

No. 13-369

In the
Supreme Court of the United States

NAUTILUS, INC.,

Petitioner,

v.

BIOSIG INSTRUMENTS, INC.,

Respondent.

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

**BRIEF OF BIOTECHNOLOGY INDUSTRY
ORGANIZATION AS AMICUS CURIAE
IN SUPPORT OF RESPONDENT**

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INTEREST OF *AMICUS CURIAE*

The Biotechnology Industry Organization (BIO) is the country's largest biotechnology trade organization, representing over 1100 companies, academic institutions, and biotechnology centers in all 50 States and countries around the world.¹ BIO members undertake research and development of biotechnological healthcare, agricultural, environmental, and industrial products. While some of BIO's corporate members are Fortune 500 companies, 90% of its members are small or mid-size businesses, with annual revenues of less than \$25 million. All of BIO's members share a strong commitment to the stability of the Nation's patent system and, indeed, for most members the reliability and durability of patents is vital to their ability to raise the investment capital that funds their research and product development efforts. The question presented in this case is of great importance to BIO's members because acceptance of petitioner's radical view of the Patent Act's definiteness requirement would upset "the delicate balance that the law attempts to maintain between inventors, who rely on the promise of the law to bring the invention forth, and the public, which should be encouraged to pursue innovations, creations, and new ideas beyond the inventor's exclusive rights." *Festo*

¹ 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 other than *amicus curiae*, or its counsel, made a monetary contribution intended to fund its preparation or submission. The parties filed blanket letters of consent for *amicus* briefs.

Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 731 (2002).

STATEMENT

Under the Patent Act, each patent application must include “a specification as prescribed by Section 112.” 35 U.S.C. § 111.² The specification must “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 make and use it. 35 U.S.C. § 112, ¶ 1. And the specification must “conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.” 35 U.S.C. § 112, ¶ 2. The latter is known as the definiteness requirement.

The patent challenged by petitioner Nautilus, Inc., is directed to a heart rate monitor in the handles of exercise equipment, such as treadmills or stationary bikes. Pet. App. 4a; U.S. Patent No. 5,337,753.³ The apparatus is designed to allow more accurate detection of the user’s heart rate by eliminating signals given off by other muscles. Pet. App. 4a. To do that, the claim provides that, in each handle, there are two electrodes that are in a “spaced relationship with each other.” Pet. App. 7a (quoting claim). The district court held

² Statutory citations are to the version in effect prior to the Leahy-Smith America Invents Act, Pub. L. No. 112-29, §4(c), 125 Stat. 284, 296 (2011).

³ Although some *amici* focus on issues relating to patent-assertion entities, *see, e.g.*, EFF Br. 14-16; Microsoft Br. 29-31, this action is a routine matter involving established competitors.

that the “spaced relationship” term is indefinite under § 112, ¶ 2 because it “did not tell [the court] or anyone what precisely the space should be” or “even any parameters as to what the space should be.” Pet. App. 72a. The Federal Circuit reversed, holding that the patent’s “claim language, specification, and the figures illustrating the ‘spaced relationship’ ... provide sufficient clarity to skilled artisans as to the bounds of this disputed term.” Pet. App. 16a. The court explained that the patent “discloses certain inherent parameters of the claimed apparatus” because the electrodes cannot be further apart than the width of a person’s hand and cannot be so close as to be touching each other. *Id.* Also, the court held, a skilled artisan could “readily ascertain the bounds of the ‘spaced relationship’ through tests using standard equipment” by determining the spacing necessary to remove the unwanted (noise) signals. Pet. App. 25a.

Petitioner now argues that claims containing the term “spaced relationship” are invalid as indefinite under § 112, ¶ 2 because that term could conceivably have more than one reasonable interpretation, even if one interpretation is more plausible than the other. This Court should reject petitioner’s position for three fundamental reasons

First, petitioner misrepresents the Federal Circuit’s test and its holding. Petitioner focuses heavily on certain language from the opinion—“insolubly ambiguous”—painting it as an extra-statutory standard that the Federal Circuit has erroneously grafted onto the Patent Act. But it is nothing of the sort. A careful reading of the court’s decisions shows that “insolubly ambiguous” is merely a label that the court uses when it concludes for any of

a number of reasons that a skilled artisan could not discern the scope of the claims (*i.e.*, the claims are indefinite) even after using all of the ordinary tools of claim construction to determine what the claims meant to a skilled artisan at the time they were filed.

The more specific issue petitioner seeks to litigate is not properly before the Court. The thrust of petitioner's position is that the Federal Circuit wrongly found the claims definite even though they could be reasonably interpreted in multiple ways. But petitioner did not make that argument to the panel, and the panel never held that there are multiple reasonable interpretations in this case—it simply determined what, in its view, is the *correct* interpretation. Thus, petitioner now asks this Court to decide this case based on an issue that was not pressed or passed on below. This Court could consider dismissing the writ as improvidently granted.

