No. 2017-2603

IN THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

ERFINDERGEMEINSCHAFT UROPEP GBR,

Plaintiff-Appellee,

v.

ELI LILLY AND COMPANY,

Defendant-Appellant.

Appeal from the United States District Court
for the Eastern District of Texas, Civil Case No. 15-1202-WCB,
Judge William C. Bryson

BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF DEFENDANT-APPELLANT'S PETITION FOR REHEARING EN BANC

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Dated: December 10, 2018

CERTIFICATE OF INTEREST

Counsel for *amicus curiae* Washington Legal Foundation certifies the following:

1. **The full name of every party or amicus represented by me is**:

Washington Legal Foundation

2. **The name of the real party in interest represented by me is**:

Washington Legal Foundation

3. **All parent corporations and any publicly held companies that own 10 percent or more of the stock of the parties or *amicus curiae* represented by me are listed below**:

None

4. **The names of all law firms and the partners and associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are**:

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases:

Statutes and Rules:

Miscellaneous:

INTERESTS OF *AMICUS CURIAE* AND INTRODUCTION

The interests of *amicus curiae* Washington Legal Foundation (WLF) are set out in the attached motion for leave to file this brief.[1]

WLF agrees with Appellant Eli Lilly & Co. that the Court should grant rehearing to correct the district court's erroneous understanding of 35 U.S.C. § 112's written-description requirement. Given Judge Bryson's stature and acknowledged expertise, there is serious danger that his views regarding § 112 will continue to be adopted by other district courts unless the Court grants rehearing *en banc* to explain why those views are based on a misunderstanding of § 112.

WLF writes separately to focus primarily on the venue issue. The panel's decision conflicts with the Court's prior decision in *In re: Micron Technology, Inc.*, 875 F.3d 1091 (Fed. Cir. 2017). Rehearing *en banc* is warranted to resolve the conflict.

The panel affirmed the district court's determination that Lilly waived its otherwise-valid objection to venue in the Eastern District of Texas. That affirmance directly conflicts with *Micron*, which unequivocally rejects waiver claims of the sort asserted here by Appellee ("UroPep"). *Micron* makes clear that a

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[1] Pursuant to Fed.R.App.P. 29(c)(5), WLF states that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than WLF and its counsel, contributed monetarily to the preparation and submission of this brief.

waiver finding can only be based on evidence that the alleged patent infringer has delayed assertion of its venue challenge. The panel affirmed the district court's waiver determination despite the absence of any evidence that Lilly delayed its challenge. WLF surmises that the panel was reluctant to require a district-court do-over given that the district court's error was not firmly established until after entry of judgment (the district court entered judgment in May 2017, six months before *Micron* was decided). But if the panel did not wish to follow *Micron*, it should have called for *en banc* review, not issued a summary affirmance under Rule 36—an affirmance that masked the conflict.

STATEMENT OF THE CASE

UroPep filed its infringement lawsuit in 2015 in the Eastern District of Texas. Lilly asserted its venue challenge *on the same day* that it answered the complaint. That challenge, Lilly's § 1404(a) motion to transfer venue to the Southern District of Indiana, argued that a change of venue was warranted because it was headquartered and incorporated in Indiana and had virtually *no* ties to the Eastern District of Texas. Appx022, Appx2130-2168. UroPep based its venue claim solely on Lilly's sale of Cialis® (the allegedly infringing product) in Texas. Under then-existing case law, such allegations were sufficient to authorize the

Texas court to hear the suit;[2] but Lilly nonetheless objected that venue was much more appropriate in another district given Lilly's razor-thin contacts with East Texas.

The district court denied Lilly's § 1404 motion. As the case proceeded toward trial, Lilly possessed no additional legal bases for challenging venue, particularly in light of the Court's 2016 reaffirmation of its interpretation of § 1400(b). It was not until the Supreme Court granted the *TC Heartland* certiorari petition in December 2016 that patent-infringement defendants had any reason even to suspect that venue law might change.

