

No. 18-1515

In the
Supreme Court of the United States

ELI LILLY AND COMPANY,
Petitioner,

v.

ERFINDERGEMEINSCHAFT UROPEP GBR,
Respondent.

**On Petition for Writ of Certiorari to the
United States Court of Appeals
for the Federal Circuit**

**BRIEF FOR *AMICI CURIAE*
SANOFI, SANOFI-AVENTIS U.S. LLC,
AVENTISUB LLC, f/d/b/a AVENTIS
PHARMACEUTICALS INC., AND
REGENERON PHARMACEUTICALS, INC.
IN SUPPORT OF PETITIONER**

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STATEMENT OF INTEREST¹

Amici Sanofi, Sanofi-Aventis U.S. LLC, Aventisub LLC, f/d/b/a Aventis Pharmaceuticals Inc., and Regeneron Pharmaceuticals, Inc. are pharmaceutical companies that invest significant time and resources in drug research and development. Given the threat that overly broad functional claims pose to research-based pharmaceutical companies, *amici* are well positioned to explain how such claims create legal and practical confusion, endanger investments in R&D, and stifle innovation, all to the detriment of patients and providers.

SUMMARY OF ARGUMENT

The evils of overly broad functional claims have long been acknowledged by this Court and commentators. As is almost universally recognized, functional claims allow patentees to claim ownership of more than they invented and thus deter innovation by impeding investment in the research and development of new therapeutics. For these reasons (among others), this Court eliminated functional claiming many decades ago. *See, e.g., Halliburton Oil Well Cementing Co. v. Walker*, 329 U.S. 1 (1946).

In 1952, Congress amended the Patent Act to add a section, currently codified at 35 U.S.C. § 112(f), that

¹ Pursuant to Supreme Court Rule 37.6, *amici curiae* state that no counsel for any party authored this brief in whole or in part and that no entity or person, aside from *amici curiae*, its members, and its counsel, made any monetary contribution toward the preparation or submission of this brief. Pursuant to Supreme Court Rule 37.3, counsel of record for all parties have timely received notice of this filing and consented to it in letters on file with the Clerk's office.

allowed the use of functional claim language but limited its effect to the structures disclosed by the specification.² Over time, however, the Federal Circuit has misinterpreted this textually limited provision so as to completely abrogate *Halliburton* and permit patentees to obtain and enforce claims containing functional language without abiding by the restrictions of the amendment or this Court's limitations on claims defined in functional terms. The Federal Circuit has done this despite the fact that the purpose of the 1952 amendment was to limit functional claims and despite the absence of any congressional intent to permit a patentee to obtain claims with a scope defined in functional terms without being limited by the structures disclosed in the specification.

The Federal Circuit's abandonment of the *Halliburton* line of authority and its misapplication of the 1952 Patent Act has caused serious confusion and inconsistency in the way in which § 112(f) is applied and has resulted in broad functional claims that deter R&D and provide a disproportionate reward for much narrower inventions. Because the Federal Circuit has shown no signs of adhering to the directives that Congress and this Court have set forth, this Court's intervention is necessary to restore proper limits on overly broad functional claims and prevent the deterrence of innovation and investments in important technologies.

² This section, originally codified at 35 U.S.C. § 112(6), was later re-labeled by the America Invents Act of 2011 as 35 U.S.C. § 112(f). The text of this section, however, was not modified.

ARGUMENT

I. This Court Has Long Recognized the Evils of Broad Functional Claims and Prohibited Them.

Overly broad functional claims allow patentees to own more than has been invented, which stymies innovation. For literally centuries, this Court has recognized the dangers of functional claims, referring to “a description in terms of function” as a “vice,” *Gen. Elec. Co v. Wabash Appliance Corp.*, 304 U.S. 364, 371 (1938), and warning that claiming any means by which a certain “result is accomplished” is “too broad, and not warranted by law,” *O’Reilly v. Morse*, 56 U.S. 62, 113 (1853).

This longstanding recognition culminated in the Court’s elimination of functional claiming in *General Electric* and subsequent cases when it pronounced that a “patentee may not broaden his claims by describing the product in terms of function,” *United Carbon Co. v. Binney & Smith Co.*, 317 U.S. 228, 234 (1942), and, ultimately, *Halliburton*. In *United Carbon*, the Supreme Court reaffirmed its decision in *General Electric* and held that “the claims are but inaccurate suggestions of the functions of the product, and fall afoul of the rule that a patentee may not broaden his claims by describing the product in terms of function.” 317 U.S. at 234. The *Halliburton* Court reaffirmed this principle several years later. *See* 329 U.S. at 12 (“In this age of technological development there may be many other devices beyond our present information or indeed our imagination which will perform that function and yet fit these claims. And unless frightened from the course of experimentation

by broad functional claims like these, inventive genius may evolve many more devices to accomplish the same purpose.”).

