IN THE

# Supreme Court of the United States

BAXTER CORPORATION ENGLEWOOD,

*Petitioner,*

v.

BECTON, DICKINSON AND COMPANY,

*Respondent.*

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

## PETITION FOR A WRIT OF CERTIORARI


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## QUESTIONS PRESENTED

A petitioner may challenge an issued patent in an inter partes review (IPR) before the Patent Trial and Appeal Board, an agency tribunal, but "only on the basis of prior art consisting of patents or printed publications." 35 U.S.C. § 311(b). The Federal Circuit reviews the Board's decisions under the standards set out in the Administrative Procedure Act.

The questions presented are:

1. Whether the Federal Circuit's practice of allowing IPR petitioners to rely on evidence other than patents and printed publications, such as expert testimony, to fill in gaps in the prior art violates the plain text of § 311(b).

2. Whether the Federal Circuit's practice of resolving contested issues of patentability on appeal from Board decisions—rather than remanding those issues for the agency to decide in the first instance—violates the "ordinary remand rule."

## RULE 29.6 STATEMENT

Baxter Corporation Englewood is a wholly owned subsidiary of Baxter International Inc., a publicly traded company. No other publicly held company owns 10% or more of the stock of Baxter Corporation Englewood.

## RELATED PROCEEDINGS

U.S. Court of Appeals for the Federal Circuit:

*Becton, Dickinson & Co.* v. *Baxter Corp. Englewood*, No. 2020-1937 (May 28, 2021, *reh'g denied*, Sept. 1, 2021)

U.S. Patent and Trademark Office, Patent Trial and Appeal Board:

*Becton, Dickinson & Co.* v. *Baxter Corp. Englewood*, No. IPR2019-00119 (April 29, 2020)

U.S. District Court for the Southern District of California:

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Baxter Corporation Englewood (Baxter) respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit.

## INTRODUCTION

The appeal in this case was supposed to be a limited review of a limited agency decision. But the Federal Circuit, repeating two errors it has made multiple times, broke through both sets of guardrails to invalidate a patent that the agency had upheld.

First, the Federal Circuit once again disregarded a key statutory constraint on agency re-review of an issued patent. This case involves an inter partes review—a streamlined proceeding in which the Patent Trial and Appeal Board (Board or PTAB) can cancel an issued patent if it finds the invention obvious, or otherwise not novel, in light of the "prior art." But Congress has specified that an IPR decision can cancel a patent "only" based on a specific *subset* of the prior art: "prior art consisting of patents and printed publications." 35 U.S.C. § 311(b). That limitation is important, because IPRs involve little discovery and no live testimony; they must be based on *written* "prior art" whose content is incontrovertible. Yet the Federal Circuit regularly disregards that limitation and rests its decision on other sources, such as oral testimony; it has expressly held that the same rule applies to a case is in district court, where there is no statutory limit, and to an IPR, where there is. The Federal Circuit may think the distinction does not matter, but Congress plainly did. And the cost of disregarding the statute is the cancellation of innovative patents that no written prior art can show to be invalid.

Second, the Federal Circuit also disregarded an important limitation that governs all appellate review of agency adjudications. Rather than remand to allow the Board to decide whether the patent must be cancelled, the court decided that question for itself. It reversed without remand, and it did so by reaching questions the agency had not. That is exactly the opposite of what this Court has called the "ordinary remand rule." In other courts, the case would be sent back to the agency to decide unresolved issues; in the Federal Circuit, the Board gets no such respect, and the court resolves contested issues of patentability itself. This Court has previously had to caution the Federal Circuit that it must review the Board's decisions as any federal court reviews the decisions of any federal agency. *See, e.g.*, *Dickinson* v. *Zurko*, 527 U.S. 150 (1999). It is time to repeat the admonition.

