to interact with other substances [for example binding] to PCSK9 in a manner that prevents or reduces the likelihood that PCSK9 will bind to [the receptors, called] LDLR … [A]ltering the interactions between PCSK9 and LDLR can increase the amount of LDLR available for binding to LDL, which in turn decreases the amount of serum LDL in a subject, resulting in a reduction in the subject's serum cholesterol level.

'165 patent 21:27-50.

Over about 366 pages (text, drawings),[7] Petitioners' '165 Patent details the efforts to

[7] The '165 Patent reflects a sophisticated knowledge of the involved and sophisticated technology and details of patent law. In addition to the patent's hundreds of pages of text and figures, the summary of invention has a nearly unending description of "aspects" of invention, such as not seen in almost all past patents. The detailed description includes about 100-plus definitions and extensive limitations of definitions under the heading

characterize the structure of the region of the target antigen that is key to the binding of antibodies to the antigen, screen thousands of antibodies for potential activity in that region, and identify hundreds of antibodies that block target antigen activity. *Amgen Inc. v. Sanofi*, 227 F.Supp.3d 333, 342-48 (D. Del. 2017)(parties "largely agreed" to facts). The patents also provide the structure of twenty-six antibodies and describe two specific antibodies that are highly effective at binding to PCSK9, to the point of an exact, ordered recitation of the hundreds of nucleotides that combine to make up those antibodies. *Id.*; '165 Patent, *e.g.*, Fig. 3E.

Petitioners' patent claims vary from narrow to more. Some cover antibody structures synthesized and found to be effective, while others—like the claims of this case—identify parts of the binding region of the target antigen (each part called a "residue") and claim antibodies that bind to the parts. *Compare* U.S. Pat. 8,030,457 claim 1 (unasserted claim based on structure of antibody) with '165 Patent

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"Definitions and Embodiments" and in a concluding universal incorporation by reference also unlike almost all past patents. The also nearly unending details of the definitions reflects detailed preparations of them, as reflected in their number, lengths, detail, and sophistication of content. The term "antibody," for example, includes a 223 word, expansive, detailed, complex definition. The patent, however, while it asserts enablement, does not assert it is enabled to the extent of the choice (b) standard of the Court of Appeals (nor need it).

claim 7 (asserted claim covering antibody that binds to particular residue in PCSK9).[8]

Petitioners sued for infringement of seven patents. *See, e.g.*, Proposed Pretrial Order ¶¶1-15 ECF 237. Petitioners generally alleged infringement of each and Respond'ents generally denied infringement of any valid, enforceable claim. *Id.,* ¶18; Am. Compl. ¶¶64-96, ECF 10.

Infringement was straightforward. Petitioners' case distilled to eight claims; others reciting specific antibody structures were eliminated. Asserted claims covered "isolated monoclonal" antibodies identified as such and by their characteristic of binding to one or more residues identified as present in the target antigen's key region. *E.g.,* '165 Patent claim 7; Proposed Pretrial Order ¶¶20-22 ECF 237. Respondents stipulated to infringement. Stipulated Order ¶¶1-3, ECF 237.

The case turned to validity disputes on a further narrowed set of five claims: 165 Patent claims 7, 15, 19, and 29 and '741 Patent claim 7. Jury verdict, ECF 304.

Petitioners prevailed on a validity dispute of alleged non-obviousness, through arguments that are now somewhat ironic—since Petitioners argued non-enablement—of the prior art. Respondents attempted

[8] Some dependent claims claim both antibody structure and PCKS9 structures to which the antibodies bind. '741 Patent claim 6 (This unasserted claim covers an antibody with a particular structure that binds to a particular residue in PCKS9).

proof that the claims were obvious in light of two references. Mot. J. ¶1 ECF 282. Petitioners argued in part that even though one reference characterized the full structure of PCSK9—260 amino acids—it failed to direct an artisan to produce antibodies binding to the parts of the target antigen in Petitioners' claims. *Id.* ¶22. Petitioners further argued there was no "expectation of success" from the reference because an artisan following it would make an antibody binding to other parts. *Id.* ¶23.

Non-obviousness turned on Petitioners' argument that the references failed to provide written description and enablement support in their priority documents, without which they were not timely prior art at all. *Id.* ¶¶3-15; Mem. Evidentiary Issues, ECF 240-1 ("The written description analysis requires showing that a POSITA would recognize the applicant possessed the later claimed antibodies, and [Respondents] indisputably [have] not done this."). Respondents conceded before trial that it did not offer a factual analysis on these issues, and later argued that a "full-blown written description and enablement analysis" was not necessary for the prior art, where, it argued, "less demanding" standards applied, enablement is "presumed," and describing a "species" is enough for written description "rather than the entire breadth of [a] broad functional genus claim." *Id.*, Mot. J. ¶¶7-10ECF 282; *Amgen Inc. v. Sanofi*, No. 17-1480, 2017 WL 1013453 *49-50 (Fed. Cir. Mar. 3 2017). The District Court granted JMOL for Petitioners after trial, finding the references were not prior art. *Amgen Inc. v. Sanofi*, 872 F.3d 1367, 1380 (Fed. Cir. 2017). These findings were affirmed on

appeal after Petitioners reiterated their arguments and further asserted the references were prophetic and without any antibody examples, meaning Respondents could not prove written description or enablement in light of their own position alleging insufficiency in Petitioners' disclosure of twenty-six antibodies. *Id.*; *Amgen*, No. 17-1480, 2017 WL 1251183, *49-51 (Fed. Cir. Mar. 24, 2017).

