No. 10-426

In the Supreme Court of the United States

APPLERA CORP., ET AL., PETITIONERS

v.

ENZO BIOCHEM, INC., ET AL.

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

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

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QUESTION PRESENTED

Whether respondents' patent claims satisfy the requirement of Section 112 of the Patent Act, 35 U.S.C. 112, that the specification of a patent "shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention."

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BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

This brief is filed in response to the Court's order inviting the Acting Solicitor General to express the views of the United States. In the view of the United States, the petition for a writ of certiorari should be denied.

STATEMENT

1. Each written application for a patent must include "a specification as prescribed by section 112" of the Patent Act. 35 U.S.C. 111. 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 which it pertains * * * to make and use the same." 35 U.S.C. 112, ¶ 1. "The specification shall 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 last of those provisions imposes what is known in patent parlance as the "definiteness" requirement: each patent must conclude with specific "claims" that, when construed in light of the specification and the relevant prosecution history, communicate to persons skilled in the art the legal scope of the patent grant. *Markman* v. *Westview Instruments, Inc.*, 517 U.S. 370, 373 (1996); *Carnegie Steel Co.* v. *Cambria Iron Co.*, 185 U.S. 403, 432, 437 (1902); see generally *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 (2011) (*PTO Definiteness Guidelines*). Compliance with Section 112 serves the dual purposes of "secur[ing] to [the patentee] all to which he is entitled, [and] appris[ing] the public of what is still open to them." *Markman*, 517 U.S. at 373 (quoting *McClain* v. *Ortmayer*, 141 U.S. 419, 424 (1891)) (second set of brackets in original); see *Festo Corp.* v. *Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 731 (2002). An inventor's failure to comply with any requirement of Section 112 renders the patent or claim in suit invalid. See 35 U.S.C. 282(3).

2. a. The patents at issue in this case concern laboratory techniques for detecting nucleic acids—such as deoxyribonucleic acid (DNA)—in a test sample. Pet. App. 2a. The basic structure of DNA includes two strands of repeating chemical units, known as "nucleotides" or "bases," bound together like a zipper and twisted into a distinctive double helix. The four standard nucleotides—adenine (A), thymine (T), cytosine (C), and guanine (G)—are chemically paired such that cytosine

always binds (or "hybridizes") with guanine, and adenine with thymine. *Id.* at 2a-3a.

Because of the predictable way in which nucleotides pair to form the "teeth" of the zipper, it is possible to infer from a nucleotide sequence on one strand of DNA the corresponding nucleotide sequence on the strand with which it may hybridize. Pet. App. 3a. Scientists may therefore detect whether a specific nucleotide sequence on a strand of DNA—for example, the sequence associated with a particular genetic condition—is present in a test sample. *Ibid.* Scientists attach a readily detected chemical entity (a "label") to a nucleic acid strand of a known sequence (a "probe") that will hybridize with the complementary sequence of interest (the "target"). *Ibid.* Copies of the labeled probe are then introduced into a test sample containing DNA strands of unknown sequence under conditions that permit the probe to hybridize with the target nucleic acid, if present. *Ibid.* After removing any unhybridized probes, scientists look for evidence that the label remains in the sample. Detection of the label implies that a probe has successfully hybridized, which in turn implies that the target nucleic acid is present. *Ibid.*; see *id.* at 80a-81a.

b. Although the use of labeled probes to detect nucleic acids has long been known in the art, previous detection methods generally involved the use of radioactive labels, which can be expensive, unstable, and hazardous. See Pet. App. 3a-4a. The patents at issue in this case are directed to nucleic acid detection probes and related methods that do not require the use of radioactive labels. Respondents are assignees of the relevant patents, U.S. Patents No. 5,328,824 (the '824 patent), No. 5,449,767 (the '767 patent), No. 5,476,928 (the '928 patent), and No. 5,082,830 (the '830 patent). *Id.* at 4a.