As petitioner has ably explained, however, *see, e.g.*, Pet.17-19, the Federal Circuit has, over time, systematically ignored the Supreme Court’s precedent regarding functional claiming. As a result, claims with functionally-defined scope have returned. Commentators have observed the dangers caused by this renewed functional claiming. They allow patentees to “effectively capture[] ownership not of what they built, but of anything that achieves the same goal, no matter how different it is. They claim to own the function itself.” Mark A. Lemley, *Software Patents and the Return of Functional Claiming*, 2013 Wis. L. Rev. 905, 908 (2013); *see also* David J. Kappos & Christopher P. Davis, *Functional Claiming and the Patent Balance*, 18 Stan. Tech. L. Rev. 365, 372 (2015) (“[T]hrough borderline functional claiming, some may achieve protections that outweigh their actual contributions to the knowledge pool.”); Kevin Emerson Collins, *Patent Law’s Functionality Malfunction and the Problem of Overbroad, Functional Software Patents*, 90 Wash U. L. Rev. 1399, 1402, 1403 n.7 (2013) (noting that “functional claiming is widely viewed as leading to overbroad patents” because such claims “encompass all structures that are capable of performing the claimed behaviors, meaning that they reach ... beyond an inventor’s invention.”). Ultimately, the real danger of these “wild card” claims for not “just one invention” but “a thousand inventions,” Stephen Winslow, Note, *Means for Improving Modern Functional Patent Claiming*, 98 Georgetown L. J. 1891, 1892 (2010), is their ability to

impede innovation and “discourage investment in neighboring technology,” Kappos & Davis 372. Functional patent claims “grant an absolute monopoly for those functions claimed. The grant of this monopoly is against public policy because it discourages innovation.” Russell Moy, *A Case Against Software Patents*, 17 Santa Clara Computer & High Tech. L. J. 67, 87 (2000).

As a result of the Federal Circuit’s abandonment of the Supreme Court’s prohibition against overly broad functional claims, this Court must once again reassert the vitality of *Halliburton* so that patents can “spur competition by preventing direct imitation while leaving open avenues for alternative development.” Only then will “inventors own their idea, but not the ideas of others,” thus “ensur[ing] that patents encourage rather than retard” innovation. Lemley 964.

II. Because The 1952 Patent Act Endorsed The Supreme Court’s Concern Over Functionally-Defined Claim Scope, *Halliburton* Should Still Bar Any Functional Claims Not Covered by § 112(f).

After almost 100 years of Supreme Court jurisprudence denouncing functional claiming, Congress enacted the 1952 Patent Act, which, *inter alia*, included the functional claiming provision, § 112, paragraph 6 (now codified as § 112(f)). With this amendment, claims that fell within the ambit of § 112(f) were no longer deemed invalid based on *Halliburton*. See 35 U.S.C. § 112(f). Instead, the functional language in such claims was limited to the structures disclosed by the patent specification and

their equivalents. *Id.* This amendment accomplished the same ends sought by the *Halliburton* line of authority, however, because it prevented patentees from obtaining overly broad claim scope coverage based on function untethered to specific structures. *See, e.g., Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1256 n.7 (Fed. Cir. 2008) (“[I]n the 1952 Patent Act, Congress authorized functional claiming, *but with limits*, in 35 U.S.C. § 112, ¶ 6.... This statutory provision was meant to *preclude the overbreadth inherent in open-ended functional claims*, such as those ... which effectively purport to cover any and all means so long as they perform the recited functions.”) (emphases added).

Congress’ intent in permitting a limited category of functional claims was to support, not reverse, the general prohibition on functionally-defined claim scope. The purpose of adding § 112(f) to the 1952 Patent Act was not to permit claims with a broad, functionally-defined scope. It was the exact opposite. The purpose of § 112(f) was to *limit* the scope of functional claims to the patentee’s disclosure in the specification. *See Kappos & Davis* 366 (“Section 112(f) narrows the scope of protection afforded to patentees employing functional claims by limiting the literal scope of the claims to the structure, material, or acts specifically disclosed in the specification.”). In other words, § 112(f) allows for functional claim language when the patentee upholds her end of the bargain—making a particular disclosure in the specification—but then limits the scope of those claims to the disclosed structures and their equivalents.