Second, on the merits, petitioner's approach is contrary to well-established law. This Court has long recognized that absolute clarity is not always possible, and thus not always required, in drafting claims. *See, e.g., Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 389-90 (1996); *Minerals Separation, Ltd. v. Hyde*, 242 U.S. 261, 271 (1916). Indeed, when endorsing the doctrine of equivalents, this Court expressly rejected the notion, urged here by petitioner, that absolute certainty is required to give adequate notice. *Festo*, 535 U.S. at 732. The Court expressly acknowledged that a certain amount of "uncertainty" is "the price of ensuring the appropriate incentives for innovation." *Id.* Petitioner's contrary approach ignores these controlling precedents. It is, moreover, fundamentally at odds with how courts routinely interpret other

written documents—such as statutes, contracts, and deeds—that often require at least as much clarity as patent claims.

Petitioner’s approach is also incompatible with the statutory presumption of validity afforded to issued claims. *See* 35 U.S.C. § 282(a). Requiring a court to declare a claim invalid whenever it is faced with a disagreement between competing experts would flip the presumption and place a heavy, nearly dispositive, thumb on the scale in favor of invalidity. Indeed, under petitioner’s view, any disagreement among judges as to the construction of a term would strongly suggest the term is indefinite, and thus invalid. Among other things, acceptance of that view would make it almost impossible for a patentee to challenge an adverse claim construction on appeal: Alleged infringers would doubtlessly insist that the claim must either bear the meaning given it by the district court or be declared indefinite—creating a classic heads-I-win/tails-you-lose situation. That is not and has never been the law. To the contrary, the courts, including the Federal Circuit, have long interpreted claims by resolving any ambiguity in favor of the most reasonable interpretation, even if other interpretations are arguably available. And, notably, Congress has repeatedly reenacted the definiteness provision in § 112 without disturbing that understanding. If petitioner wants a change, it should ask Congress, not this Court.

Third, petitioner’s approach would upset the balance that Congress has struck to encourage innovation and would inject a damaging uncertainty into the patent system. Especially in leading-edge fields, such as biotechnology and pharmaceuticals, the

rewards of patent-protection are vital to encouraging and continuing innovation. Petitioner's expansive interpretation of the statutory definiteness requirement would make investment a speculative gamble, at best, in areas of technology where it is all but impossible to draft claims with absolute clarity—particularly in the biotechnology field, where innovations often must be described in terms of degree and ranges, rather than precise amounts.

Petitioner suggests that its approach must be workable because the patent office currently uses it when it is examining applications in the first place. But that argument conflates the distinct roles of the patent office (which construes the claims broadly and, in the to and fro of examination, rightly presses applicants to remove ambiguity) and the district courts (which construe issued claims in light of the statutory presumption of validity, based on the completed prosecution history and other intrinsic evidence). By ignoring those differences, petitioner would further unsettle the patent system.

This Court should reject petitioner's position and affirm the Federal Circuit's judgment.

ARGUMENT

I. PETITIONER MISREPRESENTS THE FEDERAL CIRCUIT'S DEFINITENESS TEST AND SEEKS TO LITIGATE AN ISSUE NOT PROPERLY BEFORE THIS COURT

Petitioner's position, echoed by some of its *amici*, is flawed from the outset because it describes and then attacks a caricature of the Federal Circuit's indefiniteness test. Even more troubling, it misrepresents the Federal Circuit's holding and asks

this Court to resolve this case on a ground not pressed or passed upon below. This Court should consider dismissing the writ as improvidently granted.

1. In order to paint the court of appeals in the least favorable light, petitioner and its *amici* repeatedly criticize the Federal Circuit’s “‘insolubly ambiguous’ test” as if it were a novel and freestanding mode of analysis. Pet. Br. 37-39; *see also, e.g., id.* at 4-5, 21, 46-47; EFF Br. 6-8; Microsoft Br. 24. It is not a freestanding mode of analysis. Instead, it is merely a label that the court uses for its *conclusion* when the court finds, after applying the traditional tools for claim construction (including examining the claim language, specification, and prosecution history) that a claim still “fails to provide sufficient clarity delineating the bounds of the claim to one skilled in the art.” Pet. App. 15a.

The Federal Circuit has used this label to summarize the broad range of circumstances in which a claim may be found indefinite, such as when a claim (i) “recites means-plus-function elements without disclosing corresponding structure in the specification,” (ii) “includes a numeric limitation without disclosing which of multiple methods of measuring that number should be used,” (iii) “contains a term that is ‘completely dependent on a person’s subjective opinion,’” or (iv) “does not have proper antecedent basis where such basis is not otherwise present by implication or the meaning is not reasonably ascertainable.” *Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1249 (Fed. Cir. 2008) (citations omitted). The court has explained that “[t]he common thread in all of these cases is that claims were held indefinite only where *a person of ordinary skill in the art could not determine the*

bounds of the claims, i.e., the claims were insolubly ambiguous.” *Id.* (emphasis added). In other words, “insolubly ambiguous” is merely shorthand for the statutory standard, not a departure from it. The Acting Solicitor General recognized as much in a prior case, advising this Court that the Federal Circuit has primarily used the term “insolubly ambiguous” not as a standard with independent significance but instead “to express principles that are well grounded in this Court’s Section 112 jurisprudence.” Br. for the U.S. as *Amicus Curiae* 13, *Applera Corp. v. Enzo Biochem, Inc.*, No. 10-426, 2011 WL 1881824 (filed May 17, 2011) (“U.S. *Applera* Br.”); *see also, e.g.*, ABA Br. 16 (“[I]nsolubly ambiguous’ is not an expression of a rigid rule, as some have argued, but rather a shorthand”).