This case affords the opportunity to correct both erroneous lines of Federal Circuit precedent. Without this Court's intervention, those practices will continue. Left unchecked, the Federal Circuit's approach threatens the excessive invalidation of properly issued patents—creating uncertainty for patentees and the public and discouraging innovation and investment. The Court should grant the petition.

## OPINIONS BELOW

The decision of the court of appeals (Pet. App. 1a-20a) is reported at 998 F.3d 1337. The final written decision of the Patent Trial and Appeal Board (Pet. App. 21a-87a) is unreported; it is available at 2019 WL 1979703.

## JURISDICTION

The Federal Circuit entered judgment on May 28, 2021. A petition for rehearing was denied on September 1, 2021 (Pet. App. 88a-89a). The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

## STATUTORY PROVISIONS INVOLVED

The text of 35 U.S.C. § 311 provides, in relevant part:

> **§311. Inter partes review**
>
> * * *
>
> (b) SCOPE.—A petitioner in an inter partes review may request to cancel as unpatentable 1 or more claims of a patent only on a ground that could be raised under section 102 or 103 and only on the basis of prior art consisting of patents or printed publications.
>
> * * *

The pre-AIA[1] text of 35 U.S.C. § 102 provided, in relevant part:

> **§102. Conditions for patentability; novelty and loss of right to patent**
>
> A person shall be entitled to a patent unless—

[1] Section 102 was amended by the Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, § 3(b), 125 Stat. 284, 285-287 (2011). Because Baxter filed the relevant patent application before the AIA's effective date, the validity of Baxter's patent is evaluated under the pre-AIA version. *See* AIA § 3(n), 125 Stat. at 293. As explained in greater detail below, the amendments to § 102 have no bearing on the questions presented. *See infra*, at 8 n.3.

> (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 patent, or
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States * * * .

## STATEMENT

### A. Baxter invents a novel telepharmacy system and secures the '579 patent.

Preparing doses of medication at a pharmacy allows little room for error. That is especially true at the dedicated pharmacy in a medical facility like a hospital, which fills orders for medications that will be administered directly to patients. For instance, some medications are stored in concentrated or powdered form; preparing a dose for injection or intravenous administration requires "reconstituting" the medication by adding the correct amount of diluent.

Yet several aspects of the process "are susceptible to miscommunication or loss of information." C.A. App. 80 (col. 1, ll. 38-39). One source of error relates to the method that many pharmacies have traditionally used to keep track of incoming orders: printed labels. *Id.* (col. 1, ll. 42-53). Paper labels often "lack detailed preparation steps," requiring a pharmacy technician either to rely on his or her memory or to hunt for the right instructions for preparing a particular medication. *Id.* (col. 1, ll. 52-56). Physical labels are also prone to loss or damage. *Id.* (col. 1, l. 59).

Another source of error relates to the supervision of pharmacy technicians. Although a pharmacist must approve the filling of each drug order, many jurisdictions allow nonpharmacists to perform basic pharmacy functions under a pharmacist's supervision. *See* C.A. App. 2984-2985. But because it is often impractical for a pharmacist to watch each step in a technician's process live, supervising pharmacists have historically reviewed technicians' work after the fact—which is less reliable as a method of verification. *See* C.A. App. 2985-2987.

Baxter invented a novel telepharmacy system that avoids these problems.[2] Its invention consists of several interconnected parts, including an "order processing server" that receives medication orders, a "dose preparation station" that gives the technician "a set of steps to fill [each] drug order," and a communication relay that captures relevant data and sends it "to a remote site for review and approval by a pharmacist." C.A. App. 65. This system improved upon the existing technology in two important ways. First, Baxter's system provides step-by-step instructions for filling a dose order and allows a technician to highlight a single step to receive more detailed information about that step. C.A. App. 87 (col. 15, l. 58 to col. 16, l. 3). Second, Baxter's system requires that *each step* of a technician's work be verified as properly completed before the operator may continue: "At any point, if a task performed in one of the steps is not verified as being correct, the operator is prevented

[2] Baxter was previously known as Baxa Corporation. In 2011, it was acquired by Baxter International Inc. and renamed Baxter Corporation Englewood.

from going onto the next step and the dose is not prepared." C.A. App. 88 (col. 18, ll. 25-27).

