NO. 21-757

In the
Supreme Court of the United States

AMGEN INC., *et al.*,
Petitioners,
v.
SANOFI, AVENTISUB LLC, *et al.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF AMICUS CURIAE INTELLECTUAL PROPERTY OWNERS ASSOCIATION IN SUPPORT OF NEITHER PARTY

Karen Cochran
President
Henry Hadad
Chair,
Amicus Brief Committee
Samantha Aguayo
Deputy Executive Director & Chief Policy Counsel
INTELLECTUAL PROPERTY OWNERS ASSOCIATION
1501 M Street NW
Suite 1150
Washington, DC 20005

Vanessa Yen
Counsel of Record
Evan Diamond
KING & SPALDING LLP
1185 Ave. of the Americas
34th Floor
New York, NY 10036
(212) 556-2100
vyen@kslaw.com

Counsel for Amicus Curiae Intellectual Property Owners Association

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INTEREST OF AMICUS CURIAE

Amicus curiae Intellectual Property Owners Association (IPO)[1] is an international trade association representing a "big tent" of diverse companies, law firms, service providers, and individuals in all industries and fields of technology that own, or are interested in, intellectual property (IP) rights. IPO represents some of the most innovative companies in the United States. IPO's almost 200 corporate members develop, manufacture, and sell technology-based products in a wide range of industries. IPO is committed to serving the interests of all intellectual property owners in all industries and all fields of technology.

Founded in 1972, IPO's mission is to promote high quality and enforceable IP rights and predictable legal systems for all industries and technologies. IPO advocates effective, affordable, and balanced IP rights before both Congress and the United States Patent and Trademark Office (USPTO) and has filed amicus *curiae* briefs in this Court and other courts on significant issues of intellectual property law. The members of IPO's Board of Directors, which approved the filing of this brief, are listed in the attached Appendix.[2]

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[1] No counsel of record for any party authored this brief in whole or in part, and no person or entity other than *amicus curiae* made a monetary contribution to the preparation or submission of this brief. All parties have consented to the filing of this brief.

[2] IPO procedures require approval of positions in briefs by a two-thirds majority of directors present and voting.

INTRODUCTION AND SUMMARY OF THE ARGUMENT

IPO's corporate members invest tens of billions of dollars annually on research and development and employ hundreds of thousands of scientists, engineers, and others in the United States to develop, produce, and market innovative new products and services. To protect their inventions, IPO's members collectively hold tens of thousands of U.S. patents and account for a substantial portion of the patent applications filed every year at the USPTO.

This case presents an issue of substantial practical importance to IPO. The legal doctrine and statutory provision at issue here—"enablement" under 35 U.S.C. § 112(a)—have been a critical component of United States patent law from the earliest days of the nation and remain so today. The enablement standard of § 112(a) reflects the balance between the public disclosure function of the patent specification (*i.e.*, teaching others skilled in the art to make and use the claimed invention) and the time-limited innovation encouragement functions of patent claims (*i.e.*, granting the patentee the right to exclude others from infringing the claimed invention).

The enablement analysis under § 112(a) should be applied in a predictable and fair manner that is consistent with the statutory language and longstanding precedent and should not "disrupt the settled expectations of the inventing community." *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 739 (2002). Section 112(a) and this Court's precedent require that the enablement analysis is to be performed from the perspective of a

"person skilled in the art." In assessing § 112(a) enablement, courts are to consider whether a skilled person reading the patent specification (and armed with the prior art knowledge and technical skills available to a skilled person) could make and use the claimed invention without undue experimentation. Taken together, these principles ground enablement in a fact-specific, flexible analysis that is adaptable to the particular technological field at hand and reflects the understanding, knowledge, and abilities of a skilled person in that field.

The Federal Circuit also has developed the eight-component "*Wands* factors" analysis that is a helpful tool for evaluating and balancing the various competing considerations in the enablement analysis under § 112(a), though it is not an exhaustive list of all relevant considerations. The ultimate question under § 112(a) remains whether, on the factual record at hand, the specification would enable a person skilled in the art to make and use the claimed invention without undue experimentation.