2. Petitioner also insists that the Federal Circuit’s analysis ignores claims’ core notice function, because “a test that upholds claims so long as a construction *adopted years later* by a court is not ‘insolubly ambiguous’ fails to require clear public notice of the claim’s scope when the patent is issued.” Pet. Br. 38 (emphasis added). Here, again, petitioner misrepresents the Federal Circuit’s approach.

The Federal Circuit recognizes that claims need not “be plain on their face in order to avoid condemnation for indefiniteness” because, otherwise, “all but the clearest claim construction issues could be regarded as giving rise to invalidating indefiniteness in the claims at issue.” *Exxon Research & Eng’g Co. v. United States*, 265 F.3d 1371, 1375 (Fed. Cir. 2001). But the court does not treat the construction and potential indefiniteness of a term as a *post hoc* exercise. Instead, the court maintains its attention on what the claim meant *at the time it was filed*. The

court recognizes that, as long as a skilled artisan could “determine the bounds of the claims” at the time they were filed, the claims are not indefinite and the notice function is fully served. *Halliburton*, 514 F.3d at 1249. But at the same time “the scope of the claims [must] be sufficiently definite to inform the public of the bounds of the protected invention, i.e., what subject matter is covered by the exclusive rights of the patent,” because “[o]therwise, competitors cannot avoid infringement, defeating the public notice function of patent claims.” *Id.*

3. At bottom, the thrust of petitioner’s argument is that the Federal Circuit is wrong to accept “ambiguous patent claims with multiple reasonable interpretations,” as set forth in the first of the two questions presented. Pet. Br. i. That charge permeates petitioner’s brief and drives its forceful rhetoric about the need for clarity under § 112. *See also, e.g.*, Pet. Br. 2, 3, 4, 16, 21, 22, 25, 34, 35, 36, 37, 38, 45, 46, 47, 48, 49. Although petitioner’s criticism of the Federal Circuit is wrong on the merits (for reasons discussed below), the simple fact is *the issue is not properly presented in this case.*

The Federal Circuit did not hold in this case that the claims here were susceptible to more than one reasonable interpretation but nonetheless sufficiently definite. To the contrary, the court concluded that “skilled artisans *can readily ascertain* the bounds of the ‘spaced relationship.’” Pet. App. 25a (emphasis added). As the court explained, the specification disclosed certain “inherent parameters” such that the electrodes could not be more than a hands-width apart and could not be so close as to effectively merge the two signal detection points. Pet. App. 16a, 20a. The court, moreover, determined that the ability of the

claimed heart rate monitor to remove unwanted signals—which is described in additional claim language (a “whereby” clause) and the specification and which “provided the basis for overcoming the PTO’s office action rejections”—further clarifies the meaning of “spaced relationship.” Pet. App. 16a. And the court concluded that “a skilled artisan could apply a test” using “standard equipment” to determine the spaced relationship necessary to remove the unwanted signals. Pet. App. 20a, 25a. Thus, unlike the district court (and petitioner), the Federal Circuit read the “spaced relationship” language in the full context of the claim language, specification and prosecution history. Pet. App. 16a; *cf., e.g.*, *Nautilus* CAFC Br. 42 (rejecting reliance on “whereby” clause); Pet. App. 93a-94a.

The Federal Circuit did not consider whether the “spaced relationship” term was susceptible to multiple reasonable interpretations for good reason: petitioner never pressed that argument. Instead, petitioner presented a laundry list of reasons why the claim term was purportedly not susceptible to *any* reasonable interpretation. *See* *Nautilus* CAFC Br. at 41-58. The court, reading the term in light of all the intrinsic evidence, disagreed with petitioner and held that the term did have a discernable meaning. It did not choose from two proffered reasonable interpretations as petitioner now implies. Had petitioner raised its present argument, the court could have addressed it expressly. And if the court believed there was such ambiguity (which it did not), it might have selected the narrower of the two to preserve the claims’ validity. *See, e.g., Exxon Research & Eng’g*, 265 F.3d at 1375. But petitioner did not make any such argument.

Thus, petitioner puts this Court in the undesirable position of “decid[ing] in the first instance issues not decided below.” *Adarand Constructors, Inc. v. Mineta*, 534 U.S. 103, 109, 111 (2001) (citation omitted) (dismissing writ of certiorari as improvidently granted). For that reason, *amicus* respectfully suggests, it would be appropriate for the Court to dismiss the writ of certiorari as improvidently granted. *See id.*

II. PETITIONER’S APPROACH RADICALLY DEPARTS FROM ESTABLISHED LAW AND PRACTICE

Petitioner and its *amici* primarily argue that claims are indefinite any time skilled artisans could reasonably disagree over their meaning. Advancing an even more aggressive form of that argument, some of petitioner’s *amici* suggest that the claim language *itself* must be “clear and unambiguous.” EFF Br. 21; *see also* Microsoft Br. 2. That is not the law. This Court has expressly recognized that claim language should not be interpreted in isolation, but must instead be construed in context, in light of the specification and prosecution history. *See Markman*, 517 U.S. at 389-90; *Festo*, 535 U.S. at 733. As the Court has explained, this is a “necessarily sophisticated analysis of the whole document, required by the standard construction rule that a term can be defined only in a way that comports with the instrument as a whole.” *Markman*, 517 U.S. at 389. The view that a court must throw its hands up and declare invalidity whenever claim construction requires that sort of sophisticated analysis—whenever it requires hard work—ignores decades of practice and this Court’s specific instruction to the contrary.

