No. _____

IN THE

Supreme Court of the United States

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

v.

NORWICH PHARMACEUTICALS INC.,
Respondent.

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

PETITION FOR WRIT OF CERTIORARI

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September 11, 2024

QUESTIONS PRESENTED

This petition concerns core appellate procedure. In reviewing bench trials, the courts of appeals must "discuss" and "analyze" the district court's findings, not make factual findings on their own. *Icicle Seafoods, Inc. v. Worthington*, 475 U.S. 709, 714 (1986).

The Federal Circuit disregards this limitation. In the decision below, the panel majority affirmed a judgment based on evidence never credited by the district court. Crediting this evidence required the panel majority to decide a critical factual dispute left unresolved in the district court's findings.

The panel majority's willingness to find facts in the first instance led to a second error: the district court relied heavily on an impermissible piece of evidence. The decision below holds that this error was harmless because, according to the panel majority's findings, other evidence "established" the disputed fact.

The questions presented are:

1. When a district court's findings of fact are unsupported by the evidence the district court relied on, may a court of appeals affirm based on other evidence in the record, particularly when the relevance of that evidence depends on unresolved factual disputes.

2. When a district court's findings of fact rely on impermissible evidence, what standard applies to determine whether the error is harmless.

PARTIES TO THE PROCEEDINGS AND RULE 29.6 STATEMENT

The parties to the proceedings include those listed on the cover. Pursuant to Rule 29.6, Bausch Health Companies Inc. owns 10% or more of the stock of all three petitioners.

RELATED PROCEEDINGS

United States Court of Appeals (Fed. Cir.):

Salix Pharms., Ltd. v. Norwich Pharms. Inc., Nos. 2022-2153, 2023-1952 (Apr. 11, 2024)

United States District Court (D. Del.):

Salix Pharms., Ltd. v. Norwich Pharms. Inc., No. 20-430 (Aug. 10, 2022)

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PETITION FOR WRIT OF CERTIORARI

Salix Pharmaceuticals, Ltd., Salix Pharmaceuticals, Inc., and Bausch Health Ireland Ltd. (collectively, "Salix") respectfully petition this Court for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit.

OPINIONS AND ORDERS BELOW

The Federal Circuit's order denying the petition for panel rehearing and rehearing en banc is not reported but is reprinted in the Appendix at 96a–97a. The Federal Circuit's opinion is reported at 98 F.4th 1056 and is reprinted in the Appendix at 1a–32a. The district court's trial opinion is not reported but was published at *Salix Pharms., Ltd. v. Norwich Pharms., Inc.*, No. CV 20-430-RGA, 2022 WL 3225381, at *1 (D. Del. Aug. 10, 2022), and reprinted in the Appendix at 33a–89a. The district court's memorandum order denying the motion under Federal Rule of Civil Procedure 60 is not reported but was published at *Salix Pharms., Ltd. v. Norwich Pharms., Inc.*, No. CV 20-430-RGA, 2023 WL 3496373 (D. Del. May 17, 2023), and reprinted in the Appendix at 90a–95a.

STATEMENT OF JURISDICTION

The court of appeals entered judgment on April 11, 2024, and denied rehearing on June 13, 2024. This Court has jurisdiction under 28 U.S.C. § 1254.

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

Rule 52(a) of the Federal Rules of Civil Procedure Provides, in pertinent part:

> (1) *In General.* In an action tried on the facts without a jury or with an advisory jury, the court must find the facts specially and state its conclusions of law separately. . . .
>
> . . .
>
> (6) *Setting Aside the Findings.* Findings of fact, whether based on oral or other evidence, must not be set aside unless clearly erroneous, and the reviewing court must give due regard to the trial court's opportunity to judge the witnesses' credibility.

Section 102 of the pre-America Invents Act version of Title 35 of the United States Code provides, in pertinent part:

> A person shall be entitled to a patent unless -
>
> > (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Section 103 of the pre-America Invents Act version of Title 35 of the United States Code provides, in pertinent part:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102, if the differences

between the subject matter sought to be patented and the prior art are such that the claimed invention as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains.

INTRODUCTION

Both questions presented concern a fundamental principle of appellate procedure: in an appeal from a bench trial, a court of appeals must review the reasoning and findings of the district court, not ask whether any view of the evidence might support the district court's ultimate conclusion.

It follows that (1) when the district court's reasoning is erroneous but other disputed evidence—not credited or relied upon by the district court—might support the same result, a court of appeals must remand; and (2) if the district court relied on impermissible evidence in its findings, then remand is necessary to determine whether the district court would reach the same result in the absence of that evidence.

The decision below violates both rules. First, the panel majority—over a dissent—affirmed by substituting its reasoning for that of the district court, resolving factual disputes in the first instance, and crediting evidence not relied upon below. Second, the panel majority treated as harmless the district court's reliance on impermissible evidence because, based on the panel's findings, other evidence "established" the crucial facts.

The Federal Circuit regularly follows this erroneous approach to appellate review. Commentators have described the Federal Circuit 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).

In a speech, the author of the decision below candidly acknowledged the Federal Circuit's approach to appellate procedure. 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 exemplifies that practice. Rather than reviewing the district court's reasoning and the evidence it credited, the panel majority examined the record itself to determine what the result should be, effectively finding facts in the first instance.

On the first question presented, the Federal Circuit has departed from the other circuits—and this Court—by its practice of reviewing the record and making its own findings in support of a district court's ultimate conclusion. But this Court has never clearly spoken to the issue, and it arises frequently, including before this Court last term.

This Court has never addressed the second question presented, and the courts of appeals are divided on the standard for harmless error when a district court relies on impermissible evidence.

These are core questions of appellate procedure, on which there should be no uncertainty. This Court should grant certiorari on either or both questions presented.

STATEMENT OF THE CASE

Although the questions presented concern appellate procedure implicated in every appeal of a bench trial, some background in patent law is necessary to understand their significance in the decision below.

This petition concerns two extremely valuable patents that claim methods of using a particular dosage of rifaximin—an antibiotic—to treat IBS-D (diarrhea-predominant irritable bowel syndrome), a condition affecting millions of Americans.