Further, it is important to maintain the appropriate burden of proof when assessing enablement under § 112(a). For example, when enablement arises as an invalidity defense in federal district court, the burden always rests on the patent challenger to prove lack of enablement by clear and convincing evidence. *See Microsoft Corp. v. i4i Limited P'ship*, 564 U.S. 91, 100-03 (2011). Likewise, because the § 112(a) enablement analysis is a fact-intensive inquiry that can depend heavily on technical evidence regarding the perspective of a person skilled in the art, it is important for courts on appeal to give due

deference to the fact-finder's credibility determinations in weighing competing expert evidence. *See, e.g.*, *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 611 (1950).

ARGUMENT

I. Section 112(a) Grounds Enablement in the Perspective of a Person Skilled in the Art, and Strikes a Balance Between Ensuring Claimed Inventions Are Not Unfairly Avoided and Are Not Given Undue Breadth

1. The statutory standard for enablement is found in 35 U.S.C. § 112(a), which states:

> ***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*** . . . .[3]

This statutory language derives from predecessor statutes dating back to the founding of the country,[4]

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[3] Unless otherwise noted, all emphasis is added, and all internal citations and internal quotation marks are omitted.

[4] The 1836 and 1870 Patent Acts included provisions with essentially the same statutory language (*see* Act of July 4, 1836, ch. 357 § 6, 5 Stat. 117, 119; Act of July 8, 1870, ch. 230, § 26, 16 Stat. 198, 201). The 1793 Patent Act further provided that the written description "shall . . . distinguish [the invention] from all other things before known" (Act of Feb. 21, 1793, ch. 11, § 3, 1 Stat. 318, 321–22)—a requirement that the 1836 Act

and was carried forward into the 1952 Patent Act as 35 U.S.C. § 112, ¶ 1 (pre-AIA), now recodified as § 112(a) (AIA).

The language of § 112(a) first addresses what the patent specification (*i.e.*, the body of the patent) must contain: "a written description of the invention, and of the manner and process of making and using it." Second, § 112(a) provides that the aforementioned written description is to be "in such full, clear, concise, and exact terms as to ***enable any person skilled in the art*** to which it pertains . . . ***to make and use the same***." Put simply, the enablement inquiry under the statutory language of § 112(a) asks whether, for a "***person skilled in the art,***" the written description is sufficiently "full, clear, concise, and exact" to "***enable***" the skilled person to "***make and use***" the invention claimed.

As discussed below, while the Federal Circuit has developed helpful frameworks to assess whether a patent's specification comports with the statutory enablement requirement, such as the "*Wands* factors" (*see* Section II *infra*), it is important that the enablement analysis remains faithful to the statutory language of § 112(a) and the balance reflected by that language. *See, e.g.*, *Bilski v. Kappos*, 561 U.S. 593, 602 (2010) ("[C]ourts should not read into the patent laws limitations and conditions which the legislature has not expressed.").

2. This Court and others have ruled that enablement under § 112(a) and its statutory

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subsequently eliminated in conjunction with introducing patent claims separate from the specification.

predecessors is assessed from the perspective of a "person skilled in the art"—the intended audience for patents. *See, e.g.*, *In re Storrs*, 245 F.2d 474, 478 (C.C.P.A. 1957) ("In determining the certainty required [under § 112(a)], it cannot be forgotten that the disclosure is not addressed to the public generally, but to those skilled in the art.") (citing *Mowry v. Whitney*, 81 (14 Wall.) U.S. 620 (1871)); *Mowry*, 81 U.S. at 644 ("The specification . . . is to be addressed to those skilled in the art, and is to be comprehensible by them.").