Petitioner ultimately concedes this. Petitioner acknowledges that claims are not read in isolation, and must instead be construed in the context of the specification and other intrinsic evidence, using all relevant “interpretive tools.” Pet. Br. 35-36. Petitioner nonetheless argues that a claim is invalid if, after that interpretative process, it is still “susceptible of multiple reasonable interpretations to one skilled in the relevant art.” Pet. Br. 22. According to petitioner, for claims to survive § 112, ¶ 2, a “skilled artisan must be able to conclude that no other reasonable readings exist” lest the claims fail to give sufficient notice of the scope of the invention. Pet. Br. 46-47. That proposed standard would mark a departure from established law in at least four respects.

1. Petitioner’s approach is inconsistent with this Court’s case law on indefiniteness, which has never required absolute certainty. For example, the Court rejected an accused infringer’s contention that a patented process was not claimed with sufficient precision because aspects of the process had to be varied, through experimentation, to achieve the best results for different substances. *Minerals Separation*, 242 U.S. at 271. The Court explained that a claim may “leav[e] something to the skill of persons applying the invention,” as long as it is “sufficiently definite to guide those skilled in the art to its successful application.” *Id.*⁴ It made clear that “the certainty which the law requires in patents is not greater than is

⁴ Such is the case here. As discussed, the “spaced relationship” is subject to the inherent hand-width limitations and must provide the functionality required by the “wherein” clause and the other intrinsic evidence.

reasonable, having regard to their subject-matter.” *Id.* at 270. Similarly, this Court held that a patent for an improved paper-making machine was not indefinite because a skilled artisan would have “no difficulty ... determining what was the substantial pitch needed” for the machine to move fast enough to prevent ripples from forming in the stock of paper being made. *Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45, 65-66 (1923). This Court emphasized that “[i]t was difficult for [the patentee] to be more definite, due to the varying conditions” of paper stock.” *Id.* at 65.

And, more recently, this Court recognized that the “language in the patent claims may not capture every nuance of the invention or *describe with complete precision* the range of its novelty.” *Festo*, 535 U.S. at 731 (emphasis added). “Often the invention is novel and words do not exist to describe it,” particularly in leading-edge fields and contexts. *Id.* (quoting *Autogiro Co. of Am. v. United States*, 384 F.2d 391, 397 (Ct. Cl. 1967)); *see also* U.S. App. Br. 8 (“This Court has recognized ... that it is often impossible to reduce an invention ... to writing with faultless precision and clarity.”).

In fact, this Court has specifically recognized that courts must sometimes decide which of two competing reasonable constructions is the correct one. In *Markman*, the Court explained that “there could be a case in which a simple credibility judgment would suffice to *choose* between experts whose testimony was *equally consistent with a patent’s internal logic*.” 517 U.S. at 389 (emphasis added). The Court did not suggest that such a claim is invalid. To the contrary, the Court understood that there might be two reasonable interpretations and that it is the courts’ role to determine which of the two would be correct to

a skilled artisan. *See id.*; *see also Smith v. Snow*, 294 U.S. 1, 14 (1935) (“[I]f the claim were fairly susceptible of two constructions, that should be adopted which will secure to the patentee his actual invention, rather than to adopt a construction fatal to the grant.” (citations omitted)); *McClain v. Ortmayer*, 141 U.S. 419, 425 (1891) (“[I]n a case of doubt, where the claim is fairly susceptible of two constructions, that one will be adopted which will preserve to the patentee his actual invention ...”). That is the law. The Court has never insisted on the pristine clarity that petitioner would require.

Petitioner’s insistence that such pristine clarity is required for patents to serve their notice function also is defeated by this Court’s holding that, under the doctrine of equivalents, patents may infringe even though the literal claim language is not satisfied. *See Festo*, 535 U.S. at 731-33 (“The scope of a patent is not limited to its literal terms but instead embraces all equivalents to the claims described.”); *see also, e.g., Graver Tank & Mfg. Co. v. Linde Air Products Co.*, 339 U.S. 605, 607-09 (1950); *Winans v. Denmead*, 56 U.S. (15 How.) 330, 347 (1854). The Court has acknowledged that “[i]t is true that the doctrine of equivalents renders the scope of patents less certain,” that “[i]t may be difficult to determine what is, or is not, an equivalent to a particular element of an invention,” and that “[i]f competitors cannot be certain about a patent’s extent, they may be deterred from engaging in legitimate manufactures outside its limits.” *Festo*, 535 U.S. at 732. Nonetheless, this Court has repeatedly (and unanimously) rejected a “rule of literalism” and stressed that the “uncertainty” is “the price of ensuring the appropriate incentives for innovation.” *Id.* Petitioner’s assertion, insisting that

the notice function of patents requires providing perfect clarity of claim scope, ignores altogether the concomitant need to “ensur[e] the appropriate incentives for innovation” and, as such, is fundamentally inconsistent with this Court’s balanced approach.