The primary validity disputes between the Parties on claims still at issue focused on written description and enablement, which were tried twice before juries, once after a remand addressing evidentiary and jury instructions issues. *Amgen Inc. v. Sanofi*, 987 F.3d 1080, 1083-84 (Fed. Cir. 2021).

On written description, Respondents contended that Petitioners failed to disclose enough species to support their claimed genus as, it further contended, the twenty-six antibody species were "dwarfed" by "the tens of thousands to millions of other antibodies falling within," it argued, the claims. Br. Supporting Mot. J. 1, ECF 905. Respondents asserted that their own product and others were within the claims but had materially different structures, arguing this confirmed that Petitioners' examples could not "reflect the structural diversity of the claimed genus," or show there was a common structural feature that could support written description of Petitioners' genus claims. *Id.* 5-9. Respondents further argued that Petitioners' claims recited structures of PCSK9, not antibodies, and that this failed to inform artisans what antibody structures would work. *Id. 9-13.*

Petitioners argued there was a "reasonable structure-function correlation" for their claims and that the location "where an antibody binds to an antigen" provides the structure-function correlation. Mot. J. 2-7, ECF 842.

Petitioners prevailed before both juries on written description, and the District Court denied JMOL after both trials. *Amgen*, 987 F.3d at 1083-84.

On enablement, Respondents contended to the trial court that the claims were not enabled because, they asserted, Petitioners' witnesses conceded that nearly all antibodies covered by the claims are impossible to make, such as an antibody that only binds to certain residues of PCSK9. Br. Supporting Mot. J. 14-15, ECF 905. Respondents further argued that the claims required undue experimentation to practice and thus could not be enabled given the Respondents-asserted immense breadth of the claims and unpredictability in antibody activity—quoting Respondents, "even the most highly skilled person could not determine an antibody's function (*i.e.*, where it will bind) from its structure (*i.e.*, its amino acid sequence), or *vice-versa*." *Id.* 15-20.

The Parties agreed the level of skill in the art was that of an M.D. or a Ph.D. in immunology or a related field with years of experience studying the structural and/or functional properties of complex proteins like antibodies. Jury Instructions 10, ECF 812. Petitioners argued the enablement issue by explaining that such a highly capable artisan could employ "conventional and routine technologies for making antibodies," apply "standard techniques" to make claimed

antibodies, and that such work, even if repetitive, was not "undue." Mot. J. 7-11, ECF 842. Petitioners further argued it was "well-established" that screening work, such as preparation and testing of antibody activity, has been held to provide sufficient enablement in this technology area, showing experimentation in this case was not undue. *Id.* 11.

Petitioners prevailed on enablement before both juries, but after the second trial, the District Court granted JMOL for Respondents on the issue (which it had denied after the first trial). The Court of Appeals affirmed. *Amgen*, 872 F.3d at 1379; *Amgen,* 987 F.3d at 1083-84.

Petitioners maintain the claims are enabled because embodiments can be "made quickly and easily" by an artisan following Petitioners' "roadmap" using routine methods. Pet. 9-10, 23. Petitioners further argue that Respondents have tellingly been unable to identify any embodiment that could not be easily and cheaply made by a skilled artisan. *Id.* Respondents assert that the verdicts of enablement were based on a case-specific application of the enablement factors, and that Petitioners' claims still must fail because, at best, they enabled only "part" of the invention. Opp. 29-30.[9]

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[9] The Opposition includes seemingly misdirecting statements, including, *e.g.,* that "Amgen's experts admitted that the amount of experimentation necessary to make and use (*i.e.*, enable) the claimed antibodies was 'an enormous amount of work' and not 'practical'; no 'antibody scientist would even contemplate doing' it." Opp. 9. The position seems to be *sub silentio* that "the" claimed antibodies are "all" claimed

SUMMARY OF ARGUMENT

Amicus suggests the Court make the decision on the one issue presented, that patent enablement—specifically claim enablement[10]—is to be decided by the statutory and time-honored standard that the specification teach artisans how to make and use the invention.

The decision should be made for reasons of *stare decisis,* settled expectations, and most, because enablement is not, because it never has been and never should be—but for decisions such as the reviewed one—a matter of whether the specification has catalogued all possible embodiments of invention and taught each of them; that is not the law.