The Patent Act should be interpreted as superseding *Halliburton* only to the extent that a claim falls within the scope of § 112(f); otherwise, nothing Congress did overrides *Halliburton*. Any other interpretation would result in sweeping changes to pre-existing authority from this Court that were clearly not intended by Congress. The Federal Circuit itself has acknowledged that this would be improper in other circumstances. The Hatch-Waxman Act provides one example. Congress partially abrogated *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.*, 733 F.2d 858 (Fed. Cir. 1984), by enactment of the Hatch-Waxman Act. The Federal Circuit’s subsequent jurisprudence interpreting the interplay of the statute and *Roche* demonstrates the correct way to determine the effects of Congressional action on pre-existing Federal Circuit authority—one that the Federal Circuit has not followed with respect to § 112(f).

In *Roche*, the Federal Circuit held that the use of an infringing product to “derive FDA required test data” constitutes patent infringement. *Id.* at 863. In response to *Roche*, “Congress changed the law enunciated in the *Roche* case.” *Deuterium Corp. v. United States*, 19 Cl. Ct. 624, 632 n. 14 (1990). It enacted 35 U.S.C. § 271(e)(1), which “permits individuals to ‘make, use, or sell, a patented invention ... solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.’” *Id.* Although the enactment of § 271(e) “changed the law enunciated in the *Roche* case” with respect to required testing for FDA approval, the *Roche* holding did not disappear altogether. In

Deuterium, citing *Roche*, the Court of Federal Claims held that experimental use related to running a “pilot” plant was infringed and explained that “[a]lthough [Congress] *changed that narrow application* of the doctrine affecting reporting requirements for federal drug laws, Congress *did not disturb* the Federal Circuit’s enunciation of the parameters of the experimental use exception.” 19 Cl. Ct. at 632 n.14 (emphases added). The Federal Circuit made a similar observation in *Madey v. Duke University*, 307 F.3d 1351 (Fed. Cir. 2002), explaining that “[a]fter the *Roche* decision ... Congress changed the law, overruling *Roche in part, but without impacting* the experimental use doctrine. Congress provided limited ability for a company to practice a patent in furtherance of a drug approval application.” *Id.* at 1355 n.3 (emphasis added).

The same analysis should follow here. The only exception to *Halliburton*’s broad rejection of functional claiming is found in § 112(f). That exception should be narrowly construed to apply only to claims that fall squarely within § 112(f)’s scope. Instead, however, the Federal Circuit has permitted § 112(f) to encroach upon, if not completely envelop, this Court’s *Halliburton* holding.

III. The Federal Circuit Is Now Disregarding The *Halliburton* Line of Cases.

A. The Federal Circuit Openly Acknowledges That It Has Completely Discarded *Halliburton*.

Unlike the Federal Circuit’s continued willingness to follow *Roche* subsequent to the enactment of the Hatch-Waxman Act for activity not

covered by that Act, the Federal Circuit has refused to apply *Halliburton* even in circumstances not governed by § 112(f). Numerous decisions reveal the Federal Circuit's belief that the 1952 Patent Act abrogated *Halliburton* entirely. For example, the Federal Circuit has explained that “[w]ith th[e] new section [112 ¶6, now 112(f)], the 1952 Act rendered *Halliburton* obsolete.” *Valmont Indus., Inc. v. Reinke Mfg. Co., Inc.*, 983 F.2d 1039, 1042 (Fed. Cir. 1993) (emphasis added). Similarly, according to the Federal Circuit, “[t]he record is clear on why paragraph six was enacted ... to *statutorily overrule* [the *Halliburton*] holding.” *In re Donaldson Co., Inc.*, 16 F.3d 1189, 1194 (Fed. Cir. 1994) (emphasis added).

Indeed, without explanation for why it is free to disregard Supreme Court precedent, the Federal Circuit has observed that “there is nothing intrinsically wrong with” using functional language in claims. *Halliburton*, 514 F.3d at 1255.³ The Federal Circuit has never explained *why* it believes Congress’ supposed intent in enacting § 112(f) was to permit a patentee to obtain coverage for overly broad functionally-defined claim scope. It has never cited anything in the text or legislative history that supports its conclusion, and it has ignored the fact that the language of the statute reflects a contrary intent.

³ In that same case, the Federal Circuit inconsistently acknowledged that the Patent Act was enacted to *limit* the scope of claims employing functional claim language while relying on the 1952 Patent Act as evidence that Congress intended to permit functional claiming by rendering *Halliburton* obsolete. See 514 F.3d at 1255 n.7.

B. The Federal Circuit’s Application of § 112(f) and Abandonment of *Halliburton* Has Resulted in the Restoration of Overly Broad Functionally-Defined Claims.

