No. 24-292

IN THE

Supreme Court of the United States

SALIX PHARMACEUTICALS, LTD.,
SALIX PHARMACEUTICALS, INC.,
BAUSCH HEALTH IRELAND LTD.,
Petitioners,

v.

NORWICH PHARMACEUTICALS INC.,
Respondent.

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

REPLY BRIEF FOR PETITIONERS

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ARGUMENT

This petition squarely presents two important, recurring questions of core appellate procedure. Litigants and the lower courts would benefit from guidance from this Court on both issues.

The first question—concerning evidence not relied on in a district court's findings—has arisen twice before this Court in Voting Rights Act cases, including last term in *Alexander v. South Carolina State Conference of the NAACP*, 602 U.S. 1 (2024). This petition allows this Court to resolve this open procedural question outside the complex and sensitive context of the Voting Rights Act.

The second question—concerning a district court's reliance on impermissible evidence—arises frequently in the courts of appeals, which apply inconsistent tests for harmless error. Pet. 29-34.

On both questions, the panel majority departed from first principles of appellate procedure. As Judge Cunningham explained in dissent, the majority "ma[d]e . . . fact-findings . . . in the first instance." App. 32a.

Norwich identifies no serious ground for denying certiorari. It makes no effort to defend the Federal Circuit's errors, even though it urged the panel to commit them. Norwich instead mischaracterizes the opinion by suggesting that the questions are not implicated. But the dissent below makes clear that the decision below committed the serious procedural errors raised in the petition.

The stakes are high: sales of Salix's drug protected by the wrongfully-invalidated patents exceed a billion

dollars annually. This Court should not sit idle as the Federal Circuit's errors destroy valuable intellectual property. This Court should grant certiorari or, alternatively, summarily reverse and remand.

I. At Norwich's Urging, the Federal Circuit Committed Two Procedural Errors.

Norwich's principal argument against certiorari is that the questions presented are not implicated by the decision below. *See* Resp. 11 (denying that the decision below "embod[ies] the sins that the petition alleges").

Norwich is wrong. Its argument misleadingly focuses only on the specific prior art combination at issue: Pimentel and the RFIB2001 Study. *See*, *e.g.,* Resp. 7 (stating that these references "disclose every limitation" of the claims).

But obviousness requires more: "a reasonable expectation of achieving" the claimed results. *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367 (Fed. Cir. 2016). The claims at issue were invalid as obvious only if skilled artisans would have reasonably expected the claimed dosage—1,650 mg/day—to successfully treat IBS-D.[1] Norwich bore the burden to prove this fact by clear and convincing evidence.

[1] Claim 3 of the '667 Patent requires that the administration of rifaximin "trea[t] one or more symptoms of IBS-D in [a] subject 65 years of age or older." Claim 2 of the '569 Patent requires a "durability of response" that "comprises about 12 weeks of adequate relief from [IBS-D symptoms]" after the subject is removed from treatment.

In finding a reasonable expectation of success, the district court relied primarily on an impermissible piece of evidence: the RFIB2001 Press Release. The question regarding the test for harmful error is squarely presented.

In affirming the finding of a reasonable expectation of success, the panel majority relied heavily on evidence not credited by the district court: Lauritano, Scarpellini, and Lin. App. 11a-12a. The question regarding whether an appellate court may rely on evidence not credited in a district court's findings is squarely presented.

A. The District Court's "Reasonable Expectation of Success" Finding Relied Primarily on the RFIB2001 Press Release.

The district court's opinion shows that the RFIB2001 Press Release was essential to its finding an expectation of success: "[The RFIB2001 Press Release's] disclosure of positive results would give a [skilled artisan] a reasonable expectation of success in using rifaximin to treat IBS-D." App. 83a. "More importantly, a POSA would look to the top-line results from the RFIB 2001 Protocol [i.e., the RFIB2001 Press Release] as evidence that rifaximin could be effective in treating IBS-D[.]" App. 85a; *see also* Pet. 31-32. The district court rejected the skeptical literature Salix presented because "the RFIB 2001 Press Release . . . was not cited" in those articles. App. 84a.

Below, Norwich never denied that the district court relied on the RFIB2001 Press Release. It admitted that the district court "consider[ed] the RFIB2001 Press Release as 'one piece of evidence' in making its findings." Principal & Resp. Br. 41-42.