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antibodies. The Opposition does not dispute that Petitioner enabled, was FDA approved for, and sells a claimed antibody, see Opp. at 3-4, Pet. 8; Petitioners' patents disclose 3,000 antibodies that bind to PCSK9, Opp. at 5; 384 antibodies that block PCSK9 "well," Pet. 8; 85 antibodies that block by 90% or greater, Pet. 8, Opp. 5; "roughly two dozen" antibody amino acid sequences for antibodies that bind PCSK9's "sweet spot," which can be made using the sequences, Opp. 5, Pet. 8; and 2 antibody three dimensional structures, Opp. 5. Respondents also apparently relied on cleverness elsewhere, as, for example, asserting different standards of enablement applied to their prior art references *versus* the claims it infringed. Additional factual statements supporting enablement appear undisputed.

[10] Claim-by-claim analysis is demonstrated in *O'Reilly v. Morse*, 56 U.S. 62 (1853).

ARGUMENT

I. The enablement standard of the patent law has a clear expression in the statutory patent law, the same expression it has had since 1790.

The Court should vacate the decision that led to this case to the extent of resolving that patent enablement is to be decided by whether the specification of the patent teaches artisans to make and use the invention. The applicable patent law, in 35 U.S.C. §112, states the patent law standard for enablement as quoted in the parties' briefs. No doubt can possibly exist that the stated standard is, and long has been, the standard of the law (insignificant wordsmithing excepted). The same standard is stated in U.S. patent law as far back as the Patent Act of 1790—passed the year after the adoption of the Constitution in 1789—and then the Act of 1836 (quoted, interpreted, and applied in *O'Reilly v. Morse*, 56 U.S. 62, 118-119 (1853)).

Consistently, "[p]atent law's enablement requirement rests on a two-century old statutory foundation." Jason Rantanen, *The Doctrinal Structure of Patent Law's Enablement Requirement*, 69 Vanderbilt L. Rev. 1679, 1680 (2019)("Rantanen"), scholarship. law. vanderbilt.edu/ vlr/vol69/iss6/8. "The enablement requirement is a fundamental component of the patent law *quid pro quo*: in return for a patent, an inventor must disclose sufficient information about the invention." *Id.*

II. The enablement standard, further, arose from English common law roots, that used the same standard.

The purpose of letters patent in England in the 1300's was to promote trade and the transfer of knowledge. In one example, King Edward III issued letters patent so a Belgian weaver would move to England and teach his trade there. E. Wyndham Hulme, "The History of the Patent System Under the Prerogative and at Common Law" (1826) 12 LQ Rev 141, 142.

A writing was required about 1740. Hulme, "On the History of Patent Law in the 17th and 18th Centuries" (1902) 18 LQ Rev 280, 283. Lord Mansfield stated that "The general questions on patents are … whether the specification is sufficient to enable others to make it up." *Liardet v. Johnson* (1778), 1 Hayward's Patent Cases 195, 198 (KB).

Noted in *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996), English patent litigation then involved "novelty actions" and "enablement cases." Juries were "to determine whether the specification described the invention well enough to allow members of the appropriate trade to reproduce it." *Markman,* 517 U.S. at 379. For example, in *R v Arkwright* (1785), the patent involved a textile spinning machine. 1 Hayward's Patent Cases 249. Justice Buller instructed the jury that if mechanical men of common understanding could comprehend the specification and make the machine by following the specification and without any inventions or additions of their own, then the specification was sufficient. *Id.*

For another *Arkwright* case from the same period and more recent English case law, see the Petitioners' merits brief at 32-34, 43.

III. Exemplary law review articles not written for the purpose of advocacy in this case document that the Court of Appeals has recently varied greatly from deciding enablement issues based on the time-honored standard and has muddled its own jurisprudence.

Two exemplary law review articles should inform the Court's consideration of the issue of the case in favor of choice (a), that enablement is to be decided by deciding whether relevant people have been taught by the patent's own description how to make and use the invention. Both were not written for the purpose of advocacy in a case. One proves that the Court of Appeals has recently varied greatly from deciding enablement in a proper manner, and both demonstrate that the Court of Appeals has muddled its own jurisprudence on the issue. The first is Dmitry Karshtedt, Mark Lemley, Sean Seymore, *The Death of the Genus Claim*, 35 Harvard J. of L. & Tech. 1 (2012) (in keeping with the Petitioners' merits brief, "Karshtedt")(quotations herein exclude footnote markers). The second is the previously-cited Rantanen.