1. Patents are presumed valid. 35 U.S.C. § 282. A party seeking to invalidate a patent bears the burden of persuasion and must satisfy a heightened standard of proof: clear-and-convincing evidence. *Microsoft Corp. v. I4I Ltd. P'ship*, 564 U.S. 91, 95, 102 (2011).

One ground to invalidate a patent is obviousness: "[I]f the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a) (pre-AIA). "Skilled artisan" is shorthand for "a person having ordinary skill in the art."

Only some materials—"prior art"—can be used to prove obviousness. The requirement at issue in this appeal is that prior art must be "by others." 35 U.S.C. § 102(a) (pre-AIA).[1] Under this provision, the

[1] Because these patents were filed before March 15, 2013, the statutes in effect before the America Invents Act apply.

inventor's "own work is not prior art." *In re Katz*, 687 F.2d 450, 454 (C.C.P.A. 1982).

"Whether a reference is a work of others for the purposes of [pre-AIA] § 102(a) is . . . a question of law based on underlying facts." *Google LLC v. IPA Techs. Inc.*, 34 F.4th 1081, 1085 (Fed. Cir. 2022). Like other facts, the party seeking to invalidate a patent must prove by clear-and-convincing evidence that a reference qualifies as prior art. *Id.*

A patent is invalid as obvious if "a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention" and "would have had a reasonable expectation of success in doing so." *Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, 845 F.3d 1357, 1372 (Fed. Cir. 2017).

If a patent claims a method of treatment using a specific dosage, the reasonable-expectation-of-success analysis must focus on the specific dosage claimed. *Teva Pharms. USA, Inc. v. Corcept Therapeutics, Inc.*, 18 F.4th 1377, 1381 (Fed. Cir. 2021).

Where a patent claims particular results (such as successful treatment or alleviation of symptoms), the party seeking to invalidate the patent must prove "a reasonable expectation of success in achieving" the claimed results. *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1381 (Fed. Cir. 2016).

2. Petitioners Salix Pharmaceuticals, Ltd., Salix Pharmaceuticals, Inc., and Bausch Health Ireland Ltd. (collectively, "Salix") are related companies that are parts of one of the largest specialty pharmaceutical companies in the world committed to the

prevention and treatment of gastrointestinal diseases. Salix's flagship product—the antibiotic Xifaxan® (the brand name for the drug rifaximin)—provides relief for a variety of conditions.

FDA approved Xifaxan 550 mg tablets for preventing overt hepatic encephalopathy recurrence in 2010 and, following years of research and studies, for treatment of irritable bowel syndrome with diarrhea ("IBS-D") in 2015. App. 3a.

Irritable bowel syndrome (IBS) affects millions of Americans. CAFedAppx3027-3028. It is "a functional bowel disorder in which abdominal pain or discomfort is associated with defecation or a change in bowel habit." CAFedAppx3024. Symptoms include abdominal pain, bloating, frequency, urgency, gas, and changed bowel habits. App. 71a. Roughly one-third of IBS patients suffer from IBS-D, in which diarrhea is predominant. *Id.*

IBS is a "syndrome" rather than a "disease" because it describes a collection of symptoms without a known cause. Doctors diagnose IBS based on a patient's subjective symptoms and the absence of finding other disorders. No medical test—not blood analysis, colonoscopy, CT scan, or anything else—allows a doctor to verify whether a patient has IBS. App. 88a. Even today, IBS is "a black box," and doctors do not know its underlying cause." App. 84a.

With such uncertainty, treating IBS-D is challenging. This was particularly true in February 2008, the priority date for the IBS-D Patents.

Before FDA approved Xifaxan 550 mg in 2015, doctors had no good options for treating IBS-D.

CAFedAppx3316 (noting the "big unmet need"). At the time of patent filing in 2008, numerous therapies were being tried out of hope and desperation, without any real expectation that they would succeed.

Dr. Mark Pimentel, a clinician at the Cedars-Sinai Medical Center, was researching treatments for IBS. CAFedAppx3115. He—and others at Cedars-Sinai, CAFedAppx3276—theorized that "buildup of bacteria was a contributing factor to symptoms of irritable bowel syndrome" and thus attempted to treat IBS with antibiotics, CAFedAppx3117-3118.

In 2006, Dr. Pimentel published a study on the effects of treating IBS (not IBS-D) with 1,200 mg/day rifaximin. App. 6a–7a ("Pimentel 2006"). According to Dr. Pimentel's calculations, "rifaximin resulted in statistically greater global improvement in IBS than placebo." App. 78a. But no improvement in the symptoms of abdominal pain and diarrhea was found. App. 82a.

The broader medical community never accepted Dr. Pimentel's work. In his own words, he was "the lone voice in the wilderness." CAFedAppx3117. Pimentel 2006, for example, involved idiosyncratic calculations, never used by any other study. CAFedAppx3284. An editorial published alongside Pimentel 2006 by Dr. Douglas Drossman —"one of the world's experts in irritable bowel syndrome," CAFedAppx3287—noted that Pimentel 2006's limitations made its "findings inconclusive and raise[d] questions about the clinical significance of the results." App. 82a-84a. Dr. Pimentel's results—and those of his colleagues at Cedars-Sinai—could not be reproduced by other researchers.

Several mainstream medical publications expressed skepticism in the use of antibiotics to treat IBS-D shortly before the IBS-D Patents were filed. A 2007 Education Practice note by Dr. Eamonn M.M. Quigley, CAFedAppx5537 ("Quigley"), stated that "sound rationale for antibiotic therapy has not been established," and "[t]here is insufficient evidence to recommend antibiotics for the treatment of [IBS] at present." CAFedAppx3298. "[O]ne cannot yet recommend . . . empiric antibiotic therapy in IBS." CAFedAppx5537.

