

No. 21-757

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**In the Supreme Court of the United States**

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AMGEN INC., ET AL., PETITIONERS

*v.*

SANOFI, ET AL.

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

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**BRIEF FOR VIATRIS INC. AS *AMICUS  
CURIAE* IN SUPPORT OF RESPONDENTS**

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STEFFEN N. JOHNSON  
*Counsel of Record*  
RICHARD TORCZON  
PAXTON M. LEWIS  
*Wilson Sonsini  
Goodrich & Rosati, P.C.  
1700 K Street, N.W.  
Washington, DC 20006  
(202) 973-8800  
sjohnson@wsgr.com*

*Counsel for Amicus Curiae Viatrix Inc.*

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## **QUESTION PRESENTED**

Whether 35 U.S.C. 112(a) requires an inventor, as a condition of obtaining a patent, to provide a written description of the claimed invention that enables skilled artisans to make and use the full scope of the invention without undue experimentation.

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[https://www.uspto.gov/web/offices/ac/ido/o  
eip/taf/us\\_stat.htm](https://www.uspto.gov/web/offices/ac/ido/o<br/>eip/taf/us_stat.htm) (last modified Feb. 9,  
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**INTRODUCTION AND STATEMENT OF  
INTEREST OF *AMICUS CURIAE*\***

*Amicus curiae* Viatris Inc. is a United States-based pharmaceutical company whose various subsidiaries research, develop, and manufacture prescription generic drugs, branded nebulized and injectable drugs, active pharmaceutical ingredients, and over-the-counter health products. As a global company with an industry-leading pipeline including both complex generics and key global brands, Viatris and its subsidiaries often find themselves litigating patent infringement and validity—sometimes as patentees, sometimes as accused infringers.

Viatris is thus keenly interested in promoting legal rules that reward innovation while ensuring that the public benefits from the patent system’s “quid pro quo” with inventors. *Universal Oil Prods. Co. v. Globe Oil & Refin. Co.*, 322 U.S. 471, 484 (1944). The patent law should preserve the “delicate balance” between the interests of “inventors, who rely on the promise of the law to bring the invention forth,” and those of “the public, which should be encouraged to pursue innovations, creations, and new ideas beyond the inventor’s exclusive rights.” *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 731 (2002).

The enablement question as framed by the parties to this case is in one sense quite narrow. All agree that a patent’s written specification must enable the

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\* Pursuant to Rule 37.6, Viatris Inc. affirms that no counsel for any party authored this brief in whole or in part, and that no person or entity other than Viatris and its counsel made a monetary contribution intended to fund the brief’s preparation or submission.

claimed “invention” in “full” (35 U.S.C. 112(a)), that this requirement is not satisfied if making and using the invention requires “undue experimentation,” and that the Federal Circuit’s longstanding decision in *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988), correctly interprets § 112(a) to advance these ends. Pet. Br. 28, 23-24; Resp. Br. 28, 31. The parties differ only over whether the decision below departed from *Wands*, thus establishing a “new test,” and over how the *Wands* standard applies to petitioners’ patents, which broadly claim a genus of antibodies defined in functional terms. Pet. Br. 45; Resp. Br. 48-53.

A decision from this Court that breaks from or significantly reconceptualizes the *Wands* framework could have greatly destabilizing effects on U.S. patent law and innovation. Given the close relationship of enablement to other areas of patentability—and in particular obviousness—the effects of such a decision would not likely be limited to enablement cases. Rather, it could have major ripple effects throughout every area of patent law that probes what gaps ordinarily skilled artisans can reasonably be expected to fill—areas that range from indefiniteness and written description to anticipation and obviousness.

Viatrix has a strong interest in a principled textual approach to enablement—one that ensures courts will continue applying § 112(a) in a predictable, stable, and reasonable manner. Such an approach should require two things: first, that the written specification enable the “full scope” of the claimed invention; and second, that the written specification enable the skilled artisan to make and use that invention without “undue experimentation.” As explained below, that reading of § 112(a) honors the plain text of the statute, nearly two

centuries of this Court’s decisions, and the Court’s flexible approach to obviousness law.

### SUMMARY OF ARGUMENT

I. Section 112(a) of the Patent Act supports the Federal Circuit’s precedent holding that a patent’s specification must enable a skilled artisan to make and use the “full scope” of whatever is claimed without having to engage in “undue experimentation.”

I.A. For centuries, Congress has required inventors seeking a patent under U.S. law to inform ordinarily skilled artisans—in “full, clear, concise, and exact terms”—how to make and use the claimed “invention.” Congress’s use of the words “full” and “exact” plainly supports the “full scope” requirement of current enablement law. Congress cannot plausibly have intended that the term “invention” would mean something different in § 112(a) than in other parts of the Patent Act, and in particular § 112(b), which provides that the patent’s claims must “particularly point[] out and distinctly claim[] \* \* \* the invention.” Moreover, as this Court has observed in interpreting § 102, “the word ‘invention’ in the Patent Act \* \* \* must refer to a concept that is complete, rather than merely one that is ‘substantially complete.’” *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 60, 66 (1998). Thus, the scope of the invention for enablement purposes must be essentially commensurate with the “full” scope of the invention that is claimed.