2. Petitioner’s approach is also fundamentally inconsistent with the statutory presumption of validity afforded to issued patents. *See* 35 U.S.C. § 282(a) (“A patent shall be presumed valid.”); *see also Microsoft Corp. v. i4i Ltd. P’ship*, 131 S. Ct. 2238, 2244-45 (2011). At a minimum, the statutory presumption of validity cannot tolerate an approach, like petitioner’s, that places a heavy thumb on the scale in favor of *invalidity*. “Were a disagreement among reasonable persons enough to invalidate a patent claim as indefinite, there would be few patents remaining.” AIPLA Br. 12; *see also* ABA Br. 5 (“[F]ew claims will be so clear that *no* uncertainty can be found in their interpretation.”). Under petitioner’s test, for example, a claim that would be interpreted the same definite way by 100% of skilled practitioners would nonetheless be indefinite if any of them believed that an alternative reading was reasonable.

This approach would render the resolution of claim construction disputes largely a thing of the past because, once two different interpretations of a claim limitation are proffered, inconsistent with each other but not unreasonable, the inquiry would end and the claim would be invalidated without any need for a definitive construction. That is not an unlikely scenario. Accused infringers would have every incentive to—and undoubtedly would—present “reasonable” alternatives in “nearly every case,” thereby “frustrat[ing] the court’s efforts to construe

the asserted claims.” ABA Br. 19-20. Especially in technical fields, lay judges are likely to view each side’s technical expert—a person skilled in the art—as “reasonable.” *Cf. Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 600-01 (1993) (Rehnquist, C.J., concurring in part, dissenting in part) (cautioning that the Court should not require judges to become “amateur scientists” to perform their role). Faced with competing expert testimony many judges will be more prone to find a claim indefinite on that ground than to go through the difficult process for a layman of figuring out what one skilled in the art would have understood the claims to disclose when they were filed. That result is contrary to the process this Court required in *Markman*, which contemplates that claim construction is necessary, even when arduous.

Petitioner’s approach would also severely handicap appellate review of any district court claim construction that has led to a non-infringement finding: An appellate court could disturb such a finding only by concluding that the district court’s construction was not only wrong but *unreasonable*—because if the district court’s construction was wrong but *reasonable* then the claim would be invalid as indefinite. Similarly, any time two judges on a panel disagreed about the construction of a patent term, the Federal Circuit would either have to invalidate the claim as indefinite or label a colleague unreasonable. Indeed, petitioner repeatedly argues that the claims in this case are invalid because the majority and concurrence viewed the claim language somewhat differently, even though each believed it reached the correct result. *See, e.g.*, Pet. Br. 22, 38, 48-49, 51-52. If the presumption of validity means anything, it must at least ensure that claims are not, in effect, presumed

invalid anytime two jurists disagree and that courts, at all levels use all of the traditional tools of construction before rejecting a duly issued patent as indefinite.

3. Petitioner's approach also is untenable because the Federal Circuit has consistently been construing claims to resolve ambiguity since its formation and, despite amending the Patent Act numerous times, Congress has never disturbed that understanding. For example, in *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, the court held that the term "so dimensioned" was definite because it was "as accurate as the subject matter permits, automobiles being of various sizes." 806 F.2d 1565, 1576 (Fed. Cir. 1986). And, in *Modine Manufacturing. Co. v. United States International Trade Commission*, the court rejected an indefiniteness argument, holding that, "[w]hen claims are amenable to more than one construction," the claims should be construed narrowly to avoid invalidity. 75 F.3d 1545, 1557 (Fed. Cir.), *cert. denied*, 518 U.S. 1005 (1996); *see also, e.g., Athletic Alternatives, Inc. v. Prince Mfg., Inc.*, 73 F.3d 1573, 1581 (Fed. Cir. 1996) (construing narrowly to avoid invalidity); *N. Am. Vaccine, Inc. v. Am. Cyanamid Co.*, 7 F.3d 1571, 1579 (Fed. Cir. 1993) (finding claims sufficiently definite notwithstanding reasonable dispute over meaning); *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1557 (Fed. Cir. 1983) (holding that claims are not indefinite merely because some experimentation is necessary to determine the claims' scope), *cert. denied*, 469 U.S. 851 (1984). And the Federal Circuit's predecessor and other courts have been doing the same since Congress added the definiteness requirement to the Patent Act in 1870. *See, e.g., In re Caldwell*, 319 F.2d 254, 255 (C.C.P.A.

1963) (upholding method claim for administering “an effective amount” of aspirin “for growth stimulation”); *Samson-United Corp. v. Sears, Roebuck & Co.*, 103 F.2d 312, 315 (2d Cir. 1939) (“[T]he patent claims should be construed, if possible, so as to preserve the substance of the patent.”).

