

No. 18-1515

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IN THE  
**Supreme Court of the United States**

ELI LILLY AND COMPANY,  
*Petitioner,*

v.

ERFINDERGEMEINSCHAFT UROPEP GBR,  
*Respondent.*

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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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**BRIEF OF AMICI CURIAE EISAI CO., LTD.  
AND EISAI INC. IN SUPPORT OF PETITIONER**

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## STATEMENT OF INTEREST OF *AMICI CURIAE*

*Amici Curiae* Eisai Co., Ltd. and Eisai Inc. (collectively, “Eisai”) respectfully submit this brief in support of Petitioner Eli Lilly and Company’s petition for a writ of certiorari.<sup>1</sup> Eisai Co., Ltd. is a global research-based human health care company that discovers, develops, and markets products and services that contribute to the well-being of patients and their families worldwide. Eisai Inc. is Eisai Co., Ltd.’s U.S. pharmaceutical subsidiary. Drawing on the research and development strengths of its parent company, Eisai Inc. focuses on prevention and treatment of diseases with significant unmet medical need, particularly in the fields of neurology and oncology. In those areas, the ability to conduct innovative research—which requires extensive and costly investment of both time and resources—is essential for the development of safe and effective therapeutic solutions.

As one of the leaders in the development of pioneering pharmaceutical drugs, Eisai has a strong interest in a U.S. patent system that incentivizes and rewards innovation while offering predictability and protection from opportunistic infringement claims. Eisai is concerned that the Federal Circuit’s lack of consistency in the application of precedent to functional claims upends the predictability of the

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<sup>1</sup> Pursuant to Supreme Court Rule 37.2, amici indicate that counsel of record for all parties received timely notice of the intent to file the brief, and all parties have consented to the filing of this brief. Pursuant to Rule 37.6, amici affirm that no counsel for a party authored this brief in whole or in part and that no person other than amici or their counsel have made any monetary contributions intended to fund the preparation or submission of this brief.

patent system, undermining pharmaceutical companies' incentives to pursue innovative research into products that treat complex diseases and provide much-needed relief to patients.

### **INTRODUCTION AND SUMMARY OF ARGUMENT**

This Court's precedents prohibiting unbounded functional patent claims should provide patent holders with clear and settled guidance. But recent decisions by the Federal Circuit, culminating in the judgment below, risk obscuring and destabilizing those precedents. Respondent UroPep advanced a patent claiming a method of preventing or treating benign prostatic hyperplasia ("BPH") by "administering . . . an effective amount of an inhibitor of [the enzyme PDE V]," without listing a single example of a compound found to actually accomplish that result. The class of potential compounds covered by the claim numbers in the billions, and the claim, if upheld, reserves all of them for UroPep, regardless of whether UroPep has the inclination or capability to develop them. The claim at issue improperly attempts to preempt future development by seeking to close off an entire biological pathway from further innovation.

Despite the significance of this question for patent law, the Federal Circuit affirmed the district court's lengthy opinion via summary affirmance under Federal Circuit Rule 36. The Federal Circuit has increasingly (and inappropriately) relied on these one-word, non-precedential judgments, even when an appeal merits a full opinion with the requisite legal analysis. The Federal Circuit's use of Rule 36 in this case should not shield its judgment from this Court's certiorari review.

Supreme Court review is imperative because the Federal Circuit's affirmance of the district court's erroneous opinion will have serious negative consequences for the pharmaceutical industry. The Federal Circuit's endorsement of the district court's judgment with regard to the practically limitless functional claim at issue threatens to undermine this Court's consistent effort to ensure that only inventions that are adequately disclosed and enabled receive patent protection. Non-practicing entities or patent trolls will be free to claim future inventions by merely identifying a desired, useful result and claiming all potential ways of achieving it. This Court's review is acutely needed to prevent these undesired consequences and to ensure that unscrupulous patent-holders do not "extend the monopoly beyond the invention." *Holland Furniture Co. v. Perkins Glue Co.*, 277 U.S. 245, 258 (1928).

## ARGUMENT

### A. *The Decision Below Is Contrary To Long-Established Law*

Congress has authorized patents only for an invention or discovery of "any new and useful *process, machine, manufacture, or composition of matter*, or any new and useful improvement thereof." 35 U.S.C. § 101 (emphasis added). The patent specification further "shall 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 the same," *id.* § 112(a) (emphasis added), and must "distinctly claim[] the subject matter which the inventor or a joint inventor regards as the invention," *id.* § 112(b).