The Federal Circuit’s holding that *Halliburton* is “obsolete” would not be a problem had it construed the § 112(f) scope limitations broadly as applying to all claims containing functional language. It has not chosen to do so, however, and therefore patentees have been able to obtain claims containing functional claim language that do not meet the scope limitations of § 112(f).

There are many claims containing functional language to which the Federal Circuit has said § 112(f) does not apply. For example, the Federal Circuit has held that § 112(f) does not apply to single means claims, *i.e.*, claims drafted in means-plus-function format that recite only one element because the Federal Circuit has held that § 112(f) only applies to a claim “for a combination.” *In re Hyatt*, 708 F.2d 712, 713 n.3, 714 (Fed. Cir. 1983).⁴ Although the *Hyatt* court upheld the Patent Office’s rejection of the single means claims on other grounds, it did not apply *Halliburton* and left open the possibility that a patentee, such as respondent UroPep, could obtain a single means claim that would not be limited to the

⁴ Under the Federal Circuit’s jurisprudence, § 112(f) does not apply to UroPep’s claims because it is a single-means claim, not a combination. See Pet.10 (“a method for prophylaxis or treatment of [benign prostatic hyperplasia] comprising administering ... an effective amount of an inhibitor of PDE V, excluding”).

disclosed structure because *Hyatt* held that § 112(f) does not apply to such claims.

The Federal Circuit has also refused to apply § 112(f) to claims for which there was no evident intent by the patentee to invoke § 112(f) when drafting the claim. Although its test for measuring this intent to invoke has evolved over time, that test nevertheless remains; accordingly, claims containing functional language will continue to slip past the corrective, narrowing effect of § 112(f) when the Federal Circuit refuses to apply § 112(f) to claims containing functional language such as the claims in UroPep's patent.

Prior to *Williamson v. Citrix Online, LLC*, the Federal Circuit employed a “strong” presumption that a patentee did not intend to invoke § 112(f) if the claim did not use the term “means.” 792 F.3d 1339, 1347 (Fed. Cir. 2015) (“Means-plus-function claiming occurs when a claim term is drafted in a manner that invokes 35 U.S.C. § 112, para. 6.”); *Diebold Nixdorf, Inc. v. Int’l Trade Comm’n*, 899 F.3d 1291, 1297 (Fed. Cir. 2018) (explaining that “[m]eans-plus-function claiming occurs when a claim term is drafted in a manner that invokes § 112, para. 6”) (emphasis added)); *Greenberg v. Ethicon Endo-Surgery, Inc.*, 91 F.3d 1580, 1584 (Fed. Cir. 1996) (holding that claim language “was not intended to invoke section 112(6) and should not be construed to do so.”). That standard essentially permits a patentee to decide whether she needs to comply with Congress’ limitations on functional claiming. By determining that certain functional claims are not within the ambit of § 112(f), by allowing a patentee to choose to invoke § 112(f), and by

expressly stating that *Halliburton* is “obsolete,” the Federal Circuit permits the use of overly broad functional claims, contrary to both this Court’s directives and Congress’ intent.

Even the Federal Circuit has ultimately recognized that its strong presumption that § 112(f) does not apply in the absence of using the term “means” results in large numbers of claims with overly broad functionally-defined claim scope falling outside of the ambit of § 112(f). The *Williamson* majority explained that the Federal Circuit permitted too much functional claiming outside of § 112(f). See *Williamson*, 792 F.3d at 1349 (“It has shifted the balance struck by Congress in passing § 112, para. 6 and has resulted in a proliferation of functional claiming untethered to § 112, para. 6 and free of the strictures set forth in the statute.”). The Federal Circuit’s solution, however, was a half-measure that maintained the presumption that § 112(f) does not apply to claims that do not recite the term “means,” but reduced it from a “strong” presumption to a regular presumption. See *id.* (holding that claim was subject to § 112(f) and invalid despite the fact that the functional claim-at-issue did not use the word “means”). Thus, after *Williamson*, there are still claims employing functional language to which § 112(f) does not apply because they do not recite the term “means.”

By considering *Halliburton* obsolete, by applying the single means test to claims such as the claims in UroPep’s patent here, and by maintaining a presumption that § 112(f) does not apply in the absence of the use of the term “means,” the Federal

Circuit allows patentees to seek, obtain, and enforce claims with purely functionally-defined claim scope, which are exactly the type of claims that this Court has held invalid for nearly 100 years prior to enactment of the 1952 Patent Act. The Federal Circuit predicates its rejection of *Halliburton*'s authority on Congress' enactment of § 112(f)—yet that amendment *placed limitations* on functional claims, restricting them to the disclosed structures in the specification, and did nothing to endorse functionally-defined claim scope.