A 2007 publication from the British Society of Gastroenterology recognized that antibiotic treatment "cannot be recommended until replicated in well designed studies by others [i.e., doctors outside of Cedars-Sinai]." CAFedAppx5506. A February 2008 article by Dr. Steve Vanner, CAFedAppx5539 ("Vanner"), surveyed the evidence, including "virtually every publication from the Cedars-Sinai group," CAFedAppx3300, and concluded that Dr. Pimentel's research (and other studies on using antibiotics to treat IBS-D) presented an "intriguing" but ultimately "unproven hypothesis." CAFedAppx5544. In February 2008, less than a month before the priority date of the IBS-D Patents, Dr. Vanner wrote: "There is insufficient evidence to recommend antibiotics for the treatment of irritable bowel syndrome at present." App. 84a–85a.

3. Against this backdrop of medical skepticism, Salix conducted the first serious clinical research into the use of rifaximin for treating IBS-D.

Salix began by filing an investigational new drug application with FDA in November 2005. CAFedAppx3041. Shortly afterwards, Salix conducted a study called "RFIB2001," a "Phase II" clinical trial that tested a variety of different dosages and durations. App. 78a.

The protocol for the RFIB2001 study was published on ClinicalTrials.gov. App. 6a. The study tested twice-daily doses of (i) a placebo, (ii) rifaximin 275 mg (550 mg/day), (iii) rifaximin 550 mg (1,100 mg/day) for both 14 and 28 days; and (iv) rifaximin 1,100 mg (2,200 mg/day). App. 6a-8a.

Skilled artisans would not expect success merely because a Phase II clinical trial is being conducted. CAFedAppx3313-3314. Many Phase II trials do not yield positive results, CAFedAppx3314, and the RFIB2001 study was no exception. Its results were "confusing." CAFedAppx3042. The study showed adequate relief of IBS symptoms using the 550-milligram-twice-daily dosage (1,100 mg/day) for 14 days but not from the same dosage for 28 days and not from the higher dosage (2,200 mg/day). App. 28a; App. 78a.

On September 5, 2007, Salix reported results of its RFIB2001 study in a press release (the "RFIB2001 Press Release"). App. 12a–13a. The press release reports success only for the 1,100-milligram-per-day dose. App. 28a. Skilled artisans understood (correctly) that this indicated that the other dosages were unsuccessful. *Id.*

In Phase III clinical trials initiated in June 2008, Salix tested 550 mg three times a day for 14 days. CAFedAppx3043. After its Phase III trials demonstrated improvement compared to the placebo, Salix

submitted its new drug application to FDA in June 2010. CAFedAppx3044. But FDA rejected the sufficiency of Salix's data and required more studies. CAFedAppx5127. Finally, in 2015, after Salix conducted an additional multiyear Phase III clinical trial, FDA approved rifaximin for the treatment of IBS-D. App. 3a; App. 35a.

In February 2008, Salix filed a patent application that later became U.S. Patent Nos. 8,309,569 and 10,765,667. Both patents discuss the RFIB2001 study at length. Dr. Bill Forbes—the individual quoted discussing the results of "our study" in the RFIB2001 Press Release—is a named inventor on both patents.

Claim 3 of the '667 Patent and Claim 2 of the '569 Patent ("the IBS-D Claims") recite methods of treating IBS-D with 550 milligrams of rifaximin three times per day (a total of 1,650 milligrams per day) for 14 days that lead to successful results. App. 72a.

4. In December 2019, Norwich filed an Abbreviated New Drug Application ("ANDA") seeking to make and sell generic rifaximin 550 mg tablets with the same indications and uses as Xifaxan. App. 4a.

Salix sued Norwich under the Hatch-Waxman Act in March 2020, which treats filing an ANDA as an "artificial form of infringement." *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990). Because no infringing drug has been sold, the only available relief is equitable, so these cases are tried to the bench. *See In re Apotex, Inc.*, 49 F. App'x 902 (Fed. Cir. 2002).

At trial, Norwich argued that the IBS-D Claims were obvious. For these claims, the trial focused on whether skilled artisans would have expected the

claimed dosage (1,650 mg/day for 14 days) of rifaximin to achieve the claimed results in treating IBS-D.

Very few prior-art studies showed positive results in treating IBS-D with rifaximin, and these studies concerned dosages no greater than 1,200 mg/day, far less than the claimed 1,650 mg/day dosage.

To fill in this evidentiary gap, Norwich relied on prior art concerning the use of rifaximin to treat other diseases, such as small intestinal bacterial overgrowth ("SIBO"). As a result, one key dispute at trial was the relationship of IBS-D and SIBO.

Norwich argued that skilled artisans viewed SIBO as a possible cause of IBS-D, and, as a result, they would have expected SIBO treatments to treat IBS-D.

Salix vehemently disagreed. Its expert testified that "[SIBO] is a separate disease" from IBS. CAFedAppx3260; CAFedAppx3261-3162 ("[I]t's one of those things you might look for and treat as a separate disease because it mimics the symptoms of IBS with diarrhea."). Numerous publications confirmed Salix's view. CAFedAppx3262-3264.

The district court did not expressly resolve this dispute. Relying only on references that "disclosed positive results in using rifaximin to treat IBS-D"—and not references involving the treatment of SIBO—the district court found that skilled artisans would have an expectation of success. App. 73a.

The district court found that "the prior art disclosed positive results in using rifaximin to treat IBS-D for a range of doses," and "[t]he asserted IBS-D claims describe a dosing regimen within the known range." App. 73a. The district court then applied

cases regarding claiming a value within a known range to hold that the claims were obvious. *See* App. 80a ("Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or working ranges by routine experimentation." (quoting *In re Applied Materials, Inc.*, 692 F.3d 1289, 1295 (Fed. Cir. 2012)).

Throughout its analysis, the district court relied heavily on Salix's RFIB2001 Press Release: "Its disclosure of positive results would give a POSA a reasonable expectation of success in using rifaximin to treat IBS-D." App. 83a; *see also, e.g.*, App. 80a ("The RFIB 2001 Press Release reported that a '14-day course of rifaximin at 550 mg twice-a-day' dosage saw effective results.").

The district court discredited Salix's evidence of skepticism largely because the RFIB2001 Press Release "was not cited by Quigley, Vanner, or Drossman." App. 84a. Fundamentally, the district court concluded, a skilled artisan "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.

