

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.,  
*Respondents.*

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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 THE AMERICAN INTELLECTUAL  
PROPERTY LAW ASSOCIATION AS  
AMICUS CURIAE SUGGESTING AFFIRMANCE**

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## INTEREST OF AMICUS CURIAE

*Amicus Curiae* American Intellectual Property Law Association (“AIPLA”) submits this brief to suggest affirmance.<sup>1</sup>

AIPLA is a national bar association of approximately 7,000 members who are engaged in private and corporate practice, in government service, and in the academic community. AIPLA’s members represent a wide and diverse spectrum of individuals, companies, and institutions involved directly and indirectly in the practice of patent, trademark, copyright, trade secret, and unfair competition law, as well as other fields of law affecting intellectual property. Our members represent both owners and users of intellectual property. AIPLA’s mission includes providing courts with objective analyses to promote an intellectual property system that stimulates and rewards invention, creativity, and

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<sup>1</sup> In accordance with Supreme Court Rule 37.6, AIPLA states that this brief was not authored, in whole or in part, by counsel to a party, and that no monetary contribution to the preparation or submission of this brief was made by any person or entity other than AIPLA and its counsel. Specifically, after reasonable investigation, AIPLA believes that (i) no member of its Board or Amicus Committee who voted to file this brief, or any attorney in the law firm or corporation of such a member, represents a party to the litigation in this matter; (ii) no representative of any party to this litigation participated in the authorship of this brief; and (iii) no one other than AIPLA, or its members who authored this brief and their law firms or employers, made a monetary contribution to the preparation or submission of this brief.

investment while also accommodating the public's interest in healthy competition, reasonable costs, and basic fairness. AIPLA has no stake in the parties to this litigation or in the result of this case other than its interest in the correct and consistent interpretation of the laws affecting intellectual property.

### **SUMMARY OF ARGUMENT**

The Federal Circuit's patent invalidity decision in this case was based on established law for judging the enablement of genus claims that use functional language. It did not rewrite or create a new test for determining the sufficiency of an enablement disclosure. Rather, the decision is consistent with the statutory provisions and case law requirements to determine whether the claimed invention was sufficiently enabled under Section 112(a) of Title 35. Section 112(a) does not require disclosure of "all" possible embodiments to enable genus claims. Rather it requires disclosure of only those that teach a person of skill in the art to make and use the invention.

The enabling disclosure requirement is a critical element of the longstanding bargain with the public that ensures innovations are accessible to persons of skill in exchange for the limited exclusive rights under the patent. This important role of the specification requires strict adherence to language of the statute that calls not only for a "full, clear, and exact" description of the invention, but also for a "concise" disclosure directed to persons of skill in the art. For more than 50 years, 35 U.S.C. 112(a) has been



understood to require that patent disclosures enable persons of skill in the art to make and use the claimed invention. The Federal Circuit and the district court applied the factors set out in *In re Wands*, a decision from more than 35 years ago, and found in the case being appealed here that undue experimentation would have been required for a person of skill in the art to make and use the claimed invention. This fact-intensive determination under *Wands* considered eight factors that courts may apply to tailor the findings to the particular claims and technology at issue.

The determination that the enablement disclosures in this case were inadequate was made with a time-tested method of analysis that has served the patent well by balancing the disclosure burdens on the inventor against the public interest in providing access to the invention. Moreover, the longevity and effectiveness of Federal Circuit law for evaluating the sufficiency of enablement disclosures has produced settled expectations in the inventing community. Any changes to this law are for Congress, not for the courts.

This Court should confirm that the Federal Circuit's *Wands* factors are important considerations in determining under Section 112(a) whether a specification adequately describes the invention in full, clear, concise, and exact terms to enable one of ordinary skill to make and use the invention as claimed.