As Karshtedt explain, the Court of Appeals' enablement "law has changed dramatically in the last thirty years." Karshtedt 1, Abstract. This has been "a surprising shift in the law." *Id.* Karshtedt "explain [that the change] represents both bad law and bad policy." *Id.* "In the last thirty years, the [Court of

Appeals] has struck down [patent] claim after claim on the theory that whatever the patentee has done to justify a broad claim to a group of chemicals, it isn't enough." *Id.* 4. Karshtedt "argue … that doctrinal shifts … reflect a misunderstanding of the purposes that the patent law is supposed to serve. The Court of Appeals has abandoned a practical focus on whether others could make and use the claimed invention, instead favoring a fruitless search for the exact boundaries of that invention. … If the doctrine continues down this path, it may threaten innovation in an important sector of the economy," *i.e.,* "the biotechnology, chemical and pharmaceutical industries." *Id.*

More, Karshtedt assert "the law should go back to the way it was. [C]laims should survive as long as they enable other researchers to make effective use of the teachings of the patent to make and use chemicals …" *Id.* 5. They relate that "Courts' initially favorable response to biotechnology patents helped to spur research and development in this industry and to bring forth groundbreaking, commercially significant inventions." *Id.* 22. But then the Court of Appeals did a shift that "is dramatic." *Id.* 23. The shift "reflects a fundamental—and not widely appreciated—change in patent doctrine." *Id.* Court of Appeals' actions have "led to instability," *id.* 25-26, and created "a troubling dynamic, *id.* 30. "Yes, the PHOSITA [person of ordinary skill in the art] needs to find a species that works. But the [artisan] doesn't need to find *every* species that works to make and use the invention." *Id.* 31. "The concern of enablement law has always been with practical workability: Does the patent teach

others what they need to know. [Recent appellate decisions] represent a categorical shift in thinking away from teaching the [artisan] and toward a precise delineation of the boundaries of the claim". *Id.* "This approach is problematic. It focuses on 'knowing' instead of 'making and using,' which is what the text of [35 U.S.C.] §112 actually requires." *Id.* 33. "This doctrinal shift is a massive change in the Federal Circuit's enablement doctrine." *Id.* 34. The Court of Appeals "has conflated different legal theories and justifications … it has broken the symmetry that has traditionally existed between obviousness analysis under §103 and the disclosure rules of §112." *Id.* 54. This

> move … to a search for a clear definition of which species work and which don't misunderstands the basic purpose of the §112 inquiry. If the patentee defines a clear genus, so that people will know whether or not the chemicals they make fall within the genus, the PHOSITA will be able to make and use the full scope of the genus so long as she can determine how to make chemicals within the genus and assess whether they work for the intended purpose without having to engage in undue experimentation. True, she won't be able to make every species. But why should she want to? That is not the point of §112(a).

Id. 57.

> Unfortunately, courts have expanded … into a general requirement that patentees must "possess" the full scope of the invention, by

> which they seem to mean "know which species work and which ones don't." In effect, courts have converted the full-scope enablement inquiry from "did I teach you enough such that you can make use of the full scope of the invention?" to "did I give you enough information to assess the full list of what works and what doesn't without undue experimentation?" That's an impossible requirement to meet. And it doesn't serve the purposes of §112. It's asking the wrong question, because it's confusing possession of the genus (a written description question) with how people can use what you taught them (an enablement question). An inventor can develop a new genus without pre-identifying every species in that genus. This [is] categorical error.

Id. 62-63.[11]

Karshtedt thus proves that appellate cases have recently varied greatly from deciding enablement in a proper manner. And both Karshtedt and Rantanen demonstrate that the Court of Appeals has muddled its own jurisprudence on the issue. Turning to Rantanen, Rantanen examines a split in appellate jurisprudence: between requiring only one embodiment for enablement, and requiring full-claim-

[11] Note that possession *is* the current standard of the written description requirement, and that Respondents had two bites at the full-scope position, one as to written description possession (with two juries), where it belonged. *Supra* at 8-9.

scope enablement. As Rantanen observes, [d]espite its statutory foundation, much of the actual doctrine of enablement takes the form of statements in judicial opinions. Rantanen 1680-1681. Rantanen then notes that "[w]ithin this layer of express judicial statements exists a well-recognized split: whether enablement of a single mode or embodiment of the claimed invention is sufficient, or whether the full scope of the claim must be enabled." *Id.* 1681.

This is not a split between District Courts, or between cases from the Court of Appeals' predecessor courts and the Court. This is different lines of Court of Appeals cases.

> One line of Federal Circuit cases contains variations on the theme that "[t]he enablement requirement is met if the description enables any mode of making and using the invention." This language does not say that disclosure of one mode can or may be sufficient to enable the claims. It says that one mode necessarily enables the claims: the enablement requirement "is met" if the description enables any mode of making and using the invention. The outcomes of these cases leave no doubt that one is enough.

Rantanen 1681.

"These two pronouncements stand in direct contradiction. The first says that enablement of one mode is enough, the other that it is definitely not enough." *Id.*

"Notwithstanding [appellate cases that require full-scope enablement], recent Federal Circuit and district court opinions cite [another appellate case] for its [following] 'any mode' language: 'It is well established that the "enablement requirement is met if the description enables any mode of making and using the invention."'" *Id.* 1682. "Other recent cases cite [another appellate case] for the requirement that '[t]he full scope of the claimed invention must be enabled.'" *Id.* This is "apparent contradiction," recognized by "scholars (and litigants)." *Id.* Rantanen quotes three other scholars who recognize the split, and disparage it, one of whom describes appellate cases on enablement (and written description) as "'inconsistent and chaotic.'" *Id.* 1683.