Those patents describe the use of a new type of label consisting of a chemical moiety that is covalently bonded to the probe either directly or through a "linkage group." *Ibid.* The linkage group is a chemical structure designed to hold the signaling moiety (the label) physically away from the probe to prevent it from interfering with either the probe's ability to hybridize with the target nucleic acid or the label's ability to be detected after hybridization is complete. *Id.* at 4a-6a. In effect, the patents teach that a successfully hybridized probe can be made detectable by attaching to the probe a kind of chemical flagpole with a distinctive chemical flag on the end, rather than by using radioactive isotopes.

The claims of the '824, '767, and '928 patents specifically recite the chemical structure of the claimed probe. See Pet. App. 4a-6a. The claims also indicate the range of covered labels, both by describing their chemical structure and by reciting examples of acceptable labels. See *id.* at 5a-6a. The linkage group (*i.e.*, the flagpole), however, is described in functional rather than structural terms: it is identified by its essential characteristic of "not interfering substantially" with the probe's ability to hybridize with the target or with the label's ability to be detected. *Id.* at 4a-5a.

3. In June 2004, respondents sued petitioners for patent infringement. Pet. App. 6a. After the district court construed the asserted patent claims, cf. *Markman*, 517 U.S. at 372, respondents conceded noninfringement of the '830 patent. Pet. App. 7a-8a. Petitioners then moved for summary judgment of invalidity of all asserted claims of the '824, '767, and '928 patents, arguing that those claims were anticipated under 35 U.S.C. 102 and that they failed to comply with the writ-

ten description, enablement, and definiteness requirements of 35 U.S.C. 112. Pet. App. 8a.

The district court granted the motion and declared all of the asserted claims invalid. See Pet. App. 34a-73a. The court concluded that each claim was anticipated by published scientific articles in the prior art. *Id.* at 8a & n.3, 61a-73a. The court also held that the asserted claims were invalid because the "not interfering substantially" language rendered the scope of the claims indefinite. *Id.* at 8a, 51a-61a. The court concluded that the "specifications neither set forth how one would gauge substantial interference, nor delimit the threshold at which interference with the procedure prevents [the] method from being implemented." *Id.* at 60a.

4. The court of appeals reversed in part, affirmed in part, and remanded. Pet. App. 1a-33a.

The court of appeals reversed the district court's finding of indefiniteness. Pet. App. 10a-19a. The court explained that the relevant inquiry was "whether those skilled in the art would understand what is claimed" in light of "the claim language, the specification, and the prosecution history." *Id.* at 11a (quoting *Young* v. *Lumenis, Inc.*, 492 F.3d 1336, 1346 (Fed. Cir. 2007)). Applying that standard, the court concluded that the term "substantially interfere," as used in the claims, was sufficiently definite because the claims, specification, and prosecution history provide not only general instructions for selecting linkage groups that satisfy the claims, but also specific examples of acceptable linkage groups identified by chemical structure. See *id.* at 12a-19a. The court held that the asserted claims are not indefinite because a person skilled in the art can deter-

mine whether a particular linkage group falls within the scope of the claims. *Id.* at 16a-17a.[1]

The court of appeals reversed the district court's summary judgment ruling that the '824 and '767 patents are invalid as anticipated by the prior art, but it affirmed the finding of invalidity as to the '928 patent. Pet. App. 19a-27a. The court also affirmed the judgment of noninfringement as to the '830 patent. *Id.* at 27a-32a.

5. Petitioners filed a petition for panel rehearing and rehearing en banc, which was denied. Pet. App. 74a-75a. Senior Judge Plager dissented from the denial of panel rehearing, urging that the Federal Circuit's "definiteness doctrine could go considerably further in promoting" the public notice function of patent claims under Section 112. *Id.* at 78a.

DISCUSSION

The court of appeals correctly held that Section 112's definiteness requirement was satisfied here because a person with ordinary skill in the art of designing probes for nucleic acid detection would reasonably understand the scope of the asserted patent claims in light of the specification and the prosecution history of the patents. That approach is consistent with this Court's precedents. It is also consistent with the views of the Patent and Trademark Office (PTO), which the agency recently restated in formal guidelines to assist examiners in applying the definiteness requirement. See generally *PTO Definiteness Guidelines*, 76 Fed. Reg. 7162 (2011). This Court's review is not warranted.

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[1] "[F]or most of the same reasons," the court held that the requirement that the linkage group not substantially interfere with detection of the signaling moiety likewise was not indefinite. Pet. App. 18a-19a.