Norwich instead urged affirmance on the ground that any error was "harmless" because the district court did not rely "solely" on the impermissible evidence:

> None of the examples cited by Salix show that the court resolved any issue solely based on the RFIB2001 Press Release. Thus, any error is harmless.

Id. at 44-45 (citation omitted). Norwich returned to this point in oral argument, emphasizing that the district court "did not **only rely** on that single document in finding reasonable expectation of success." Oral Arg. at 13:24-28.

The panel majority adopted Norwich's test for harmless error, holding that the district court's reliance on the press release was harmless because other evidence "established the obviousness of the claims." App. 13a.

Salix argued that remand was required under the correct harmless-error test because the press release "induced the [district] court to make an essential finding which it otherwise would not have made," *Weinhoffer v. Davie Shoring, Inc.*, 23 F.4th 579, 582 (5th Cir. 2022). Pet. 30-33. Unlike its position before the Federal Circuit, Norwich's opposition now appears to concede Salix's argument regarding the harmless-error standard.

The question regarding the Federal Circuit's improper harmless error test is both squarely presented and determinative.

B. The Panel Majority Relied on Evidence Not Credited by the District Court.

Nor does Norwich accurately describe the panel majority's affirmance of the district court.

The majority did not find an expectation of success based solely on Pimentel and the RFIB2001 Protocol. It acknowledged that the highest rifaximin dosage evaluated by Pimentel was 1,200 mg/day. App. 8a.[2] The RFIB2001 Protocol described a "clinical trial plan" that noted dosages "to be investigated." *Id.*

Because none of the evidence credited by the district court showed a reasonable expectation of success in treating IBS-D with dosages exceeding 1,200 mg/day, Norwich urged the Federal Circuit to rely on different evidence:

> Viscomi 2005, Lin 2006, Lauritano, and Scarpellini . . . also support a POSA's reasonable expectation in using rifaximin to treat IBS-D in the claimed dosage amount.

Principal & Resp. Br. 52.

The panel majority—over a dissent from Judge Cunningham—accepted Norwich's invitation to rely on this uncredited evidence:

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[2] The majority highlighted Pimentel's statement that the optimal dosage "may, in fact be higher." App. 9a. Not only did the district court "not rely on this sentence in its reasonable expectation of success analysis," but Norwich "never made this argument before [the Federal Circuit]." App. 31a (Cunningham, J., dissenting). In any event, "may . . . be higher" falls far short of satisfying the clear-and-convincing evidence standard of proof.

> Lauritano teaches an increase in rifaximin efficacy for the treatment of SIBO as doses were increased from 600 mg/day to 1,200 mg/day. . . . Scarpellini reported that a 1,600 mg/day dose "showed a significantly higher efficacy" compared with 1,200 mg/day for the treatment of SIBO.

App. 11a. Based on these references—"the record before us"—the panel majority saw "no clear error in the finding that a skilled artisan would have had a reasonable expectation of success in administering the claimed 1,650 mg/day regimen for the treatment of IBS-D." App. 12a.

But the district court did not rely on these references—which concern treatment of SIBO, not IBS-D—in its analysis finding an expectation of success. Pet. 15-17.[3]

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[3] Norwich misleadingly suggests that the district court credited "SIBO-related references." Resp. 9. In truth, the district court stated, "I do not think a POSA would have discounted prior art sources that were **based upon the theory** that SIBO contributed to IBS[.]" App. 84a-85a (emphasis added).

The district court was referring to studies of IBS treatment that were prompted by the hypothesis that SIBO contributed to IBS. For example, Pimentel—on which the district court relied—is one such study. App. 9a. That is, studies of IBS treatments are relevant, regardless of the theory underlying the study.

This does not mean that skilled artisans would treat studies showing successful SIBO treatments as proving success in treating IBS-D. The district court carefully relied only on IBS-D studies, not on SIBO studies. Pet. 20. The subtlety and importance of this distinction, which the panel majority apparently overlooked, App. 10a-11a, illustrate why appellate courts may not find facts in the first instance.

Judge Cunningham's dissent details the majority's error: "Although the majority may be right that Lauritano's and Scarpellini's disclosures on treating SIBO also support finding a reasonable expectation of success for treating IBS-D, the district court never made this finding." App. 31a (internal citation omitted). "I would not make such fact-findings about Scarpellini and Lauritano in the first instance." App. 32a.

