

No.

In the Supreme Court of the United States

ELI LILLY AND COMPANY, PETITIONER

v.

ERFINDERGEMEINSCHAFT UROPEP GbR

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

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether a single-step patent claim that describes its point of novelty solely in functional terms violates the rule against functional claiming set forth in *Halliburton Oil Well Cementing Co. v. Walker*, 329 U.S. 1 (1946).

CORPORATE DISCLOSURE STATEMENT

Petitioner Eli Lilly and Company has no parent corporation, and no publicly held company owns 10% or more of its stock.

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PETITION FOR A WRIT OF CERTIORARI

Eli Lilly and Company respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals (App., *infra*, 1a-2a) is unreported. The district court's opinion and order denying petitioner's motion for judgment as a matter of law or a new trial (App., *infra*, 3a-94a) is reported at 276 F. Supp. 3d 629. The district court's opinion and order construing the patent claim and denying petitioner's motions for summary judgment (App., *infra*, 164a-207a) is

unreported. The district court's opinion and order denying the parties' earlier motions for summary judgment (App., *infra*, 109a-163a) is reported at 240 F. Supp. 3d 605.

JURISDICTION

The judgment of the court of appeals was entered on October 10, 2018. A petition of rehearing was denied on February 5, 2019 (App., *infra*, 208a-209a). On April 25, 2019, the Chief Justice extended the time within which to file a petition for a writ of certiorari to and including June 5, 2019. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATUTORY PROVISIONS INVOLVED

Section 112 of Title 35 of the United States Code provides in relevant part:

(a) In General

The specification 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 which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

(b) Conclusion

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

* * *

(f) Element in Claim for a Combination

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

STATEMENT

After gradually chipping away at this Court’s rule against functional claiming, the Federal Circuit has now seemingly dispensed with that rule altogether. This case involves a patent claim that covers a method of using a staggeringly broad universe of compounds described in purely functional language—language that describes the invention in terms of what it *does*, rather than what it *is*. This Court has long held such patent claims invalid. See, e.g., *Halliburton Oil Well Cementing Co. v. Walker*, 329 U.S. 1, 9 (1946).

Purely functional claims discourage innovation by “extend[ing]” the patent monopoly “beyond the discovery” itself. *Holland Furniture Co. v. Perkins Glue Co.*, 277 U.S. 245, 257 (1928). The rule against functional claiming ensures fair notice of an invention’s scope and adequate disclosure of how to make and use it. See Donald S. Chisum, 3 *Chisum on Patents* § 8.04[3], at 406-407 (2018 ed.). In the face of that rule, the Federal Circuit blessed the claim in this case, upholding a non-practicing entity’s audacious attempt to obtain patent protection for a new use of petitioner’s drug—a use that petitioner had in fact pioneered.

In 2001, petitioner sought approval from the Food and Drug Administration (FDA) for Cialis®, a drug to treat

erectile dysfunction. A short time later, petitioner proposed evaluating tadalafil, the active ingredient in Cialis, as a new treatment for a different condition, benign prostatic hyperplasia (BPH). After investing millions of dollars and many years in research and development, petitioner proved in human clinical trials that tadalafil was a safe and effective treatment for that condition and obtained FDA approval to market tadalafil for BPH treatment.

A few months later, respondent—a shadowy non-practicing entity based in Germany—filed the patent application that ultimately became the patent at issue here, claiming priority to an application from 1997. As is relevant here, the patent claims a method of preventing or treating BPH by “administering * * * an effective amount of an inhibitor of [a particular enzyme],” excluding eight specific compounds. App., *infra*, 228a. In other words, it covers a method of treating BPH by administering an effective amount of a compound defined by the very result it seeks to accomplish—namely, inhibiting a specific type of enzyme. The patent thereby captures the use of tadalafil and billions of other compounds, including many yet to be discovered.