Baxter applied for a patent on its invention in 2008, and the U.S. Patent and Trademark Office (PTO) issued U.S. Patent No. 8,554,579 ('579 patent) in 2013. *See* C.A. App. 65. The patent contains 22 claims directed to Baxter's invention. Claim 8 is illustrative; it covers "[a] system for preparing and managing patient-specific dose orders" that incorporates "a dose preparation station" with the two innovative features discussed above. Pet. App. 19a-20a. In particular, claim 8 states that "the dose preparation station includ[es] an interactive screen that includes prompts that can be highlighted by an operator to receive additional information relative to one particular step" in the process. Pet. App. 20a. The claim further states that "each of the steps must be verified as being properly completed before the operator can continue with the other steps of [the] drug preparation process." *Id.* The parties and the court below have referred to these two claim elements as the "highlighting" and "verification" limitations, respectively.

Since 2008, Baxter has sold its patented invention under the commercial name DoseEdge. C.A. App. 3166. The DoseEdge system has been installed in hundreds of locations, winning praise for its contributions to patient safety. C.A. App. 3045-3047, 3166.

Respondent Becton, Dickinson and Company competes with Baxter and has its own product line for medication and supply management, which it marketed as "Cato." That product line infringes Baxter's intellectual property, including the '579 patent, and Baxter has sued Becton for patent infringement in the Southern District of California.

### B. Becton seeks inter partes review, but the Patent Trial and Appeal Board upholds the '579 patent's validity.

Accused patent infringers have always been able to defend against a claim of infringement by arguing that the asserted patent is invalid, including on the ground that the prior art makes the patent obvious or otherwise non-novel. *See* 35 U.S.C. § 282(b)(2). In 2011, however, Congress created IPRs as a "more efficient and streamlined" way to challenge any issued patent. *Thryv, Inc.* v. *Click-to-Call Technologies, LP*, 140 S. Ct. 1367, 1374 (2020) (quoting H.R. Rep. No. 112-98, pt. 1, at 40 (2011)). To ensure that they would remain streamlined, Congress limited IPRs in several important ways, including the one relevant here: IPRs can consider only certain types of invalidity arguments, based on certain types of written prior art.

Specifically, an IPR can consider *only* arguments that a patent, or "1 or more claims of a patent," is "unpatentable" on "a ground that could be raised under section 102 or 103 [of title 35]." 35 U.S.C. § 311(b). Sections 102 and 103, in turn, make an invention ineligible for a patent if it was anticipated by, or obvious in light of, the "prior art." But not all prior art that could be raised in other proceedings (such as a district-court trial) can be raised in an IPR. Rather, § 311(b) makes clear that a petitioner may bring an

obviousness or anticipation challenge "*only* on the basis of prior art consisting of patents or printed publications." *Id.* (emphasis added).[3]

Becton invoked this IPR process, asking the PTAB to review and cancel claims 1-13 and 22 of the '579 patent. Pet. App. 22a. As relevant here, Becton's petition argued that the challenged claims were obvious in light of two prior-art patents, known as "Alexander" and "Liff" after their inventors. Pet. App. 38a. According to Becton, Alexander and Liff disclosed the verification and highlighting limitations, respectively. *See, e.g.*, Pet. App. 57a-58a, 63a-65a. Looking to those two patents, Becton argued, a person of ordinary skill in the art would have arrived at Baxter's claimed invention. *See, e.g.*, *Dome Patent L.P.* v. *Lee*, 799 F.3d 1372, 1380 (Fed. Cir. 2015) (explaining that a patent claim is obvious if "all elements of a claim are found in the prior art" and if "a person of ordinary skill in the art" would have been motivated to combine the asserted prior-art references with a "reasonable expectation of success" in synthesizing the claimed invention).