All the while, Congress has amended the Patent Act numerous times, including adding a new paragraph specifically to § 112 in 1952 and reorganizing § 112 in 2011, without taking any steps to overturn the Federal Circuit’s understanding of the meaning of the definiteness requirement. *See Leahy-Smith America Invents Act*, Pub. L. No. 112-29, § 4(c), 125 Stat 284, 296 (2011); *Bryson Act*, Pub. L. No. 82-593, 66 Stat. 792 (1952). Despite ample opportunities to amend § 112’s definiteness requirement, Congress has instead reenacted it, thereby ratifying the courts’ well-established understanding. *See Lorillard v. Pons*, 434 U.S. 575, 580 (1978) (“Congress is presumed to be aware of an administrative or judicial interpretation of a statute and to adopt that interpretation when it re-enacts a statute without change.”). This Court should not disturb what Congress has chosen to leave intact.

4. Finally, petitioner’s approach is fundamentally inconsistent with how courts have interpreted other written instruments—such as statutes, contracts, and deeds—for hundreds of years. Although clarity is certainly necessary in those contexts as well (in some, perhaps even more so than for patent claims), the courts have not hesitated to resolve ambiguity when and as necessary to reach the correct interpretation.

It is well established, for example, that a statute or regulation may be susceptible to multiple reasonable interpretations without being unconstitutionally

vague. In *United States Civil Service Commission v. National Association of Letter Carriers*, this Court rejected precisely such a vagueness challenge, stressing that “there are limitations in the English language with respect to being both specific and manageably brief, and it seems to us that although the prohibitions may not satisfy those intent on finding fault at any cost, they are set out in terms that the ordinary person exercising ordinary common sense can sufficiently understand and comply with, without sacrifice to the public interest.” 413 U.S. 548, 578-79 (1973).

Likewise, when contracts—including patent licensing agreements that determine the parties’ intellectual property rights and risks—have multiple reasonable interpretations, courts routinely work to ascertain the correct meaning. *See, e.g., Mid-West Conveyor Co. v. Jervis B. Webb Co.*, 92 F.3d 992, 995-98 (10th Cir. 1996) (resolving ambiguity in patent licensing agreement that was “susceptible to more than one reasonable interpretation”). They do not discard ambiguous agreements out of hand.

The same is true for real estate deeds. One of petitioner’s *amici* begins its brief with a cautionary tale of an unclear real estate deed and how a developer, unable to discern the western boundary, would be chilled from making productive use of the land. EFF Br. 2. But of course in that situation, a court would not void the deed—it would instead use all available interpretative tools to figure out the right answer. *See, e.g., Hathaway v. Rancourt*, 409 A.2d 209, 213 (Me. 1979) (resolving ambiguity in westerly boundary of land conveyed in a deed); *Brew v. Nugent*, 117 N.W. 813, 814 (Wisc. 1908) (holding that when original monuments delineating boundaries have

disappeared, “they must be established by the best evidence the nature of the situation is susceptible of”). Courts construing claim terms are equally capable of selecting the most reasonable (and thus correct) construction among multiple reasonable ones, even when the interpretative process is difficult.

III. PETITIONER’S APPROACH WOULD DESTABILIZE THE PATENT SYSTEM

A ruling for petitioner would mark a drastic change in the law that would dramatically alter the status quo and upset settled expectations. It would inject substantial new uncertainty into the patent system and thereby substantially diminish the patent-based incentives that have made the United States the world leader in fields like biotechnology and decrease funding for future research and development. This Court should reject petitioner’s invitation to disrupt settled expectations and change the patent system in such a fundamental way, with profoundly harmful consequences.

A. Petitioner’s Approach Would Inject Substantial New Uncertainty Into The Patent System And Stifle Innovation

Section 112 is one part of “the delicate balance the law attempts to maintain between inventors, who rely on the promise of the law to bring the invention forth, and 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. Petitioner’s approach would disrupt that delicate balance by imposing a heavy bias in favor of indefiniteness and shifting to the inventor the often virtually impossible burden of describing an invention

with absolute precision. That would discourage investment and innovation in at least two ways.

1. Petitioner's approach would upset settled interests and create new and harmful uncertainty. Patentees have been drafting patents with reasonable precision, not strict precision, for centuries, and adopting petitioner's "unreasonably stringent test for definiteness for issued patents ... would adversely change this Court's definiteness jurisprudence for all patents and patent owners." ABA Br. 4. Investment-backed reliance interests in existing patents and trust in the patent system counsel strongly against adopting petitioner's new approach. It is well-recognized that "the degree of legal certainty, as to patentability and enforceability, is a significant factor in innovation decisions." Pauline Newman, *The Federal Circuit: A Reminiscence*, 14 Geo. Mason U. L. Rev. 513, 515 (1992); *see also id.* ("The patent grant particularly aids new businesses, for it supports entry of new products against established competitors, and facilitates entrepreneurial investment—but only to the extent that the patent grant is legally reliable."). After all, "[w]hat farmer or manufacturer will lay himself out for the encouragement given to any particular cultivation or establishment when he can have no assurance that his preparatory labors and advances will not render him a victim to an inconstant government?" The Federalist No. 62 (James Madison). The sea change that petitioner proposes would inject substantial uncertainty, as well as spurring additional litigation over previously-settled rights—both of which discourage investment.