Respondent filed suit against petitioner, asserting that petitioner had infringed respondent’s patent by marketing Cialis for the treatment of BPH. The case was assigned to Judge Bryson of the Federal Circuit, who was sitting by designation as a district judge. After trial, the jury returned a verdict for respondent. The district court then denied petitioner’s motion for judgment as a matter of law, rejecting the argument that the claim impermissibly describes its point of novelty “using functional language.” App., *infra*, 16a. The Federal Circuit affirmed.

The decision below reflected a broader trend in the Federal Circuit’s jurisprudence. For years, the Federal

Circuit has eroded the rule against functional claiming, to the point that one member of that court has wondered whether the rationale for the rule remains valid. See *Williamson v. Citrix Online LLC*, 792 F.3d 1339, 1355 (Fed. Cir. 2015) (Reyna, J., concurring in part and dissenting in part).

This case is a particularly egregious example of purely functional claiming that preempts future discoveries. Yet the Federal Circuit affirmed a decision in favor of the patentee—and, worse yet, did so in a summary order. Without this Court’s intervention, non-practicing entities will be free to claim future inventions through the simple expedient of identifying a desired result in the context of method claims. That outcome flies in the face of the policies underlying patent law. This Court should grant review to restore the rule against functional claiming and reverse the Federal Circuit’s deeply flawed judgment.

A. Background

1. In the middle of the nineteenth century, patentees began broadly defining their claims in an attempt to cover not just their inventions, but anything else that performed the same function. See Mark A. Lemley, *Software Patents and the Return of Functional Claiming*, 2013 Wis. L. Rev. 905, 911-912 (2013) (Lemley). Such claims sought to erect “fence posts” around entire markets and to prevent “any substitute technologies from competing with” patentees’ inventions, thereby undermining one of patent law’s primary goals—namely, the promotion of new technologies that necessarily compete with existing patents. *Id.* at 911-912.

The Court intervened in *O’Reilly v. Morse*, 56 U.S. (15 How.) 62 (1853), announcing the rule that purely functional claims are invalid. In that case, which involved a

patent relating to Samuel Morse’s invention of the telegraph, the Court rejected Morse’s attempt 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.* at 112. The Court noted that allowing such a claim would permit Morse’s telegraph patent to cover “some future inventor[’s]” discovery of 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 future invention may well be “less complicated” or “less expensive,” the Court explained, “yet if it is covered by [Morse’s] patent the inventor could not use it, nor the public have the benefit of it without [his] permission.” *Ibid.*

In the decades that followed, the Court repeatedly reaffirmed the rule against functional claiming in a wide range of contexts. See, e.g., *Risdon Iron & Locomotive Works v. Medart*, 158 U.S. 68, 77 (1895); *Holland Furniture*, 277 U.S. at 257-258; *General Electric Co. v. Wabash Appliance Corp.*, 304 U.S. 364, 368 (1938); *United Carbon Co. v. Binney & Smith Co.*, 317 U.S. 228, 234-236 (1942); *Halliburton*, 329 U.S. at 9. In those decisions, the Court consistently held that a patentee may not “extend” the scope of a patent by claiming merely an intended “result or function.” *Holland Furniture*, 277 U.S. at 257.

The rule against functional claiming is rooted in the written-description, enablement, and definiteness requirements now codified in 35 U.S.C. 112. See Donald S. Chisum, 3 *Chisum on Patents* § 8.04[3], at 406-407 (2018 ed.). Section 112 generally functions to prevent the claiming of more than what has actually been invented. The written-description requirement ensures fair notice of the actual scope of an invention; the enablement requirement ensures disclosure of how to make and use the invention

in a way that is commensurate with the scope of the claim; and the definiteness requirement ensures that the claim language makes clear what subject matter is within the claim. See *ibid.* When a claim uses language that is purely functional at the point of novelty, it fails some or all of those requirements. See, e.g., *Holland Furniture*, 277 U.S. at 257 (enablement); *General Electric*, 304 U.S. at 368 (definiteness); *Halliburton*, 329 U.S. at 8, 10 (written description and definiteness).