Karshtedt confirms this muddle, as above, and in further stating,

> [t]raditionally we've not seen strict application of the §112 doctrines to either the mechanical arts or to the IT industry. …But that's changing. [T]he court has sometimes applied the idea of full-scope enablement to invalidate genus claims outside chemistry, even where those genuses are quite small. A number of commentators have noted the conflict between single-embodiment and full-scope enablement in non-pharmaceutical areas. We may see more such cases in the future.

Id. 72. An example case is the side impact crash sensor case cited in Petitioners' merits brief at 44, a case of two embodiments.

Karshtedt cites to three other scholarly articles, including Rantanen.[12] Thus, Karshtedt confirms Rantanen's noted Court of Appeals inconsistency, with a traditional approach that had existed, but a traditional approach that is changing, yet only for some, not all, cases, but with any line between chemistry and all other cases breaking down, but only "sometimes."

IV. Related aspects of the Court of Appeals' jurisprudence also cause confusion and doubt.

Related aspects of enablement case law also cause confusion and doubt for patent system users, including practitioners such as the members of amicus. First, Court of Appeals enablement cases recognize the use of "prophetic examples" in patents as appropriate to establish bounds of enablement. "The U.S. Patent and Trademark Office first recognized prophetic examples in 1981." Janet Freilich, Prophetic Examples, 53 U.C. Davis L. Rev. 663, 720 (2019) ("Freilich"), https://lawreview.law.ucdavis.edu/issues/53/2/articles/files/53-2_Freilich.pdf. "Prophetic examples are experiments that report protocols [*i.e.,* plans for tests and experiments] that were not actually conducted and describe results that are made up, or prophesized." Freilich 671. "The PTO

[12] Karshtedt cites Rantanen as making an effort to reconcile the cases, as a "cf" citation. But Rantanen attempts reconciliation through the scholarly invention of the fanciful: "the operation of another, unseen layer of the law." *Id.* The attempt at reconciliation, while laudable, fails in positing "unseen" law, and only further proves the lack of reconcilable decisions.

defines prophetic examples as 'an embodiment of the invention based on predicted results rather than work actually conducted or results actually achieved.'" Freilich 673.

> The PTO and the federal courts explicitly permit prophetic examples can be used to satisfy the enablement and written description requirements in the same manner as working examples. To satisfy the enablement requirement, applicants must describe the invention sufficiently to enable another person in the field to make and use the claimed invention. Prophetic examples teach strategies for making and using the invention and thus help satisfy the enablement requirement.

Freilich 673-674. "The law of prophetic examples has stayed substantially static since 1981. The relevant provision in the [Manual of Patent Examination Procedure, "MPEP"] has not changed. Case law has by and large simply pointed to the MPEP as a source of permission for prophetic examples." Freilich 680.

Unfortunately, "[m]ost cases that address prophetic examples simply accept that the prophetic example supports the invention and include no discussion of the examples' value or any controversies or doctrinal points." Freilich 680. More unfortunately, the "seminal case," Freilich 680, at the Court of Appeals for the evidentiary factors to decide enablement is *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988). And *Wands* does not seem to permit of

consideration of prophetic examples, or perhaps it does.

> Though it is well settled that prophetic examples can be used to satisfy the disclosure requirements, the issue still arises frequently, which suggests that litigants remain somewhat skeptical. This skepticism is not entirely unfounded. The *Wands* factors, which embody the seminal test for enablement, list the presence or absence of "working examples" as a factor in the analysis, but omit prophetic examples. Furthermore, courts will often hint that prophetic examples are not quite as good as working examples by prefacing prophetic evidence with a word suggesting hesitation, such as bemoaning the lack of "working or *even* prophetic examples."

Freilich 680.

Freilich itself suggests "measures against prophetic examples," in spite of the use of prophetic examples arising "out of early twentieth-century notions of fairness across industries as well as out of administrative necessity," and their use having "never been seriously questioned by scholars." Freilich 726.

Second, and apparently a basis for wrong decision in this case, the Court of Appeals has not made a claim's need for new invention or non-routine experimentation a claim's only enablement problem. It has made "*routine but undue"* experimentation an enablement problem, causing invalidity. Karshtedt 26-27.

Third, related to the subject of this case, as well as prophetic examples, routine and non-routine experimentation, and *Wands* factors, *Wands* states that where an issue of need for experimentation arises as to enablement, there are factors for analysis as to whether the experimentation is "due" or "undue." *Wands* 737. *Wands* states further that eight factors are to be considered. *Id.* One of the factors is "(1) the quantity of experimentation necessary." *Id.* But on the subject of what is the final standard of whether experimentation is "due" or "undue," *Wands* is silent. What is it that makes experimentation "due" or "undue"? How are the *Wands* factors to be analyzed relative to any standard of weighting, balance, or ultimate decision? *Wands* and the Court of Appeals do not say.