I.B. The “undue experimentation” element of enablement law is likewise supported by the text of the Patent Act, this Court’s precedents, and Congress’s repeated actions in response to those precedents. To be sure, § 112(a) does not speak of “undue experimentation” in so many words. But whether the patent’s

specification equips those “skilled” in the relevant art to “make” and “use” the claimed invention invariably turns on the ordinary level of skill in that art and the types of experiments that skilled artisans routinely perform. Accordingly, this Court has long held that the specification—“[a]ddressed as it is to those skilled in the art”—“may leave something to their skill in applying the invention” (*Mowry v. Whitney*, 81 U.S. 620, 644 (1872)), provided the requisite experimentation is routine rather than “painstaking” (*Consol. Elec. Light Co. v. McKeesport Light Co.*, 159 U.S. 465, 475 (1895)) or “elaborate” (*Holland Furniture Co. v. Perkins Glue Co.*, 277 U.S. 245, 256-257 (1928)). And Congress has repeatedly reenacted the operative language of § 112 “against the backdrop of [this] substantial body of law,” thus “adopt[ing] the earlier judicial construction.” *Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, 139 S. Ct. 628, 633-634 (2019).

I.C. This Court’s approach to obviousness, a closely related concept, confirms that enablement law should take account of whether the amount of experimentation required to replicate an invention is “undue.” Both enablement and obviousness adopt the vantage point of one of “ordinary skill in the art.” 35 U.S.C. 103; cf. 35 U.S.C. 112(a). Both inquiries thus turn on art-by-art analysis of “the inferences and creative steps that a person of ordinary skill in the art would employ,” and both call for a “flexible approach” rather than “[r]igid preventative rules” that ignore “common sense.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418, 415, 421 (2007). Moreover, changing what is required for defendants to show that a patent does not enable a skilled artisan to make and use the claimed invention will invariably change what is required for defendants to show that the invention is

obvious—warranting double caution in reconceptualizing current enablement law.

II.A. Viewed in light of the foregoing analysis, the Federal Circuit’s enablement precedent is fully rooted in the text of § 112(a) and this Court’s precedents. First, *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988), recognizes that the patent’s specification must “fully enable[] the claimed invention” (*id.* at 736)—in keeping with Congress’s mandate to describe “the *invention*, and \* \* \* 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 “make and use” it. 35 U.S.C. 112(a) (emphasis added). Second, *Wands* recognizes that the need for “routine” testing does not mean that a claim is not enabled, provided the “experimentation needed to practice the invention” is not “undue” (858 F.2d at 736-737)—in keeping with § 112(a)’s directive to analyze enablement from the vantage point of the skilled artisan and this Court’s venerable teaching that patents requiring “elaborate experimentation” go too far. *Holland Furniture*, 277 U.S. at 257. Third, *Wands* takes a balanced, case-by-case approach to the type of experimentation required to “make and use” the claimed invention (858 F.2d at 737)—in keeping with the “common sense” and “flexible approach” that this Court takes to obviousness, a closely related area of law. *KSR*, 550 U.S. at 421, 415.

II.B. The court below did not forge a “new,” “categorically different,” or “exponentially more demanding [enablement] standard”—an “all or nearly all embodiments” test. Pet. Br. 28, 2. On the contrary, it reaffirmed *Wands*. Pet. App. 7a-15a. Petitioners repeatedly cite the court’s statement that the inventor must enable a skilled artisan “to reach the full scope of claimed embodiments” without undue

experimentation. Pet. Br. i (quoting Pet. App. 14a). But there is no basis for their *gloss* on that statement—*i.e.*, for equating “*to reach the full scope of claimed embodiments*’ without undue experimentation” with “to cumulatively identify and make all or nearly all embodiments of the invention without ‘substantial time and effort.’” *Ibid.* Rather, the court below held that “a specification does not need to ‘describe how to make and use every possible variant of the claimed invention’” (Pet. App. 8a (citation omitted)), and petitioners concede that “a patent must reasonably enable the entire scope of the claim—there cannot be large tracts of claimed subject matter that are not enabled.” Br. 28.

II.C. The decision below, like *Wands* itself, “did not proclaim that all broad claims to antibodies are necessarily enabled.” Pet. App. 10a. It simply held that broader claims typically require broader support, particularly where, as here, the art is less predictable—a conclusion that petitioners improperly attempt to challenge in this Court. Pet. Br. 25, 28. Unlike the claims in *Wands*—which recited a *method* of using antibodies—Amgen claims *the antibodies themselves*, broadly defining them in functional terms. The court below correctly held that those broad claims are not enabled. See *Holland Furniture*, 277 U.S. at 257-258.