As the Court has explained, claims described in purely functional terms preempt future developments in the same field by “extend[ing]” the patent monopoly “beyond the discovery” itself. *Holland Furniture*, 277 U.S. at 257. Allowing such claims would thus “discourage rather than promote invention.” *Ibid.*

2. In *Halliburton*, the most recent of this Court’s cases reaffirming the rule against functional claiming, the Court applied the rule to invalidate combination claims—*i.e.*, claims that unite existing components in a novel way—that described all “means” for performing a certain function. See 329 U.S. at 12-13. The patentee in *Halliburton* asserted claims that combined a mechanical acoustical resonator with a preexisting apparatus to measure the depth of oil wells. See *id.* at 7. The combination was an improvement over earlier, unsuccessful efforts to accomplish the same goal. The specification disclosed only the use of the resonator, but the claims purported to cover all “means” of sound detection by which the purpose of measuring oil-well depth could be accomplished—including those means not yet invented. See *id.* at 8-9.

The Court deemed the claims invalid because their language described the “most crucial element” of the claims “in terms of what it will do rather than in terms of its own physical characteristics or its arrangement in the new combination apparatus.” *Halliburton*, 329 U.S. at 9.

If those “blanket claims” were permitted, the Court reasoned, they would either cover the “many more devices” likely to be invented to accomplish the same purpose, or hinder that innovation by “frighten[ing]” potential inventors “from the course of experimentation.” *Id.* at 12.

3. In response to *Halliburton*, as part of the 1952 Patent Act, Congress enacted 35 U.S.C. 112, ¶ 6. That provision, now codified at 35 U.S.C. 112(f), allows “[a]n element in a claim for a combination” to be “expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof.” But it instructs that “such [a] claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.”

Section 112(f) thus permits means-plus-function claiming for “combination” claims—the type of claiming at issue in *Halliburton*—but only if “the broad literal language of such claims” is limited to the “actual means shown in the patent specification” for performing the function. *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 28 (1997).

B. Facts And Procedural History

1. In 2001, petitioner sought FDA approval for Cialis®, a drug to treat erectile dysfunction. Later that year, petitioner proposed evaluating new indications for tadalafil, Cialis’s active ingredient. Those indications included a new treatment for BPH, a condition in which the benign growth of the prostate gland in older men causes constriction of the urethra and results in lower urinary-tract symptoms, such as difficulty urinating. App., *infra*, 4a, 8a.

At the time, the non-surgical options available for the treatment of BPH were not particularly effective and

caused unwanted side effects. No existing clinical data suggested that tadalafil would be effective at treating BPH. App., *infra*, 4a-5a; C.A. App. 17522.

Petitioner spent over \$150 million on extensive research and development involving multiple clinical studies that continued through at least 2009. The research showed that tadalafil could be used to treat BPH. In 2011, ten years after first hypothesizing that tadalafil might work to treat BPH, petitioner obtained FDA approval to market tadalafil for the treatment of BPH (and also for the concurrent treatment of BPH and erectile dysfunction). App., *infra*, 8a; C.A. App. 13914-13918, 13920-13939, 14002-14003.

2. A few months later, respondent filed the patent application that ultimately became U.S. Patent No. 8,791, 124 ('124 patent). The '124 patent claims priority to an application from 1997. App., *infra*, 3a-4a, 8a.

The claims of the '124 patent are directed to a method of preventing or treating BPH by administering an inhibitor of a specific enzyme, phosphodiesterase V (or PDE V). The '124 patent relies on the specification of the 1997 application, which identified ten specific compounds as “[p]referred selective inhibitors” of three different enzymes, including PDE V. Notably, tadalafil was not one of the compounds identified. Although tadalafil was known at the time to be an inhibitor of PDE V, the full degree of its selectivity as an inhibitor, and thus its safety and suitability in treating BPH, was unknown until petitioner completed its research. The specification also identified two broad classes of compounds that could potentially inhibit those enzymes, but without specifying whether any compound within those classes was suitable for inhibiting PDE V. App., *infra*, 218a-221a, 228a-229a; see Tr. 366-377.