Wands factors are considered by almost all, if not all (amicus members included), without question to be appropriate areas for evidentiary inquiry. But *Wands* does not provide adequate legal structure for analysis, since the standard of "due" and "undue" is amorphous. *Wands* admits as much in conceding only a little, that "[w]hether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." *Id.* *Wands* also admits "undue experimentation" is not a standard of 35 U.S.C. §112 but claims a case law standard: "[t]he term 'undue experimentation' does not appear in the statute, but it is well established." *Id.* Unfortunate is that if *Wands* is correct, then case law has substituted a much more amorphous standard, that of "due-ness" for a much less difficult standard, *i.e.,* whether an invention has

been explained so as to be made and used. *Wands* does not help in seeming to state that a large part of its conclusion is from "reasonable" analysis. *Id.* Reasonableness is no better than "due-ness," especially where *Wands* states that "due-ness" is not a standard of "quantity," since the quantity of experimentation needed is a *factor* in *Wands*, not a definitional term for understanding the meaning of "due-ness." *Id.*

It is not inappropriate to find guidance for this and other biotechnology cases as to what is to be considered due or undue experimentation by example, of course. *Wands* itself concludes that an antibody-antigen-related patent was enabled in spite of need for experimentation.

And this Court has set what perhaps might be considered a most significant precedent for this, biotechnology, and all cases in *Consol. Elec. Light Co. v. McKeesport Light Co. (Incandescent Lamp),* 159 U.S. 465 (1895). There, the Court found a patent claim not valid in part because Thomas Edison had proof of over six thousand failed attempts to make filaments of light bulbs of the materials, fibers and textiles, claimed by the patent owner. *Id.* 6-7. This proved the patent owner had not "discovered in fibrous and textile substances a quality common to them all, or to them generally, as distinguishing them from other materials, such as minerals, etc., and such quality or characteristic [as] adapted them peculiarly to incandescent conductors," *id.* 6*,* which, if proven, could have entitled them to a patent on the same, *id.* 6, 11.

The case, however, was arguably decided on the principle of the need for an adequate written description to support the claim, not the lack of enablement: "If the description be so vague and uncertain that no one can tell, except by independent experiments, how to construct the patented device, the patent is void." *Id.* 8. It is also arguably decided on a showing of first invention by Edison, in referencing "brilliant discoveries by others." *Id.* 7.

Even if *Incandescent Lamp* is considered on enablement, moreover, it seems *sui generis* in having proof of thousands of failed attempts to practice the invention, by both Edison, the alleged infringer, and the patent owner itself, sufficient to prove without a shadow of a doubt the lack of enablement. In the ultimate example, the patent owner had itself abandoned its own choice of filament and adopted Edison's. *Id.* 4. Certainly, where the patent owner's stated embodiment could not enable an invention sufficiently for the patent owner itself to stay with it, instead of adopting a later-developed, "brilliant discover[y] by [another]," the invention was not enabled.

That is not this case, where apparently the Respondents cannot identify *any* embodiment that cannot be easily and cheaply made by a skilled artisan. Pet. 9-10, 23. More, Respondents had a bite at the not-reach-the-full-scope position under the heading of written description (with two juries), and another (with two juries) under the heading of enablement, failed twice as to written description, twice with juries as to enablement, and once with a trial judge as to enablement. *Supra* at 8-9.

V. Because of stare decisis, settled expectations, and that the Court of Appeals has varied greatly from deciding enablement issues based on the time-honored standard, the decision of the case should be vacated and the case returned to the Court of Appeals.

Contrasted with the many issues of problem case law on enablement, a central need of patent law is stability. The Court, as a result, should respect its own precedents and apply the statutory patent law as written—not accept it being overwritten. This Court quoted, interpreted, and applied the enablement standard of statutory law as now and long-stated at least as early as 1853, in *O'Reilly v. Morse*, 56 U.S. 62, 118-119 (1853), [13] while the Court has never in enablement law applied the reach-the-full-scope standard. *O'Reilly* interpreted the statutory law in summing it up "in a few words" while applying it, *id.* 119:

> Whoever [invents] is entitled to a patent …, provided he specifies the means he uses in a manner so full and exact that anyone skilled in the science to which it appertains can, by using the means he specifies, without any addition to or subtraction from them, produce precisely the result he describes. … And if it can be done, then the patent confers on him the exclusive right to use the means he

[13] The Court relied on the Patent Act of 1836 but before applying it, applied English *Neilson v. Harford,* 151 ER 1266 (1841). *Neilson* was consistent with *O'Reilly.*

> specifies to produce the result or effect he describes, and nothing more. And it makes no difference in this respect whether the effect is produced by chemical agency or combination, or by the application of discoveries or principles in natural philosophy known or unknown before his invention, or by machinery acting altogether upon mechanical principles.