A. The Court Of Appeals Correctly Held That A Patent Claim Is Sufficiently Definite If A Person Skilled In The Relevant Art Would Understand What Is Being Claimed

1. Section 112 promotes 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 Corp.* v. *Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 731 (2002). Although the practice of appending formal "claims" to the written specification of a patent did not achieve statutory recognition until 1836 and was not statutorily required until 1870, see *Markman* v. *Westview Instruments, Inc.*, 517 U.S. 370, 379 (1996), the Patent Act has provided since 1790 that a patent applicant must both (a) describe his claimed invention with sufficient clarity to enable a person skilled in the art to make or use the invention and (b) distinguish the invention from the prior art. See, *e.g.*, Act of Apr. 10, 1790, ch. 7, § 2, 1 Stat. 110-111; Act of Feb. 21, 1793, ch. 11, § 3, 1 Stat. 321-322; *Evans* v. *Eaton*, 20 U.S. (7 Wheat.) 356, 433-434 (1822).

In 1870, Congress enacted the first explicit requirement that, as part of the written specification, a patent applicant must "particularly point out and distinctly claim the part, improvement, or combination which he claims as his invention or discovery." Act of July 8, 1870, ch. 230, § 26, 16 Stat. 201; see *Markman*, 517 U.S. at 379. That 1870 amendment assisted courts in ascertaining what an inventor claimed as his contribution to the art by "very wisely requir[ing] of the applicant a distinct and specific statement of what he claims to be new, and to be his invention." *Merrill* v. *Yeomans*, 94

U.S. 568, 570 (1876); see *Keystone Bridge Co.* v. *Phoenix Iron Co.*, 95 U.S. 274, 278 (1877). The inclusion of such claims in the specification also served to "apprise the public of what is still open to them." *McClain* v. *Ortmayer*, 141 U.S. 419, 424 (1891).

2. a. As petitioners observe (Pet. 16-18), this Court has repeatedly emphasized the importance of the notice function of patent claims. See, *e.g.*, *General Elec. Co.* v. *Wabash Appliance Corp.*, 304 U.S. 364, 369 (1938); *Permutit Co.* v. *Graver Corp.*, 284 U.S. 52, 60 (1931). As the Court explained in *United Carbon Co.* v. *Binney & Smith Co.*, 317 U.S. 228, 236 (1942), "[a] zone of uncertainty which enterprise and experimentation may enter only at the risk of infringement claims would discourage invention only a little less than unequivocal foreclosure of the field." By requiring that patent claims provide clear notice of the metes and bounds of the patented invention, Section 112 reduces such uncertainty.

This Court has recognized, however, that it is often impossible to reduce an invention—including every embodiment and application to which it may extend—to writing with faultless precision and clarity. "Unfortunately, the nature of language makes it impossible to capture the essence of a thing in a patent application." *Festo*, 535 U.S. at 731. The fact that a court must interpret claim language in order to resolve questions of infringement does not mean that the language is fatally indefinite.

b. This Court has announced various principles governing the construction of disputed patent claims. First, claim language should be viewed not from the perspective of the public at large, but from the perspective of other persons "skilled in the art to which [the invention] pertains, or with which it is most nearly connected." 35

U.S.C. 112, ¶ 1. Thus, in discussing a patent for an improved method of manufacturing steel, the Court explained that "[t]he specification of the patent is not addressed to lawyers, or even to the public generally, but to the manufacturers of steel, and any description which is sufficient to apprise them in the language of the art of the definite feature of the invention, and to serve as a warning to others of what the patent claims as a monopoly, is sufficiently definite to sustain the patent." *Carnegie Steel Co.* v. *Cambria Iron Co.*, 185 U.S. 403, 437 (1902); see *Minerals Separation, Ltd.* v. *Hyde*, 242 U.S. 261, 271 (1916).