Unlike tadalafil, the compounds expressly disclosed in the specification have never been approved for the treatment of BPH. Tadalafil is uniquely suitable for such treatment because of its properties—particularly the fact that it may be administered daily. C.A. App. 13320, 13337, 14321, 20182; Tr. 962-967, 1201-1202.

Claim 1 of the '124 patent covers “[a] method for prophylaxis or treatment of [BPH] comprising administering to a person in need thereof an effective amount of an inhibitor of [PDE] V,” excluding eight of the ten compounds identified in the original specification. App., *infra*, 44a-45a; 228a-229a. Perhaps not coincidentally, the method claimed by the '124 patent is the very method for treating BPH used by Cialis, which was already on the market (and approved for that treatment) when respondent filed the application that matured into the '124 patent.

Claim 1 is not limited to the use of any specific compound. The claim covers the use of any inhibitor of PDE V that turns out to be effective in treating BPH, with the exception of eight compounds identified in the specification. That class of covered compounds includes potentially billions of compounds, including compounds not yet discovered. App., *infra*, 228a-229a; C.A. App. 13180-13183, 13709, 13738-13742, 13748, 14280.

3. Respondent filed suit against petitioner in the Eastern District of Texas under 35 U.S.C. 271, asserting that petitioner had infringed claim 1 of the '124 patent by marketing tadalafil for the treatment of BPH—a treatment, it bears underscoring, which petitioner pioneered and developed and for which petitioner obtained FDA approval. The case was assigned to Judge Bryson of the Federal Circuit, who was sitting by designation.

Before trial, the district court seemed to recognize that the claim included functional language. App., *infra*, 178a. The court also determined that the claim did not fall

within Section 112(f), the provision that permits a particular method of functional claiming for combination claims. App., *infra*, 172a-188a. The court concluded that the single-step method claim in this case was not “the sort of claim[] to which [Section 112(f)] was meant to apply.” *Id.* at 177a. In addition, the court applied a presumption that the claim was not a means-plus-function claim subject to Section 112(f), on the ground that the claim lacked the words “means for” or “step for.” *Id.* at 178a. That presumption could not be overcome, the court reasoned, because there was insufficient evidence that a person of ordinary skill in the art would have understood the phrase “an inhibitor of [PDE] V” to be “purely functional” as of the 1997 priority date. *Id.* at 178a-179a.

The court construed the claim term “inhibitor of [PDE] V” as “a selective inhibitor of PDE5, which is at least 20 times more effective in inhibiting PDE5 as compared to PDE1 through PDE4.” App., *infra*, 15a; see *id.* at 195a. Even as limited by the court, the claim captured an enormous number of compounds (including those not yet discovered) described solely in terms of what they do, rather than what they are. The district court also held that, as construed, the claim was “sufficiently definite” as a matter of law. App., *infra*, 100a; see *id.* at 163a.

At trial, petitioner argued, *inter alia*, that the claim failed to satisfy the written-description and enablement requirements set forth in Section 112(a). The jury returned a verdict in favor of respondent, determining that claim 1 was valid and infringed and awarding respondent \$20 million in damages. App., *infra*, 3a-4a.

Following the jury verdict, petitioner filed a renewed motion for judgment as a matter of law, arguing that the claim used functional language that did not satisfy the written-description and enablement requirements of Sec-

tion 112(a), and that the claim was indefinite under Section 112(b). The district court denied that motion, specifically rejecting petitioner’s argument that the claim impermissibly described its point of novelty “using functional language.” App., *infra*, 12a-13a, 16a.

4. On appeal, petitioner argued, *inter alia*, that the claim used functional language that did not satisfy the written-description and enablement requirements of Section 112(a). The court of appeals affirmed by summary order, necessarily rejecting petitioner’s arguments. App., *infra*, 1a-2a.

