

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 IN OPPOSITION

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QUESTION PRESENTED

Whether a patent claim that the district court construed as structural—a conclusion that Petitioner did not challenge in its appeal—is valid under the Patent Act.

CORPORATE DISCLOSURE STATEMENT

Respondent Erfindergemeinschaft UroPep GbR has no parent corporation, and no publicly held company owns 10% or more of its stock.

STATEMENT OF RELATED PROCEEDINGS

Petitioner seeks review of the Federal Circuit's decision in *Eli Lilly and Company v. Erfindergemeinschaft UroPep GbR*, No. 17-2603 (Fed. Cir.) (judgment issued Oct. 10, 2018; mandate issued Feb. 12, 2019), which summarily affirmed the federal district court proceedings in *Erfindergemeinschaft UroPep GbR v. Eli Lilly and Company*, No. 2:15-cv-01202-WCB (E.D. Tex.) (amended judgment issued July 18, 2017).

There are no other state or federal cases that are directly related to this case.

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INTRODUCTION

Meritorious petitions in this Court typically do not involve legal issues that the petitioner did not press and the court did not pass on below. This one does. Meritorious petitions typically present questions that are not hemmed in by predicate factual issues the Court must resolve by overruling a trial court owed deference on such facts. Yet this one does. And paid petitions from sophisticated parties like Eli Lilly typically do not resort to language that would be more at home in comic books. This petition does. Pet. 4 (referring to Respondent as “a shadowy non-practicing entity based in Germany”).¹ In just one respect is this petition typical. It should be denied.

Petitioner Eli Lilly asks this Court to set aside a jury verdict finding that Lilly infringed Respondent UroPep’s patent—a jury verdict summarily affirmed by the Federal Circuit in an unpublished, one-line opinion. Lilly believes that the claim at issue uses a “purely functional” term (that is, a term that does not convey any structure, or what it *is* beyond what it *does*). But the district court held that the relevant claim term was structural, based on its review of the patent itself, expert testimony, and the knowledge of a person of ordinary skill. Lilly did not dispute those findings or the resulting ruling in its merits appeal at

¹ At the risk of legitimizing the use of such rhetoric by responding, there is nothing “shadowy” about UroPep, which is a partnership of esteemed German urologists whose published academic work Lilly itself relied on when presenting evidence to the Food and Drug Administration. Response Brief of UroPep at 4, No. 17-2603 (Fed. Cir. Feb. 27, 2018), ECF No. 25 (citing trial transcript).

the Federal Circuit. The very premise of Lilly’s petition—that this claim is purely functional—was not properly preserved below.

Thus, even if Lilly were correct that there has been an “erosion” of a rule against purely functional claiming in the Federal Circuit—there has not been—that issue is not properly presented here.² And if it had been, deciding that question would first require this Court to revisit the district court’s highly factbound decision that the relevant claim term conveys structure. At bottom, Lilly’s request for this Court to revisit that fact finding is little more than a request for factbound error correction, where there has been no error, of an issue Lilly failed to properly preserve below.

Even setting aside this procedural posture, which alone forecloses the do-over Lilly seeks, there remains the fact that this Court has previously denied petitions raising the same or similar questions. Having refused investment in this issue before, the Court should not buy now. At the very least, this Court should await a case without the vehicle problems this one has.

STATEMENT OF THE CASE

A. The Invention

The UroPep inventors discovered that a class of compounds, called phosphodiesterase type 5 inhibitors or “PDE5 inhibitors” for short, could treat benign prostatic hyperplasia. Benign prostatic hyperplasia, a

² Lilly also errs by oversimplifying the legal issue in this case. Even if the claim term were purely “functional,” as Lilly wrongly contends, claims that use functional language are not *per se* invalid. *See infra*, pp. 20-21.

condition that affects more than half of men over 50, was historically difficult to treat and existing treatments had significant side effects. The UroPep inventors, however, discovered that PDE5 inhibitors could play an important role in treating BPH by relaxing prostate muscle cells, a treatment for BPH that overcomes the drawbacks of other options. The claim here puts that well-known class of compounds, PDE5 inhibitors, to a new use: treatment of BPH.