III. Departing from the *Wands* framework would destabilize patent law. Current law enforces the full scope requirement of § 112(a) while taking a sensible, case-by-case approach to whether the experimentation required to replicate a patented invention is “undue.” That flexible approach has led to a predictable, stable body of enablement law and robust innovation. Petitioners’ alternative approach of requiring little from the patentee in exchange for broad functional claims

would have the opposite effect. Contra *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480-481, 489 (1974). We urge the Court to tread carefully in this vital area.

## ARGUMENT

### **I. Section 112(a) of the Patent Act requires inventors to enable skilled artisans to make and use the full scope of whatever invention they claim without undue experimentation.**

Both the “full scope” requirement and the “undue experimentation” requirement are rooted in the text of 35 U.S.C. 112(a) and this Court’s longstanding interpretation of the Patent Act. Further, Congress has ratified that interpretation by reenacting the relevant text without change, and that interpretation complements the Court’s flexible approach to the closely related requirement of non-obviousness.

#### **A. The “full scope” requirement is squarely rooted in the text of Section 112(a) and this Court’s precedents.**

Ever since 1790, when Congress passed the very first Patent Act, U.S. law has required those seeking patents to provide the Patent Office with a written description of the invention that is sufficiently “particular” and “exact” as “to enable a workman or other person skilled in the art or manufacture, whereof it is a branch, \* \* \* to make, construct, or use the same, to the end that the public may have the full benefit thereof, after the expiration of the patent term.” Act of Apr. 10, 1790, § 2, 1 Stat. 110. By 1836, moreover, Congress required the inventor both to do so in “full, clear, and exact terms, avoiding unnecessary prolixity,” and to “particularly specify and point out the part, improvement, or combination, which he claims as his own invention or discovery.” Patent Act of 1836,

ch. 357, § 6, 5 Stat. 118; see also Patent Act of 1870, ch. 230, § 26, 16 Stat. 199 (requiring “full, clear, concise, and exact terms as to enable any person skilled in the art or science to which it appertains, or with which it is most nearly connected, to make, construct, compound, and use the same”).

These same basic requirements remain part of the Patent Act today. 35 U.S.C. 112. Under § 112(b), the inventor must now provide “one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the *invention*.” *Ibid.* (emphasis added). And under § 112(a), the specification must describe “the *invention*, and \* \* \* 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*.” *Ibid.* (emphases added). For nearly two centuries, then, inventors seeking a patent under U.S. law have been required not only to claim their inventions clearly and with particularity, but also to inform an ordinarily skilled artisan—in “full, clear, concise, and exact terms”—how to make and use those inventions.

The plain text of § 112 unquestionably compels the full scope requirement of current enablement law. In ordinary parlance, “full” means “containing as much or as many as is possible or normal” or “complete especially in detail, number, or duration,”<sup>1</sup> and “exact”

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<sup>1</sup> *Merriam-Webster Dictionary*, <https://www.merriam-webster.com/dictionary/full>; cf. *Black’s Law Dictionary* (11th ed. 2019) (defining “in full” as “[c]onstituting the whole or



means “exhibiting or marked by strict, particular, and complete accordance with fact or a standard.”<sup>2</sup> Under § 112(a)’s plain terms, therefore, the patent’s specification must be sufficiently *comprehensive* to account for how to make and use the invention “in its entirety,” and sufficiently *accurate in detail* to enable an ordinary skilled artisan to make and use precisely the same. *Pfaff*, 525 U.S. at 66.

Further, this Court generally “assumes that ‘identical words used in different parts of the same act are intended to have the same meaning.’” *Sorenson v. Sec’y of Treasury*, 475 U.S. 851, 860 (1986) (citation omitted). Here, Congress gave no signal that it intended the term “invention” to mean something different in § 112(a) than in § 112(b), an adjacent subsection of the Patent Act requiring that the claims “particularly point[] out and distinctly claim[] the subject matter which the inventor or a joint inventor regards as *the invention*.” 35 U.S.C. 112(b) (emphasis added). For that reason, too, the scope of the invention for enablement purposes must be essentially commensurate with the scope of the invention that is claimed.<sup>3</sup>

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complete amount”); *ibid.* (defining “full disclosure” as “[a] complete revelation of all material facts”).

<sup>2</sup> *Merriam-Webster Dictionary*, <https://www.merriam-webster.com/dictionary/exact>.

<sup>3</sup> See *McClain v. Ortmyer*, 141 U.S. 419, 424 (1891) (“The claim is the measure of his right to relief, and, while the specification may be referred to limit the claim, it can never be made available to expand it.”); *The Telephone Cases*, 126 U.S. 1, 536 (1888) (“A good mechanic, of proper skill in matters of the kind, can take the patent, and, by following the