Second, patent claims should be interpreted in light of the patent's written specification rather than in isolation. See, *e.g.*, *Markman*, 517 U.S. at 389-390; *United States* v. *Adams*, 383 U.S. 39, 49 (1966); *Carnegie Steel*, 185 U.S. at 432; *Hogg* v. *Emerson*, 52 U.S. 587, 606 (1850). Third, "the prosecution history [of a patent] is relevant to construing [its] claims." *Festo*, 535 U.S. at 741; see *Exhibit Supply Co.* v. *Ace Patents Corp.*, 315 U.S. 126, 136-137 (1942); *Schriber-Schroth Co.* v. *Cleveland Trust Co.*, 311 U.S. 211, 217-218, 220-221 (1940). In *Festo*, the Court held that amendments made during prosecution to overcome an examiner's objections under 35 U.S.C. 112 become part of the interpretive background of the allowed claims and may give rise to estoppel in litigation. See 535 U.S. at 736-737.

c. This Court's decisions make clear that a patent claim can be sufficiently definite to satisfy Section 112 even if its language requires some interpretation against the backdrop of the relevant art, the patent specification, and the prosecution history. The Court has repeatedly declined to endorse the strongest form of the argument that petitioners advance here—*i.e.*, that patent

claims must "provide the public with *certainty* * * * about the scope of [the] patent." Pet. 21 (emphasis added). For example, the Court has recognized a "doctrine of equivalents" under which the "scope of a patent is not limited to its literal terms but instead embraces all equivalents to the claims described." *Festo*, 535 U.S. at 732. Such a doctrine is necessary, the Court has explained, because "[t]he language in the patent claims may not capture every nuance of the invention or describe with complete precision the range of its novelty." *Id.* at 731. While recognizing "that the doctrine of equivalents renders the scope of patents less certain," this Court has long viewed "this uncertainty as the price of ensuring the appropriate incentives for innovation." *Id.* at 732. More generally, the Court has explained that "the certainty which the law requires in patents is not greater than is reasonable, having regard to their subject-matter." *Minerals Separation*, 242 U.S. at 270.

A claim may be sufficiently definite under Section 112 even though it employs terms of degree in order to allow for some variation in the method of applying the invention at issue. For example, the patent in *Minerals Separation* involved an improved process for extracting valuable minerals from crushed ore. The Court rejected the accused infringer's contention that the process was not claimed with sufficient precision because aspects of the process had to be varied, through experimentation, to achieve the best results with different types of ore. 242 U.S. at 270. Similarly, in *Eibel Process Co.* v. *Minnesota & Ontario Paper Co.*, 261 U.S. 45, 66 (1923), the Court upheld against an indefiniteness challenge a patent directed to a machine for manufacturing paper stock that used gravity to improve the speed of the output by starting the paper-making wire at a "high" or "substan-

tial elevation above the level." *Id.* at 50. The Court explained that it was "difficult" for the patentee to be "more definite, due to the varying conditions of speed and stock existing in the operations of [such] machines and the necessary variation in the pitch to be used to accomplish the purpose of his invention." *Id*. at 65. A person skilled in the art of using such machines, the Court continued, would have "no difficulty * * * in determining what was the substantial pitch needed" to obtain the benefit of the invention. *Id*. at 65-66.

3. The ruling below reflects a sound understanding of the principles announced in this Court's decisions. The court of appeals explained that an allegation of "[i]ndefiniteness requires a determination whether those skilled in the art would understand what is claimed" in light of "general principles of claim construction." Pet. App. 11a (quoting *Young* v. *Lumenis, Inc.*, 492 F.3d 1336, 1346 (Fed. Cir. 2007)). The court further noted that "claim construction involves consideration of primarily the intrinsic evidence, *viz.*, the claim language, the specification, and the prosecution history." *Ibid.* The court also rejected petitioners' argument that the claims were indefinite because the choice of a linkage group might vary depending on the length and sequence of the relevant DNA strand. *Id.* at 17a-18a. The court's application of the standard imposed by Section 112 is faithful both to the language of the statute and to this Court's interpretation of that language.

B. There Is No Conflict Warranting This Court's Intervention

Petitioners assert (Pet. 16-22) that the Federal Circuit's definiteness standard is inconsistent with the language of Section 112 and with this Court's decisions.