UroPep patented this method of treating BPH using a PDE5 inhibitor. The patent, U.S. Patent 8,791,124 (or the '124 patent), claims the following: “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 [eight particular compounds].” As the district court recognized, “inhibitor of phosphodiesterase (PDE) V” (synonymous with PDE5 inhibitor) is a descriptor for the class of compounds that, *based on their common structural features*, are able to relax human prostatic muscles. Pet.App.184. The “PDE5 inhibitor” claim term is not merely functional. It is also structural—a PDE5 inhibitor must have a structure that allows it to bind with PDE5 at a specific place and block its function. *Id.*

The term “inhibitor” in this context is structural in the same way that the term “coffee maker” is. In the functional sense, “coffee maker” describes a machine that makes coffee, like “inhibitor” describes a compound that can inhibit an enzyme. A coffee maker, like an inhibitor, must also incorporate certain structural features—a container to hold coffee

grounds, a filter that allows water to pass through the coffee grounds, a receptacle for brewed coffee, and the like—otherwise it is not a coffee maker. A consumer understands that the exact appearance of those structural features and their arrangement may vary from coffee maker to coffee maker, and yet can immediately envision the class of machines that are coffee makers when using that term. And that consumer would still be able to recognize what qualifies as a coffee maker if someone invented a new use for the machine, such as a method of making a cake using a coffee maker. That the term “coffee maker” may, on its face, have some functional meaning does not detract from the structure it represents to people familiar with coffee makers.

Lilly’s description of the claim as “purely functional insofar as it describes the claimed compounds by what they do, rather than what they are” is contrary to the district court’s factbound ruling on claim construction. Pet. 13. And yet Lilly never asked the Federal Circuit to reverse that construction. As the district court correctly found, the claim is not purely functional because it conveys to a person of skill in the art information about the structure of the inhibitor compounds. Pet.App.185. Lilly did not appeal that ruling.

B. The Claim Construction Disputes

In front of the district court, Lilly argued for the first and only time that because the claim term “inhibitor of phosphodiesterase (PDE) V” describes the function (inhibit PDE5) rather than the structure of compounds that perform that function, it should be construed under section 112 paragraph 6. *Id.* at 178.

(Lilly’s argument is that the term “describes the compound by what it does—*i.e.*, it inhibits PDE V by any means—rather than by reference to a specific chemical structure.”)

The district court rejected Lilly’s position. In its lengthy ruling, the court held that the “inhibitor” claim term conveyed structure and was not purely functional: “The question whether section 112 paragraph 6 applies to a particular claim element turns on whether the words of the claim element”—here ‘inhibitor of phosphodiesterase (PDE) V’—“would be understood by persons of ordinary skill in the art to have a sufficiently definite meaning as the name for a structure or an act.” *Id.* at 177. The district court agreed with UroPep and found that the term conveyed structure. *Id.* at 178. The district court explained that the term “is described *in part* by its function” but “the fact that a thing is defined in part by its function does not necessarily compel the conclusion that a person of ordinary skill would not have a sufficiently definite idea of what that thing is.” *Id.* (emphasis added).

Judge Bryson further acknowledged that to one outside the art, the term “inhibitor” may seem to be named by function but dispelled that lay confusion:

[I]t is not uncommon for functional language to be used to describe particular structural objects, such as a brake, a drill, a lock, a putter, or a post-hole digger. In such cases, the name of the object is not congruent with the function suggested by the name: thus, for example, a driver is not a putter simply because a golfer decides to use his driver to putt, and a trowel is not a post-hole digger

just because a gardener chooses to use the trowel to dig a post hole.

Id. at 178-79. So too here, “the term ‘an inhibitor of [PDE] V’ is not merely the description of a function, but would convey structure to a person of skill in the art at the time of the invention.” *Id.* at 179.