5. Salix appealed the invalidation of the IBS-D Claims to the Federal Circuit.

On both issues raised by Salix regarding the IBS-D Claims, the decision below does not deny that the district court erred but affirms based on independent factfinding by the panel majority.

Salix explained on appeal that the district court's analysis of the dosage was erroneous. The upper end of the "range of doses" for which the prior art

"disclosed positive results in using rifaximin to treat IBS-D" was 1,200 mg/day. App. 73a. The claimed dosage—1,650 mg/day—is nearly 40% higher. App. 29a.

The only mention of a dosage larger than 1,200 mg/day in the district court's opinion is the RFIB 2001 Protocol, which proposed testing 2,200 mg/day. But this is just a test protocol, not results. The RFIB 2001 Press Release, which reported results of a study conducted according to this protocol, showed success only for the protocol's 1,100 mg/day dosage and communicated that the higher dosage (2,200 mg/day) was unsuccessful. App. 28a.

Under the facts found by the district court, the claimed dosage was well outside, not inside, the range of dosages known to treat IBS-D successfully. Salix thus urged the Federal Circuit either to reverse or to remand for additional fact-finding. *Icicle Seafoods*, 475 U.S. at 714.

The panel majority did neither. Instead, it independently analyzed the evidence, relied on prior art not credited by the district court, and conducted its own factfinding.

The majority's analysis of the evidence began with a statement from Pimentel 2006: "Recent data suggest that the optimal dosage of rifaximin may, in fact, be higher than that used in our study." App. 30a; App. 81a.

But as Judge Cunningham noted in dissent, "the district court only relied on this sentence in its motivation to combine analysis and did not rely on this sentence in its reasonable expectation of success

analysis."[2] App. 31a. The district court did not find, by clear and convincing evidence, that the statement "the optimal dosage of rifaximin may be higher" created an expectation of success in using the claimed dosage to achieve the claimed results in treating IBS-D, and the majority erred by making the finding itself.

The panel majority then turned to three references never credited by the district court: Lauritano, Scarpellini, and Lin. App. 11a–12a. These references concern the treatment of SIBO, not IBS-D. Resp & Reply Br. 18.

The district court neither relied on these references in analyzing expectation of success nor made any findings about their teachings. App. 31a. It also made no finding about the hotly contested relationship of IBS-D and SIBO.

The majority took it upon itself to make a finding about the relationship of SIBO and IBS-D on which the district court was, at a minimum, silent. App. 11a. Based on that finding, the majority then credited the prior art and made its own findings regarding the teachings of that art in the first instance.

Judge Cunningham dissented, explaining the majority's error in engaging in factfinding: "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

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[2] Indeed, the argument was unpreserved on appeal: "The parties never made this argument before us." App. 31a.

make such fact-findings . . . in the first instance." App. 32a.

Separately, Salix argued that the district court erred in relying on the RFIB2001 Press Release as prior art to invalidate the IBS-D Claims. The district court did not find—and Norwich does not argue that it proved—that the press release was "by others" under pre-AIA Section 102(a). Instead, the district court erroneously placed the burden on Salix to prove the opposite. App. 83a; *see also Google*, 34 F.4th at 1085-86 (holding that the challenger bears the burden to prove that a reference constitutes prior art).

Remand was necessary, Salix explained, because the incompetent evidence—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).

As with the district court's finding of an expectation of success, the panel majority did not deny that the district court erred. The panel majority affirmed based on its own factfinding.

The decision declares that any error in relying on the press release was harmless because—under its findings—other evidence "established the obviousness of the claims." App. 13a.

The Federal Circuit denied rehearing en banc. Salix now respectfully petitions this Court for certiorari.

REASONS FOR GRANTING THE PETITION

Granting this petition would serve two important purposes.

First, this Court can realign the Federal Circuit's appellate procedure with that of the other circuits and ensure that the same procedures—and same rules of appellate review—apply in patent appeals as in all other civil cases.

Second, this Court can provide helpful clarity regarding review of bench trials, both as to evidence unmentioned by the district court and improper evidence relied upon by the district court.

These questions concern core principles of appellate procedure, which arise frequently and require unambiguous rules. Like the separate-document rule, "[a] conflict on an issue such as this is of importance and concern to every litigant in a federal court[.]" *United States v. Indrelunas*, 411 U.S. 216, 217–18 (1973). Certiorari is warranted.

I. This Court Should Grant Certiorari to Address Review of Bench Trials.

This petition presents important and frequently recurring questions that are significant in all bench trials and particularly significant in patent litigation, which is frequently tried to the bench (and exclusively so in Hatch-Waxman cases, where only equitable relief is available).

These are critical issues in maintaining the proper allocation of authority between district courts and appellate courts and ensuring that the courts of appeals defer to factfinding by district courts.

A. The Decision Below Erroneously—and in Conflict with Other Courts of Appeals—Affirms Based on Evidence Not Credited in the District Court's Analysis.

In reviewing a bench trial, the role of an appellate court is to "discuss" and "analyze" the district court's findings, *Icicle Seafoods,* 475 U.S. at 714, not determine whether other evidence or different reasoning might support the same ultimate conclusion.

As the decision below illustrates, the Federal Circuit has lost sight of these principles, instead finding facts in the first instance and asking whether **any** evidence and reasoning—whether or not credited below—supports the district court's judgment. The result is unpredictability and uncertainty in patent appeals, unlike other civil appeals.

The Federal Circuit has parted ways with this Court and the other circuits, and the issue warrants review from this Court.

1. The decision below erroneously resolves a crucial factual issue unresolved by the district court and relies on evidence and reasoning different from the district court.

At trial, the parties hotly disputed the relationship between SIBO and IBS-D. Did skilled artisans view SIBO as a separate disease from IBS-D? Or did they expect that any treatment for SIBO would also treat IBS-D? Both parties presented expert testimony on the issue. Both parties argued the issue at length. Both parties asked the district court to make findings about the issue.