The dispute between the majority and the dissent concerns the second question presented: In reviewing findings of fact from a bench trial, may a court of appeals rely on evidence not credited by the district court? Is it proper for an appellate court to make fact-findings about evidence "in the first instance"?

* * *

Norwich's contention that the questions presented are not implicated by the decision below is wrong.

Norwich opposes certiorari on this ground because it is unwilling to defend the Federal Circuit's procedural rulings, the very rulings that it urged the panel to make.

This Court should not reward this gamesmanship. Norwich persuaded the Federal Circuit to commit these errors, and if Norwich will not now defend them, this Court should accept Norwich's implicit confession of error and summarily reverse.

This would not be unprecedented—this Court has previously summarily reversed where the Federal Circuit failed to apply the correct standard in reviewing a district court's findings. *Dennison Mfg. Co. v. Panduit Corp.*, 475 U.S. 809, 811 (1986).

Salix has been deprived of exceptionally valuable intellectual property because of the Federal Circuit's errors. This Court should either grant certiorari or, recognizing that Norwich cannot defend the errors it urged the panel to commit, summarily reverse. Either way, the decision below should not be permitted to stand.

II. These Important, Recurring Issues of Appellate Procedure Warrant Clear Guidance from this Court.

Both questions presented concern recurring issues of appellate procedure, potentially relevant in any appeal from a bench trial. They epitomize "important question[s] of federal law that ha[ve] not been, but should be, settled by this Court." S. Ct. R. 10(c).

This Court has regularly granted certiorari to decide similar core questions of federal procedure. *See, e.g.*, *Celotex Corp. v. Catrett*, 477 U.S. 317 (1986) (summary judgment procedure); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 254 (1986) (holding that "the substantive evidentiary burden," such as clear-and-convincing evidence, must guide summary judgment and directed verdict rulings).

Like other procedural issues, these questions are important. In this case, as in others, they make the difference between whether a court of appeals must remand to the district court for factfinding or whether it may affirm based on its own view of the record.

The time for this Court to address these issues is long overdue. The next time a court of appeals is asked to affirm based on evidence not credited in a district court's findings or must review findings based

on impermissible evidence, the panel should have a decision from this Court to follow.

A. Whether Appellate Courts May Rely on Evidence Not Credited by a District Court Has Arisen Twice Before this Court.

The need for a decision is particularly clear regarding appellate review of evidence not credited by a district court.

As Salix highlighted in the petition, the issue has arisen twice before this Court in appeals under the Voting Rights Act. In *Easley v. Cromartie*, this Court suggested, without quite holding, that evidence not relied upon by the district court was irrelevant. *See* 532 U.S. 234, 250 (2001) ("And, in any event, the District Court did not rely upon the [evidence] to support its ultimate conclusion.").

Last term, in *Alexander v. South Carolina State Conference of the NAACP*, this Court noted the procedural issue— "Although the District Court did not cite Dr. Liu's report, the Challengers contend that it bolsters the District Court's findings," 602 U.S. 1, 31 (2024)—but did not address the significance of the district court's omission.

Alexandar confirms both that the law on this point is unsettled and that this issue deserves resolution. It has arisen twice before this Court in Voting Rights Act cases and will undoubtedly recur. This petition presents this Court with the opportunity to decide the question outside the sensitive context of the Voting Rights Act and in a posture that allows it to focus only on the procedural question.

Norwich has no answer on this point—*Easley* and *Alexander* go uncited and undiscussed in its response. Standing alone, the recurrence before this Court confirms the need for this issue's resolution.

B. The Test for Harm When a District Court Relies on Impermissible Evidence Arises Frequently.

The test for harm when a district court's findings rely on impermissible evidence arises frequently in the courts of appeals but has never been addressed by this Court.

Many decisions correctly ask whether the impermissible evidence "induced the [district] court to make an essential finding which it otherwise would not have made." *Weinhoffer*, 23 F.4th at 582; *see also* Pet. 30.

This approach parallels the rule for jury trials, in which evidentiary error is harmless "only 'if it is highly probable that the error did not affect the outcome of the case.'" *Glass v. Phila. Elec. Co.*, 34 F.3d 188, 191 (3d Cir. 1994) (citation omitted).