In so finding, the district court relied on and, for pages, discussed the well-developed factual record, which included expert testimony and numerous literature references detailing what was known in the art about PDE5 inhibitors. *Id.* at 177-88. That record is replete with structural information that defines the relevant compound class. As of the invention date, “evidence of the general structure of the PDE V enzyme, as well as that of its cGMP-specific catalytic site, were reported in the literature.” *Id.* at 180. The term “inhibitor” too had a well-understood and undisputed meaning in the art: “‘inhibitors’ act by binding to the enzyme in a way that ‘inhibits,’ or suppresses, its catalytic activity.” *Id.* at 180-81. Accordingly, while “PDE V inhibitors constitute a ‘diverse collection of different chemical structures,’” the district court found that “the evidence shows that they fall within the class of compounds designed to compete with cGMP to occupy the enzyme’s catalytic site.” *Id.* at 184. As a result, all PDE5 inhibitors must have “overall structural similarity ... in order to bind to the catalytic site of the PDE5 enzyme.” *Id.* (quoting expert declaration). These facts led to the district court’s finding that “the term ... as used in the ’124 patent, is not simply a term that refers to any substance that will inhibit the chemical activity of PDE V” but instead, “as both parties’ experts attest,

‘an inhibitor’ refers to a category of compounds with certain physical structures that bind to PDE V molecules in a way that prevents them from hydrolyzing cGMP.” *Id.* at 184-85.

The district court also rejected the precise argument Lilly is making at this Court—that assuming the claim term were purely functional, *Halliburton* somehow still operates to invalidate UroPep’s claim. As background, Congress enacted section 112 paragraph 6 in response to this Court’s decision in *Halliburton Oil Well Cementing Co. v. Walker*, 329 U.S. 1 (1946). There, this Court opined that claims that “use ‘conveniently functional language at the exact point of novelty’” are invalid. *Id.* at 8. Congress subsequently overruled *Halliburton* in part by enacting section 112 paragraph 6, which allows claims to be expressed using functional language (“a means or step for performing a specified function”).

Applied here, and citing *Halliburton*, the district court explained, “the ’124 patent does not contain the flaw that led to the enactment of section 112 paragraph 6, by ‘us[ing] conveniently functional language at the exact point of novelty.’” Pet.App.176-77 (quoting *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 27 (1997); *Halliburton*, 329 U.S. at 8; *Gen. Elec. Co. v. Wabash Appliance Corp.*, 304 U.S. 364, 371 (1938)). That is because “[t]he inventive contribution of the patent is not the discovery or invention of PDE V inhibitors” themselves. *Id.* at 175. Rather “the invention is based on the discovery that PDE V inhibitors can be effective in treating BPH.” *Id.* The district court analogized

that inventive contribution to “a patent that claimed a novel method for treating a particular type of cardiac arrhythmia by administering a blood thinner” and explained that such an invention “would be directed *not* to a new blood thinner, but to the use of the blood thinner (of whatever type) *to treat a disease in a novel way.*” *Id.* at 176 (emphases added). In the words of the district court, the patented invention at issue was “not the invention of compounds that inhibit PDE V, but the invention of a treatment using compounds that have that effect.” *Id.* Unlike *Halliburton*, the patent did not use “functional language at the exact point of novelty” and thus also did not implicate section 112 paragraph 6. *Id.* at 176-77 (quoting *Warner-Jenkinson*, 520 U.S. at 27; *Halliburton*, 329 U.S. at 8; *Gen. Elec.*, 304 U.S. at 371). (And that was the last time anyone heard anything about *Halliburton* until Lilly moved for rehearing *en banc* in the Federal Circuit, leapfrogging post-trial motions and Federal Circuit briefing and argument.)³

Having concluded that the claim term was not purely functional, the district court turned to ordinary claim construction principles to resolve the parties’

³ Lilly did not even argue about some lingering rule of *Halliburton* to the district court. Judge Bryson addressed *Halliburton sua sponte* in his long discussion of functional claiming. Lilly neglected to mention or even cite *Halliburton* either during claim construction or later in its merits brief at the Federal Circuit. *See* Opening Brief for Lilly, No. 2:15-cv-01202-WCB (E.D. Tex. June 15, 2017), 2017 WL 2973333; Reply Brief for Lilly, No. 2:15-cv-01202-WCB (E.D. Tex. July 27, 2017), 2017 WL 4571566; Opening Brief for Lilly, No. 17-2603 (Fed. Cir. Dec. 21, 2017), ECF No. 21; Reply Brief for Lilly, No. 17-2603 (Fed. Cir. April 3, 2018), ECF No. 27.

