

No. 18-1515

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

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ELI LILLY AND COMPANY, PETITIONER

*v.*

ERFINDERGEMEINSCHAFT UROPEP GbR

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

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**REPLY BRIEF FOR THE PETITIONER**

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In the decision below, the Federal Circuit blessed a patent claim that uses purely functional language to cover a method of using potentially billions of compounds. In so doing, the Federal Circuit effectively dispensed with the rule against functional claiming—a rule this Court has repeatedly articulated but the Federal Circuit has increasingly ignored.

In an effort to distract from the basic problem with the Federal Circuit’s decision, respondent takes haughty umbrage at being labeled a patent troll. But make no mistake about it: respondent is a non-practicing entity that asserted a deliberately overbroad claim for the purpose of profiting from a successful invention that it unquestiona-

bly did not discover itself. It was petitioner, not respondent, that pioneered the use of tadalafil as a safe and effective treatment for benign prostatic hyperplasia. Yet the Federal Circuit allowed respondent to exploit petitioner's invention by refusing to apply the rule against functional claiming.

Its rhetoric aside, respondent offers little by way of a defense of the Federal Circuit's decision. Respondent contends that, because its claim falls outside the scope of Section 112(f), the claim language is not impermissibly functional. But that contention reflects the same erroneous premise contained in the Federal Circuit's jurisprudence: namely, that the rule against functional claiming did not survive the enactment of Section 112(f).

Proceeding from that misconception, respondent asserts that this case is a poor vehicle in which to consider the question presented, principally on the ground that petitioner failed to preserve its argument below. But contrary to respondent's contention, petitioner was not required to appeal the district court's holding that Section 112(f) was inapplicable in order to preserve its functional-claiming challenge for this Court's review. The rule against functional claiming is rooted in the written-description and enablement requirements of Section 112(a), and petitioner has consistently argued that respondent's claim flunks those requirements.

Respondent identifies no valid impediment to this Court's review. And it essentially ignores the significant implications the decision below will have if it is allowed to stand. Unless the Court restores the rule against functional claiming, parties will continue to get away with outrageous behavior like respondent's. As amici have warned, that will seriously diminish innovation across a range of industries. The Court should grant the petition for writ of certiorari.

### A. The Decision Below Is Erroneous

In the face of the longstanding rule against functional claiming, see Pet. 5-8, the Federal Circuit upheld a claim covering a method of treating BPH by administering an effective amount of any one of potentially billions of compounds that perform the function of inhibiting a particular type of enzyme. See Pet. App. 228a-229a. That claim so flagrantly violates the rule against functional claiming that there can be no serious dispute the Federal Circuit is dispensing with it altogether. The Court's intervention is therefore warranted.

1. In defense of the Federal Circuit's decision, respondent primarily contends that "there is no blanket rule against functional claiming" in the wake of the enactment of Section 112(f). Br. in Opp. 20-21. Respondent is mistaken.

When Congress enacted what is now Section 112(f) as part of the 1952 Patent Act, it did not disturb the general rule that purely functional claims are invalid. See Pet. 8, 14. Instead, it merely created an exception to that rule, permitting means-plus-function claiming for combination claims in limited circumstances. See *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 28 (1997); Mark A. Lemley, *Software Patents and the Return of Functional Claiming*, 2013 Wis. L. Rev. 905, 916-918 (2013).

Respondent does not argue that its claim falls within the ambit of Section 112(f), and for good reason: if it did, the claim would not encompass tadalafil, and there would be no infringement. See Pet. 14-15. But that leaves respondent in the awkward position of having to explain how Section 112(f) somehow dissolved the rule against functional claiming for claims, such as respondent's, that undisputedly fall *outside* that provision. What explanation does respondent offer? None at all. Respondent cannot

simply wish away the longstanding rule against functional claiming. This Court should make clear, both to respondent and to the Federal Circuit, that the rule retains vitality following the enactment of Section 112(f).

2. Perhaps tacitly acknowledging that the rule against functional claiming remains good law, respondent suggests in the alternative that its claim does not constitute impermissible functional claiming. But that suggestion, too, lacks merit.

a. Respondent first implies that the term “inhibitor of [phosphodiesterase] V” (or PDE V) is structural, not functional, because such an inhibitor “must have a structure that allows it to bind with [PDE V] at a specific place to block its function.” Br. in Opp. 3; *see id.* at 12-13. But it does not follow that the claim itself conveys structure; instead, respondent is merely stating the obvious proposition that a PDE V inhibitor must *have* a structure in order to work.

Respondent’s analogy proves the point. Respondent compares the claim term “inhibitor” to the term “coffee maker,” which in its view refers to a machine that necessarily incorporates certain structural features. See Br. in Opp. 3-4. But that analogy does not help respondent. Even assuming that the term “coffee maker” is now understood to refer to a class composed of a discrete number of members (such as a drip coffee machine, a thermal coffee machine, or a French press), the term “inhibitor of [PDE] V” refers to an unbounded class of potentially billions of chemical compounds, most of which have not yet been discovered and can be known only through testing.