5. The court of appeals subsequently denied a petition for rehearing. App., *infra*, 208a-209a.

REASONS FOR GRANTING THE PETITION

In this case, the Federal Circuit approved a purely functional single-step patent claim. The rule against functional claiming is a critically important protection against broad claims that deter future innovation. Those claims assert patent protection extending far beyond the claimant’s actual discovery, imposing a monopoly on all alternative ways of achieving the same result (and without teaching the public how to identify and use those alternatives). This case is a textbook example of that phenomenon: respondent used functional language to cut off petitioner’s access to the use of its own drug for a method of treatment that petitioner had pioneered and developed at great cost.

Without this Court’s intervention, the Federal Circuit will continue to render the rule against functional claiming a dead letter. As this case well illustrates, the Federal Circuit’s approach opens the door for non-practicing entities across industries to obtain broad patents without inventing anything of substance. That threatens to stifle innovation and invite extensive patent-troll activity in many

industries, even in those that have not historically been the principal target of such activity—such as the pharmaceutical industry. The Court long ago foresaw the problems with purely functional claims and wisely rejected them. Because the decision of the court below cannot be reconciled with the decisions of this Court, and because this case presents a question of great legal and practical significance, the petition for a writ of certiorari should be granted.

A. The Decision Below Is Erroneous

The Federal Circuit erred in this case by approving a single-step claim that describes its point of novelty in purely functional terms. Functional claiming is permitted only in the limited circumstances set out in 35 U.S.C. 112(f), and it is now undisputed that Section 112(f) does not apply to the claim at issue here. It also cannot be disputed that the claim at issue is purely functional insofar as it describes the claimed compounds by what they do, rather than what they are. As a result, the claim is sweepingly broad—broad enough to enable respondent to capture petitioner’s innovation here in a patent that does not mention, suggest, or teach the use of tadalafil. Because the claim violates the rule against functional claiming, the Federal Circuit was wrong to uphold it.

1. As an initial matter, there can be no serious doubt that the general rule against functional claiming survived the enactment of Section 112(f). This Court had articulated the rule in a long line of decisions beginning with *O’Reilly v. Morse*, 56 U.S. (15 How.) 62 (1853), long before it applied the rule to a combination claim in *Halliburton Oil Well Cementing Co. v. Walker*, 329 U.S. 1 (1946). When Congress enacted what was then Section 112, ¶ 6, as part of the 1952 Patent Act, it abrogated the specific

holding of *Halliburton*, but it did not disturb the broader rule against functional claiming. See p. 8, *supra*.

Rather than providing *carte blanche* for functional claiming, Section 112(f) permits means-plus-function claiming (*i.e.*, claims that describe the means for performing a function), and it does so only for combination claims—that is, claims that rely on uniting existing components in a novel way. And even then, it requires that the “broad literal language” of the claim be limited by the “actual means” for performing the function that is “shown in the patent specification.” *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 28 (1997). For that reason, the option Section 112(f) offers is “not really functional claiming at all”; rather, its effect is to provide a “narrow” avenue for allowing means-plus-function claiming by limiting the scope of such claims to structures equivalent to those disclosed in the specification. Lemley 916-918.

Nothing about the language of Section 112(f) suggests that Congress intended to alter this Court’s approach to functional claiming outside the specific context addressed in that provision. And the fact that Congress carefully crafted an exception in Section 112(f) suggests the opposite. See, *e.g.*, *Russello v. United States*, 464 U.S. 16, 23 (1983). Accordingly, the rule continues to govern for claims that fall outside that provision.

That includes the claim at issue in this case. Indeed, the district court expressly held that Section 112(f) does not apply to the claim here. See App., *infra*, 177a-179a. If it had held to the contrary, the claim would have been limited to the two compounds disclosed in the specification and their equivalents (and not expressly excluded from the claim). So limited, the claim would not encompass tadalafil, and there would be no infringement. Indeed, respondent itself argued below that Section 112(f) does not

apply, presumably recognizing that, if it did, the construction it requires would have devastated its infringement claim and defeated the *raison d'être* of its (unpracticed) patent.