Because “[t]he claims measure the invention” (*Gen. Elec. Co. v. Wabash Appliance Corp.*, 304 U.S. 364, 369 (1938)), inventors who claim narrow inventions need only enable narrow inventions, but inventors who claim broad inventions must enable broad inventions. As this Court has explained, “the word ‘invention’ in the Patent Act unquestionably refers to the inventor’s conception rather than to a physical embodiment of that idea,” and “must refer to a concept that is complete, rather than merely one that is ‘substantially complete.’” *Pfaff*, 525 U.S. at 60, 66 (interpreting 35 U.S.C. 102(b)). And since “a patentee cannot obtain greater coverage by failing to describe his invention than by describing it as the statute commands” (*Halliburton Oil Well Cementing Co. v. Walker*, 329 U.S. 1, 13 (1946)), if the specification equips a skilled artisan to make and use only *part* of the claimed invention, the invention is not enabled. Accordingly, the panel below was correct in stating that U.S. law “has always been, or at least has been since the Patent Act of 1870, that

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specification strictly, can, without more, construct an apparatus which, when used in the way pointed out, will do all that it is claimed the method or process will do.”); *O’Reilly v. Morse*, 56 U.S. 62, 120-121 (1853) (“The words of the acts of Congress [regarding the enablement requirement] show that no patent can lawfully issue upon such a claim. For he claims what he has not described in the manner required by law. And a patent for such a claim is as strongly forbidden by the act of Congress, as if some other person had invented it before him. \* \* \* He can lawfully claim only what he has invented and described, and if he claims more his patent is void.”); *Evans v. Eaton*, 20 U.S. 356, 388, 434-435 (1822) (“[T]he specification is a part of the patent for the purpose of ascertaining the nature and extent of the alleged invention.”).

a patent applicant must enable one's *invention*, whatever the invention is." Pet. App. 62a (Lourie, J., authoring separate majority opinion on denial of panel rehearing) (emphasis added).

**B. The “undue experimentation” element of enablement law is likewise grounded in the Patent Act’s text, this Court’s precedents, and Congress’s actions.**

Although Section 112(a) of the Patent Act does not refer explicitly to the concept of “undue experimentation,” that requirement too is supported by the statute’s text and longstanding precedent.

1. Congress has always tied the enablement requirement to whether the patent’s specification equips a person “skilled” in the relevant art to “make” and “use” the claimed invention. See *supra* at 7-8 (comparing, e.g., Act of Apr. 10, 1790, § 2, 1 Stat. 110, with 35 U.S.C. 112(a)). Whether the patent’s “concise” disclosure is sufficiently “full, clear, \* \* \* and exact” to enable a skilled artisan to make and use the claimed invention will of course vary with the level of ordinary skill in the art, the art itself, and the types of tests and experimentation that such artisans routinely perform.

Thus, during the nineteenth century—including before Congress adopted the Patent Act of 1870, and well before the 1952 Act—this Court required patentees to describe their inventions in a manner that enabled “skilled” artisans to make and use them, while acknowledging that the statute required courts to assess the extent to which the artisan needed to conduct “experiments of his own” to “compound and use” the invention. *Wood v. Underhill*, 46 U.S. 1, 4 (1847); see also, e.g., *The Telephone Cases*, 126 U.S. 1, 535-536 (1888); *O’Reilly v. Morse*, 56 U.S. 62, 121 (1853). As

the Court put it in *Mowry v. Whitney*, “[a]ddressed as it is to those skilled in the art, [the specification] may leave something to their skill in applying the invention”—“to the judgment of the operator.” 81 U.S. 620, 644, 645 (1871).

At the same time, other nineteenth century and early twentieth century decisions of this Court invalidated patents on the ground that they required the skilled artisan to conduct excessive experiments to make and use the claimed invention. In *Consolidated Electric Light Co. v. McKeesport Light Co.*, 159 U.S. 465 (1895), for example, the Court struck down a patent that claimed filaments composed of any “carbonized fibrous or textile material.” *Id.* at 468, 472-473. Because the specification did not identify “some general quality, running through the whole fibrous and textile kingdom, which distinguished it from every other, and gave it a peculiar fitness for the particular purpose,” “the most careful and painstaking experimentation” was required for a skilled artisan “to know what fibrous or textile material was adapted to the purpose of an incandescent conductor.” *Id.* at 475. Likewise, the Court in *Holland Furniture Co. v. Perkins Glue Co.*, 277 U.S. 245 (1928), invalidated a patent that recited “a particular starch glue” that served a specific function, explaining that “[o]ne attempting to use or avoid the use of [the] discovery as so claimed and described functionally could do so only after elaborate experimentation.” *Id.* at 256, 257.

As these venerable precedents confirm, it only makes sense to read the enablement requirement of § 112(a) to turn on the extent of experimentation needed to make and use the claimed invention. Replicating an invention necessarily requires some sort of testing or experimentation known in the prior art. It

logically follows that courts should ask whether an ordinarily skilled artisan can replicate the invention using such testing, together with the scientific advance disclosed by the patent, or whether, instead, making and using the invention requires something more—inventive activity or “undue” experimentation. See also, e.g., *Halliburton*, 329 U.S. at 12; *Minerals Separation, Ltd. v. Hyde*, 242 U.S. 261, 270-271 (1916); cf. *Seymour v. Osborne*, 78 U.S. 516, 555 (1870).