A patent specification thus need not disclose all information known to a person skilled in the art—such that a skilled person could fill in the patent disclosure with their knowledge. In other words, a patent specification might be sufficiently enabling when read in view of the technical comprehension, prior art knowledge, and routine experimental techniques available to a person skilled in the art, though it may not be apparent as such to a lay person. *See, e.g.*, *Mowry*, 81 U.S. at 644 ("The specification . . . may be sufficient, though the unskilled may not be able to gather from it how to use the invention. . . . Addressed as it is to those skilled in the art, it may leave something to their skill in applying the invention . . . ."). The extent of description sufficient to enable a claimed invention may vary depending on the nature of the technological art at hand and the knowledge and abilities of a person skilled in that art. *See, e.g.*, *Minerals Separation Ltd. v. Hyde*, 242 U.S. 261, 270 (1916) ("[T]he certainty which the law requires in patents is not greater than is reasonable, having regard to their subject matter."); *Mowry*, 81 U.S. at 644 ("[I]t is evident that the definiteness of a

specification must vary with the nature of its subject.").

For example, because patents are "directed to those skilled in the art," this Court and others have held that the "specification need not teach or point out in detail that which is well-known in the art." *In re Myers*, 410 F.2d 420, 424 (C.C.P.A. 1969); *see also In re Bosy*, 360 F.2d 972, 976 (C.C.P.A. 1966) ("That which is common and well known [to a person skilled in the art] is as if it were written out in the patent.") (quoting *Loom Co. v. Higgins*, 105 U.S. 580, 586 (1881)); *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986) ("[A] patent need not teach, and preferably omits, what is well known in the art."). Accordingly, the "omission" of some claimed subject matter from the specification "is not fatal" to enablement under § 112(a) "where . . . the disclosure is sufficient to enable ***those skilled in the art*** to practice the invention." *See Myers*, 410 F.2d at 424 (emphasis in original).

Likewise, "an applicant is not required to describe in the specification every conceivable possible and future embodiment of his invention." *Cordis Corp. v. Medtronic AVE, Inc.*, 339 F.3d 1352, 1365 (Fed. Cir. 2003); *see also In re Angstadt*, 537 F.2d 498, 503 (C.C.P.A. 1976) (explaining that patentees "are ***not*** required to disclose ***every*** species encompassed by their claims even in an unpredictable art," and that "each case must be determined on its own facts") (emphasis in original). While specific "working examples" can be helpful to consider in assessing enablement under § 112(a), "the number and variety of examples are irrelevant if the disclosure is

'enabling' . . . ." *See In re Borkowski*, 422 F.2d 904, 910 (C.C.P.A. 1970) ("[T]here is no magical relation between the number of representative examples and the breadth of the claims."). Depending on the facts, it is even possible for a patent specification to be enabling though it contains no working examples of the claimed invention. *See, e.g.*, *id.* at 908 ("[A] specification need not contain a working example if the invention is otherwise disclosed in such a manner that one skilled in the art will be able to practice it without an undue amount of experimentation."); *Alcon Rsch. Ltd. v. Barr Labs., Inc.*, 745 F.3d 1180, 1189 (Fed. Cir. 2014) ("[A] patent does not need to guarantee that the invention works for a claim to be enabled. . . . [A] patentee is not required to provide actual working examples . . . .").

Depending on the level of skill and the facts—courts have also found that patents can claim more than their specific exemplary embodiments, and that patent claims may be enabled even where making and using the claimed invention may involve some routine experimentation or testing by a skilled person—so long as such testing does not amount to "undue experimentation." *See, e.g.*, *Monsanto Co. v. Scruggs*, 459 F.3d 1328, 1338 (Fed. Cir. 2006), *cert. denied*, 127 S. Ct. 2062 (2007) ("The fact that ***some*** experimentation may be necessary to produce the invention does not render the [patent-in-suit] invalid for lack of enablement.") (emphasis in original); *Atlas Powder Co. v. E.I. Du Pont de Nemours & Co.*, 750 F.2d. 1569, 1576 (Fed. Cir. 1984) ("That some experimentation is necessary does not preclude enablement; the amount of experimentation, however, must not be unduly extensive."); *In re Geerdes*, 491

F.2d 1260, 1265 (C.C.P.A. 1974) ("[Whether] 'experimentation' is involved in [practicing the claimed invention] . . . is not determinative of the question of scope of enablement. It is only ***undue*** experimentation which is fatal.") (emphasis in original).