While the Federal Circuit has sometimes used imprecise language to describe the definiteness standard, the court has generally adhered to the principles articulated by this Court. Petitioners are also wrong in contending (Pet. 23-26) that the Federal Circuit's jurisprudence impermissibly conflicts with the PTO's approach to resolving issues of definiteness during the examination process. Rather, the difference between the two entities' approaches is attributable to the distinct roles that the PTO and the Federal Circuit perform.

1. a. In applying the definiteness requirement of Section 112, the Federal Circuit has repeatedly stated that claims must be understood from the perspective of a person skilled in the relevant art and must be construed in light of the patent's specification and prosecution history. See, *e.g.*, *Phillips* v. *AWH Corp.*, 415 F.3d 1303, 1312-1313 (2005) (en banc), cert. denied, 546 U.S. 1170 (2006). Although a particular claim may "present a difficult task of claim construction," such a claim is invalid as indefinite only if "a skilled artisan could not discern the boundaries of the claim based on the claim language, the specification, and the prosecution history, as well as her knowledge of the relevant art area." *Halliburton Energy Servs., Inc.* v. *M-I LLC*, 514 F.3d 1244, 1249-1250 (Fed. Cir. 2008) (*Halliburton*). The Federal Circuit has applied some version of that standard to resolve indefiniteness issues for nearly the entire period that the court has been in existence. See, *e.g.*, *Shatterproof Glass Corp.* v. *Libbey-Owens Ford Co.*, 758 F.2d 613, 624 (Fed. Cir.), cert. dismissed, 474 U.S. 976 (1985); *Orthokinetics, Inc.* v. *Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576 (Fed. Cir. 1986); *Amgen, Inc.* v. *Chugai Pharm. Co.*, 927 F.2d 1200, 1217 (Fed. Cir.), cert. denied, 502 U.S. 856 (1991); *Personalized Media*

Commc'ns, LLC v. *ITC*, 161 F.3d 696, 705 (Fed. Cir. 1998). As petitioners acknowledged in their rehearing petition in the court of appeals (at 6), those decisions correctly articulate Section 112's definiteness standard as interpreted by this Court.

b. In arguing that the Federal Circuit's standard for definiteness is inconsistent with the text of Section 112 and with this Court's precedents, petitioners focus primarily (*e.g.*, Pet. 19) on Federal Circuit opinions stating that patent claims are sufficiently definite if they are "capable of construction" and not "insolubly ambiguous." Read in isolation, those phrases might suggest an insufficiently demanding definiteness standard to a district court looking for guidance. At least in the main run of its decisions, however, the Federal Circuit has used those phrases to express principles that are well grounded in this Court's Section 112 jurisprudence.

The Federal Circuit has most frequently used the relevant phrases to express the insight that a patent claim may be sufficiently definite to satisfy Section 112 even though considerable study and analysis are required to discern its meaning. See, *e.g.*, *Bancorp Servs., L.L.C.* v. *Hartford Life Ins. Co.*, 359 F.3d 1367, 1371 (2004) ("[A] claim is not indefinite merely because it poses a difficult issue of claim construction; if the claim is subject to construction, i.e., it is not insolubly ambiguous, it is not invalid for indefiniteness."); *Star Scientific, Inc.* v. *R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1371 (2008); *Halliburton*, 514 F.3d at 1249; *Exxon Research & Eng'g Co.* v. *United States*, 265 F.3d 1371, 1375 (2001) (*Exxon*). The proposition that substantial effort may be required to construe even a "definite" claim is not open to serious dispute. Because individual claims are construed in light of the patent as a whole, and because the

definiteness inquiry focuses on the claim's comprehensibility to a person skilled in the art (rather than to a generalist judge who may initially lack relevant technical expertise), a claim may satisfy Section 112 even though an arduous inquiry is required to ascertain its meaning. Cf. *Markman*, 517 U.S. at 387, 389 (explaining that trial court's construction of a patent claim may be informed by expert testimony concerning the relevant art, and that claim construction requires a "necessarily sophisticated analysis of the whole document").[2] Insofar as phrases like "insolubly ambiguous" function as shorthand references to those principles, they are fully consistent with this Court's precedents.