remaining disputes over the meaning of the PDE5 inhibitor claim term. *Id.* at 188-89. The district court rejected some of UroPep's contentions but agreed that such an inhibitor must be selective. *Id.* at 189-95. The district court ultimately construed "an inhibitor of phosphodiesterase (PDE) V" to mean "a compound that selectively inhibits PDE V." *Id.* at 195.

C. The Jury Trial

During the course of a five-day jury trial, the parties presented competing evidence and expert testimony regarding infringement, invalidity, and damages. Lilly presented four theories of invalidity to the jury: anticipation under section 102, obviousness under section 103, lack of adequate written description under section 112 paragraph 1 (that the patent's disclosure is inadequate to describe the genus encompassed by the PDE5 inhibitor claim term as construed), and lack of enablement under section 112 paragraph 1 (that undue experimentation is required to determine whether a compound is a selective PDE5 inhibitor). *See id.* at 12.

Lilly also requested a jury instruction that laws of nature are not patentable. The district court refused to give the instruction because Lilly never raised section 101 as a defense in this case. *See id.* at 74-75.

The jury returned a verdict in UroPep's favor, finding that Lilly infringed the '124 patent and that the '124 patent was not invalid under any of Lilly's four theories. *See id.* at 3-4.

D. Judge Bryson Denies Lilly's Motions for Judgment as a Matter of Law and a New Trial

In a lengthy, reasoned opinion, the district court rejected no fewer than ten arguments raised by Lilly in post-trial briefing. The court was unconvinced by Lilly's "march through each of the defenses recognized by title 35," none of which argued that UroPep's patent ran afoul of *Halliburton*. *Id.* at 58; *see id.* at 14-47 (written description); 47-55 (enablement); 55-58 (obviousness); 58-65 (anticipation); 65-68 (indefiniteness); 68-69 (claim construction); 70-76 (jury instructions on enablement); 73-66 (lack of instruction of laws of nature); 77-90 (exclusion of evidence); 90-94 (cross-examination of Lilly's expert). And the district court rejected Lilly's argument that a new trial was warranted because the district court refused to instruct the jury that "the simple discovery that PDE5 is in the prostate or that PDE5 plays a functional role in the prostate is not ... part of the analysis for this claim" and that "the discovery of a phenomenon in nature cannot be the basis for patent protection." Pet.App.74. Such an instruction would have been "clearly wrong," and had been waived by Lilly in any event because it failed to assert a section 101 defense. *Id.* at 75-76.

Finally, the district court also refused to revisit Lilly's assertion that the court's earlier construction of "inhibitor of phosphodiesterase (PDE) V" was erroneous. *Id.* at 68. That assertion was "without supporting argument" according to the district court. *Id.* Lilly conclusorily asserted in a single sentence that the claim construction of that term was incorrect,

without citing *Halliburton*, invoking section 112 paragraph 6, or any other indication of what it viewed as erroneous about the construction. *See* Opening Brief for Lilly at 51-52, No. 2:15-cv-01202-WCB (E.D. Tex. June 15, 2017), 2017 WL 2973333.

Not once did Lilly cite *Halliburton* or suggest that the district court's functional claiming analysis was incorrect in its post-trial arguments. *See id.*; Reply Brief for Lilly, No. 2:15-cv-01202-WCB (E.D. Tex. July 27, 2017), 2017 WL 4571566. No surprise, then, that the merits briefs at the Federal Circuit were similarly devoid of such arguments.

E. Federal Circuit Proceedings

On appeal to the Federal Circuit, Lilly again raised various arguments in the hopes of upsetting the jury verdict, some waived below and some made for the first time. Lilly argued that (1) venue was improper; (2) the written description of the '124 patent was inadequate and (3) did not enable a person of skill to practice the claim patent without undue experimentation; (4) obviousness; (5) anticipation; and (6) a new trial was required on indefiniteness. Nowhere in Lilly's appellate briefs did Lilly argue that the district court erred during claim construction by ruling that the "inhibitor" claim term was structural or that the claim violated the rule of *Halliburton*.