The district court did not make any findings about the relationship between SIBO and IBS-D, but its analysis relied only on prior art showing successful treatment of IBS-D (and not on Norwich's prior art involving treatment of SIBO). That suggests the district court agreed with Salix that skilled artisans would view SIBO and IBS-D as separate diseases. But in all events, the district court never resolved the issue against Salix nor relied on Norwich's prior art concerning the treatment of SIBO.

On appeal, however, the Federal Circuit panel majority resolved this factual dispute in the first instance, adopting Norwich's view (and crediting its expert's testimony) that skilled artisans viewed SIBO as a cause of IBS-D, rather than an alternative diagnosis to IBS-D. The decision below relies on prior art—Lauritano, Scarpellini, and Lin—that the district court did not find created an expectation of success. App. 11a–12a; App. 31a. The majority's reasoning bears little relationship to the district court's reasoning.

The panel majority's analysis contravenes the role of a court of appeals in reviewing district courts' decisions. The Federal Circuit could have applied the law to the district court's findings. *Icicle Seafoods,* 475 U.S. at 714. Or it could have remanded for the district court to resolve unresolved issues. *Id.* But it was not free to resolve those factual disputes in the first instance. *Id.*

In effect, the panel majority acted as if it were reviewing a denial of judgment as a matter of law, which is warranted when a reasonable jury would not "have a legally sufficient evidentiary basis to find for the party on that issue." Fed. R. Civ. P. 50(a)(1). When

reviewing the denial of a Rule 50 motion, courts of appeals properly "conside[r] the evidence in the light most favorable to the non-moving party and dra[w] all reasonable evidentiary inferences in that party's favor." *Nimely v. City of New York*, 414 F.3d 381, 390 (2d Cir. 2005).

The decision below, in effect, applies the standard for judgment as a matter of law: surveying all evidence in the record, it asks whether sufficient evidence could have supported the ultimate conclusion.

But a different standard applies to reviewing a district court's findings of fact and conclusions of law following a bench trial. In these circumstances, a panel must review the correctness of the district court's reasoning and its analysis of the evidence, not ask whether a reasonable factfinder could have reached the same result.

Judge Cunningham's dissent describes the correct approach: "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.

2. The decision below violates the familiar appellate principle that courts of appeals may not resolve factual disputes in the first instance.

This Court's decision in *SEC v. Chenery Corporation* relies on the "familiar appellate procedure" that courts of appeals may affirm only based on alternative

grounds "within the power of the appellate court to formulate" and not on unmade determinations of fact:

> [I]n reviewing the decision of a lower court, it must be affirmed if the result is correct although the lower court relied upon a wrong ground or gave a wrong reason. . . . It would be wasteful to send a case back to a lower court to reinstate a decision which . . . should properly be based on another ground within the power of the appellate court to formulate. But it is also familiar appellate procedure that where the correctness of the lower court's decision depends upon a determination of fact which only a jury could make but which has not been made, the appellate court cannot take the place of the jury.

318 U.S. 80, 88 (1943) (internal citations omitted).

These principles apply equally to review of findings from a bench trial. A court of appeals may affirm "on another ground within the power of the appellate court to formulate." *Id.* But where, as here, "the correctness of the lower court's decision depends upon a determination of fact" that has not been made by the factfinder, the appellate court cannot take the place of the district court as the trier of fact. *Id.*

Rule 52(a)(1) mandates that a district court "must find the facts specially" in a bench trial. Fed. R. Civ. P. 52(a)(1). Such findings "are obviously necessary to the intelligent and orderly presentation and proper disposition of an appeal." *Mayo v. Lakeland Highlands Canning Co.*, 309 U.S. 310, 317 (1940).

Although the level of detail required by Rule 52 will differ based on the circumstances of each case, the findings must be "sufficient to indicate the factual basis for the [district court's] ultimate conclusion." *Kelley v. Everglades Drainage Dist.*, 319 U.S. 415, 422 (1943). It is not the function of appellate courts "to search the record and analyze the evidence in order to supply findings which the trial court failed to make." *Id.* at 421-22.

The requirement for facts to be found "specially" in Rule 52(a)(1) links closely to the familiar principles of appellate review discussed in *Chenery*. "Rule 52(a) calls for a level of detail adequate to permit appellate review on factual issues." *Knapp Shoes, Inc. v. Sylvania Shoe Mfg. Corp.*, 15 F.3d 1222, 1228 (1st Cir. 1994). Courts of appeals must be able to understand "why certain witnesses were credited, what data was used or how it was construed, or why competing evidence was rejected." *Id.* A district court must "make the subsidiary findings necessary for [the court of appeals] to follow its chain of reasoning." *Mozee v. Jeffboat, Inc.*, 746 F.2d 365, 370 (7th Cir. 1984).

Where a district court has "failed to make a finding" or made an "infirm" finding "because of an erroneous view of the law," the courts of appeals must remand and cannot supply the missing findings themselves. *Pullman-Standard v. Swint*, 456 U.S. 273, 290-91 (1982).

This Court has rejected the panel majority's approach. In *Easley v. Cromartie*, this Court reviewed a three-judge district court's determinations under the Voting Rights Act. 532 U.S. 234 (2001). In arguing for an affirmance, the appellees sought to rely on

evidence—a "1998 plan"—not credited by the district court. Relying on *Kelley* and its requirement that district court find facts specially, this Court rejected that argument: "And, in any event, the District Court did not rely upon the existence of the 1998 plan to support its ultimate conclusion." *Id.* at 250 (citing *Kelley*, 319 U.S. at 420-22). The Federal Circuit should follow the same approach.

Clear error review does not ask whether the district court's ultimate conclusion is correct but whether its "account of the evidence is plausible." *Anderson v. City of Bessemer City, N.C.*, 470 U.S. 564, 574 (1985). As *Chenery* held for administrative agencies, "[t]he grounds upon which [a judgment arising from a bench trial] must be judged" are those findings upon which the district court based its judgment. 318 U.S. at 88. Where, as here, the district court's findings do not support the ultimate conclusion, the court of appeals cannot act as the factfinder in the first instance. The Federal Circuit's departure from these principles warrants review by this Court.