2. If any doubt remained, it would be dispelled by Congress’s own actions. Congress has repeatedly reenacted the operative language of the enablement requirement “against the backdrop of a substantial body of law interpreting [it]” to contain an undue experimentation limitation. See *Helsinn*, 139 S. Ct. at 633 (interpreting 35 U.S.C. 102(b)). “[S]ettled \* \* \* precedent” thus allows the Court to “presume that when Congress reenacted the same language in [later Patent Acts], it adopted the earlier judicial construction of that phrase.” *Id.* at 633-634.

In *Helsinn*, for example, the Court held that Congress had adopted the settled meaning of the on-sale bar as construed in pre-AIA *Federal Circuit* precedent, which “made explicit what was implicit in [this Court’s] precedents.” *Id.* at 633. This case is easier, as the longstanding precedents of *both* this Court *and* the Federal Circuit establish the principle of undue experimentation. E.g., *Mowry*, 81 U.S. at 644-645; *Consol. Elec.*, 159 U.S. at 472-475; *Holland Furniture*, 277 U.S. at 256-257; *Wands*, 858 F.2d at 737; see also *Microsoft Corp. v. i4i Ltd. P’ship*, 564 U.S. 91, 104, 102 (2011) (“Congress adopted the heightened standard of proof reflected in [the Court’s] pre-1952 cases” where, “by the time Congress enacted § 282 and declared that

a patent is ‘presumed valid,’ the presumption of patent validity had long been a fixture of the common law.”)<sup>4</sup>

In sum, although “[t]he term ‘undue experimentation’ does not appear in the statute,” it is for good reason “well established that enablement requires that the specification teach those in the art to make and use the invention without undue experimentation.” *Wands*, 858 F.2d at 737.

**C. The Court’s reading of the enablement requirement should be informed by its flexible approach to obviousness law.**

This Court’s obviousness precedent further confirms that the enablement requirement should be interpreted flexibly to account for the skill of the artisan, the sophistication of the art, and whether the extent of experimentation required to make and use the claimed invention is “undue.”

1. Like enablement, obviousness is viewed from the perspective of “a person having ordinary skill in the art to which the claimed invention pertains.”

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<sup>4</sup> See also *Shapiro v. United States*, 335 U.S. 1, 16 (1948) (“In adopting the language used in the earlier act, Congress ‘must be considered to have adopted also the construction given by this Court to such language, and made it a part of the enactment.’”); *Ryan v. Gonzales*, 568 U.S. 57, 66 (2013) (The Court “normally assume[s] that, when Congress enacts statutes, it is aware of relevant judicial precedent.” (citation omitted)); *Tex. Dep’t of Hous. & Cmty. Affs. v. Inclusive Cmty. Project, Inc.*, 576 U.S. 519, 536 (2015) (Where Congress amends a law “while still adhering to the operative language” that has come to have a settled meaning, that is strong evidence that Congress has ratified the judicial consensus as to its meaning.).

35 U.S.C. 103; cf. 35 U.S.C. 112(a) (asking whether the specification “enable[s] any person skilled in the art to which [the invention] pertains” to “make and use” it). Accordingly, both inquiries turn on what the ordinarily skilled artisan knows and can do, and both call for a flexible, case-by-case assessment of how much experimentation is needed to replicate the invention.

The Court’s decision in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), is instructive on this score. The Court there rejected the Federal Circuit’s “narrow conception” of obviousness reflected in its application of the “teaching, suggestion, or motivation” test (TSM test), under which a patent claim [was] only proved obvious if ‘some motivation or suggestion to combine the prior art teachings’ c[ould] be found in the prior art, the nature of the problem, or the knowledge of a person having ordinary skill in the art.” *Id.* at 407, 419. As the Court explained, that “rigid” and “formalistic” approach to obviousness was “incompatible” with the “expansive and flexible approach” of the Court’s precedents, and in particular the “functional approach” of *Hotchkiss v. Greenwood*, 52 U.S. 248 (1851), and reaffirmed in *Graham v. John Deere Co.*, 383 U.S. 1, 15-17 (1966). See *KSR*, 550 U.S. at 419, 415.

“The diversity of inventive pursuits and of modern technology,” the Court explained, “counsels against limiting the analysis” by using “[r]igid preventative rules that deny factfinders recourse to common sense.” *KSR*, 550 U.S. at 419, 421. What is called for, instead, is a case-by-case analysis “of the inferences and creative steps that a person of ordinary skill in the art would employ.” *Id.* at 418. Indeed, § 112(a) expressly ties the “person skill[ed]” to “the art to which [the invention] pertains, or with which it is most nearly connected.” Hence, the level of skill and the state of the

art will necessarily vary with the nature of the invention within the relevant art. Cf. *Innovation Toys, LLC v. MGA Entm't, Inc.*, 637 F.3d 1314, 1323 (Fed. Cir. 2011) (“A less sophisticated level of skill generally favors a determination of nonobviousness \* \* \* while a higher level of skill favors the reverse.”).