By not extending §112(f) to all claims that have a functionally-defined claim scope and refusing to apply *Halliburton*, the Federal Circuit has turned the clocks back to the pre-*Halliburton*, pre-*General Electric* era, and has reinstated the evils of overly broad functionally-defined claim scope that this Court specifically sought to prevent.⁵

⁵ Importantly, the Federal Circuit's treatment of functional claims has also caused significant confusion about the application of § 112(f). *See, e.g.*, *Kappos & Davis* 367 (“Problematically, court interpretations of the statutory provision for functional claiming have produced confusion over just how the provision is invoked—or, in some cases, perfunctorily triggered.”); *Winslow* 1895 (“Numerous questions have arisen regarding paragraph 6's scope and its applicability to a multitude of patent claims, and Federal Circuit precedent has provided mixed degrees of illumination on these issues.”); *see also* *Lemley* 908 (“[B]ecause of the way the means-plus-function claim rules have been interpreted by the Federal Circuit, those patentees have been able to write those broad functional claims without being subject to the limitations of section 112(f).”).

IV. This Case Is An Ideal Vehicle For Addressing This Issue.

For several reasons, this case is an ideal vehicle for the Court to address the issue of overly broad functional claims by eliminating the confusion surrounding § 112(f) and reaffirming the prohibition on overly broad functional claiming.

First, the disputed claim is indisputably functional. *See Erfindergemeinschaft v. Eli Lilly & Co.*, 276 F. Supp. 3d 629, 641 (E.D. Tex. 2017) (disputed claim recites “a method for prophylaxis or treatment of benign prostatic hyperplasia comprising administering to a person in need thereof an effective amount of an inhibitor of phosphodiesterase (PDE) V excluding” certain compounds). The Federal Circuit has recognized nearly identical claims in other cases to be functional. *See, e.g., Univ. of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916, 928 (Fed. Cir. 2004) (describing claim language requiring a cox-2 selective inhibitor as a “vague functional description”); *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1354 (Fed. Cir. 2010) (en banc) (noting that disputed claims that “compris[e] the single step of reducing NF- κ B activity” are generic, functional claims). While a method of treatment claim itself is not necessarily unpatentable, the method at issue required use of a composition that was defined in purely functional terms.

Second, the disputed claim does not invoke § 112(f), because it does not use the term “means” and also because it is a single means claim. Therefore, the claim directly implicates the Federal Circuit’s holdings that *Halliburton* is “obsolete,” because the

Federal Circuit should have applied *Halliburton* here. The disputed claim and the rulings upholding its validity, *see, e.g.*, Mem. Op. & Order at 11-12, *Erfindergemeinschaft Uropep GbR v. Eli Lilly & Co.*, No. 2:15-cv-1202-WCB (E.D. Tex. Oct. 21, 2016), D.E. 149, conflict with this Court’s case law, giving this Court an opportunity to renew its authority and restore sensible patent principles by invalidating UroPep’s overly broad functional claims.

Third, the disputed claim was allowed by the Patent Office, and its validity was upheld by the United States District Court for the Eastern District of Texas and the Federal Circuit because of an unjustifiable abandonment of established Supreme Court precedent.⁶ This will continue to occur indefinitely unless addressed, resulting in the prosecution, issuance, and enforcement of large numbers of patents with overly broad functionally-defined claim scope providing patent protection beyond what the inventor conceived of or disclosed to the public, breaking the essential bargain with the public that underlies our patent system. *See, e.g.*, *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 63 (1998) (“As we have often explained ... the patent system represents a carefully crafted bargain that encourages both the creation and the public disclosure of new and useful advances in technology, in return for an exclusive monopoly for a limited period of time.”); *see also Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*,

⁶ Judge Bryson, who presided over the district court case, is a Federal Circuit judge who was sitting by designation. The Federal Circuit issued a Rule 36 affirmance of Judge Bryson’s decision.

489 U.S. 141, 150-51 (1989); *Bilski v. Kappos*, 561 U.S. 593, 648 n.44 (2010).

In light of the Federal Circuit's disregard of both § 112(f) and this Court's jurisprudence, only this Court's review will clarify the law concerning § 112(f) and functional claiming and prevent repetition of this problem. And because the disputed claim here is indisputably functional and falls outside the purview of § 112(f) under any reasonable reading, the Court should grant review in this case.

CONCLUSION

The Court should grant the petition.

Respectfully submitted,

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