Respondent’s claim is more akin to one purporting to cover all “makers of coffee.” If the inventor of the drip coffee machine had been allowed to describe the invention in those plainly functional terms—describing what the invention *does*, not what it *is*—that claim would have

preempted the later patent for the French press by “extend[ing]” the patent monopoly “beyond the discovery” itself. *Holland Furniture Co. v. Perkins Glue Co.*, 277 U.S. 245, 257 (1928). That is precisely the sort of choke on innovation that the rule against functional claiming was meant to block. See, e.g., *O’Reilly v. Morse*, 56 U.S. (15 How.) 62, 113 (1853).

b. Respondent also appears to adopt the district court’s reasoning that the claim is not purely functional on the ground that its “inventive contribution” is not the discovery of PDE V inhibitors themselves, but rather the discovery that “PDE V inhibitors can be effective in treating BPH.” Pet. App. 175-177; see Br. in Opp. 7-8. Not so. The claim covers a method of treatment, and the allegedly inventive contribution of the claim is that BPH can be treated *by certain compounds that inhibit PDE V*. Without those compounds, there would be no inventive contribution. And the flaw in respondent’s claiming of that contribution is that the claim describes those compounds in purely functional terms, thereby covering the future treatment of BPH using compounds not yet discovered. In short, there is no way for respondent to circumvent the rule against functional claiming: if the rule remains valid, the Federal Circuit’s decision upholding the claim cannot be sustained.

**B. This Case Presents An Excellent Opportunity For The Court To Answer The Question Presented**

With little to say on the merits, respondent argues at length that this case is a poor vehicle in which to resolve the question presented. Respondent’s arguments lack merit.

1. Respondent principally contends that petitioner failed to preserve its functional-claiming challenge below.

See Br. in Opp. 12-17. In so contending, respondent mischaracterizes the proceedings below and misapprehends the doctrinal basis for the rule against functional claiming.

a. Respondent accuses petitioner of “rewrit[ing]” the case’s procedural history by “repackaging its validity defenses of written description, enablement, and indefiniteness” as functional-claiming arguments. Br. in Opp. 13-14. As petitioner has explained, however, the rule against functional claiming is based in the written-description, enablement, and definiteness requirements; a claim using purely functional language fails at least some if not all of those requirements. See Pet. 6-7. Petitioner concededly pursued its written-description and enablement defenses on appeal, see Br. in Opp. 11, and that alone was sufficient to preserve a functional-claiming challenge for this Court, see *Lebron v. National R.R. Passenger Corp.*, 513 U.S. 374, 379 (1995); *Yee v. City of Escondido*, 503 U.S. 519, 534 (1992).

In any event, petitioner went further and expressly argued on appeal that the claim used functional language that failed to satisfy the written-description and enablement requirements. As respondent acknowledges (Br. in Opp. 14), petitioner argued in its principal brief below that the written-description requirement “prohibit[ed]” respondent’s “attempt[] to preempt the future before it has arrived by patenting the use of an unknowably large number of undescribed compounds identified only by their functional ability to interfere with a natural disease process.” Pet. C.A. Br. 21; see *id.* at 20-23, 54.

Contrary to respondent’s suggestion (Br. in Opp. 14-15), it is of no moment that petitioner made additional arguments concerning the written-description requirement. Of course, a party is free to make alternative arguments below. And before this Court, a party is free to expand upon arguments it made below as long as it is doing so to

“support what has been [its] consistent claim.” *Lebron*, 513 U.S. at 379. If it were a ground for forfeiture that a party did not below cite all of the particular cases on which it is relying before this Court, see Br. in Opp. 16, the Court would have few if any cases.

b. Respondent also argues that petitioner did not preserve its functional-claiming challenge because it did not appeal the district court’s holding that Section 112(f) did not apply to the claim. See Br. in Opp. 13. That argument fundamentally misapprehends the nature of petitioner’s challenge and is premised on the erroneous notion that the rule against purely functional claiming did not survive the enactment of Section 112(f). See pp. 3-4, *supra*. In fact, petitioner now does not dispute that Section 112(f) is inapplicable here; it instead argues that the single-step claim at issue violates this Court’s rule against functional claiming, which continues to govern outside the narrow context of Section 112(f) claims. See Pet. 13-15.

2. Respondent contends that the question presented cannot be resolved without revisiting the district court’s factual findings supporting its determination that the claim was structural. See Br. in Opp. 17-19. The district court observed that a skilled artisan would not have understood the phrase “an inhibitor of [PDE] V” to be “purely functional” as of the 1997 priority date. Pet. App. 178a-179a. In so observing, however, the court obviously presupposed a particular view of what it means to be purely functional. There can be no dispute that the phrase “an inhibitor of [PDE] V” encompassed a huge number of compounds yet to be discovered. Whether it is permissible to capture the future in this way is a pure question of law that is properly presented for the Court’s resolution in this case.