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[3] What constitutes the full universe of "prior art" is governed by §§ 102 and 103. Different versions of those sections apply depending on whether a patent application's filing date was before or after the effective date of the AIA, which "revise[d] what qualifies as prior art." Manual of Patent Examining Procedure § 2151, *available at* https://www.uspto.gov/web/offices/pac/mpep/s2151.html; *see* AIA § 3(b)-(c), 125 Stat. at 285-288. That change has no bearing on the question presented, which turns on the language of § 311(b), not the scope of the cross-referenced §§ 102 and 103. And the operative clause of § 311(b) does not vary: for both pre- and post-AIA patents, an IPR may proceed "only on the basis of prior art consisting of patents or printed publications."

The Board instituted an IPR, but rejected Becton's arguments on the merits. In particular, the Board agreed with Baxter that Alexander and Liff did not actually teach the verification and highlighting limitations.

Beginning with the verification limitation, the Board observed that the system claimed in the '579 patent "will not allow the operator to proceed to the next step until the prior step has been verified"—that is, "each of the steps *must* be verified as being properly completed before the operator can continue." Pet. App. 35a (emphasis added). As Baxter explained, however, Alexander only discusses a system in which "a remote pharmacist *may* verify each step." Pet. App. 59a (quoting Baxter PTAB Resp. 27). Reviewing the parties' arguments and Alexander's teachings, the Board "f[ou]nd that [Becton] ha[d] not demonstrated by a preponderance of the evidence that Alexander teaches or renders obvious" the verification limitation. Pet. App. 60a.

Turning to the highlighting limitation, the Board reached a similar conclusion. The invention claimed in the '579 patent contains "an interactive screen that includes prompts that can be highlighted by an operator to receive additional information relative to one particular step." Pet. App. 25a-26a. Becton contended that Liff discloses a similar "user interface screen with multiple areas for entering user inputs and displaying information," and "teaches that the user can highlight various inputs and information displayed on th[at] screen." Pet. App. 66a. As the Board explained, however, the "highlighting" described in Liff related to "*patient* characteristics when dispensing a prepackaged medication"; Becton did not establish that Liff's

disclosure "would lead one of ordinary skill to highlight prompts in a drug formulation context to receive additional information relative to one particular step in that process"—let alone "what additional information might be relevant." Pet. App. 67a.

Based on its reading of Alexander and Liff, the Board entered a final written decision rejecting Becton's argument that claims 1-13 and 22 of the '579 patent are obvious. Pet. App. 86a.

### C. The Federal Circuit allows Becton to supplement the published prior art with expert testimony and resolves contested issues of patentability for itself.

The Federal Circuit reversed. The court first rejected the Board's reading of the prior art. Then it went on to declare the '579 patent's claims invalid as obvious under its *own* reading of the prior art.

1. With respect to the highlighting limitation, the court rejected the Board's treatment of Liff. Liff's system includes an interface through which a "user can highlight various inputs and information displayed on the screen." Pet. App. 12a. The court acknowledged that Liff does not "directly disclose[] highlighting to receive additional language about a drug preparation step," and indeed, "Becton [did] not argue" that it does. *Id.* (quotation marks omitted). After all, "Liff is directed to an automated drug dispensing" for "prepackaged pharmaceuticals"—it does not relate to drug preparation. Pet. App. 11a (brackets and quotation marks omitted). So the court turned to the testimony of a Becton expert, Marc Young, to expand on the teachings of Liff. Dr. Young testified that "addi-

tional information could be displayed" on Liff's interface. Pet. App. 13a. For the Federal Circuit, this was enough: "Dr. Young, without contradiction, testified . . . that a person of ordinary skill in the art would have found it obvious to include in the user interface taught by Liff a tab for the prescription order and information regarding the prescription order that the operator was fulfilling." Pet. App. 14a (quotation marks omitted).