At that point, Lilly did not wait for the Supreme Court to rule. Instead, it renewed its challenge to venue in the March 2017 pre-trial order. Appx2377, Appx2384. Judge Bryson denied the challenge, ruling that Lilly had waived its right to challenge venue under § 1400(b) by failing to raise that issue in its answer

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[2] 28 U.S.C. § 1400(b) authorizes the filing of a patent-infringement action in any judicial district in which the defendant "resides." The Court held in *VE Holding Corp. v. Johnson Gas Appliance Co.*, 917 F.2d 1574 (Fed. Cir. 1990), that a patent-infringement defendant "resides" in any district in which it is subject to personal jurisdiction. In applying *VE Holding*, the Court held that a defendant is subject to personal jurisdiction in any State in which it is alleged to have sold the infringing product. *Beverly Hills Fan Co. v. Royal Sovereign Corp.*, 21 F.3d 1558 (Fed. Cir. 1994). The Court affirmed both rulings in 2016. *In re TC Heartland*, 821 F.3d 1338 (Fed. Cir. 2016), *rev'd*, 137 S. Ct. 1514 (2017).

to the complaint. Appx19928.[3] He stated he would abide by his waiver ruling "regardless of how *TC Heartland* gets decided" by the Supreme Court. *Id.*

The district court later entered judgment on a jury verdict that Lilly infringed UroPep's '124 patent. Only *after* entry of final judgment did the Supreme Court (on May 22, 2017) issue its *TC Heartland* decision overturning this Court's longstanding interpretation of § 1400(b). It is now uncontested that Lilly did not "reside" in the Eastern District of Texas within the meaning of § 1400(b) and thus that venue did not lie in the district court. UroPep defends the judgment below based solely on an assertion that Lilly waived the right to challenge venue.

The first argument in Lilly's principal appeal brief (at 19) was, "Venue in East Texas was Improper." A three-judge panel affirmed the judgment *per curiam* without opinion.

SUMMARY OF ARGUMENT

By affirming the judgment below, the panel implicitly accepted UroPep's argument that Lilly forfeited its right to challenge venue. That ruling directly conflicts with *Micron*, which held that a defendant does *not* waive objections to venue under the circumstances of this case. Rehearing *en banc* is warranted to

[3] It is now undisputed that the FRCP 12(h) waiver ruling was erroneous in light of the Court's later decision in *Micron*.

resolve the conflict.

Micron made clear that improper venue cannot be overlooked in the name of judicial economy (*e.g.*, "The case has already gone to trial, and it would waste resources to overturn the judgment on venue grounds and thereby require an entirely new trial."). Rather, while *Micron* held that district courts "have authority to find forfeiture of a venue objection," it denied that the authority is "broad" and stressed that any such findings must be based on the defendant's conduct—such as that venue objections "were presented close to trial" or that the defendant delayed pressing his objections for "tactical wait-and-see reasons." 875 F.3d at 1101-02. In sharp contrast, the panel rejected Lilly's venue objections despite the absence of evidence that Lilly did anything that could give rise to forfeiture. That rejection cannot be reconciled with *Micron* and warrants rehearing *en banc*. In the absence of rehearing, the Court has sent an unmistakable signal that the it no longer abides by *Micron* and that alleged infringers caught in the *TC Heartland* trap (even those, such as Lilly, who objected to venue throughout the proceedings) are not entitled to relief.

Rehearing is also warranted to review the ruling upholding the validity of a patent that failed to comply with the written description and enablement requirements of § 112. Indeed, it was the district court's misapplication of those

requirements that first caught our attention and persuaded WLF to file a brief urging rehearing. The brief's principal focus on venue should not be interpreted as an indication that WLF places lesser importance on the patent invalidity issue. Rather, WLF focused this brief on venue only after determining that Lilly's petition fully covers the invalidity issue.