Because one can patent only distinctly claimed inventions and discoveries of new and useful processes or products that are described and enabled in the specification, one cannot claim a desired effect, *Halliburton Oil Well Cementing Co. v. Walker*, 329 U.S. 1, 9 (1946), or claim the functional properties of existing products or processes, *Application of Swinehart*, 439 F.2d 210, 212-13 (C.C.P.A. 1971) (“it is elementary that the mere recitation of a newly discovered function or property, inherently possessed by things in the prior art, does not cause a claim drawn to those things to distinguish over the prior art”) (footnote omitted). Without this principle, a patentee could identify (and monopolize) a useful function without actually defining an invention or innovation that achieves that function.

This Court first declared the impropriety of such claiming in *O’Reilly v. Morse*, when it invalidated a patent claim relating to Samuel Morse’s invention of the telegraph. 56 U.S. 62, 112 (1853). Morse attempted to claim “the exclusive right to every improvement where the motive power is the electric or galvanic current, and the result is the marking or printing [of] intelligible characters, signs, or letters at a distance.” *Id.* This Court recognized that “some future inventor . . . may discover a mode of writing or printing at a distance by means of the electric or galvanic current, without using any part of [Morse’s] process.” *Id.* at 113. The new invention may be “less complicated” or “less expensive,” but would nevertheless be “covered by this patent,” depriving the public of “the benefit of it without the permission of this patentee.” *Id.*

This Court has continued to uphold the rule against functional claiming. *See* Pet. Br. at 6 (listing cases). That does not mean that functional limitations are always inappropriate in claims. Congress has specifically authorized combination claims “expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof,” but such claims are construed only “to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.” 35 U.S.C. § 112(f); *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 28 (1997). And even apart from means-plus-function claims, a recital of structure, material, or acts *and* function in a claim may suffice (in light of the specification) to identify an adequately described and enabled new process or product. *See Application of Swinehart*, 439 F.2d at 211, 214 (upholding a claim to “a new composition of matter ... being a solidified melt of two components present in proportion approximately eutectic, one of said components being BaF<sub>2</sub> and the other being CaF<sub>2</sub>” with the function of being “transparent to infra-red rays and resistant to thermal shock,” because the claims in light of the specification defined a novel composition).

In this case, UroPep clearly engaged in unbounded functional claiming. Claim 1 of the patent covers “[a] method for prophylaxis or treatment of benign prostatic hyperplasia [BPH] comprising administering to a person in need thereof an effective amount of an inhibitor of [PDE] V,” except for eight compounds identified in the specification. Pet. App. 228a-229a. Much like Samuel Morse’s attempt to claim any and all methods of producing text at a distance using electricity, UroPep attempts to claim any and all methods of treating BPH

using an inhibitor of PDE V. It is a single-step claim reciting use of any compound by a broadly stated function (inhibition of PDE V, which the district court construed to mean inhibition at least 20 times more effective than the compound's inhibition of PDE I to PDE IV, Pet. App. 99a) to achieve a function (prophylaxis or treatment of BPH). UroPep identified no inventive process of administering PDE V inhibitors, nor did it invent any new class of compounds. PDE V inhibitors were found to be well known in the art. Pet. App. 5a.

It is not a sufficient answer, as the district court believed, that a person of skill in the art could work to identify PDE V inhibitors. *See* Pet. App. 178-179. The flaw is that UroPep at most discovered a functional property of a functionally defined (but existing) class of compounds, and then claimed *all methods* of achieving that function. This violates the most “elementary” rule against boundless functional claiming. *Application of Swinehart*, 439 F.2d at 212-13.

By claiming the function—inhibition of PDE V—UroPep has fenced off every potential avenue of achieving that outcome, even though it has not performed the work of identifying compounds that will actually produce the desired results. Certain compounds may be better at treating BPH than others—they may produce fewer negative side effects, be easier to administer, be “less complicated,” or be “less expensive.” *O'Reilly*, 56 U.S. at 113. Innovators would have no incentive to perform the resource-intensive labor required to develop and market better treatments when UroPep's improper patent would prevent them from reaping the rewards of such innovation.

Purely functional claiming is no less an unwelcome practice now than when Samuel Morse was patenting the telegraph. While this Court has been consistent in denying the validity of such claims, it has not heard a case involving the issue since 1946. *See Halliburton Oil Well Cementing Co. v. Walker*, 329 U.S. 1 (1946). This case would be an opportunity for this Court to reaffirm—and clarify—the vitality of this important principle of patent law.

**B. *The Federal Circuit’s Use of Summary Affirmance Underscores the Need for this Court’s Review***

The Federal Circuit summarily affirmed the district court’s decision without opinion, pursuant to Federal Circuit Rule 36. Such affirmances lack precedential value and dispose of cases without explanation.