3. The Federal Circuit has disregarded the limit on alternative grounds for affirmance explained in *Chenery*.

The Federal Circuit's erroneous approach to appellate review can be seen in *Medtronic, Inc. v. Daig Corporation*, 789 F.2d 903 (Fed. Cir. 1986), where, in reviewing a bench trial, the Federal Circuit quoted the proposition that it "review[s] judgments, not opinions." *Id.* at 906 (quoting *Jones v. Hardy*, 727 F.2d 1524, 1531 (Fed. Cir. 1984)).

This is incorrect—in reviewing a bench trial, a court of appeals must review the district court's

reasoning and ask whether particular findings by the district court were clearly erroneous. Fed. R. Civ. P. 52(a)(6). A court of appeals reviews findings and reasoning from a bench trial, not simply the ultimate judgment.

From that false premise, the Federal Circuit announced it "presume[s] that a fact finder reviews all the evidence presented unless he explicitly expresses otherwise." 789 F.2d at 906.[3]

On its face, the proposition is unobjectionable, but in context, the Federal Circuit meant that it would presume that the factfinder **credited** all evidence that might support its ultimate conclusion.

The Federal Circuit confirmed this understanding the following year: "[F]ailure to mention does not mean failure to consider when the evidence supplies support for the district court's determination." *FMC Corp. v. Hennessy Indus., Inc.*, 836 F.2d 521, 524 (Fed. Cir. 1987).

The application of this rule can be seen in *IQASR LLC v. Wendt Corporation*, where the district court's findings "did not cite the evidence from [a party's] expert." 825 F. App'x 900, 902 (Fed. Cir. 2020). But because the district court "could properly rely on that testimony," the panel assumed that it did. *Id.* at 903 (citing *Aventis Pharma S.A. v. Hospira, Inc.*, 675 F.3d 1324, 1331 (Fed. Cir. 2012)).

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[3] This broad statement was unnecessary. In that case, the Federal Circuit identified particular statements in the opinion that supported the inference that the district court performed the analysis in question. 789 F.2d at 906 n.7.

The panel then held that the (nonexistent) finding did not constitute clear error, explaining that other evidence "d[id] not foreclose the district court from finding [the] expert's testimony clear and convincing evidence" of a key factual issue in the case, *id.* at 903, even though the district court made no such finding.

As in this case, the Federal Circuit's review in *IQASR* erroneously focused on the correctness or incorrectness of the ultimate conclusion, not the district court's reasoning or whether the district court made the necessary findings.

This line of cases, which track the reasoning and approach of the decision below, demonstrates the Federal Circuit's departure from the ordinary principles of appellate procedure, as explained by this Court and followed by the other circuits. This Court should not allow this split to persist.

4. The issue arises frequently.

This issue, which concerns core principles of appellate procedure, is significant in every bench trial and arises frequently. It came before this Court last Term, in *Alexander v. S.C. State Conference of the NAACP*, 144 S. Ct. 1221, 1233 (2024).

In that Voting Rights Act case, the plaintiffs presented four experts in support of their racial-gerrymandering claim, *id.* at 1240, but the district court relied on only two in its analysis.

Before this Court, the appellants argued that the other experts, including Dr. Liu—whose opinion was not relied on in the panel's findings—were "completely out of the case":

> The panel didn't even cite to Dr. Liu in its opinion because the glaring error and glaring flaw in his VTD set became so clear on cross-examination. So Dr. Liu's completely out of the case because his VTD data set was worthless.

Tr. of Oral Arg. 42, *Alexander v. S.C. State Conference of the NAACP*, No. 22-807.

This Court's opinion 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," 144 S. Ct. at 1248—but this Court did not address the significance of the district court not citing the report, instead rejecting the expert's opinion on the merits. *See id.* ("Dr. Liu's methodology was plainly flawed.").

Alexander confirms both the frequency with which parties attempt to defend district court's findings based on evidence and reasoning not relied upon by a district court and the need for greater clarity from this Court on the use of evidence not credited by a district court in appellate review.

5. Courts of appeals are ill-equipped to find facts in the first instance.

The decision below illustrates precisely why courts of appeals may not engage in fact finding in the first instance. Unlike district courts, courts of appeals do not hear live testimony or lengthy argument.

The panel here lacked the full context necessary to conduct fact-finding. For example, the majority opinion erroneously conflates "bacterial alteration" as a potential cause of IBS-D with Norwich's theory that treatment of SIBO equates to treatment of IBS-D.

App. 10a. Moreover, the majority overlooked the strong, perhaps even overwhelming, evidence of skepticism presented by Salix. Opening Br. 12. If the majority wanted to replace the district court as fact-finder, it needed to consider the evidence that weighed against, as well as in favor of, its findings.

The applicable standard of proof—"clear and convincing evidence"—appears nowhere in the majority's opinion. If the Federal Circuit were truly responsible for analyzing whether other evidence supported the district court's ultimate conclusion, it was at least required to apply the correct standard.

Given the limits on appellate briefs and argument, parties on appeal cannot address every conceivable misinterpretation of the record, and courts of appeals spend far less time with a case than a district judge who sits through trial and receives the evidence firsthand. The district court heard days of witness testimony, but the Federal Circuit heard only 30 minutes of attorney argument. The joint appendix, which the Federal Circuit relied upon as the record, contained only a small portion of the district court proceedings. *See* Fed. Cir. R. 30(b)(5) (limiting the joint appendix to "pages [from the record] specifically cited in the briefs of the parties").

Courts of appeals are "less experienced than trial judges at making fact-findings and in making discretionary judgments of the kind that trial judges often have to make." Joan Steinman, *Appellate Courts As First Responders: The Constitutionality and Propriety of Appellate Courts' Resolving Issues in the First Instance*, 87 Notre Dame L. Rev. 1521, 1604 (Apr. 2012). Any "doubt should be resolved in favor of remand to

the district court so that the record can be fully developed and district courts can fulfill the functions that ordinarily are theirs." *Id.* at 1607.

If parties must truly prepare to retry their case factually on appeal, then appeals must be briefed and argued very differently. Such a radical alteration of appellate procedure should be announced by this Court.