### **Factual Background**

In 2011, Amgen obtained a patent on a monoclonal antibody that blocks a protein (PCSK9) from interfering with the liver's ability to remove LDL cholesterol. This antibody was claimed structurally by describing its specific amino acid sequence. Three years later, Amgen obtained two additional patents (8,829,165 and 8,859,741) with claims directed to a genus of antibodies defined by their function. Thus, the claims are directed to monoclonal antibodies that function to "bind" with certain amino acids (or "residues") on the PCSK9 protein, and that function to "block" that protein from binding with LDL receptors.

Sanofi was alleged to infringe the generic claims of the '165 and '741 patents. A first jury declined to find invalidity based on inadequate written description and enablement disclosures, but the Federal Circuit reversed and remanded because of an erroneous jury instruction. 872 F.3d 1367 (Fed. Cir. 2017). On remand, a second jury again declined to find invalidity for inadequate enablement, but the district court reversed with an invalidity judgment as a matter of law.

The Federal Circuit affirmed, ruling that the scope of the claims to the functionally defined monoclonal antibodies was not adequately enabled. According to the court, the patents failed to disclose sufficient embodiments to permit a person of skill in the art to make or use the invention as claimed.

## ARGUMENT

### **I. The Federal Circuit Applied Established Law to Find Genus Patent Claims Using Functional Language Were Not Enabled.**

The Federal Circuit decision in this case applied well-established law to determine that Amgen’s genus patent claims, drafted with functional language, were not sufficiently enabled under the terms of 35 U.S.C. 112(a). The appellate court reviewed the extensive expert evidence developed by the district court and agreed that a person of ordinary skill in the art could not make and use the invention without “undue experimentation.”

#### **A. Enablement Does Not Require Disclosure of All Embodiments for Genus Claims Using Functional Language.**

Petitioner erroneously contends that the Federal Circuit has rewritten the law of enablement to require that genus claims using functional language must disclose “all” embodiments of the invention. Petitioner misstates the law of enablement and misstates the Federal Circuit’s holding in this case.

The error in the Petitioner’s argument is foreshadowed in its Question Presented:

Whether enablement is governed by the statutory requirement that the specification teach those skilled in the art to ‘make and use’ the claimed invention, 35 U.S.C. § 112, or whether it must instead enable those skilled in the art “*to reach the full scope* of claimed embodiments” without undue experimentation—i.e., to

cumulatively identify and make all or nearly all embodiments of the invention without substantial “time and effort.”

With this question, Petitioner has erected a facile strawman proposition about the patent owner’s obligation under the statute and under the case law. Petitioner glosses over the specific obligation in the statute that the inventor disclose the invention in such “full, clear, concise, and exact terms” that a person of ordinary skill in the art can make and use the invention. The issue to be decided in appraising an enablement disclosure is not whether the patent discloses “all” embodiments. Rather, it is whether the patent reasonably discloses “enough” information for a person of ordinary skill in the art to make and use the invention defined by the claims.

**B. The Importance of the Enablement Disclosure to the Patent System Requires Strict Adherence to the Statute.**

**1. Enablement Disclosure Is Central to the Public-Inventor Bargain of the Patent System.**

The statutory requirement to enable a claimed invention is central to the patent system’s bargain between the inventor and the public and therefore requires strict adherence to Section 112(a).

The statute in force today contemplates a disclosure to enable “any person skilled in the art to which it pertains, or with which it is most nearly connected.” This is essentially the same formulation

originally enacted in the Patent Act of 1790 (requiring a disclosure “to enable a workman or other person skilled in the art.”).<sup>2</sup> Compliance with the enablement requirement enriches the storehouse of public knowledge and is demanded from the inventor in exchange for rights of limited exclusivity.<sup>3</sup>

The important and careful balance of inventor and public interests found in the patent system has been recognized often by this Court:

“In consideration of its disclosure and the consequent benefit to the community, the patent is granted. An exclusive enjoyment is guaranteed him for seventeen years, but upon expiration of that period, the *knowledge of the invention inures to the people, who are thus enabled without restriction to practice it and profit by its use.*”

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<sup>2</sup> “Sec. 2. *And be it further enacted*, That the grantee or grantees of each patent shall, at the time of granting the same, deliver to the Secretary of State a specification ... *which specification shall be so particular, and said models so exact, as not only to distinguish the invention or discovery from other things before known and used, but also to enable a workman or other person skilled in the art or manufacture....*” 1 Stat. 109, 110 (emphasis added).