REASONS FOR GRANTING THE PETITION

I. REHEARING IS WARRANTED TO RESOLVE THE CONFLICT BETWEEN *MICRON* AND THE PANEL DECISION ON WHEN A DEFENDANT WAIVES VENUE OBJECTIONS

The Petition raises an extremely important venue-law issue. The Supreme Court's 2017 *TC Heartland* decision overturned this Court's longstanding interpretation of § 1400(b) and thereby significantly reduced the number of federal districts in which patent-infringement suits may be filed. UroPep's choice of forum was similar to the choice made by a majority of non-practicing entities before 2017: it filed suit in the plaintiff-friendly Eastern District of Texas despite the absence of any meaningful connections between that forum and either the parties or the cause of action. *TC Heartland* established that the Eastern District never possessed authority to hear such cases. This Court now faces the difficult task of picking up the pieces: what to do about the many pending appeals and mandamus petitions from cases inappropriately filed (and in some instances tried

to judgment) in the Eastern District?

The Court addressed that issue in *Micron*. It held that a district court has only limited authority to find that a defendant has forfeited venue rights and that "[t]his authority must be exercised with caution to avoid the forbidden circumvention" of those rights. 875 F.3d at 1101. *Micron* came too late to provide guidance to Judge Bryson; he held that Lilly waived its venue objections based on a rationale that *Micron* later rejected.

The panel's affirmance of the judgment below cannot be squared with *Micron*. The record here contains no evidence of any conduct by Lilly that would justify waiver under the *Micron* standard. The panel can only have ruled as it did by rejecting that standard. Rehearing *en banc* is warranted to resolve the conflict.

A. *Micron* Rejected the District Court's Rationale for Finding Waiver

The district court held that Lilly waived its venue claims by failing to raise a § 1400(b) objection to venue in its initial answer to the complaint. Appx 19928 (citing FRCP 12(h)). *Micron* expressly rejected that rationale. The Court reasoned that "*TC Heartland* changed the controlling law," that under the law as it existed in 2015-2017 a § 1400(b) defense was not "available" to defendants who sold allegedly infringing goods on a nationwide basis, and thus that Rule 12(h) did not bar post-pleading reliance on *TC Heartland* as a ground for challenging venue.

875 F.3d at 1094.

The panel affirmed the district court's waiver ruling without explanation. In the absence of an explanation, a plausible inference is that the panel endorsed the district court's Rule 12(h) rationale. If so, the conflict between the panel's ruling and *Micron* is stark. In light of the numerous pending cases that raise venue-waiver issues, review is warranted to resolve the conflict.

B. *Micron* Foreclosed Other Grounds for Ruling that Lilly Waived Its Venue Challenge

Micron held that Rule 12(h) is not the only permissible basis for finding that a defendant has forfeited objections to venue. It held that Congress, through its adoption of 28 U.S.C. § 1406(b), "has provided express statutory confirmation of judicial authority to consider the timeliness and adequacy of a venue objection." 875 F.3d at 1101.

But *Micron* made clear that the focus of any forfeiture inquiry must be *the defendant's litigation conduct*, not a generalized interest in conserving judicial resources. It explained, "The right to have a case heard in the court of proper venue may be lost unless seasonably asserted." *Id.* (quoting *Panhandle Eastern Pipeline Co. v. FPC*, 324 U.S. 635, 639 (1945)). The Court added that waiver "may occur 'in any of several ways: by express waiver, by conduct amounting to

waiver as a matter of law, or by failure to interpose a timely and sufficient objection.'" *Id.* (quoting *Manley v. Engram*, 755 F.2d 1463, 1468 (11th Cir. 1985)). The factors cited by the Court in determining whether a defendant has waived venue objections included "how near is the trial" when the defendant challenges venue and whether the defendant has engaged in "tactical wait-and-see bypassing of an opportunity to declare a desire for a different forum." *Id.*[4]

Had the panel followed *Micron*, it would have honored Lilly's venue objections. Lilly engaged in no conduct that could even arguably give rise to forfeiture. On the same day that it filed its answer, Lilly challenged venue in the Eastern District of Texas by filing a § 1404 transfer motion asserting that its minimal contacts with the district were insufficient to justify requiring it to defend the lawsuit there. We now know (per *TC Heartland*) that Lilly's challenge was meritorious; it cannot be faulted for the district court's erroneous decision to deny the motion. Lilly renewed its venue challenge in advance of trial, presciently predicting that the Supreme Court would overturn this Court's overly broad

[4] A recent Court decision closely adhered to *Micron*. It held that a defendant did not waive venue when it waited 15 months after suit was filed (and after *TC Heartland* was decided) to raise its venue objections, concluding that the defendant's conduct entailed "nothing close to the type of 'wait-and-see' tactical behavior that *Micron* suggested was a potential basis for forfeiture." *In re Oath Holdings Inc.*, __ F.3d __, 2018 WL 5930405 (Fed. Cir., Nov. 14, 2018).

construction of § 1400(b).