O'Reilly states, importantly, that enablement depends on whether an inventor "specifies the *means* he uses in a manner so full and exact that anyone skilled in the science to which it appertains can, *by using the means* he specifies, without any addition to or subtraction from them, produce precisely the result he describes," including within the allowable *means* "chemical *agency* or combination, … *application of discoveries*, … or … machinery acting … upon mechanical *principles*." *O'Reilly* thus stands as a precedent interpreting a statutory standard, an interpretation and a standard that have held sway—but for Court of Appeals decisions as in this case—for about 170 and 230 years respectively. The interpretation includes giving respect to "*means," "agency,"* and *"applications of discoveries and principles,"* not details of nuts and bolts. And the interpretation and standard are one, and only one, for all the sciences and useful arts, as they should be.[14]

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[14] Nearly all claims across all technologies include functions, and are "genus" claims, to major extents. Many nouns in claims evoke functions not structures, and cover genuses, like "detent," "brake," clamp." Certainly, functions are permitted in claims—

O'Reilly thereby invokes the *stare decisis* rules of *Kimble v. Marvel Entertainment LLC,* 576 U.S. 446 (2015).[15] First, it is important the law remain settled. *Id.* Second, "*stare decisis* carries enhanced force when a decision … interprets a statute. Then, … Congress can correct any mistake it sees." *Id.* Congress has overhauled the patent law many times since 1790, only tinkering with details of the language, not the rule, of patent enablement law. See Petitioners' merits brief for enablement law history. "Congress's continual reworking of the patent laws—but never of the [enablement] rule—further supports leaving the [*O'Reilly*] decision"—and the enablement law as written—"in place." *Id.* ("Enablement" and *O'Reilly*

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claim elements may even be expressed as means to accomplish functions, and cover undisclosed equivalent structures in their genus. *Warner-Jenkinson, infra* 29-30 n. 16. No good claim has ever detailed an invention to its nuts and bolts, amino acids, or ropes and pulleys, no matter how much its invention is in need of a nuts-and-bolts explanation of its enablement. *See, e.g.*, C. Shifley, *The Wright Brothers: Would Their Patent Survive Today's Patent Law Rigors? Doubtful,* 100 J. Pat. & Trademark Off. Soc'y 12, 12-16 (2018)(Wright Brothers' claims used broad clauses; Wrights had one embodiment; claims held to also cover Curtiss embodiment). Why? For a patent that lawfully "protects against [always present] efforts of copyists to evade liability." *Festo* 726-727.

[15] Amicus also urges the inclusion with *O'Reilly* in favor of *stare decisis* of all the cases of this Court that state and/or assume the correct standard of the patent law, being, for example, those relied on in the Petition at 5 in support of the first issue, *i.e.,* cases such as *Markman*, *Minerals Separation, Ltd. v. Hyde*, 242 U.S. 261, 271 (1916), *The Telephone Cases*, 126 U.S. 1, 534-536 (1888), and *Wood v. Underhill*, 46 U.S. (5 How.) 1, 4 (1846).

inserted, as considered appropriate, by amicus). Third, patent law cases are property cases; patents are property. "[T]he subject matter of [the case, as a result] adds to the case for adhering to precedent." *Id.* 457. As this Court has "often recognized," in "'cases involving property and contract rights'—considerations favoring *stare decisis* are "at their acme." *Id.* Nor is *O'Reilly* a "doctrinal dinosaur or legal last-man-standing." *Id.* 458. The Court, as a result, should respect its own precedent and accept the statutory patent law as written, not as being rewritten by the Court of Appeals.

The settled expectations of users of the patent system are also to at least some extent paramount. See, e.g., *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002). Karshtedt notes that patent system users are maintaining their approach to patent enablement consistent with the statutory law and cases such as *O'Reilly* and those of the Court of Appeals from a time before decisions like the one under review. That maintenance reflects settled expectations. Karshtedt notes the maintenance, and posits two ideas for it, such as lack of knowledge of the change in the Court of Appeals, and lack of caring. Karshtedt 64-70. But these ideas—speculations—only step right past the most obvious—that users have a settled expectation consistent with the words of 35 U.S.C. §112. Why would they have that? Obviously, lifetimes of the law as written, and they know—it cannot reasonably be doubted—that the Court of Appeals cases are split, *see supra a*t 19 (Rantanen, "recognized by … litigants"), it is not the final authority on patent law, this Court has

frequently overturned decisions of the Court of Appeals in numerous areas of patent law,[16] and such an overturning could come as well to enablement law. (An example of knowing users are Petitioners. *See supra* 3-6. *See also*, *e.g.*, "U.S. Supreme Court Decision Limits Extraterritorial Reach of U.S. Patents: What Manufacturers and Exporters Need to Know," a law firm law update: the "Supreme Court's