<sup>3</sup> *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 481 (1974) (Additions that patent information makes to the general store of knowledge are of such importance that the government “is willing to pay the high price of 17 years of exclusive use for its disclosure,” which disclosure will stimulate ideas and the eventual development of further significant advances.); *Grant v. Raymond*, 31 U.S. 218, 244 (1832) (“The communication of the discovery to the public has been made in pursuance of law, with the intent to exercise a privilege which is the consideration paid by the public for the future use of the machine.”).

*United States v. Dubilier Condenser Corp.*, 289 U. S. 178, 186-187 (1933) (emphasis added).

The public-inventor bargain more recently has also been framed by this Court as follows:

“From their inception, the federal patent laws have embodied a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy.”

*Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989).

These passages demonstrate the importance of the public disclosures required to obtain patent protection for a claimed invention, particularly in the case of enablement. The objective of the requirement is not only to put the public in possession of the claimed invention so that it can be made and used after the patent expires but also to teach a person of skill in the art where infringement may be avoided during the term of the patent.<sup>4</sup>

## **2. Statute’s Enablement Requirement Is Directed to Persons of Skill.**

It follows from the importance of such disclosures that inventors should be held to the specific language of the statute requiring these disclosures. Section 112(a), among other things, requires a patent specification to describe the claimed invention “in such full, clear, concise, and exact terms *as to enable any person skilled in the art* to which it pertains,

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<sup>4</sup> *Evans v. Eaton*, 20 U.S. (7 Wheat.) 356, 418 (1822).

or with which it is most nearly connected, to make and use the same.” Thus, the statute itself makes clear that the intended audience for the enablement disclosure is a “person skilled in the art.”

The required disclosure meets the needs of skilled artisans in the relevant technology to make and use the claimed invention. This statutory language recognizes that basic information, or information that is well-known to a person of skill, need not be included. As pointedly expressed by this Court, “the specification is not addressed to lawyers or even to the public,” but to those skilled in the art, an objective standard identifying those who must be taught how to make and use the invention in the language of the relevant technology.<sup>5</sup>

The “person of ordinary skill” standard has long been part of evaluating the sufficiency of the enablement disclosure.<sup>6</sup> On the issue of how much information or examples will satisfy that standard, Section 112(a) includes “reasonableness” limitations that moderate the disclosure requirements.<sup>7</sup> Although the manner of making and using the invention must be described in “full,” clear, and

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<sup>5</sup> *Carnegie Steel Co. v. Cambria Iron Co.*, 185 U.S. 403, 437 (1902).

<sup>6</sup> *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 373 (1996) (“It has long been understood that a patent must describe the exact scope of an invention and its manufacture....”). *O’Reilly v. Morse*, 56 U.S. 62, 120 (1853) (“[H]e claims a patent, for an effect produced by the use of electro-magnetism distinct from the process or machinery necessary to produce it.”).

<sup>7</sup> *McRO, Inc. v. Bandai Namco Games Am. Inc.*, 959 F.3d 1091, 1100 (Fed. Cir. 2020) (enablement does not require disclosure of every variant of the claimed invention, but there must be reasonable enablement of the scope of the range).

“exact” terms, that description must also be “concise.” Another reasonableness limitation is found in case law stating that an invention can be enabled even where some experimentation is necessary for a person of skill to make and use the invention.<sup>8</sup> It is not until such experimentation becomes “undue” that enablement fails.