In the absence of evidence that Lilly forfeited venue objections through its conduct, the panel's affirmance of the judgment below directly conflicts with *Micron*. The most likely explanation for the panel's decision: it concluded that judicial-economy considerations (*e.g.*, the many hours devoted to the trial would be for naught if the venue objection were not deemed waived) warranted overlooking the unarguably improper venue. But basing a waiver finding solely on such considerations conflicts with *Micron.*

C. The JMOL Motion Is Irrelevant to the Waiver Issue

UroPep argued on appeal (at 6) that Lilly waived venue objections by failing to renew them in its post-trial JMOL motion. That argument is frivolous. Rule 50 motions for judgment as a matter of law test whether there is "a legally sufficient evidentiary basis for the jury to find" for the nonmoving party. These motions challenge the sufficiency of the evidence, not the correctness of prior rulings on legal issues. A party who properly raises issues of law before trial need not include them in a Rule 50 motion to preserve them for appeal. 9B Wright & Miller, *Federal Practice & Procedure,* § 2540 (3d ed.). In any event, renewing the venue objection in the JMOL motion would have been a pointless gesture; Judge Bryson had previously stated that the outcome of *TC Heartland* would not affect his

waiver finding.

II. REHEARING IS WARRANTED TO CORRECT THE DISTRICT COURT'S ERRONEOUS UNDERSTANDING OF THE WRITTEN-DESCRIPTION REQUIREMENT

Rehearing is particularly warranted because the panel decision leaves in place a district court decision regarding 35 U.S.C. § 112 that is contrary to numerous decisions of this Court and the Supreme Court. The negative impact of that decision goes far beyond the multi-million dollar judgment erroneously entered against Lilly. Because a member of this Court authored the district court opinion upholding the judgment, the opinion has been cited by other courts as an authoritative explication of § 112—and will continue to be cited unless overturned by this Court.

The decision is deeply troubling because it upholds a patent that covers potentially millions of compounds that might someday be found to be effective in treating BPH, yet provides virtually no clues that would enable others to determine which of the compounds should be of particular interest for research. It is left for companies such as Lilly to spend hundreds of millions of dollars to determine whether any of the compounds within UroPep's vast smorgasbord are actually effective. Upholding the '124 patent significantly decreases the financial incentives for researchers to undertake that investment.

The § 112 written description requirement "plays a vital role in curtailing claims ... that have not been invented, and thus cannot be described." *Ariad Pharms., Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1352 (Fed. Cir. 2010) (*en banc*). Rehearing is warranted because the district court's decision eviscerates that requirement. The decision upholds a patent that fails to describe an invention that a skilled artisan could employ for the benefit of society.

CONCLUSION

WLF requests that the Court grant the petition.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I am an attorney for *amicus curiae* Washington Legal Foundation. Pursuant to Fed.R.App.P. 32(a)(7)(C), I hereby certify that the foregoing brief of WLF is in 14-point, proportionately spaced Times New Roman type. According to the word processing system used to prepare this brief (WordPerfect X5), the word count of the brief is 2,600, not including the certificate of interest, table of contents, table of authorities, certificate of service, and this certificate of compliance.

/s/ Richard A. Samp
Richard A. Samp

CERTIFICATE OF SERVICE

I hereby certify that on this 10th day of December, 2018, I electronically filed the brief of *amicus curiae* Washington Legal Foundation with the Clerk of the Court for the U.S. Court of Appeals for the Federal Circuit by using the appellate CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

/s/ Richard A. Samp
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