The injection of that substantial new uncertainty would be especially damaging to the very high-tech

and cutting-edge fields for which strong and stable patent protection is essential. As discussed, lay judges engaged in claim construction would be particularly hard-pressed to reject as “unreasonable” the testimony of experts regarding the interpretation of language describing highly technical inventions, and thus particularly likely to invalidate disputed claims as indefinite. And that prospect would have devastating consequences for innovation in important industries. For example, “innovation in the biotechnology and pharmaceutical industries is highly dependent on patent protection” because the rewards “allow pioneer firms to recoup the substantial capital investments made to discover, test, and obtain regulatory approval of new drug products.” FTC, *Emerging Health Care Issues: Follow-up Biologic Drug Competition* 30 (2009). Absent such “essential” strong intellectual property protection, pharmaceutical and biotechnology companies will be unwilling to “make the large, high-risk R&D investments required to develop novel medical products.” President’s Council of Advisors on Science and Technology, *Priorities for Personalized Medicine* 21 (Sept. 2008). And “increased uncertainty and IP litigation in biotech ... would have major negative-incentive effects on capital market decisions for developing private and public biotech firms with promising pipelines.” Henry Grabowski et al., *The Market for Follow-On Biologics: How Will It Evolve?*, 25 *Health Affairs* 1291, 1300 (2006).

2. Petitioner’s approach would also discourage investment in many cutting-edge technologies that would be difficult if not impossible to claim with the absolute precision that petitioner would require.

Some inventions by their nature are necessarily described in terms of degree and ranges, rather than more specific quantification. For example, if an inventor seeks to patent a method for making bacteria with an increased ability to take up and replicate exogenous DNA (which those in the art call “improved competence”), it is not necessarily possible to quantify the specific improvement. The improvement varies based on the size of DNA, the number of times the bacteria is frozen, the medium in which the bacteria is grown, and other factors. And, as these conditions were not always standardized, the inventor could not more precisely define “improved” to cover all possible conditions. But a skilled artisan would understand that the bacteria had “improved competence” if they took up more DNA under whatever the conditions and if the skilled artisan could measure that improvement. *See Invitrogen Corp. v. Biocrest Mfg., L.P.*, 424 F.3d 1374, 1383 (Fed. Cir. 2005) (holding that “improved” in the term “improved competence” is not indefinite). Similarly, an inventor might need to describe an innovative mixture of molecules with varying lengths and weights using a range of values by percent, rather than precise amounts. *See, e.g., Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 723 F.3d 1363, 1370 (Fed. Cir. 2013) (holding definite claims describing copolymer composed of a specific percentage of polypeptides within a specific weight range but not specifying the weight of each polypeptide), *cert. granted on other grounds*, 82 U.S.L.W. 3469 (U.S. Mar. 31, 2014) (No. 13-854).

Likewise, many cutting-edge technologies are disclosed in functional terms (such as biological activities, affinities, or noninterference). Although

petitioner's approach would essentially forbid functional limitations (Pet. Br. 36), they are not inherently suspect: they are judged in light of the relevant context, just like other limitations. As the PTO has explained, "[w]hen a claim limitation employs functional language, the examiner's determination of whether the limitation is sufficiently definite will be highly dependent on context (*e.g.*, the disclosure in the specification and the knowledge of a person of ordinary skill in the art)." PTO, *Supplementary Examination Guidelines for Determining Compliance With 35 U.S.C. 112 and for Treatment of Related Issues in Patent Applications*, 76 Fed. Reg. 7162, 7165 (Feb. 9, 2011) ("*PTO Definiteness Guidelines*"). Even when claimed as precisely as the subject matter permits, functional limitations can be essential in informing a skilled artisan of the metes and bounds of the invention.

For example, an inventor developing immunization-related technology cannot describe the affinity of an antibody to an antigen with perfect precision because there is "no standard set of experimental conditions which are used to measure affinities." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385 (Fed. Cir. 1986) (internal quotation marks omitted). However, although antibody affinity varies with factors such as concentration, temperature, and purity, skilled artisans know that an antibody has the requisite affinity if the antibody binds well enough to give a true positive result under optimized reaction conditions that are exemplified in the patent specification. Therefore, claims directed to the necessary "affinity," when "read in light of the specification, reasonably

apprise those skilled in the art and are as precise as the subject matter permits.” *Id.* “As a matter of law, no court can demand more.” *Id.*; *see also, e.g., Enzo Biochem, Inc. v. Applera Corp.*, 599 F.3d 1325, 1336 (Fed. Cir. 2010) (holding that “linkage group” claim term recited as “not interfering substantially” with hybridization and detection is not indefinite), *cert. denied*, 131 S. Ct. 3020 (2011).