For example, in a case concerning the oil treatment of metal ores, this Court upheld claims covering "a large class of [ore] substances and . . . range of treatment [conditions]"—despite finding that "preliminary tests" were needed to successfully practice the invention for each individual ore potentially within the claim scope. *See Minerals Separation*, 242 U.S. at 270-71. The Court found the specification was "clearly sufficiently definite to guide those skilled in the art to its successful application," even though (1) "[t]he composition of ores [within the scope of the claims] varie[d] infinitely, each one presenting its special problem," and (2) the specification depended upon "the skill of persons applying the invention" to test and identify the appropriate treatment conditions for each ore embodiment. *See id.* The Court recognized that a person skilled in the art would have viewed such testing as "reasonable" given the subject matter—including because "it is obviously impossible to specify in a patent the precise treatment . . . in each case" to successfully practice the claimed invention across the "large"—perhaps "infinit[e]"—class of ores within its scope. *See id.*

3. Courts have recognized that enablement under § 112(a) requires a balanced analysis with sensitivity to the particular facts of each case, including the

knowledge and abilities of skilled persons to whom patents are addressed, and the practicalities of disclosure and routine experimentation in the pertinent art.

Consistent with the decisions of this Court and others described above, the enablement requirement should not be read to compel a recitation of every potential embodiment a claim covers. Applying a standard where patents can only claim the specific embodiments actually made and disclosed might not provide effective patent protection—especially in fields such as biotechnology where narrow claims are easily designed around with minor, non-innovative changes. *See, e.g.*, *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 966 (Fed. Cir. 2002); *see also Angstadt*, 537 F.2d at 502-03 (expressing concern over "discourag[ing] inventors from filing patent applications in an unpredictable area").

On the other hand, courts have held that the enablement requirement prevents patent claim scope from extending beyond what a skilled person would be enabled to make and use without "undue experimentation." *See* Section III *infra*. In each case, it is critical to apply the perspective of a person skilled in the art, including in assessing the ability of such a person to perform any experimentation required to make and use the claimed invention, and whether the amount of experimentation would be undue.

II. The Enablement Analysis Is a Fact-Intensive Inquiry Aided by, but Not Exhaustively Limited to, the Federal Circuit's "*Wands* Factors" Test, as Applied from the Perspective of a Person Skilled in the Art

IPO comments briefly here on the Federal Circuit's "*Wands* factors" analysis for assessing enablement under § 112(a).

1. The "*Wands* factors," first promulgated in a 1988 Federal Circuit decision as guidance for patent examiners, is a list of eight factors for assessing whether patent claims fail the Federal Circuit's "undue experimentation" standard for lack of enablement under § 112(a)—*i.e.*, whether a person skilled in the art could not make and use the claimed invention without "undue experimentation." *See In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). The Federal Circuit has regularly relied upon these factors in assessing enablement for matters on appeal from both federal district courts and the Patent Office. The Federal Circuit's *Wands* factors include:

(1) the quantity of experimentation necessary,

(2) the amount of direction or guidance presented,

(3) the presence or absence of working examples,

(4) the nature of the invention,

(5) the state of the prior art,

(6) the relative skill of those in the art,

(7) the predictability or unpredictability of the art, and

(8) the breadth of the claims.

See id.

2. IPO notes that the *Wands* factors are not an exhaustive list of all considerations that may be pertinent to assessing enablement under § 112(a) in a given case. That said, IPO views the *Wands* factors as a useful analytical framework for assessing whether a patent specification is sufficient to enable a skilled person to make and use the claimed invention without undue experimentation.