The contexts in which the Federal Circuit has used phrases like "insolubly ambiguous" and "open to construction" indicate that the court views those tests as synonymous with (or at least complementary to) the inquiry whether the relevant claim is understandable to one skilled in the art. See, *e.g.*, *Haemonetics Corp.* v. *Baxter Healthcare Corp.*, 607 F.3d 776, 783 (2010) (identifying "not amenable to construction" and "insolubly ambiguous" as the governing standards, and then stating that a party asserting indefiniteness must show "that one of ordinary skill in the relevant art could not discern the boundaries of the claim"); *Halliburton*, 514 F.3d at 1249 ("[C]laims [are] held indefinite only where a person of ordinary skill in the art could not determine the bounds of the claims, i.e., the claims [are] insolubly ambiguous."); *Star Scientific*, 537 F.3d at 1371 ("[I]f

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[2] Cf. *Barber* v. *Thomas*, 130 S. Ct. 2499, 2508 (2010) ("[T]he rule of lenity only applies if, after considering text, structure, history, and purpose, there remains a 'grievous ambiguity or uncertainty in the statute.'") (quoting *Muscarello* v. *United States*, 524 U.S. 125, 139 (1998)).

reasonable efforts at claim construction result in a definition that does not provide sufficient particularity and clarity to inform skilled artisans of the bounds of the claim, the claim is insolubly ambiguous and invalid for indefiniteness."). To be sure, any legal standard is capable of misapplication in particular cases, and the Federal Circuit may on occasion have used phrases like "insolubly ambiguous" and "capable of construction" while conducting a definiteness inquiry that in substance was insufficiently rigorous. But given the frequency and explicitness with which the Federal Circuit has linked those phrases to the principles of law announced in this Court's decisions, the court of appeals' terminology does not reflect any systematic deviation from correct application of Section 112.

c. In any event, the court of appeals did not use either the phrase "insolubly ambiguous" or the phrase "capable of construction" in its opinion below. Rather, the court explained that "[i]ndefiniteness requires a determination whether those skilled in the art would understand what is claimed," and that "general principles of claim construction apply" in resolving that question, including "consideration of primarily the intrinsic evidence, *viz.*, the claim language, the specification, and the prosecution history." Pet. App. 11a (internal citations and quotation marks omitted). The court then analyzed the intrinsic evidence concerning "substantial interference" at length and in considerable scientific detail, focusing on the meaning that particular disclosures would convey to a person skilled in the art of designing and labeling nucleic acid probes. *Id.* at 12a-19a.

Resolving the factbound (and highly technical) merits question this case presents—*i.e.*, whether petitioners' claims adequately conveyed the scope of their inventions

to persons skilled in the art of designing and labeling nucleic acid probes—would not be a prudent use of this Court's resources. And a decision by this Court remanding with instructions not to use the phrase "insolubly ambiguous" or "capable of construction" would serve no useful purpose, since the court of appeals has already decided the definiteness issue without using those phrases. This case therefore provides an unsuitable vehicle for determining whether the Federal Circuit in *other* decisions has used phrases like "insolubly ambiguous" to announce a separate, legally deficient definiteness standard, or simply as shorthand for established principles of law.

Furthermore, the interlocutory posture of the case provides an additional reason for this Court to deny review. The court of appeals affirmed the judgment of anticipation under 35 U.S.C. 102 as to one of the four patents on appeal, Pet. App. 27a; affirmed the judgment of noninfringement as to another, *id.* at 32a; and remanded for resolution of genuine issues of material fact regarding the validity of the remaining two patents under Section 102, see *id.* at 21a. The surviving claims could therefore be invalidated on remand despite the court of appeals' rejection of petitioners' indefiniteness challenge.

2. Petitioners contend (Pet. 23-26) that this Court's intervention is necessary to resolve a "conflict" between the Federal Circuit's decisions and the PTO's interpretation of Section 112, Paragraph 2. No such conflict exists. As the PTO's recently published guidelines for examiners under Paragraph 2 of Section 112 make clear, the agency conducts essentially the same definiteness inquiry that courts apply, asking whether a person skilled in the art can reasonably understand what is

claimed in light of the specification and other intrinsic evidence. See *PTO Definiteness Guidelines*, 76 Fed. Reg. at 7164; see also U.S. Patent & Trademark Office, *Manual of Patent Examining Procedure* §§ 2171, 2173.02 (rev. ed. 2010).