Thus, in the court's view, "[t]he Board erred in looking to Liff as the only source a person of ordinary skill would consider for what 'additional information might be relevant.'" Pet. App. 14a (quoting Pet. App. 67a). Even though Liff was the only "patent or printed publication" asserted to teach the highlighting limitation, the court held that the Board was required to consider Dr. Young's testimony as well. If Baxter wanted the court not to rely on Dr. Young, the court suggested, it should have "point[ed] to . . . contrary testimony." Pet. App. 15a. And so, the court concluded, "[t]he Board's determination that the highlighting limitation is not obvious over Alexander and Liff" was "not supported by substantial evidence." *Id.*

The court similarly rejected the Board's treatment of Alexander and the verification limitation. The court acknowledged Alexander's language that "a remote pharmacist *may* verify each step as it is performed." Pet. App. 6a (emphasis added). In the court's view, however, it was "quite clear" from "the context of Alexander" that "'may' does not mean 'occasionally,' but rather that one 'may' choose to systematically check each step." *Id.* In response to Baxter's argument that Alexander differed from the claims of the '579 patent

because the Alexander system did not actually prevent a step from going forward without authorization, the court relied on a statement from Baxter's counsel at oral argument. When asked whether an operator of Alexander's system "would be disciplined if he didn't stop" when "the pharmacist tells him to stop," counsel answered "possibly." C.A. Oral Arg. at 26:15-36, *available at* http://oralarguments.cafc.uscourts.gov/default.aspx?fl=20-1937_04082021.mp3. Based on that answer (rather than anything in Alexander), the Federal Circuit concluded that the remote operator in Alexander's system "*cannot* further process the work without authorization." Pet. App. 8a (emphasis added). And so, the court concluded, "the Board's determination that Alexander does not teach the verification limitation [was] not supported by substantial evidence" either. Pet. App. 10a.

2. But the court did not stop there. In adjudicating Becton's obviousness challenge, the Board was required to make "several basic factual inquiries." *Graham* v. *John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966). These included (1) "the scope and content of the prior art," (2) "differences between the prior art and the claims at issue," (3) "the level of ordinary skill in the pertinent art," and (4) "any objective indicia of non-obviousness."[4] *E.g.*, *Randall Mfg.* v. *Rea*, 733 F.3d 1355, 1362 (Fed. Cir. 2013) (citing *Graham*, 383 U.S. at 17-18; *KSR Int'l Co.* v. *Teleflex Inc.*, 550 U.S. 398, 406 (2007)). The Board then had to weigh those "*Graham* factors" against one another to reach a final decision. *E.g.*, *id.* But rather than remand to the Board to engage in any other factfinding or to re-

[4] These objective indicia are sometimes called "secondary considerations." *Graham*, 383 U.S. at 17-18.

weigh the *Graham* factors in the first instance, the Federal Circuit instead took that task on itself. According to the Court, "[t]he Board found that Baxter's evidence of [objective indicia of non-obviousness] was 'weak.'" Pet. App. 17a. Because "Baxter [did] not argue that the Board's determination in this respect was in error," the court held that these "secondary considerations . . . simply cannot overcome [a] strong showing of obviousness." *Id.* (quoting *ZUP, LLC* v. *Nash Mfg., Inc.*, 896 F.3d 1365, 1375 (Fed. Cir. 2018)) (ellipsis in original). Deeming the '579 patent obvious, the court reversed the Board outright.

## REASONS FOR GRANTING THE WRIT

The decision below reflects two entrenched practices in the Federal Circuit's case law that have warped the process of inter partes review. First, despite the plain text of 35 U.S.C. § 311(b), the Federal Circuit now requires the Board to accept obviousness arguments based on evidence beyond just "patents and printed publications." Second, despite the well-established "ordinary remand rule," the Federal Circuit has claimed for itself the power to resolve contested issues properly reserved for the agency in the first instance.