B. Petitioner’s Approach Conflates The Distinct Roles Of The PTO And District Courts In The Patent System

Petitioner argues that its view “will not impose an onerous, unbearable burden” because the PTO already rejects a claim as indefinite if it has “more than one reasonable interpretation” to a skilled artisan. Pet. Br. 45 (quoting PTO, *Manual of Patent Examining Procedure* (“MPEP”) § 2173.02(I) (8th ed. Rev. 9, Aug. 2012)). However, petitioner’s approach conflates the distinct roles of the PTO and the federal courts in the patent system. Were the Court to adopt this lower standard, it would rob the system of the stability that is crucial in this area and undermine the statutory presumption of validity.

The PTO has explained that it applies a “lower threshold” during examination “because the patent record is in development and not fixed.” MPEP § 2173.02(I); *see also Ex parte Miyazaki*, No. 2007-3300, 2008 WL 5105055, at *5 (B.P.A.I. Nov. 19, 2008); *PTO Definiteness Guidelines*, 76 Fed. Reg. at 7164. The PTO examiner will “construe claims in the broadest reasonable manner during prosecution in an effort to establish a clear record of what [the] applicant intends to claim.” MPEP § 2173.02(I). If, under that broad reading, the claim would have “more

than one reasonable interpretation” to a skilled artisan, then the PTO examiner rejects it as indefinite and the “applicant has the ability to provide explanation and/or amend the claims to ensure that the meaning of the language is clear and definite prior to issuance.” *Id.* The PTO’s goal is to ensure claims are as precise as possible, which may be more precise than necessary to put competitors on notice of the claims’ scope. As a practical matter, moreover, a lower threshold at this point makes sense because patent examiners, being persons of skill in the art, are less likely than lay judges to see an ambiguity in highly technical claims where no real ambiguity exists. And the opinion of the patent examiner, as one skilled in the art, regarding whether the claim terms and claim as whole are indefinite, is entitled to some deference.

In contrast, as the PTO has recognized, when claims are challenged in court, they “can be interpreted based on a fully developed prosecution record” and they “enjoy a presumption of validity” under § 282(a). *Id.* They must meet the lower bar of being sufficiently definite to delineate the bounds of the claimed invention, but need do no more. To this end, unlike the PTO’s broadest reasonable reading, courts adopt a *narrower* reading (one that skilled artisans would have agreed the claims at minimum encompass) as necessary to avoid finding claims indefinite. *Id.* (citing *Exxon Research & Eng’g*, 265 F.3d at 1375). As the Acting Solicitor General has explained, that difference is appropriate due to “the distinct roles that the PTO and the courts play in the patent system.” U.S. *Applera* Br. 17. The courts “appropriately require challengers to overcome the

presumption of validity by offering a persuasive demonstration of indefiniteness, including a showing that reasonable efforts at claim construction are unavailing.” *Id.* at 18. This Court should decline petitioner’s invitation to upend those well-established, and distinct, roles.

C. Petitioner’s Concerns About The “Zone Of Uncertainty” Are Misplaced

From a policy perspective, petitioner claims that the Federal Circuit’s doctrine has created a “zone of uncertainty” that “chill[s]” innovation and burdens competitors with the costs of determining a “patent’s valid scope.” Pet. Br. 38-39; *see also* Amazon Br. 4-5; Microsoft Br. 34-35. But the evidence does not bear that out. “[E]mpirical studies find few clear signs that the patenting of biotechnology inventions is adversely affecting biomedical innovation.” David E. Adelman & Kathryn L. DeAngelis, *Patent Metrics: The Mismeasure of Innovation in the Biotech Patent Debate*, 85 Tex. L. Rev. 1677, 1681 (2007); *see also* Adam B. Jaffe, *The U.S. Patent System in Transition: Policy Innovation and the Innovation Process*, 29 Research Policy 531, 540 (2000). Similarly, in the biomedical field, “patenting does not seem to limit research activity significantly, particularly among those doing basic [academic or non-competitive] research.” John P. Walsh et al., *Patents, Material Transfers and Access to Research Inputs in Biomedical Research* 3 (Sept. 20, 2005).

Competitors, moreover, are hardly incapable of making rational business decisions in the face of some uncertainty. *Cf.* Pet. Br. 29-30. Claim interpretation, including reasonable alternate interpretations and an analysis of those interpretations in light of the

specification and prosecution history, is a core aspect of any reasoned due diligence opinion. Commercially reasonable actors understand perfectly well that, if they launch products that are very close to the patented competition, they do so at their own peril. And most patent claims include many other limitations that allow for unambiguous design-arounds. Encouraging competitors to develop unambiguously non-infringing products increases diversity in the marketplace and spurs further innovation. Competitors who merely wish to practice the prior art are of course free to do so by marketing faithful copies of old products without any risk of infringement. But petitioner's concern for adequate notice rings hollow where, as here, it understood the claim well enough to consciously incorporate each and every one of its limitations into its product.

What petitioner describes as a deplorable "zone of uncertainty" thus reflects nothing more than the commercially commonplace understanding of every business that the risk of a lawsuit increases the closer they "creep" to a competitor's patent. Under petitioner's proposal, potential competitors would no longer do so at their own peril—they only need satisfy themselves that they could convince a district court that their claim interpretation is one of several objectively reasonable possible interpretations.

CONCLUSION

If the writ is not dismissed as improvidently granted, the judgment of the Federal Circuit should be affirmed.

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