The PTO does instruct agency examiners to employ "a lower threshold of ambiguity when reviewing a pending claim for indefiniteness" than that used by the Federal Circuit. *Ex parte Miyazaki*, No. 2007-3300, 2008 WL 5105055, at *5 (Bd. Pat. App. & Inter. Nov. 19, 2008); see *PTO Definiteness Guidelines*, 76 Fed. Reg. at 7164. Rather than apply a limiting construction as courts do, PTO examiners will reject a claim as indefinite if, when viewed in light of the specification as understood by a person skilled in the art, the claim is amenable to two or more plausible claim constructions. *Miyazaki*, 2008 WL 5105055, at *5-*6; *PTO Definiteness Guidelines*, 76 Fed. Reg. at 7164. That difference, however, stems not from different interpretations of Section 112, but from the distinct roles that the PTO and the courts play in the patent system. As the PTO has explained, "[t]he lower threshold is applied [during patent examination] because the patent record is in development and not fixed." *Ibid.* At that point, the PTO construes patent claims broadly "in an effort to establish a clear record of what [the] applicant intends to claim." *Ibid.* If such a construction yields more than one plausible interpretation of a claim during examination, the PTO appropriately requires the applicant "to more precisely define the metes and bounds of the claimed invention." *Miyazaki*, 2008 WL 5105055, at *5-*6; see *PTO Definiteness Guidelines*, 76 Fed. Reg. at 7164; *Halliburton*, 514 F.3d at 1255.

In contrast, when a patent is under review before a court, the patent enjoys a statutory presumption of validity, see 35 U.S.C. 282, and the court generally has access to a fuller prosecution record from which the meaning of claim terms can be gleaned, *PTO Definiteness Guidelines*, 76 Fed. Reg. at 7164. At that juncture, 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. See *Exxon*, 265 F.3d at 1375; see also *PTO Definiteness Guidelines*, 76 Fed. Reg. at 7164 ("[W]hen possible, courts construe patented claims in favor of finding a valid interpretation."). Petitioners are therefore wrong in asserting (Pet. 23) that the PTO "has expressly rejected the statutory test employed by the Federal Circuit." Both entities inquire whether a person skilled in the art would understand what is being claimed in light of the intrinsic evidence, and both acknowledge the different roles each entity serves in the patent process. See *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997); *PTO Definiteness Guidelines*, 76 Fed. Reg. at 7164.

C. The Court Of Appeals' Decision Is Correct

The court of appeals correctly held that the challenged claims, when construed in light of the specification and the relevant prosecution history, are sufficiently definite to allow a person skilled in the art of designing and labeling nucleic acid probes to understand the scope of respondents' invention. The patents disclose a technique for labeling nucleic acid probes without using costly, unstable, and potentially dangerous radioisotopes. Pet. App. 3a-6a. That technique employs "linkage groups" covalently bonded to the polynucleo-

tide probe to hold a signaling moiety (*e.g.*, a fluorescent dye) physically separated from the probe in a manner that "does not interfere substantially" with the ability of the probe to hybridize with the target nucleic acid, or with the ability of scientists to detect the signal after hybridization. *Ibid.*

Petitioners contend (Pet. 21-23, 26-29) that the claim terms are invalid because the phrase "not interfering substantially" does not provide the requisite notice of the "boundaries" of what is being claimed. In particular, petitioners argue both that the challenged claims are invalid because they merely provide "examples of what the patent is meant to cover" (Pet. 21), and because practitioners would need to engage in experimentation to determine whether a particular linkage group would be covered (Pet. 27-28). The court of appeals correctly rejected those arguments.

The Federal Circuit appropriately concluded that the claims at issue are definite because the intrinsic evidence "provides 'a general guideline and examples sufficient to enable a person of ordinary skill in the art to determine [the scope of the claims].'" Pet. App. 16a-17a (quoting *In re Marosi*, 710 F.2d 799, 803 (Fed. Cir. 1983)) (brackets in original). For example, the specification identifies the preferred type and structure of the linkage group, as well as the preferred method of binding the group to the probe. See *id.* at 15a-17a. The specification also identifies "essential criteria" for selecting a linkage group and teaches that the melting temperatures (as determined by the thermal denaturation profile) and hybridization properties of target polynucleotides "can be used to measure the degree to which a linkage group interferes with hybridization."