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[16] The list of areas of patent law in which this Court has overturned the Court of Appeals is long, and the frequency of the overrulings notorious. The list includes: patentable subject matter, *Bilski v. Kappos*, 561 U.S. 593 (2010), *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012), obviousness, *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), definiteness, *Nautilus, Inc. v. Biosig Instruments, Inc*, 572 U.S. 898 (2014), doctrine of equivalents, *Warner-Jenkinson Co., Inc. v. Hilton Davis Chemical Co.*, 520 U.S. 17 (1997), prosecution history estoppel, *Festo*, indirect infringement, *Limelight Networks, Inc. v. Akamai Techs, Inc.*, 572 U.S. 915 (2014), 35 U.S.C. §271(f) infringement, *Microsoft Corp. v. AT&T Corp.*, 550 U.S. 437 (2007), *Life Technologies Corp. v. Promega Corp.*, 580 U.S. 140 (2017), injunctions, *eBay Inc. v. Merchexchange L.L.C.*, 547 U.S. 388 (2006), laches, *SCA Hygiene Products v. First Quality Baby Products, LLC*, 137 S. Ct. 954 (2017) offshore damages, *WesternGeco LLC v. Ion Geophysical Corp.*, 138 S.Ct. 2129 (2018), design patent damages, *Samsung Electronics Co. v. Apple Inc.* , 580 U.S. 53 (2016), attorneys fees awards, *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 572 U.S. 545 (2014), and venue, *Christianson v. Colt Indus.*, 486 U.S. 800 (1988), *Holmes Group, Inc. v. Vornado Air Circulation Systems, Inc.*, 535 U.S. 826 (2002), *TC Heartland LLC v. Kraft Foods Group Brands LLC*, 137 S.Ct. 1514 (2017). See, *e.g.*, Gary Hoffman & Robert Kinder, *Supreme Court Review of Federal Circuit Patent Cases: Placing the Recent Scrutiny in Context and Determining If it Will Continue*, 20 DePaul J. Art, Tech. & Intell. Prop. L. 227 (2010), available at: https://via.library.depaul.edu/jatip/vol20/iss2/2.

general trend [is] of striking down the Federal Circuit's bright-line rules in favor of more nuanced, standard-based approaches to patent law." https://www.hinshawlaw.com/newsroom-updates-792.html).)

However, the Court should principally make the decision here that claim enablement is to be decided by the statutory and time-honored standard, because it is the right decision, consistent with the statutory law of about 232 years, and all the precedents of the federal courts other than those few that are like the decision of this case. The alternative is deviant from the statutory law, the great weight of precedents, and is only a recent construct. Patent law does not need it—101, 103 and description analyses already resolve whether a patent is too broad.

As well, as in nearly all if not all patent decisions, the specific phrasings of details count, greatly. No phrasing of a patent law standard for enablement should control that is at variance with the statutory standard, and this Court's precedents. The patent law is a finely wrought balance of even more matters than usually referenced—encouragement of innovation, including invention and enhancement of inventions, encouragement of prompt and appropriate public disclosure of innovation, recognition of innovation, reward for innovation through the granting of temporary non-public and limited rights to innovation, prevention of copying and piracy—or, for a non-patent actor, the reward of free competition, and the gain of permanent public knowledge and rights to innovation. While the matters of an exchange of limited rights for gain of permanent public

knowledge and rights to innovation are often referenced,[17] the other matters of the balance exist and are important.[18]

Patent law has come to this time as a complex system of interconnected and inter-reliant parts having matured here from long-standing, time-honored—sometimes Congressionally tweaked—standards over centuries. The law is here, for example, with a long-standing and time-honored—and tweaked—standard for enablement. For a Court of Appeals to have substituted alternate phrasings for statutory and time-honored standards, such as enablement, has been to cause the patent system disruption, with consequences including damages to the balance of system interests and the interests themselves, uncertainties in the system and its future, and increased disputatiousness, all of which is the opposite of the continuous and finely-tuned balance and stability the system deserves and needs. Changed enablement has unbalanced the interests of applicants (also known, and to be respected as, inventors), owners (including governments), other innovators, and all interests around them. Change has done damage primarily to the interests of applicants and owners—but then again, applicants, owners, and other innovators are most often the same people. For all, the change has created uncertainty, at least the uncertainty of whether the change is to last,

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[17] *E.g., Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 63 (1998).

[18] *E.g., Warner-Jenkinson, supra* 29-30 n. 16 at 34 (prevention of copying and piracy).

be overruled, or changed by Congress. Each change, including the one made here, certainly increases disputatiousness. A prime example is Respondents' surprising disputation that one standard of enablement does not apply to both litigated patent claims and prior art, *supra* 7. Another is their position they could argue their full-scope position under both written description and enablement. *Id.* The system has subjected itself to all the more numbers, complexities, poor justice, and missteps of patent litigation.

Enablement *is not—see, e.g.,* history, *O'Reilly*, and this Court's other cases—a matter of whether the specification has catalogued all possible embodiments of invention and taught each.

VI. Stating the correct standard for decision, and vacating and returning the case to the Court of Appeals is what the case needs, all that it needs.

Stating the correct standard answers the question of this case. Stating so is right, necessary, and appropriate to the situation of the Court having granted consideration of the one issue of the case. It's choice (a) or choice (b), it's that simple.

CONCLUSION

Amicus respectfully suggests that the Court use a straightforward approach, and vacates and returns the case to the Court of Appeals for further proceedings.

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