

IN THE SUPREME COURT OF THE UNITED STATES

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No. A-\_\_\_\_\_

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ELI LILLY AND COMPANY, APPLICANT

v.

ERFINDERGEMEINSCHAFT UROPEP GBR

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APPLICATION FOR AN EXTENSION OF TIME  
WITHIN WHICH TO FILE A PETITION FOR A WRIT OF CERTIORARI  
TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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Pursuant to Rules 13.5 and 30.2 of this Court, counsel for Eli Lilly and Company respectfully requests a 30-day extension of time, to and including June 5, 2019, within which to file a petition for writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit in this case. The Federal Circuit entered its judgment on October 10, 2018. App., infra, 1a-2a. It denied a petition for rehearing on February 5, 2019. Id. at 3a-4a. Unless extended, the time for filing a petition for a writ of certiorari will expire on May 6, 2019. The jurisdiction of this Court would be invoked under 28 U.S.C. 1254(1).

1. In a long line of decisions culminating in Halliburton Oil Well Cementing Co. v. Walker, 329 U.S. 1 (1946), this Court has made clear that a patent claim is invalid if it describes its point of novelty in purely functional terms -- that is, in terms of what it accomplishes, rather than what it is. Purely functional

claims "discourage" innovation because they preempt future inventions 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 ensures fair notice of the scope of the invention and adequate disclosure of how to make and use it. See 3 Donald S. Chisum, Chisum on Patents § 8.04[3], at 406-407 (2018 ed.).

In Halliburton, the Court applied the rule against purely functional claiming to invalidate a combination claim -- i.e., a claim that unites existing components in a novel way -- describing all "means" for performing a certain function, including those means not yet discovered. 329 U.S. at 12-13. In response, Congress enacted 35 U.S.C. 112, ¶ 6 (now 35 U.S.C. 112(f)), as part of the 1952 Patent Act. That provision narrowly permits means-plus-function claiming for combination claims, 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). By its terms, Section 112, ¶ 6, does not reach single-step claims such as the one at issue here.

2. In 2001, applicant sought FDA approval for Cialis®, a drug to treat erectile dysfunction. In May 2001, following pre-clinical evaluations, applicant proposed evaluating new indications for tadalafil, the active ingredient in Cialis. Those indications included a new treatment for benign prostatic hyperplasia (BPH), a condition in which the benign growth of the prostate gland in older males causes constriction of the neighboring

urethra and results in lower urinary tract symptoms, such as difficulty urinating. App., infra, 9a.

At the time, BPH was treated by surgery or the use of alpha-receptor blockers, which were not particularly effective and caused severe side effects. App., infra, 6a. Applicant spent over \$150 million on research and an extensive drug development process involving multiple clinical studies of tadalafil that continued through at least 2009. See C.A. App. 13914-13918, 13920-13939, 14002-14003. On October 6, 2011, applicant obtained FDA approval to market tadalafil for low-dose, once-daily treatment of BPH, and also for the concurrent treatment of BPH and erectile dysfunction. App., infra, 9a.

A few months later, respondent, a non-practicing German association with only a handful of employees, filed the patent application that ultimately became U.S. Patent No. 8,791,124. Respondent's patent claims priority to an application dated July 9, 1997. App., infra, 5a-6a.

Respondent's patent is directed to a method for preventing or treating BPH -- namely, by administering an inhibitor of a specific enzyme, phosphodiesterase V (or PDE V). Claim 1 of that patent encompasses "[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 a compound selected from [a particular] group" identified in that claim. App., infra, 10a. That is the very method for treating BPH used by Cialis, which was already on the market when respondent filed the application that matured into its patent.

3. Respondent filed suit against applicant in the Eastern District of Texas, asserting that applicant had infringed claim 1 of its patent in violation of 35 U.S.C. 271. As is relevant here, the district court recognized that the claim included functional language, but it determined that the claim did not fall within Section 112, ¶ 6. C.A. App. 53-65.

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." C.A. App. 147; see id. at 71. As construed by the court, the claim captures billions of compounds, described solely in terms of what they do, rather than what they are. App., infra, 20a. The court nevertheless held that the claim was "sufficiently definite" as a matter of law. C.A. App. 128, 133-134.

At trial, applicant argued, inter alia, that claim 1 was invalid because it failed to satisfy the written-description and enablement requirements in Section 112, ¶ 1 (now Section 112(a)). The jury returned a verdict for respondent, finding claim 1 not invalid and infringed and awarding respondent damages. App., infra, 11a-13a.

Following the jury verdict, applicant renewed its motion for judgment as a matter of law, arguing, inter alia, that the claim was invalid for failing to comply with the written-description and enablement requirements of Section 112, ¶ 1, and that the claim was indefinite under Section 112, ¶ 2. The district court denied

that motion, rejecting applicant's argument that the claim impermissibly describes its point of novelty "using functional language." App., infra, 16a, 82a.

3. The court of appeals affirmed in a summary order. App., infra, 1a-2a. In so doing, it rejected applicant's argument that the claim used purely functional language that did not satisfy the requirements of Section 112.

4. The court of appeals subsequently denied a petition for rehearing. App., infra, 3a-4a.

5. Counsel for applicant respectfully requests a 30-day extension of time, to and including June 5, 2019, within which to file a petition for a writ of certiorari. This case presents complex issues concerning the continued viability of the rule against functional claiming. The undersigned counsel did not represent applicant below and needs additional time to review the record and underlying opinions. In addition, the undersigned counsel is preparing petitions for writs of certiorari in several other cases. Additional time is therefore needed to prepare and print the petition in this case.

Respectfully submitted.

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