This reasonableness standard, expressly stated in Section 112(a) for the written description and enablement disclosures, also applies to the so-called “definiteness” requirement for patent claims in Section 112(b). In *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898 (2014), this Court said that a patent must inform those skilled in the art about the scope of the invention “with reasonable certainty.” *Id.* at 910.

The same test applies to enablement: a patent is invalid for lack of enablement if the disclosure fails to inform, with reasonable certainty, those skilled in the art how to make and use the claimed invention. This does not require an exhaustive and comprehensive disclosure of every embodiment within the scope of the claims. In *Nautilus*, this standard reconciled competing concerns about the limitations of language and the requirement to draft precise claims. Here, the “reasonable certainty” standard reconciles competing enablement concerns of exhaustive disclosure requirements that burden inventors, on the one hand, and the need to ensure that persons of skill are able

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<sup>8</sup> *Minerals Separation, Ltd. v. Hyde*, 242 U.S. 261, 270-71 (1919); *WL Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1557 (Fed. Cir. 1983); *Atlas Powder Co. v. E.I. Du Pont De Nemours & Co.*, 750 F.2d 1569, 1576 (Fed.Cir.1984).



to make and use the invention without undue experimentation.

Section 112(a) has long been understood to require disclosures to be “at least commensurate with the scope of the claims.”<sup>9</sup> In a decision about the Samuel Morse telegraph invention, this Court famously recognized that a patent is invalid if it is not supported by a sufficient teaching about the claimed invention. In his Eighth Claim, Morse said his invention essentially was the use of electromagnetism to communicate at a distance, without any limitation to the specific machinery or parts of machinery described in the specification. Justice Taney added the following:

“And if he can secure the exclusive use by his present patent he may vary it with every new discovery and development of the science, and need place no description of the new manner, process, or machinery, upon the records of the patent office. And when his patent expires, the public must apply to him to learn what it is. *In fine*

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<sup>9</sup> *In re Hyatt*, 708 F.2d 712, 714 (Fed. Cir. 1983) (enabling disclosure of the specification be commensurate in scope with the claim under consideration); *National Recovery Technologies v. Magnetic Separation Systems*, 166 F.3d 1190, 1195-96 (Fed. Cir. 1999) (enablement requirement ensures public knowledge is enriched to a degree at least commensurate with the scope of claims); *In re Goodman*, 11 F.3d 1046, 1059 (Fed. Cir. 1993) (specification does not contain sufficient information to enable the broad scope of the claims); *In re Vaeck*, 947 F.2d 488, 495 (Fed. Cir. 1991) (there must be a reasonable correlation between the narrow disclosure in the specification and the broad scope of protection sought in the claims); *In re Fisher*, 427 F.2d 833, 839 (CCPA 1970) (Section 112(a) requires the scope of the claims to bear a reasonable correlation to the scope of enablement).

*he claims an exclusive right to use a manner and process which he has not described and indeed had not invented, and therefore could not describe when he obtained his patent. The court is of opinion that the claim is too broad, and not warranted by law.”*

*O’Reilly*, 56 U.S. at 113 (emphasis added).

As stated elsewhere by this Court, variations that are found in embodiments may be present, but they must be within the scope of the claims.<sup>10</sup>

## **II. *In re Wands* Provides the Correct Framework for Determining “Undue Experimentation.”**

While a disclosure can be enabling where some experimentation is necessary, the disclosure will fail if a person of skill needs to engage in “undue experimentation” to practice the claimed invention. This test has been used for decades and was elaborated in *In re Wands*, 858 F.2d 731, 736 (Fed. Cir. 1988).<sup>11</sup> In *Wands*, the Federal Circuit identified a series of factors that a court may consider in deciding whether any necessary experimentation is “undue”:

- (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;

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<sup>10</sup> *Minerals Separation*, 242 U.S. at 270

<sup>11</sup> The case law history of the “undue experimentation” standard, going back at least 50 years, is set out in the *Wands* opinion.