If this test had been applied in the decision below, there is no doubt that remand would have been required. Pet. 31-33.

But Norwich persuaded the panel majority to apply an erroneous standard, conflating sufficiency with admissibility and arguing that "any error [wa]s harmless" because the district court did not "resolv[e] any issue solely based on the RFIB2001 Press Release." Principal & Resp. Br. 44-45.

Other cases have committed the same error. In *Crawford v. Hawaii*, the Ninth Circuit found a district

court's reliance on improper evidence harmless because "other evidence in the record supports the court's finding." 87 F.3d 1318 (9th Cir. 1996) (table). Although unpublished, *Crawford* relied on a published decision for the proposition that a "trial court's reliance on inadmissible evidence 'will not ordinarily be a ground of reversal if there was competent evidence received sufficient to support the findings.'" *Id.* (quoting *Plummer v. W. Int'l Hotels Co.*, 656 F.2d 502, 505 (9th Cir. 1981)). All Norwich can say is that *Crawford* found that a different piece of evidence was harmless for a different reason. Resp. 16.

The Eighth and Fourth Circuits also made the same mistake. *See* Pet. 33-34 (discussing *Delph v. Dr. Pepper Bottling Co. of Paragould, Inc.*, 130 F.3d 349 (8th Cir. 1997); *Israelitt v. Enter. Sers. LLC*, 78 F.4th 647, 661 (4th Cir. 2023)).

In response, Norwich speculates that perhaps these decisions did not truly mean what they said. Resp. 16. Perhaps *Delph* truly meant to hold that the remaining evidence established the disputed fact "as a matter of law." Resp. 16. Perhaps the Fourth Circuit truly meant to ask "whether the district court's conclusion would have remained the same absent the evidence." *Id.* at 17.

But this speculation has no grounding in the text of these opinions. *Crawford*, *Delph*, and *Israelitt* committed the same error that Norwich persuaded the panel below to commit: asking whether other evidence supported the district court's ultimate finding rather than whether the district court would have made the same finding in the absence of the invalid evidence.

Courts of appeals frequently grapple with the test for harmless error when a district court's findings rely on impermissible evidence. As the confusion in these decisions (and the decision below) demonstrates, guidance from this Court is warranted.

C. The Federal Circuit Hesitates to Remand When It Believes the Result Is Plain.

The panel majority's approach to both issues exemplifies the Federal Circuit's approach to appellate procedure, which commentators have described as "los[ing] track of the important distinction between trial and appellate roles and engag[ing] in a form of decision-making at odds with traditional notions of appellate review." William C. Rooklidge & Mathew F. Weil, *Judicial Hyperactivity: The Federal Circuit's Discomfort With Its Appellate Role*, 15 Berkeley Tech. L.J. 725 (2000).

The author of the decision below candidly admitted this practice in a speech a quarter-century ago. Even when "a remand rather than a reversal is in order," the Federal Circuit "hesitate[s] to send a case back to the district court when it is plain to us what the result will be." Alan D. Lourie, Judge, U.S. Court of Appeals for the Fed. Circuit, Speech to the Patent, Trademark, and Copyright Section of the D.C. Bar (June 12, 2000), reprinted in 60 Pat. Trademark & Copyright J. 1479.

The decision below followed this practice to the letter. The panel majority apparently thought the result was plain and believed that Salix's patents should be invalidated. Rather than confine itself to the proper role of an appellate court, the panel majority bent the rules, finding facts in the first instance even though "a remand . . . [wa]s in order."

Norwich cannot rehabilitate this speech, which admits an unwillingness to follow rules requiring remand. Resp. 14-15. Norwich's quotation omits the last line, which suggests that district courts would "rather have the case decided by us" than have the Federal Circuit remand. *Compare* Resp. 15, *with* Pet. 35.

The author of the panel majority admitted the Federal Circuit's practice of flouting standards of appellate review, and the panel majority followed that practice in this case. Granting certiorari allows this Court to reaffirm that the Federal Circuit must follow the same rules as the other courts of appeals and may not find facts in the first instance, even when a panel believes the result is plain.

CONCLUSION

For these reasons, this Court should grant certiorari.

November 26, 2024 Respectfully submitted,

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