Id. at 15a (quoting '824 patent specification, col. 18, ll.61-62).

As a person skilled in the art would know, melting temperature can be used as a proxy for the strength of the hydrogen bonds that form between hybridized strands of complementary DNA: a lower melting point indicates fewer or weaker bonds. Pet. App. 17a. A decrease in the melting temperature of a hybridized probe, relative to that of an unmodified control molecule, therefore provides an objective gauge for measuring the degree of interference with hybridization attributable to the linkage group attached to the probe. *Id.* at 15a-16a. The specification gives several examples of acceptable decreases of melting temperatures for DNA probes having a specified length and sequence. See *id.* at 16a. The court of appeals therefore concluded that, "[w]hen deciding whether a particular linkage group is or is not 'substantially' interfering with hybridization * * * , a person of ordinary skill would likely look to the thermal denaturation profiles and hybridization properties * * * of the modified nucleotide, to see whether they fall within the range of exemplary values disclosed in the intrinsic evidence." *Id.* at 17a.

The court of appeals further found that a skilled practitioner would draw reasonable inferences from the specific examples provided in the claims, specification, and prosecution history of linkage groups that satisfy the requirements of the invention. Pet. App. 14a, 16a. Dependent claims in the '824 and '767 patents, for example, recite a linkage group with a specific chemical structure. *Id.* at 14a. A person skilled in the art therefore would "presume[] that the term 'not interfering substantially' in the independent claims allows for at least as much interference as that exhibited when the linkage

group has the structure specified in the dependent claims." *Ibid.* In overcoming an initial indefiniteness rejection by the PTO, respondents also provided a declaration listing eight specific examples of linkage groups that did not substantially interfere with hybridization or detection. *Id.* at 16a.

The court of appeals also correctly rejected petitioners' objection that the claims were indefinite because a particular linkage group would fall within the scope of the patent with respect to some polynucleotides but not with respect to others. Pet. App. 18a. The Federal Circuit's analysis is in keeping with *Eibel Process*, in which this Court upheld the use of a term of degree as a reasonable solution to the problem of describing a wide variety of alternative arrangements that a person skilled in the art would recognize as sufficient to serve the purposes of the invention. 261 U.S. at 65-66; see pp. 10-11, *supra*. Indeed, respondents overcame an indefiniteness rejection by the PTO by demonstrating to the satisfaction of the examiner that a skilled practitioner would recognize that a "wide structural variety" of linkage groups, consistent with the teachings of the specification, would enable the invention to work. Br. in Opp. App. 44a. As the PTO has stated, "[a] broad claim is not indefinite merely because it encompasses a wide scope of subject matter provided the scope is clearly defined." *PTO Definiteness Guidelines*, 76 Fed. Reg. at 7164.

Petitioners' overarching objection (Pet. 27) is that "the Federal Circuit has permitted data points to substitute for boundaries, contrary to the statutory requirement of particularity and distinctness." But the court of appeals correctly concluded that the specification and prosecution history provide enough detail for a person skilled in the art to understand the scope of the claims.

That is sufficient to satisfy Section 112's definiteness requirement. Cf. *Minerals Separation*, 242 U.S. at 270 ("[T]he certainty which the law requires in patents is not greater than is reasonable."). And in any event, the court of appeals appears to have construed the claims to encompass only modified polynucleotide probes having "thermal denaturation profiles and hybridization properties * * * [that] fall *within the range of exemplary values disclosed* in the intrinsic evidence." Pet. App. 17a (emphasis added). As this Court has explained, it is well within the authority of a court to construe patent claims narrowly to avoid any ambiguity and preserve the proper scope of the invention. *Smith* v. *Snow*, 294 U.S. 1, 14 (1935); *McClain*, 141 U.S. at 425. The construction adopted by the court of appeals will control on remand, both for purposes of infringement and for evaluating petitioners' arguments concerning anticipation.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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