- (6) the relative skill of those in the art;
- (7) the predictability or unpredictability of the art;
- and
- (8) the breadth of the claims.

These eight factual considerations have been in use for nearly 35 years in the Federal Circuit and for 37 years in the Patent and Trademark Office. They originated in a 1986 decision of the Board of Patent Appeals and Interferences. *In re Forman*, 230 USPQ 546, 547 (BPAI 1986). Over multiple decades they have provided a helpful framework for evaluating the sufficiency of a disclosure.

The fact-intensive character of the “undue experimentation” inquiry adapts to different technologies and different ways inventions in these different technologies are claimed. These differences have a direct bearing on the degree of disclosure required for any given invention and play an important part in the analysis of this case.<sup>12</sup>

The Federal Circuit in this case applied established case law on enablement and agreed with the factual determinations by the district court that a person of skill in the art could not make and use the generically claimed invention without undue experimentation. The district court heard extensive evidence showing that the scope of the claims is broad and that the invention is in an unpredictable field of science. Based on the record, the Federal Circuit

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<sup>12</sup> *Minerals Separation*, 242 U.S. at 271 (“[T]he certainty which the law requires in patents is not greater than is reasonable, having regard to their subject-matter.”).

concluded that the claimed invention in this case was not enabled.<sup>13</sup>

### **III. Enablement of “Invention” Is Informed By the Terms of the Claims.**

#### **A. The Claims’ Definition of the Invention Determines the Number of Embodiments That Must Be Disclosed.**

Petitioner contends that the Federal Circuit has rewritten the substantive standard for an enablement disclosure, i.e., to enable a person of skill in the art to make and use “the invention.” The argument is misguided because it fails to recognize that the definition of “the invention” is determined by claim language the inventor chose to use. Where an invention is claimed generically, it encompasses more embodiments than when it claims one species of the genus.

The Federal Circuit did not substitute a standard of its own devising here. The reason a great number of embodiments must be disclosed in this case is

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<sup>13</sup> There should be no confusion about the standard of review in this case. Although the ultimate determination of enablement is a question of law, that determination under Federal Circuit law must be based on underlying factual findings that are reviewable for clear error. *See Alcon Research Ltd. v. Barr Labs., Inc.*, 745 F.3d 1180, 1188 (Fed. Cir. 2014). This formulation mirrors other patent validity issues that involve mixed questions of law and fact, such as nonobviousness or the on-sale bar, and this Court declined Petitioner’s invitation to consider the issue here. *See Microsoft Corp. v. i4i Ltd. Partnership*, 564 U.S. 91, 96–97 (2011).

because this inventor chose to define the invention generically with functional language. The disclosure requirement here serves as a limit on overbreadth. It requires that enablement is commensurate with the claims, i.e., that the generic claims defining the invention are no broader than what is taught in the patent's enabling disclosure.<sup>14</sup>

Nor did the Federal Circuit hold, as Petitioner contends, that a patent is not enabled if substantial time and effort would be required to identify and make all or almost all possible antibodies covered by the claims. The Federal Circuit made clear that an enabling disclosure need not exhaust all of the possible embodiments encompassed by a genus. Pet. App. 14a.

This Court should resist Petitioner's invitation to adopt a bright-line standard for determining the sufficiency of an enabling disclosure and should embrace the well-established, fact-specific approach used for years in the Federal Circuit. It is the only effective way to deal equitably with the diversity of

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<sup>14</sup> The Federal Circuit has used a "representative species test" to evaluate the sufficiency of a written description disclosure for genus claims. See *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 966-967 (Fed. Cir. 2002), and *Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1350 (Fed. Cir. 2010). Although the *en banc Ariad* court held that written description and enablement requirements are distinct, the representative species test could be usefully applied to enablement with the same constraints as a way to provide a reasonable limit on the disclosure requirement. See also *AbbVie Deutschland GmbH v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1300 (Fed. Cir. 2014) (requiring disclosure of sufficient representative species encompassing the breadth of the genus).

technology and the claim drafting choices made by inventors.