In any event, the district court did not purport to find that the claim had sufficient structure for purposes of the

rule against functional claiming. Rather, the court concluded that the presumption that the claim had structure could not be overcome. See Pet. App. 178a-179a. But that presumption applies only when determining whether Section 112(f) covers a claim. See, e.g., *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1347 (Fed. Cir. 2015) (en banc); see generally HTIA Br. 12-13. The district court thus made no factual findings that would interfere with the Court’s consideration of the question presented.

3. In addition, respondent contends that this case is a poor vehicle because the Federal Circuit issued an unpublished summary affirmance. See Br. in Opp. 19-20. If anything, however, the summary nature of the decision below will make the Federal Circuit’s approval of the district court’s decision—itsself written, as respondent repeatedly notes, by a Federal Circuit judge, see *id.* at 5, 8, 10, 19—seem all the more authoritative. The Federal Circuit should not be allowed to “cert-proof[]” decisions that resolve significant legal questions through the mechanism of summary affirmance. See Andrew Hoffman, *The Federal Circuit’s Summary Affirmance Habit*, 2018 B.Y.U. L. Rev. 419, 439, 442 (2018).\*

In a footnote, respondent deems “unconvincing” the numerous instances cited by petitioner in which this Court has reviewed unpublished decisions. See Br. in Opp. 20 n.6. In particular, respondent brushes aside this Court’s review of the Federal Circuit’s similar summary affirmance in *Oil States Energy Services, LLC v. Greene’s Energy Group, LLC*, 138 S. Ct. 1365 (2018), noting that the Federal Circuit had issued an opinion in a different

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\* A petition for certiorari specifically challenging the Federal Circuit’s practice of issuing unpublished summary affirmances is currently pending before the Court. See *Straight Path IP Group, LLC v. Apple Inc.*, No. 19-253 (filed Aug. 23, 2019).

case concerning the same question presented. But this case presents materially identical circumstances: as petitioner has shown, the Federal Circuit has repeatedly demonstrated in published opinions that it is unwilling to enforce the rule against functional claiming, prompting at least one Federal Circuit judge to call for clarification on the issue. See *Williamson*, 792 F.3d at 1358 (Reyna, J., concurring in part and dissenting in part); Pet. 18-19.

**C. The Question Presented Is An Important One That Warrants The Court's Review**

Beyond identifying illusory vehicle problems, respondent does virtually nothing to challenge the obvious importance of the question presented. As petitioner has shown, the Federal Circuit's refusal to apply the rule against functional claiming has grave implications for many industries. See Pet. 18-19. For that reason, amici from both the pharmaceutical and technological industries—two industries that rarely agree on intellectual-property issues—have filed briefs explaining how the Federal Circuit's flawed approach preempts entire fields of innovation. See HTIA Br. 21-23; Eisai Br. 8-10. This case has also attracted significant attention from multiple commentators, with one calling it “[o]ne of the more interesting” petitions now pending before the Court. Dennis Crouch, *Supreme Court: What is the Role of Functional Claim Limitations?*, Patently-O (Sept. 23, 2019) <[tinyurl.com/functionalclaimlimitations](http://tinyurl.com/functionalclaimlimitations)>; see Tiffany Hu, *'Shadowy' Co. Can't Ignore Eli Lilly's \$20M High Court Appeal*, Law360 (Aug. 20, 2019) <[tinyurl.com/shadowyco](http://tinyurl.com/shadowyco)>. Yet respondent brushes past the significant implications of this case—and ignores the amicus briefs altogether.

Respondent instead cites several earlier petitions that were denied. Br. in Opp. 21. But all but one of those petitions did not present a question about the rule against functional claiming; they sought review on questions about the application of Section 112(f) or principles of claim construction. See *Farstone Technology, Inc. v. Apple Inc.*, 2016 WL 6819724 (filed Nov. 14, 2016), cert. denied, 137 S. Ct. 684 (2017) (No. 16-651); *Universal Lighting Technologies, Inc. v. Lighting Ballast Control LLC*, 2016 WL 159572 (filed Jan. 11, 2016), cert. denied, 136 S. Ct. 1226 (2016) (No. 15-893); *Media Rights Technologies, Inc. v. Capital One Financial Corp.*, 2015 WL 7831389 (filed Dec. 3, 2015), cert. denied, 136 S. Ct. 1173 (2016) (No. 15-725); *Aerotel, Ltd. v. Telco Group, Inc.*, 2012 WL 122285 (filed Jan. 11, 2012), cert. denied, 565 U.S. 1261 (2012) (No. 11-871). And in the only petition that did raise a similar question, that question was subsidiary to another question concerning the “all elements” rule of claim construction. See *Cox Communications, Inc. v. Sprint Communications Co. LP*, 2017 WL 975402 (filed Mar. 13, 2017), cert. denied, 137 S. Ct. 2267 (2017) (No. 16-1106). The petition in this case, by contrast, cleanly and solely presents the question whether a single-step patent claim that describes its point of novelty solely in functional terms violates the rule against functional claiming.

That question warrants the Court’s review, and this case is an excellent vehicle in which to consider it. The Court should grant review to answer the question and to prevent non-practicing entities such as respondent from using functional language to preempt innovation.

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The petition for a writ of certiorari should be granted.

Respectfully submitted.

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