2. What a skilled artisan aware of the scope and content of the prior art would make of a patent claim or the specification is an issue that cuts across a wide swath of patentability law, from indefiniteness, written description, and enablement to obviousness and anticipation. Enablement and obviousness law in particular ask a similar question: What gaps can an artisan of ordinary skill reasonably be expected to fill?

In the enablement context, that question helps ensure that the inventor has disclosed an invention that can be replicated, thus benefitting the public after the patent term expires. See *Kewanee Oil*, 416 U.S. at 480-481. In the obviousness context, that question helps ensure that the patent does not preclude the use of inventions that combine familiar elements in ways that yield predictable results to skilled artisans using the ordinary tools in their toolbox. Making changes in one context will invariably affect the other. For example, shrinking the gap to be filled by the person of ordinary skill would affect both a patentee’s ability to defeat an enablement challenge as well as a defendant’s ability to mount an obviousness challenge. See *Seymour*, 78 U.S. at 552, 555. Conversely, a low level of skill could undercut both enablement and obviousness. See *Innovation Toys*, 637 F.3d at 1323.

It follows that the Court should be doubly cautious about abandoning current enablement law in favor of a new test, and more generally in speaking



categorically about artisan skill or the predictability of any art, lest it inadvertently interfere with case-sensitive tests in other areas of patent law—and especially obviousness. As discussed below, current law properly preserves the “delicate balance” between the interests of “inventors, who rely on the promise of the law to bring the invention forth,” and the interests of “the public, which should be encouraged to pursue innovations, creations, and new ideas beyond the inventor’s exclusive rights.” *Festo*, 535 U.S. at 731.

## **II. The Federal Circuit’s enablement precedent is consistent with the text of the Patent Act and this Court’s precedents.**

The Federal Circuit’s enablement jurisprudence, and its “undue experimentation” test in particular, are fully supported by the text of 35 U.S.C. 112(a) and this Court’s decisions. Indeed, petitioners and many of their amici endorse *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988), which, building on insights from earlier decisions of this Court and the courts of appeals, adopted that test and set out factors for applying it.

Petitioners describe *Wands* as a “now-seminal” decision, and they concede that the specification must be “sufficiently robust to permit skilled artisans to practice claims as needed, without resort to undue experimentation.” Br. 23, 41.<sup>5</sup> But even though the court

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<sup>5</sup> *E.g.*, Pet. Br. 28 (“[N]o one denies that a patent must reasonably enable the scope of the claim—there cannot be large tracts of claimed subject matter that are not enabled.”); Pet. Br. 23 (“The patent is ‘insufficient’ when ‘independent invention would have to be exercised’ because simply following the patent’s direction does not produce ‘a practically operative invention.’” (first quoting *Webster*

below both cited and applied *Wands*, they insist that the court created a “new,” “distinct test” for “genus claims with functional elements.” Pet. Br. 45, 25. Petitioners are mistaken.

**A. *Wands* enforces the “full scope” requirement of § 112 while recognizing that a need for experimentation, if not undue, does not defeat enablement.**

*Wands* held that “[e]nablement is not precluded by the necessity for some experimentation such as routine screening,” provided the “experimentation needed to practice the invention” is not “undue.” 858 F.2d at 736-737. As the court put it: “The key word is ‘undue,’ not ‘experimentation.’” *Id.* at 737.

Drawing from factors earlier identified by the Patent Office—and applied in both this Court’s and circuit-level court’s precedents—*Wands* listed several factors for factfinders to use in assessing whether experimentation is undue (858 F.2d at 737):

- (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.

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*Loom Co. v. Higgins*, 105 U.S. 580, 591 (1881); then quoting 2 Robinson § 485); Pet. Br. 23-24 (endorsing the “undue experimentation” test); GSK Amicus Br. 14-15 (endorsing “the traditional ‘undue experimentation’ test for enablement”).

Although framed as an eight-factor test, the *Wands* factors can be reduced to three essential principles that directly track the statutory requirements of § 112(a)–(b): the skill of the artisan, the state of the art, and the scope of the claim. Specifically, factors (2), (3), and (6) focus on what a “person of skill in the art” knew and could do (§ 112(a)); factors (1), (4), (5), and (7) focus on the state of the “art to which [the invention] pertains, or with which it is most nearly connected” (§ 112(a)), and factor (8) focuses on whether the claim “particularly points out and distinctly claims” the invention (§ 112(b)). Far from innovating new requirements, the *Wands* factors simply elaborate on how to approach the statutory requirements.

Importantly, both *Wands* itself (858 F.2d at 737) and later Federal Circuit decisions confirm that “[t]hese factors while illustrative are not mandatory.” *Cephalon, Inc. v. Watson Pharms., Inc.*, 707 F.3d 1330, 1336 (Fed. Cir. 2013) (“What is relevant depends on the facts, and although experimentation must not be undue, a reasonable amount of routine experimentation required to practice a claimed invention does not violate the enablement requirement.”).