Lilly did state that the district court improperly limited PDE5 inhibitors to "selective" PDE5 inhibitors. Opening Brief for Lilly at 47, No. 17-2603, (Fed. Cir. Sept. 25, 2017), ECF No. 21. In Lilly's view, the selectivity limitation was improper. But again, Lilly did not ask the Federal Circuit to revisit the district court's separate holding that the claim term

was not purely functional. And not once did Lilly cite *Halliburton*.

The Federal Circuit summarily affirmed the district court in a one-line, non-precedential decision. Pet.App.2.

Lilly then filed a petition for rehearing. For the first time since claim construction, Lilly disputed the district court's construction of the structural nature of the claim. And for the first time ever, Lilly relied on *Halliburton*. UroPep responded by explaining Lilly had waived that argument when it failed to appeal it. The Federal Circuit denied Lilly's petition. *Id.* at 209.

REASONS FOR DENYING THE PETITION

This case is not the vehicle to resolve Lilly's alleged problem with the Federal Circuit's recent caselaw on patents that invoke functional claiming. The district court concluded—and Lilly did not appeal—that the claim term at issue is not purely functional. Even if Lilly had properly preserved that threshold claim construction issue for appeal, this Court would first have to revisit the district court's conclusion, predicated on factbound analysis of evidence and expert testimony about how the claim term would have been understood to a person of skill in the art. Only then could this Court reach Lilly's question presented, which itself does not warrant this Court's review.

I. Petitioner Failed to Preserve the Question Presented for Appeal

Lilly's petition assumes that the claim term at issue is "purely functional." Far from being indisputable, as Lilly suggests, Pet. 13, the district

court was presented with and resolved this issue against Lilly during claim construction. The district court construed “inhibitor of [PDE] V” as a structural limitation, concluding that the term “is not merely the description of a function, but would convey structure to a person of skill in the art at the time of the invention.” Pet.App.179.

Lilly did not appeal that ruling. Despite raising a laundry list of arguments relating to the “inhibitor” claim term in the Federal Circuit, none contested the district court’s threshold determination that the claim term was structural.⁴

But now Lilly attempts to rewrite that procedural history by repackaging its validity defenses of written description, enablement, and indefiniteness arguments—none of which asked the district court to reconsider its threshold finding that the “inhibitor” claim term is not purely functional—to save itself from its decision not to properly preserve its arguments on the question presented. For example, Lilly contends that it argued in the district court that the claim’s “functional language ... did not satisfy the written-description and enablement requirements of Section 112(a), and that the claim was indefinite under Section 112(b).” Pet. 11-12. In fact, none of those arguments in Lilly’s post-trial motion disputed that threshold finding that the claim term was structural.

⁴ Lilly says that “it is now undisputed that Section 112(f) does not apply to the claim at issue here.” Pet. 13. The lack of dispute proves UroPep’s point: There is no dispute on the inapplicability of section 112 paragraph 6 (now named section 112(f)) because the claim has been held to be structural, as the district court found and Lilly did not appeal. Pet.App.188.

See Pet.App.15 (written description); *id.* at 48 (enablement); *id.* at 65 (indefiniteness). And while at the Federal Circuit Lilly did passively aggressively remark that the inhibitor term covered “compounds identified only by their functional ability to interfere with a natural disease process,” Opening Brief for Lilly at 21, No. 17-2603, (Fed. Cir. Dec. 21, 2017), ECF No. 21, that was in the context of its written-description appeal. In that challenge, Lilly disputed only the jury’s finding that there was sufficient support in the UroPep patent to permit the use of the claim term under established Federal Circuit caselaw having nothing to do with *Halliburton*. *Id.* at 26-28 (quibbling with the weight that should be afforded expert evidence on the subject). That caselaw is not relevant to purely functional claims, which are indefinite—rather than lacking written-description support—if corresponding structure is not provided in the patent. See *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1351-52 (Fed. Cir. 2015). Not one of Lilly’s arguments challenged the district court’s earlier ruling that the claim term conveyed structure and was not purely functional. Lilly’s Federal Circuit briefs are devoid of analysis of that ruling, criticism of it, and critically of any reference to *Halliburton*, even a shadowy one.