Troublingly, the Federal Circuit issues summary affirmances at a rate unmatched by any other circuit. *See* Andrew Hoffman, *The Federal Circuit’s Summary Affirmance Habit*, 2018 B.Y.U. L. Rev. 419, 439 (2018) (“The Federal Circuit—whose caseload is dwarfed by other circuit courts’ dockets—uses summary affirmance on a much more regular basis[.]”). Commentators have criticized the Federal Circuit’s reliance on these nonprecedential dispositions that fail to explicate their reasons for affirming the courts below. *See, e.g.*, Dennis Crouch, *Wrongly Affirmed Without Opinion*, 52 Wake Forest L. Rev. 561 (2017); Mathew Bultman, *Fed. Circ. Issuing More ‘Hidden Decisions’ Amid Case Influx*, Law360 (Mar. 1, 2017), <https://www.law360.com/articles/894024/fed-circ-issuing-more-hidden-decisions-amid-case-influx>. And litigants have repeatedly raised their concerns—

including to this Court—about the Federal Circuit’s cavalier use of Rule 36 affirmances. *See* Pet. For Writ of Cert., *Celgard, LLC v. Matal*, No. 16–1526 at 23 (June 19, 2017) (listing multiple other petitions complaining of inappropriate use of Rule 36); Pet. For Writ of Cert., *Stambler v. Mastercard International, Inc.*, No. 17-1140 at 8 (March 15, 2018) (same).

While Rule 36 affirmances may be warranted in some cases, the Federal Circuit has increasingly employed them in situations that merit a full opinion. *See* Hoffman, *supra*, at 446–450 (listing recent important cases the Federal Circuit affirmed by Rule 36). That is the case here. The district court authored a lengthy opinion that starkly violates the rule against purely functional claiming. The Federal Circuit’s summary affirmance represents an unexplained departure from *Hyatt* and *Swinehart*, and generates substantial doubt in the industry about the vitality of functional-claiming jurisprudence. If the law is to be changed, it should be through a considered and published opinion of a Federal Circuit panel—or better yet, through an action by this Court. The Federal Circuit’s summary affirmance of the district court’s erroneous judgment should not deter this Court from granting review. *See* Pet. Br. at 21 (listing this Court’s decisions reviewing nonprecedential circuit court decisions).

**C. *The Decision Below Would Have Negative Consequences for the Pharmaceutical Industry***

If the decision below is allowed to stand, it risks impeding innovation in the pharmaceutical industry. As this Court has recognized, a patentee may not hypothesize a desired result and claim all methods of

achieving it; if allowed, “[t]he patent monopoly would thus be extended beyond the discovery, and would discourage rather than promote invention.” *Holland Furniture*, 277 U.S. at 257. Patent law should not reward a claim to a purported invention that, as in this case, “merely recite[s] a description of the problem to be solved while claiming all solutions to it.” *Ariad*, 598 F.3d at 1353.

Here, as Petitioner demonstrated, UroPep claimed all future means of treating BPH by inhibiting the PDE V enzyme, but did not describe an inhibitor that was actually shown to accomplish the claimed result. *See* Pet. Br. at 13–17. This is the classic example of the patentee claiming patent protection despite not having performed the “difficult work of invention.” *Ariad*, 598 F.3d at 1353 (quotation omitted). If the Federal Circuit’s endorsement of this patent claim’s validity is upheld, pharmaceutical companies would be deterred from innovating in the purportedly claimed space, even if there are different or better methods—none of which the patent holder foresaw or disclosed—of accomplishing the claimed mechanism of action. Better medicines and treatments for patients would go undiscovered.

Research and development into new uses of known drug products and associated patents protecting resulting inventions is critically important. New therapeutic treatments and medications are often incremental refinements of existing treatments and medications. If a patentee could foresee a function for treating a condition, it could rush to patent that function without actually inventing the treatment. The Federal Circuit’s pivot away from enforcing prohibition on such a functional claim would be a boon

for patent trolls and a disincentive for those who wish to pioneer and develop new treatments. The public health would suffer under such a system.

While the incentive to invent is undoubtedly important, the other half of the patent bargain is equally critical: It protects the public, including innovating companies, from the issuance of patents broadly stifling others from creating that which the patentee did not invent. As this Court has observed, “a patent . . . is not a reward for the search, but compensation for its successful conclusion.” *Brenner v. Manson*, 383 U.S. 519, 536 (1966). The decision below significantly curtails the rule against boundless functional claiming, and this Court should grant certiorari and reaffirm this important rule of patent law.

**CONCLUSION**

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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