*Wands* and its “undue experimentation” factors are entirely consistent with the text of § 112. First, Congress mandated that the inventor describe “the *invention*, and \* \* \* 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 “make and use” it. 35 U.S.C. 112(a) (emphases added). In keeping with this mandate, *Wands* recognizes that the patent’s written specification must “fully enable[] the claimed invention.” 858 F.2d at 736; *supra* at 19.

Second, *Wands*' "undue experimentation" test is rooted in § 112(a)'s directive to analyze enablement from the vantage point of the skilled artisan and in this Court's longstanding teaching that patents requiring "elaborate" (*Holland Furniture*, 277 U.S. at 257) or "painstaking experimentation" (*Consol. Elec.*, 159 U.S. at 475) cross the line. See *supra* at 12-13.

Third, while decided two decades before *KSR*, *Wands* reflected the wisdom of that decision: courts should take a "flexible approach" that focuses on the skilled artisan and the scope and content of the art—which varies with "[t]he diversity of inventive pursuits"—rather than use "[r]igid preventative rules that deny factfinders recourse to common sense." *KSR*, 550 U.S. at 415, 419, 421; see *supra* at 15-16.

This Court should uphold the *Wands* framework—and the decision below, which faithfully applied it.

**B. Contrary to petitioners' assertions, the decision below is consistent with *Wands* and should be affirmed.**

Petitioners say the court below failed to follow *Wands*. By their lights, the court imposed "a categorically different and exponentially more demanding standard"—such that "[i]t is no longer sufficient that the patent enable skilled artisans to 'make and use' the invention" when the claimed invention is directed to genus claims with functional elements. Pet. Br. 28. And according to them, this "new test" is an "all or nearly all embodiments" test. Pet. Br. 28, 2. But petitioners are misrepresenting the decision below, which in no way purports to break from *Wands*—indeed, it expressly applies *Wands* and discusses the decision at length. Pet. App. 7a-15a.

Note carefully how petitioners frame the question presented. Quoting one phrase from the ruling below, they assert that the Federal Circuit made it a requirement that the patent enable skilled artisans “*to reach the full scope* of claimed embodiments” without undue experimentation. Pet. Br. i (quoting Pet. App. 14a). But then they provide their own gloss on what that phrase means—the skilled artisan, petitioners say, must be enabled “to cumulatively identify and make *all or nearly all embodiments* of the invention without “substantial time and effort.” *Ibid.* (emphasis added). Petitioners repeatedly offer the same sleight of hand in the body of their brief—often verbatim. *E.g.*, Br. 2, 5; accord Pet. Br. 18 (equating “*to reach the full scope* of claimed embodiments” with “the cumulative effort necessary to identify and make all, or nearly all, variations of the invention that might exist within the genus”); Pet. Br. 27 (equating “*to reach the full scope* of claimed embodiments” with “the cumulative effort necessary to identify and make all or nearly all variations within the genus—no matter how theoretical or speculative any variation might be”).

The problem is, the Federal Circuit expressly rejected any such “all or nearly all embodiments” requirement, stating that “a specification does not need to ‘describe how to make and use every possible variant of the claimed invention.’” Pet. App. 8a (citation omitted). To be sure, the court also explained that, “when a range is claimed, there must be reasonable enablement of the scope of the range.” *Ibid.* (citation omitted). But petitioners concede that this “reasonable enablement” requirement is correct. Pet. Br. 28 (“[N]o one denies that a patent must reasonably enable the entire scope of the claim—there cannot be large tracts of claimed subject matter that are not

enabled.”). And once this becomes clear, it is evident that the Federal Circuit’s “reach the full scope of claimed embodiments” language simply restates the statutory requirement that the disclosure be “full, clear, \* \* \* and exact” enough to enable all of “the invention” that the patentee claims. 35 U.S.C. 112(a).

Citing a snippet from the ruling below, petitioners also read it to “declare[]” that “[courts] must examine the effort ‘required to make and use, not only the limited number of embodiments the patent discloses, but also the full scope of the claim.’” Pet. Br. 27 (quoting Pet. App. 11a). Here too, however, petitioners omit the context. The court was discussing the similarity between this case and earlier ones “h[olding] that due to the large number of possible candidates within the scope of the claims *and the specification’s corresponding lack of structural guidance*, it would have required undue experimentation to synthesize and screen each candidate to determine which compounds in the claimed class exhibited the claimed functionality.” Pet. App. 10a (emphasis added). Those claims “required both a particular structure and functionality,” yet “the specification failed to teach one of skill in the art whether the many embodiments of the broad claims would exhibit that required functionality.” *Ibid.* Thus, “undue experimentation would have been required to synthesize and screen the billions of possible compounds because, *given a lack of guidance across that full scope, finding functional compounds would be akin to finding a ‘needle in a haystack.’*” *Id.* at 11a (emphasis added) (citation omitted).