Lilly also misdescribes the district court’s post-trial order. The district court did not “specifically reject[] petitioner’s argument that the claim impermissibly described its point of novelty ‘using functional language,’” Pet. 11-12, because Lilly made no such argument after trial. Lilly takes three words from the district court’s post-trial order completely out of context. The district court was discussing Lilly’s

written-description argument—that the specification of the '124 patent did not contain sufficient examples of compounds that are “inhibitor[s] of PDE V” or adequately describe structural features that are common among PDE5 inhibitors. Pet.App.16. Noted above, the very premise of this validity challenge is that the claim term is structural—the question is whether the patentee has done enough to describe the claimed structural term. *See Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1350 (Fed. Cir. 2010) (“We held that a sufficient description of a genus instead requires the disclosure of either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can ‘visualize or recognize’ the members of the genus.”). The district court’s post-trial order never “specifically reject[ed]” that the “point of novelty” of UroPep’s invention is the claim term Lilly now deems purely functional. The district court made earlier findings directly to the contrary, *see* Pet.App.176-77, 184-85, which Lilly did not address in its post-trial motions or appellate briefs.

Lilly also tells a revisionist tale of the Federal Circuit’s ruling. Lilly believes that the Federal Circuit “necessarily reject[ed] petitioner’s arguments” about the patent’s “functional language” in its summary affirmance. Pet. 12. Lilly omits that the Federal Circuit did not consider any argument that the claim is “purely functional” because Lilly did not ask the Federal Circuit to review the contrary threshold finding of the district court. The Federal Circuit

necessarily did *not* reach the question presented.⁵ To repeat, Lilly’s validity defenses, including its written-description defense, are premised upon the district court’s construction and cite caselaw applicable only to structural claim terms. If Lilly were making its *Halliburton* argument to the Federal Circuit, without citing *Halliburton* or addressing the district court’s ruling that the claim term was structural, Lilly was doing so in code so encrypted no one could possibly understand it. *See State of Cal. v. Taylor*, 353 U.S. 553, 556 n.2 (1957); *Interactive Gift Express, Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1346-47 (Fed. Cir. 2001) (“[A] party’s argument should not be a moving target” but “should be consistent, thereby ensuring a clear presentation of the issue to be resolved, an adequate opportunity for response and evidentiary development by the opposing party, and a record reviewable by the appellate court that is properly crystallized around and responsive to the asserted argument.”).

Lilly’s decision to forgo its appeal of the district court’s structural claim construction alone makes this case unworthy of this Court’s certiorari jurisdiction.

⁵ Lilly revived its argument regarding the district court’s construction that the claim term is structural for the first time in its petition for rehearing to the Federal Circuit, which is not sufficient to preserve its argument in the Federal Circuit or in this Court. *See Am. Sur. Co. v. Baldwin*, 287 U.S. 156, 163 (1932) (argument made “for the first time” in a petition for rehearing “cannot serve as the basis for review by this Court”); *Pentax Corp. v. Robison*, 135 F.3d 760, 762 (Fed. Cir. 1998) (“Just as this court will not address issues raised for the first time on appeal or issues not presented on appeal, we decline to address the government’s new theory raised for the first time in its petition for rehearing.”).

See 14 Penn Plaza LLC v. Pyett, 556 U.S. 247, 273-74 (2009); *Cutter v. Wilkinson*, 544 U.S. 709, 718 n.7 (2005) (“Because these defensive pleas were not addressed by the Court of Appeals, and mindful that we are a court of review, not of first view, we do not consider them here.”); *Glover v. United States*, 531 U.S. 198, 205 (2001) (“In the ordinary course we do not decide questions neither raised nor resolved below.”).