2. When it comes to the rule against functional claiming, this is not a close case: the claim at issue here plainly runs afoul of that rule.

a. Claim 1 of the patent covers “[a] method for prophylaxis or treatment of [BPH] comprising administering to a person in need thereof an effective amount of an inhibitor of [PDE] V,” excluding eight compounds identified in the accompanying specification. App., *infra*, 228a-229a. By its terms, then, the claim covers a method of treating BPH by administering an “effective amount” of any compound that performs a certain function—namely, inhibiting a particular type of enzyme. In this way, it describes the claimed material in terms of “what it *accomplishes* rather than in terms of what it *is*.” Donald S. Chisum, 3 *Chisum on Patents* § 8.04, at 334 (2018 ed.).

The district court construed the phrase “inhibitor of [PDE] V” as “a selective inhibitor of PDE5, which is at least 20 times more effective in inhibiting PDE5 as compared to PDE1 through PDE4.” App., *infra*, 99a; see *id.* at 163a. While that construction narrowed the claim somewhat, the claim still captures an unbounded (and unknowable) number of compounds. See pp. 10-11, *supra*. Critically for present purposes, the construed claim remains purely functional: at most, it provides a modestly more specific description of how well a compound must carry out the claimed function in order to fall within the claim.

The district court dismissed that problem, opining that the phrase “inhibitor of PDE V” was not purely functional because one with ordinary skill in the art would have had a sufficiently definite idea of what it was. App.,

infra, 178a-179a. That is wrong. A particular inhibitor of PDE V would be recognized as such *once it is discovered through testing*. But one skilled in the art could not possibly know all of the inhibitors of PDE V—a universe that includes numerous compounds yet to be discovered.

b. In addition to the description of what the claimed compounds do, the claim excludes eight of the ten compounds identified in the original specification. App., *infra*, 228a-229a. The district court ascribed the exclusion to respondent’s effort to avoid a double-patenting issue based on its earlier patent covering those compounds. *Id.* at 44a-45a. Whatever its rationale, the exclusion of those compounds does not implicitly define the class of compounds in different, non-functional terms. The eight compounds share no commonality beyond that of the entire class—namely, that they inhibit at least one of three PDE enzymes, including PDE V. C.A. App. 13742-13743.

Excluding certain examples from a universe defined in purely functional terms cannot save a claim from invalidity. Suppose the patent at issue in *O’Reilly* had claimed “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, *except improvements where the resulting machine marks or prints Japanese characters*.” See 56 U.S. (15 How.) at 112 (italicized language added). That exclusion might marginally narrow the scope of the claim, but it would not fix the problem posed by the purely functional language. The claim would still preempt a future inventor’s discovery of a “mode of writing or printing at a distance by means of the electric or galvanic current” that did not “us[e] any part of [Morse’s] process.” *Id.* at 113.

Nor does the exclusion of the eight compounds address any of the underlying concerns with functional

claiming. The claim still encompasses an enormous number of compounds and—just as feared in *O’Reilly*—thereby broadly preempts innovation by others.

Because the claim in this case is a single-step claim that describes its point of novelty in purely functional terms, it violates the rule against functional claiming and thus does not satisfy the requirements of Section 112. The Federal Circuit erred by concluding otherwise, and that error merits further review and correction.

B. The Question Presented Is An Important One That Warrants The Court’s Review

The question presented is one of substantial legal and practical importance. The decision below well illustrates the Federal Circuit’s reluctance in recent years to apply this Court’s decisions barring functional claiming. Without the Court’s intervention, patent trolls and others across industries will be able to use broad functional language to claim what others either have discovered or will discover on their own. That undermines the goals of patent law and deters necessary investment in research and development. This Court’s intervention in this critical area of patent law is sorely needed.

1. In a series of decisions, culminating in the decision below, the Federal Circuit has failed properly to apply the rule against functional claiming.