**B. Failure to Identify a Single Non-Enabled Embodiment Is Not Determinative of “Undue Experimentation” Issue.**

The Petitioner also maintained that Respondent’s failure to identify a single embodiment that was not enabled demonstrates that Petitioner’s enabling disclosure was not shown to be inadequate. This argument fails to address a fact finding by the district court about the embodiment examples expressly stated in the patent specification: “Although the patent provides twenty-six working examples, the record indicates that there is no dispute that they do not teach a person of ordinary skill in the art how to predict from an antibody’s sequence whether it will bind to specific PCKS9 residues.” Pet. App. 38a. As pointed out by the district court, there is “no dispute” on this matter.

Taking Petitioner’s point for the sake of the argument, the failure to identify a single non-enabled embodiment does not settle the enablement issue. Rather the correct standard is whether the effort to discover from the multitude of possibilities the compositions that exhibit the claimed functional characteristics would have been undue.

Although Petitioner complains that it is too burdensome to hold inventors to this standard of enablement, it fails to recognize that an inadequate disclosure imposes on persons of skill the undue burden of a trial-and-error process to discover which compositions are encompassed by the functional

limitations and which are not. Petitioner's view also ignores the inventor's obligation to the public to sufficiently disclose its claimed invention in return for the exclusive rights that come with a patent. Enforcing this obligation (1) ensures that patent protection does not extend to claims that are broader than the enabled embodiments, (2) gives persons of skill the notice of how to avoid infringement, and (3) provides a full teaching of the invention for the public to make and use the invention when the patent expires.

**C. Expectations of Inventing Community  
Weigh in Favor of Retaining Established  
Rules for Judging Enablement.**

Finally, this Court should retain the well-developed and long-standing Federal Circuit rules for judging enablement to protect the settled expectations of the inventing community. These rules recognize the fact-intensive inquiry of appraising claims and their disclosures in highly complex technologies. Moreover, the rules benefit the public by balancing the interest of the inventor and the interests of the public.

The Patent Office origins of the undue experimentation factors in its 1986 *In re Forman* decision is evidence of the important technical expertise that informs this method of analyzing enablement. The Federal Circuit adopted the analysis in 1988 and has applied it consistently ever since, demonstrating its effectiveness and reliability.

This Court has instructed courts to exercise caution before adopting changes that disrupt the

settled expectations of the inventing community.<sup>15</sup> It made clear that it is for Congress to change settled law, not for the courts. The *Warner-Jenkinson* decision rejected a bright-line test alleged to bring more certainty to the intersection of doctrine of equivalents claims and prosecution history estoppel. According to the Court, “[t]o change so substantially the rules of the game now could very well subvert the various balances the PTO sought to strike when issuing the numerous patents which have not yet expired and which would be affected by our decision.” This same view was subsequently expressed in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 739 (2002), and it applies here as well.

The Federal Circuit test for enabling disclosures has not only survived the test of time, it has also survived years of amendments to the Patent Act. Most recently, Congress in 2011 undertook a major revision of patent law in the America Invents Act, and it made no revisions to Section 112(a) except in the labelling of paragraphs.<sup>16</sup> Longevity and effectiveness are the best reasons for adopting the Federal Circuit test applied in this case and for affirming the decision on review.

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<sup>15</sup> *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 28 (1997).

<sup>16</sup> Leahy-Smith America Invents Act, Pub. L. No. 112-99 (2011). The best mode requirement in Section 112(a) was examined during the legislative process. The requirement was retained in Section 112(a) but it was removed from Section 282 as grounds for invalidity.



**CONCLUSION**

This Court should confirm that the Federal Circuit's *Wands* factors are important considerations in determining under Section 112(a) whether a specification adequately describes the invention in full, clear, concise, and exact terms to enable one of ordinary skill to make and use the invention as claimed.

Respectfully submitted,

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