B. The Federal Circuit's Standard for Harmless Error is Deeply Flawed and Conflicts with Other Courts of Appeals.

The panel majority's failure to recognize that its role was to review the district court's factfinding and reasoning led to a second, related error.

The district court relied heavily on impermissible evidence in finding an expectation of success. The RFIB2001 Press Release—the most crucial piece of prior art in the district court's findings—could not be used to invalidate the IBS-D Claims. Norwich failed to meet its burden to prove (by clear and convincing evidence) that the RFIB2001 Press Release was "by others," and Norwich has never argued that it satisfied that burden.

The panel majority held that the district court's reliance on the press release was harmless because, based on the panel's findings, other evidence "established the obviousness of the claims." App. 13a.

This was precisely the analysis urged by Norwich, arguing that any error was harmless "because the evidence supporting the court's findings was not limited to the RFIB2001 Press Release." Norwich Br. 46.

1. The panel should have applied the rule from other circuits and asked whether the press release caused the district court to find the claims obvious.

The majority applied the wrong standard. The question is not whether the majority would (or a hypothetical factfinder could) have reached the same result without relying on the press release. The correct inquiry is whether the press release affected the district court's analysis.

As other courts of appeals have recognized, the panel should have asked whether the press release "induced the [district] court to make an essential finding which it otherwise would not have made." *Weinhoffer*, 23 F.4th at 582 (emphasis added); *id.* at 584 (reversing findings of a district court that relied on incompetent evidence "as the primary bases for its decision," despite other evidence); *see also Lussy v. Comm'r of IRS*, 651 F. App'x 883, 884 (11th Cir. 2016) (same standard); *Gay v. Axline*, 23 F.3d 394 (1st Cir. 1994) (same standard); *Collins & Aikman Corp. v. Carpostan Indus., Inc.*, 905 F.2d 1529 (4th Cir. 1990) (unpublished table decision) (same standard); *O'Connor v. Peru State Coll.*, 781 F.2d 632, 639 (8th Cir. 1986) (same standard); *Nw. Nat. Cas. Co. v. Glob. Moving & Storage Co.*, 533 F.2d 320, 324 (6th Cir. 1976) (same standard); *Pascouau v. Martin Marietta Corp.*, 185 F.3d 874 (10th Cir. 1999) (unpublished table decision) (noting that "the district court's findings reveal no meaningful reliance" on the improper evidence and concluding that its exclusion "would not have changed the result").

Put another way, an error is harmful unless the court of appeals can be "[c]onfident that the district court would have reached the same result even if the [press release] had been excluded." *United States v. Ortiz-Ramirez*, 143 F. App'x 729, 730 (8th Cir. 2005).

Applying the test for harmless error used in the First, Fifth, Sixth, Tenth, and Eleventh Circuits (and sometimes used in the Fourth and Eighth Circuits), the panel majority would have been required to remand to the district court.[4]

The district court's impermissible reliance on the press release caused it to make findings that it would not otherwise have made. The district court emphasized the RFIB2001 Press Release throughout its findings:

- "As of the priority date, a POSA would have known about the successful RFIB 2001 Protocol results [from the RFIB2001 Press Release]." App. 79a.
- "Rifaximin had been shown to be effective in treating IBS in Pimentel 2006 and [(because of the RFIB2001 Press Release)] IBS-D in the RFIB 2001 Protocol[.]" *Id.*
- "The RFIB 2001 Press Release reported that a '14-day course of rifaximin at 550 mg twice-a-day' dosage saw effective results." App. 80a.

[4] There is an exception if "the record permits only one resolution of the factual issue." *Pullman-Standard*, 456 U.S. at 290-91. Norwich did not argue—and the panel majority did not find—that the record permitted only one resolution of this factual issue.

- "[The RFIB2001 Press Release's] disclosure of positive results would give a POSA 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.

The district court placed particular emphasis on the RFIB2001 Press Release in overcoming the evidence of skepticism. Three articles, which were published shortly before the IBS-D Patents, reviewed the literature—including the majority of the prior art at issue—and concluded that the information available did not support using antibiotics (like rifaximin) to treat IBS-D. Less than one month before the priority date of the IBS-D Patents, Dr. Vanner surveyed the studies and wrote: "There is insufficient evidence to recommend antibiotics for the treatment of irritable bowel syndrome at present." App. 84a; App. 85a. Stronger objective evidence of skepticism would be hard to imagine.

The district court discounted these articles because they did not cite the RFIB2001 Press Release. *See* App. 86a ("Norwich argues that one of the [skeptical] articles was published before Yang and the RFIB 2001 Press Release, and the other two articles did not cite those references."); App. 84a ("[The] RFIB 2001 Press Release . . . was not cited by Quigley, Vanner, or Drossman[.]").

Applying the correct legal standard—whether the impermissible evidence affected the district court's

findings—the error was harmful, and remand was required.

2. While the Federal Circuit is an outlier, other circuits have demonstrated similar confusion concerning harmless error review of district court findings.

Granting certiorari on this issue would provide helpful guidance for other circuits as well. The Ninth Circuit has adopted the same rule as the Federal Circuit: "The 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." *Crawford v. Hawaii*, 87 F.3d 1318 (9th Cir. 1996) (unpublished table decision) (quoting *Plummer v. Western Int'l Hotels Co.*, 656 F.2d 502, 505 (9th Cir. 1981)). In *Crawford*, for example, the Ninth Circuit held an error harmless because "[e]ven if the district court improperly relied upon Exhibit 55 . . . , [o]ther evidence in the record supports the court's finding[.]" *Id.*

Without fully articulating its reasoning, the Eighth Circuit applied a test similar to that of the Ninth Circuit in *Delph v. Dr. Pepper Bottling Company of Paragould, Inc.*, 130 F.3d 349 (8th Cir. 1997). There, the district court erred in its analysis. *See id.* at 355 ("Delph's subjective belief that these actions were discriminatory is irrelevant to the objective inquiry . . . and therefore the court's finding that Delph's belief was '*reasonable*' is troubling." (emphasis in original)); *id.* ("[T]he court erred in finding that [two incidents] were the result of discrimination.").