In *In re Hyatt*, 708 F.2d 712 (1983), the Federal Circuit seemingly recognized that the rule against functional claiming survived the enactment of Section 112(f)—at least as applied to single-means claims. That case involved a claim for a “Fourier transform processor * * * *comprising incremental means for incrementally generating the Fourier transformed incremental output signals in response to the incremental input systems.*” *Id.*

at 712-713. The “problem” with that claim, the court explained, was that “it cover[ed] every conceivable means for achieving the stated result,” but disclosed “only those means known to the inventor.” *Id.* at 714 (citing *O’Reilly*, 56 U.S. at 112). The court acknowledged that Section 112(f) “save[d] combination claims drafted using [the] means-plus-function format,” but it noted that “no provision saves” a “single means claim” using that format. *Id.* at 715. According to the court, that led “irresistibly” to a “rejection based broadly on [Section] 112” of the purely functional claim. *Ibid.*

In the years since *Hyatt*, however, the Federal Circuit has increasingly ignored the rule against functional claiming. When analyzing functional language, the Federal Circuit has narrowed its focus to the written-description deficiencies in such language—to the exclusion of the more holistic mandate of Section 112. In *Boston Scientific Corp. v. Johnson & Johnson*, 647 F.3d 1353 (2011), for example, the Federal Circuit “ignore[d]” enablement concerns altogether because it “focuse[d] solely on the written description” requirement. *Id.* at 1369 (Gajarsa, J., concurring in part). And in another case, Judge Linn noted that a written-description determination “left unresolved” the “important issue” of whether single-step method claims are invalid when they are (like the claim in this case) “written broadly enough to cover any method for achieving a particular result.” *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, 560 F.3d 1366, 1381 (Fed. Cir. 2009) (concurring opinion) (citing *Hyatt*, 708 F.2d at 714), superseded by 598 F.3d 1336 (Fed. Cir. 2010) (en banc).

Even before the Federal Circuit’s decision in this case, there was serious doubt about whether the rule against functional claiming retained any purchase in the Federal Circuit. At least one judge has called for clarification on

the issue, noting that the “continued viability” of the rationale for the rule against functional claiming “merits attention.” See *Williamson v. Citrix Online LLC*, 792 F.3d 1339, 1358 (Fed. Cir. 2015) (Reyna, J., concurring in part and dissenting in part). As shown by the Federal Circuit’s decision in this case, the rule has now been reduced to a nullity.

2. The rule against functional claiming is of great significance to a broad array of stakeholders in the patent system.

To begin with, the failure to police egregious functional claiming exposes the pharmaceutical industry to nefarious activity by patent trolls and others—precisely what took place here. Such entities will now be able to exploit functional language in pharmaceutical patent claims, in connection with continuation applications, and thus to draw fences around a new potential drug target with the goal of forcing settlements and deterring much-needed investment in research and development. See John R. Allison et al., *Extreme Value or Trolls on Top? The Characteristics of the Most-Litigated Patents*, 158 U. Pa. L. Rev. 1, 3-4, 27 n.52 (2009); FTC, *The Evolving IP Marketplace: Aligning Patent Notice and Remedies with Competition* 3-5, 60-62 (2011) (FTC Report) <tinyurl.com/evolvingipmarketplace>. This case illustrates the danger of allowing that practice: respondent was able to claim a method of treatment that petitioner pioneered and developed and for which petitioner obtained FDA approval.

Beyond the pharmaceutical industry, a robust rule against functional claiming is also vitally important in the context of software patents, where such claiming is rife. Those patents have essentially “brought back functional claiming.” Lemley 924. A “plethora” of software patent claims are framed “not on the basis of the technology the

patentee actually developed,” but “on the basis of the function that technology performs.” *Id.* at 928. Indeed, “broad functional claiming” is “arguably responsible for most of the well-recognized problems with software patents.” *Id.* at 908.

For that reason, the Federal Trade Commission has “urg[ed]” courts to “address functional claiming” that “fall[s] outside the means-plus-function format.” FTC Report 11, 102. And a subsequent report from the Executive Office of the President expressed concern that “patent trolls” readily “take advantage of uncertainty about the scope or validity of patent claims, especially in software-related patents,” where it is “difficult to separate the ‘function’ of the software” from “the ‘means’ by which that function is accomplished.” Executive Office of the President, *Patent Assertion and U.S. Innovation 1* (2013) <tinyurl.com/patentassertion>.