3. As a creation of the Federal Circuit, the *Wands* factors are to be applied consistently with the statutory language of § 112(a) and the precedent of this Court—including the statutory requirement that the enablement analysis is conducted from the perspective of a person skilled in the art. For example, while "the breadth of the claims" and "the presence or absence of working examples" are two considerations under the *Wands* factors, they are to be appropriately balanced against the other *Wands* factors, including factors such as "the state of the prior art" and "the relative skill of those in the art" reflecting the background knowledge and routine experimental skills that a person skilled in the art can bring to making and using the claimed invention.

The *Wands* factors also reflect a fact-intensive analysis and should be sensitive and adapt flexibly to the particular facts in each case—including with respect to the specific technology at hand and the specialized understanding, knowledge, and abilities of a person skilled in the art. Ultimately, the facts in each case will guide whether the *Wands* factors and any other pertinent considerations weigh sufficiently towards nonenablement under the applicable burden

of proof (*e.g.*, clear and convincing evidence of invalidity as proven by the patent challenger). *See* Section III *infra*.

III. U.S. Patents are Presumed Valid, and the Patent Challenger in Federal District Court Litigation Must Prove § 112(a) Invalidity by Clear and Convincing Evidence

Issued U.S. patents are presumed valid. 35 U.S.C. § 282(a). As this Court and others have held, the burden of proving any invalidity defense in cases originating in federal district court always falls on the patent challenger to prove its defense by clear and convincing evidence. *See i4i*, 564 U.S. at 100-03. With respect to § 112(a), this means that the challenger must show by clear and convincing evidence that the patent specification fails to enable a person skilled in the art to make and use the claimed invention—rather than shifting the burden to the patent holder any time a patent claim of meaningful breadth is challenged.

Moreover, in a case where each party presents equally credible fact and expert evidence as to whether a patent's written description would have been sufficient to enable a person skilled in the art to make and use the claimed invention, the tie goes to the patentee. In light of the primacy of the "person skilled in the art" in the statutory language of § 112(a), it is critical that judges reviewing federal district court decisions on appeal (or federal district court judges reviewing jury verdicts) not substitute their lay judgment for the fact-finder's credibility assessments of fact and expert witness evidence regarding the perspective of a skilled artisan as it relates to the enablement analysis.

Whether or not enablement is ultimately considered an issue of law, the assessment of whether the specification is sufficient to enable a skilled person to make and use the claimed invention—and particularly, whether the patent challenger has proved the contrary by clear and convincing evidence—is necessarily a highly fact-dependent analysis that should be reviewed with appropriate deference and caution.

CONCLUSION

Without taking a position on the merits of the specific underlying case, IPO urges the Court to acknowledge the controlling statutory requirements of 35 U.S.C. § 112(a), including that the enablement analysis is to be conducted from the perspective of a person skilled in the art. IPO further encourages the Court to continue allowing a fact-specific analysis to determine whether the specification enables a skilled artisan to make and use the claimed invention without undue experimentation—with relevant competing factors to be balanced and assessed as a whole under the appropriate burden of proof, and with appropriate weight given on appeal to the credibility determinations of fact-finders.

Respectfully submitted,

Karen Cochran
President
Henry Hadad
Chair,
Amicus Brief Committee
Samantha Aguayo
Deputy Executive Director
& Chief Policy Counsel
INTELLECTUAL PROPERTY
OWNERS ASSOCIATION
1501 M Street NW
Suite 1150
Washington, DC 20005

Vanessa Yen
Counsel of Record
Evan Diamond
KING & SPALDING LLP
1185 Ave. of the Americas
34th Floor
New York, NY 10036
(212) 556-2100
vyen@kslaw.com

Counsel for Amicus Curiae
Intellectual Property Owners Association

January 3, 2023

APPENDIX

APPENDIX — MEMBERS OF THE BOARD OF DIRECTORS, INTELLECTUAL PROPERTY OWNERS ASSOCIATION

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Enventys

Scott M. Frank
AT&T

Appendix

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Qualcomm Inc.

Laura Ginkel
Merck & Co.

Krish Gupta
Dell Technologies

Henry Hadad
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Lori Heinrichs
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