But rather than ask whether the district court would have reached the same result in the absence of

these errors, the Eighth Circuit simply announced that it would disregard this evidence in conducting a sufficiency review. *See id.* ("[W]hen we address Dr. Pepper's sufficiency argument . . . , we will not consider the nondiscriminatory actions[.]"); *id.* ("[I]t is not necessary for us to consider either of these incidents in order to conclude that there is sufficient evidence . . . to affirm[.]").

A recent Fourth Circuit case appears to have applied the same standard, holding a district court's reliance on inadmissible evidence harmless because its conclusion was supported by other evidence:

> While it's true the district court cited an exhibit that was not admitted at trial, that was one of many pieces of evidence the district court relied on in reaching its determination. Even if the performance review was inadmissible evidence the court should not have considered, we cannot say that the district court clearly erred in holding that Israelitt could not establish causation.

Israelitt v. Enter. Sers. LLC, 78 F.4th 647, 661 (4th Cir. 2023), *cert. denied*, 144 S. Ct. 1392 (2024).[5]

The confusion among the courts of appeals warrants resolution by this Court, which has never addressed the standard for harmless error when a district court's findings from a bench trial rely on impermissible evidence. This core rule of appellate procedure should be applied consistently, based on a clear statement from this Court.

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[5] The petition for certiorari in *Israelitt* did not concern this issue.

II. This Court Should Grant Certiorari to Ensure that Patent Cases Receive the Same Review as Other Matters.

The Federal Circuit, a court of specialized jurisdiction with subject matter expertise, faces a particular temptation to overstep the ordinary limits of appellate review and decide patent appeals to reach what it views as the correct result.

In a speech, Judge Lourie, the author of the decision below, acknowledged the Federal Circuit's approach to appellate procedure:

> [W]hile in a particular case, one might consider that a remand rather than a reversal is in order, we hesitate to send a case back to the district court when it is plain to us what the result will be. I believe most district judges would rather have the case decided by us rather than for us to be too finicky about reversing and send the case back for another trial.

Speech to the Patent, Trademark, and Copyright Section of the D.C. Bar (June 12, 2000), *in* 60 Pat. Trademark & Copyright J. 147 (June 16, 2000).

Commentators have also recognized the Federal Circuit's approach to the appellate procedure. One described the Federal Circuit as applying "rules in a manner that does not align with other appellate circuits' approaches." Alan B. Parker, *Examining Distinctive Jurisprudence in the Federal Circuit: Consequences of A Specialized Court*, 3 Akron Intell. Prop. J. 269, 281 (2009).

Others have described the Federal Circuit 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, 726 (2000).

This Court has previously granted certiorari and summarily reversed the Federal Circuit where it apparently failed to restrict itself to its appellate role. *See Dennison Mfg. Co. v. Panduit Corp.*, 475 U.S. 809, 811 (1986) ("The Federal Circuit, however, did not mention Rule 52(a), did not explicitly apply the clearly-erroneous standard to any of the District Court's findings on obviousness, and did not explain why, if it was of that view, Rule 52(a) had no applicability to this issue."). One commentator described this decision as "a paradigm of the type of activity for which the Federal Circuit frequently is criticized: overstepping the bounds of its appellate authority under Rule 52(a) by engaging in de novo review." Maureen McGirr, *Panduit Corp. v. Dennison Manufacturing Co.: De Novo Review and the Federal Circuit's Application of the Clearly Erroneous Standard*, 36 Am. U.L. Rev. 963, 965 (1987).

Departure from the ordinary rules of appellate review would warrant correction in a regional court of appeals, but it is particularly harmful in a court of specialized subject-matter jurisdiction.

The effect of the Federal Circuit's departure is that patent cases are reviewed under different rules than other civil litigation, with far greater power for the court of appeals to review the evidence itself and act as a factfinder in the first instance. Such an approach

creates unpredictability and uncertainty for litigants in patent cases, who cannot know when a panel will depart from reviewing the district court's analysis in favor of conducting its own analysis of the evidence.

These issues are particularly important in Hatch-Waxman cases involving valuable pharmaceutical patents, which must always be tried to the bench because the plaintiff can seek only equitable relief. *See Apotex,* 49 F. App'x at 903–04 (denying mandamus because no jury trial right exists in these cases).

By requiring adherence to the ordinary rules of appellate review, this Court will ensure that patent cases receive the same procedural treatment on appeal as all other civil litigation.

III. The Issues are Squarely Presented, and Certiorari Is Warranted Now.

Both issues are squarely presented, with Judge Cunningham dissenting on the threshold of the majority's reliance on evidence not credited by the district court. The issues were briefed by the parties before the Federal Circuit and discussed at length at oral argument.

Both issues are determinative: If Salix is right on either, then the panel majority erred in affirming on the grounds that it did.

No vehicle issues would interfere with this Court's review. Both questions concern purely legal issues regarding appellate procedure.

The significance of the disconnection between the evidence relied on by the district court—reports of positive results in treating IBS-D—and the evidence

relied on by the court of appeals—reports of positive results in treating SIBO and other diseases—makes this a particularly good vehicle to review the first question presented and provide guidance on appellate review of evidence not credited. The evidence was not simply unmentioned by the district court, but its relevance depended on resolution of a key factual dispute that the district court did not address.

Further percolation is unnecessary. On the first question, there is no suggestion that the Federal Circuit will reconsider its approach to appellate review and its willingness to find facts in the first instance. Judge Lourie explained that the court was not "too finicky" about remand a quarter-century ago, and the Federal Circuit has adhered to that approach to the rules ever since.

On the second question, the courts of appeals have persistently applied different tests for harmless error. Many, like the decision below, have simply announced and applied a rule, without any serious analysis or consideration. Guidance from this Court is long overdue.

This Court should not tolerate uncertainty on these fundamental procedural questions. Certiorari is warranted, and it is warranted now.

CONCLUSION

The same appellate procedure must apply to patent cases in the Federal Circuit as in all other civil cases across the country. The Federal Circuit's expertise in patent law does not allow it to find facts in the first instance. The petition for writ of certiorari should be granted.

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