II. Revisiting the District Court’s Claim Construction to Decide the Question Presented for Appeal Would Be Highly Factbound

To reach the question presented, wherein Lilly assumes the “inhibitor” term is purely functional, the Court would first need to revisit and then overturn the district court’s finding that the term is in fact structural. The inquiry whether a claim term is structural or functional is highly factbound and circumstance-specific.

The finding must be made from the perspective of a person skilled in the art during the relevant time period. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc) (claim construction involves determining the “meaning of a claim term ... that the term would have to a person of ordinary skill in the art in question at the time of the invention”); *see also Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2139 (2016) (quoting *Phillips*). That in turn often depends on expert testimony and analysis of literature representing the state of the art at the time of the invention. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 840 (2015) (evidentiary underpinnings of claim construction include “consult[ing] extrinsic

evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period”).

Here, the district court considered declarations and deposition testimony of three experts, as well as numerous articles and books, to find that the claim term would convey structure to a person of skill. Pet.App.179-85. Such factbound determinations ordinarily do not warrant this Court’s review. That is especially true where, as here, *Teva* would require this Court to defer to the district court’s factual findings underlying its claim construction. *See Teva*, 135 S. Ct. at 840-41 (“clear error review” applies “when reviewing subsidiary factfinding in patent claim construction”).

Here, the district court made numerous fact findings leading to the ultimate conclusion that the claim term is not purely functional including, but not limited to: (1) “PDE V inhibitors have been ‘under investigation since around 1985’ and ‘were well-understood by the time of the invention,’” Pet.App.179-80; (2) “the general structure of the PDE V enzyme, as well as that of its cGMP-specific catalytic site, were reported in the literature,” *id.* at 180; (3) “‘inhibitors’ act by binding to the enzyme in a way that ‘inhibits,’ or suppresses, its catalytic activity,” *id.*; (4) “[b]y the time of the invention, artisans has developed hundreds of PDE V inhibitors that bound competitively to the enzyme’s catalytic site,” *id.* at 181; (5) “persons of skill in the art at the time explored inhibitors that would mimic the structure of, and therefore compete with, cGMP to occupy the catalytic site of PDE V,” *id.* at 182; and (6) “even though PDE V

inhibitors constitute a ‘diverse collection of different chemical structures,’ the evidence shows that they fall within the class of compounds designed to compete with cGMP to occupy the enzyme’s catalytic site,” *id.* at 184. Lilly’s petition makes no attempt to argue that any of these facts are incorrect, apart from baldly asserting the district court “is wrong” that the claim term conveys structure. Pet. 15-16.

III. The Federal Circuit Issued an Unreasoned, Unpublished Opinion Affirming the Jury Verdict and Judge Bryson’s Denial of Lilly’s Post-trial Motions

Lilly argues that the Federal Circuit’s summary affirmance “in the face of a plainly substantial issue” is no obstacle to review. Pet. 21. In Lilly’s words, the Federal Circuit’s “use of [its summary affirmance] power in cases presenting significant questions should not shield their decisions from further review.” *Id.* Lilly adds, “In a series of decisions, *culminating in the decision below*, the Federal Circuit has failed properly to apply the rule against functional claiming.” *Id.* at 17 (emphasis added).

But again, the supposed “substantial issue” or “significant question” Lilly now raises in its petition for writ of certiorari was not properly presented to the Federal Circuit in the first instance. *See supra*, pp. 12-17. Lilly’s *Halliburton* argument appeared nowhere in its appellate briefs. The Federal Circuit could have rejected Lilly’s many other appellate arguments on any number of grounds. And even fantasizing, as Lilly does, that a court could have deciphered Lilly’s *Halliburton* argument, that no less negates the likelihood that the Federal Circuit rejected that

argument because such super-encrypted arguments are waived. One thing is certain—the Federal Circuit cannot possibly be assumed to have endorsed an erosion of a rule against functional claiming.⁶