3. In other areas of patent law, this Court has expressed concern over the preemption of future invention—one of the fundamental policies underlying patent law. See, e.g., *Alice Corp. v. CLS Bank International*, 573 U.S. 208, 223-224 (2014); *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 589 (2013). The rule against functional claiming is an essential safeguard against such preemption. This case presents the Court with an opportunity to reinforce—and reinstate—that principle.

The Court should correct the Federal Circuit’s deviation from the Court’s precedents and reassert that the rule against functional claiming remains valid and applicable to claims like the one at issue here. The petition for a writ of certiorari should be granted.

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

The claim in this case constitutes a particularly egregious example of functional claiming. A non-practicing entity drafted a single-step claim using purely functional language to assert ownership over the use of a huge universe of compounds, including the active ingredient in a commercially successful product already on the market. It was petitioner, not respondent, that spent over \$150 million on extensive research and development to show that tadalafil could be used to treat BPH. And it was petitioner, not respondent, that obtained FDA approval to market Cialis for that purpose. Yet by giving respondent the benefit of claiming every compound covered by broad functional language, the Federal Circuit has allowed it to reap the benefits of petitioner's invention. See pp. 8-9, *supra*.

The fact that the Federal Circuit issued a summary affirmance in the face of a plainly substantial issue should be no deterrent to this Court's review—and indeed should be a further reason to grant it. Although courts of appeals “should have wide latitude in their decisions,” including “with respect to summary affirmances,” *Taylor v. McKeithen*, 407 U.S. 191, 194 n.4 (1972), their use of that power in cases presenting significant questions should not shield their decisions from further review. And this Court has not hesitated to review nonprecedential decisions, including from the Federal Circuit. See, e.g., *Lamps Plus, Inc. v. Varela*, 139 S. Ct. 1407, 1413 (2019); *Oil States Energy Services, LLC v. Greene's Energy Group, LLC*, 138 S. Ct. 1365, 1372 (2018); *Kirtsaeng v. John Wiley & Sons, Inc.*, 136 S. Ct. 1979, 1984 (2016); *Shapiro v. McManus*, 136 S. Ct. 450, 454 (2015); *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 407 (2007).

The Federal Circuit’s summary affirmance in this case is reflective of a broader trend. The Federal Circuit disposes of cases by summary affirmance far more often than other circuits—even those with caseloads that “dwarf[]” its own. Andrew Hoffman, *The Federal Circuit’s Summary Affirmance Habit*, 2018 B.Y.U. L. Rev. 419, 439 (2018) (Hoffman) (collecting data); see Ted L. Field, ‘Judicial Hyperactivity’ in the Federal Circuit: An Empirical Study, 46 U.S.F. L. Rev. 721, 746 (2012). Because many of those cases involve “substantial questions of law,” commentators have speculated that the Federal Circuit is attempting to “us[e] summary affirmance as a means of ‘cert-proofing’ cases.” Hoffman 442-443, 445-450 & n.149.

Congress established the Federal Circuit with the express purpose of promoting “uniformity” in patent law and reducing the “uncertainty of legal doctrine” that had plagued patent law in the regional circuits. H.R. Rep. No. 312, 97th Cong., 1st Sess. 21-22 (1981); S. Rep. No. 275, 97th Cong., 1st Sess. 4 (1981); see *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 390 (1996). The Federal Circuit’s disposition of this case disserves those goals by increasing uncertainty about the continued vitality of the rule against functional claiming. Intervention by this Court is essential to make clear that the rule remains intact.

* * * * *

In the decision below, the Federal Circuit has refused to enforce the rule against functional claiming by rubber-stamping a purely functional limitation in a single-step claim. That decision casts doubt on the continued validity of the rule and thus presents an exceptionally important question about the lawful scope of patents across various industries. This case is an excellent vehicle for resolving that question, and it warrants the Court’s review.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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