“What emerges from our case law,” the court of appeals explained, “is that the enablement inquiry for claims *that include functional requirements* can be particularly focused on the breadth of those

requirements, *especially where predictability and guidance fall short.*” Pet. App. 11a (emphases added). Yet petitioners inaccurately portray the court as equating the patent’s failure to enable “the full scope of the claim” with nothing more than “the limited number of embodiments that the patent discloses”—ignoring the difficulties created by the unpredictability of the art at issue and the lack of structural guidance in their claims. Pet. Br. 27. Put another way, petitioners’ merits brief is an attack on a straw man, and the “question presented” is not in fact presented.

**C. *Wands* underscores the invalidity of petitioners’ patents.**

As the decision below makes clear, the Federal Circuit has no per se rule against broad claims; nor is breadth necessarily dispositive for enablement purposes. Pet. App. 10a. Rather, the breadth of the claim is just one of the eight *Wands* factors (the last). 858 F.2d at 737.

At the same time, neither did *Wands* “proclaim that all broad claims to antibodies are necessarily enabled.” Pet. App. 10a. The court below specifically identified the breadth of petitioners’ claims as a key issue. *Id.* at 10a, 12a. And the idea that a broader claim will ordinarily require broader support is unremarkable, particularly where, as here, the art is unpredictable (*Wands* factor 7, Pet. App. 13a, 34a).

Aware of this difficulty, petitioners essentially insist that the art here *is* predictable. Br. 48. But the Federal Circuit reviewed and affirmed the district court’s contrary finding (Pet. App. 13a, 34a), and this Court denied review on petitioners’ first question presented, which asked the Court to take up the standard of review. Pet. i. Thus, as the court below put it:

“Facts control and, [on appeal], so does the standard of review.” Pet. App. 10a.

**III. Petitioners’ parade of horrors has no basis in reality, but departing from the *Wands* framework would destabilize patent law.**

As the foregoing analysis shows, the decision below is but the latest in a long line of Federal Circuit cases that give effect to the full scope requirement of § 112(a) while taking a flexible, art-by-art approach to the level of experimentation required to “make and use” the claimed invention. Far from creating a crisis of innovation, the Federal Circuit’s approach has led to a predictable, stable body of enablement law. The Patent Office’s issuance of utility patents—those most likely to be affected by the law of enablement—is near its all-time high, rising from 90,365 to 352,049 grants in the same period (between 1990 and 2020) when the genus claim was purportedly dying.<sup>6</sup>

An approach of requiring little from the patentee in exchange for broad functional claims, by contrast, would have a corrosive effect on innovation by blocking avenues of invention the patentee never contemplated. See *Kewanee Oil*, 416 U.S. at 480-481, 489-492. The Court’s decision in *O’Reilly v. Morse* is instructive in that regard. After upholding Morse’s other claims to a telegraph, the Court explained that “[t]he difficulty arises on the eighth” claim, which boldly stated: “I do not propose to limit myself to the specific machinery or

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<sup>6</sup> Pat. Tech. Monitoring Team, “U.S. Patent Statistics Chart Calendar Years 1963–2020,” U.S. Pat. & Trademark Off., [https://www.uspto.gov/web/offices/ac/ido/oeip/taf/us\\_stat.htm](https://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm) (last modified Feb. 9, 2023).



parts of machinery described in the foregoing specification and claims; the essence of my invention being the use of the motive power of the electric or galvanic current, \* \* \* however developed for marking or printing intelligible characters, signs, or letters, at any distances.” 56 U.S. at 112. As the Court recognized, “Professor Morse has not discovered, that the electric or galvanic current will always print at a distance, no matter what may be the form of the machinery or mechanical contrivances through which it passes. You may use electro-magnetism as a motive power, and yet not produce the described effect, that is, print at a distance intelligible marks or signs.” *Id.* at 117.

In short, by claiming functionally, without reference to limiting structures or steps, Morse improperly hobbled “the onward march of science,” including by inventors who might “discover a mode of writing or printing at a distance by means of the electric or galvanic current, without using any part of the process or combination set forth in the plaintiff’s specification.” *O’Reilly*, 56 U.S. at 113. In other words, Morse’s eighth claim covered technologies not even then-imagined, such as a telex, a facsimile machine, and a networked printer. And despite his real (and patented) contributions, not even Samuel Morse could claim a mere concept. *Id.* at 112-113. Today, as then, such an approach to enablement would deprive “the public [of] the benefit” of further innovations that the inventor had not enabled—even if those innovations “may be less complicated—less liable to get out of order—less expensive in construction, and in its operation.” *Id.* at 113.

In sum, the Court should tread very carefully before upsetting the “delicate balance” of the patent law, which *Wands* wisely preserves.

**CONCLUSION**

For the foregoing reasons, the judgment of the court of appeals should be affirmed.

Respectfully submitted.

STEFFEN N. JOHNSON

*Counsel of Record*

RICHARD TORCZON

PAXTON M. LEWIS

*Wilson Sonsini*

*Goodrich & Rosati, P.C.*

*1700 K Street, N.W.*

*Washington, DC 20006*

*(202) 973-8800*

*sjohnson@wsgr.com*

*Counsel for Amicus Curiae Viatrix Inc.*

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