IV. The Federal Circuit Has Not “Eroded” a Rule Against Functional Claiming

The Federal Circuit could not have “eroded” a rule against functional claiming in this case when Lilly never raised that rule as a reason for reversal. But even if that issue had been properly presented in Lilly’s appeal, Lilly’s arguments about the Federal Circuit’s recent precedents are overblown. As an initial matter, Lilly declares that “[t]his Court has long held [purely functional] patent claims invalid.” Pet. 3 (citing *Halliburton*). That is an erroneous oversimplification. This Court no longer treats functional claims as *per se* invalid and any argument to the contrary ignores federal law. In *Halliburton*, this Court held any claim invalid that used “conveniently functional language at the exact point of novelty.” 329 U.S. at 8. Congress then overruled that decision in part by enacting section 112 paragraph 6. See *Warner-Jenkinson*, 520 U.S. at 27-28.

⁶ Lilly’s invocation of other nonprecedential decisions that this Court has reviewed is unconvincing. Only one of those decisions involved an unreasoned summary affirmance, and in that instance, the Federal Circuit had “issued an opinion in a different case, rejecting the same constitutional arguments” as presented in the appeal. See *Oil States Energy Servs., LLC v. Greene’s Energy Grp., LLC*, 138 S. Ct. 1365, 1372 (2018). Nor had the petitioner waived on appeal the question presented in its petition.

Given there is no blanket rule against functional claiming, it is not surprising that functional claims are sometimes found valid. Perhaps that is why this Court has repeatedly denied petitions that raise questions regarding functional claiming. These include petitions about the Federal Circuit’s section 112 paragraph 6 decision in *Williamson v. Citrix* as well as questions so similar to Petitioner’s as to be indistinguishable. See *Cox Commc’ns, Inc. v. Sprint Commc’n Co. LP*, No. 16-1106 (U.S. Mar. 13, 2017), 2017 WL 975402 (“Do *Halliburton* and other decisions of this Court that bar pure functional claiming still control where §112, ¶6 does not apply?”); *Farstone Tech., Inc. v. Apple Inc.*, No. 16-651 (U.S. Nov. 14, 2016), 2016 WL 6819724 (“Whether the new *Williamson* standard for determining when 35 U.S.C. ¶ 112, para. 6 is invoked contravenes this Court’s precedent ... ?”); *Universal Lighting Techs., Inc. v. Lighting Ballast Control LLC*, No. 15-893 (U.S. Jan. 11, 2016), 2016 WL 159572 (“When and how can expert testimony or other extrinsic evidence be used ... to avoid the restrictions imposed by 35 U.S.C. § 112 ¶ 6 on functional claiming?”); *Media Rights Techs., Inc. v. Capital One Financial Corp.*, No. 15-725 (U.S. Dec. 3, 2015), 2015 WL 7831389 (“Whether, in accord with the statutory language, historical interpretation, congressional affirmation, and general claim construction principles, there is a strong presumption against construing as subject to 35 U.S.C. § 112, Paragraph 6 claims that do not recite ‘means?’”); *Aerotel, Ltd. v. Telco Grp., Inc.*, No. 11-871 (U.S. Jan. 11, 2012), 2012 WL 122285 (whether claim construction “effectively eliminat[es] the benefits of a means-plus-function type of claim that Congress endorsed in Section 112, ¶ 6”). Even if

the Court thought this a subject worthy of review, a far better vehicle would be a case in which no party disputes that a claim term is purely functional, in addition to one where the petitioner properly preserved the issue for appeal.

Lilly's real problem appears to be that it views the claim as "encompass[ing] an enormous number of compounds," Pet. 17, but the breadth of the patent is not the question.⁷ Is it this Court's role to assist "stakeholders in the patent system" with their commercial developments? *Id.* at 19. How should it matter to this Court that Lilly maligns a group of scientists with the pejorative "patent troll" no less than four times? *Id.* at 12, 17, 19, 20. Lilly provides no answers.

⁷ Lilly's concerns with functional claiming also sound in terms of preemption and other section 101 principles. *See* Pet. 20. As the district court cogently explained, Lilly waived any section 101 defense by failing to raise it. Pet.App.73-76.

CONCLUSION

For the foregoing reasons, this Court should deny the petition.

Respectfully submitted,

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