Both practices are wrong, and both errors are important, because they have fundamentally changed the ground rules for inter partes review—which is now a key step in any infringement dispute. Indeed, conventional litigation is regularly stayed pending completion of an IPR, including any Federal Circuit appeal from the IPR—as happened in the litigation between Baxter and Becton. In the short time since the PTAB's first decisions in IPRs (and similar reviews), this Court has granted certiorari in half a

dozen such cases. The questions presented here are just as fundamental. The Federal Circuit has distorted the procedural standards for the Board's review of patents *and* its own review of the Board. This Court should undo the damage.

## I. The Federal Circuit is persistently disregarding an important statutory limitation on IPR proceedings.

### A. Congress created a special rule for IPRs under which challengers may rely only on "patents and printed publications."

Patent law has long provided several avenues to test the validity of an issued patent. For example, a defendant accused of patent infringement may raise a full panoply of invalidity defenses in an infringement suit. *See* 35 U.S.C. § 282(b)(2). Or the PTO itself may reexamine an issued patent, sometimes at the prompting of a challenger. *See* 35 U.S.C. § 302. To provide a speedier, cheaper, and more certain alternative, Congress created the IPR mechanism to help "weed out bad patent claims efficiently." *Thryv*, 140 S. Ct. at 1374. Enacted as part of the AIA's package of reforms of the federal patent system, IPRs are "designed to establish a more efficient and streamlined patent system that . . . limit[s] unnecessary and counterproductive litigation costs." H.R. Rep. No. 112-98, pt. 1, at 40.

In keeping with the IPR's function as a quick and cost-effective alternative to litigation, Congress placed significant constraints on the scope of the proceedings. Most relevant here, Congress has strictly limited the arguments and evidence that the PTO may consider in an IPR. Under § 311(b), the agency

may institute an IPR "only on a ground that could be raised under section 102 or 103 [of title 35]," which prohibit the issuance of patents on inventions that are obvious or anticipated by the prior art. And in the text relevant here, § 311(b) states that obviousness or anticipation may be asserted "only on the basis of prior art consisting of patents or printed publications." In short, challengers may not use extrinsic evidence to supply claim limitations that are not found in the "patents or printed publications" themselves.

That restriction makes sense in light of the streamlined nature of an IPR. Discovery in an IPR is minimal: by default, parties are entitled only to depositions of witnesses who have submitted affidavits or declarations. 35 U.S.C. § 316(a)(5); *see* 37 C.F.R. § 42.51(b). Moreover, a petition for inter partes review must be filed within one year of the commencement of an infringement action, *see* 35 U.S.C. § 315(b)—meaning that, as a practical matter, parties are rarely able to use discovery from a co-pending district court litigation in an IPR involving the same patent. As for the "trial" itself, the Board decides issues almost exclusively on the parties' written submissions: "although the parties are entitled to an oral hearing, the hearings are short"—typically an hour or less per side—"and live testimony is rarely allowed." *Regents of the University of Minnesota* v. *LSI Corp.*, 926 F.3d 1327, 1336 (Fed. Cir. 2019) (citations, quotation marks, and brackets omitted); *see* 37 C.F.R. §§ 42.53, 42.70; *see also* PTAB Paper 48, at 2 (allotting 90 minutes per side for Becton's three consolidated IPRs involving three separate patents). The Board must also reach a "final determination" within one year of instituting review—that is, within months of the hearing. *See* 35 U.S.C. § 316(a)(11); *see also id.*

(allowing the PTO Director to authorize an extension of "not more than 6 months" for "good cause").

In the face of these many limitations, Congress had every reason to require the Board to adjudicate IPRs "only on the basis of prior art consisting of patents and printed publications." Those written documents are capable of establishing the teachings of the prior art on their face. Opening the door to other prior-art evidence like expert testimony, by contrast, would require the Board to engage in factfinding that it is poorly positioned to undertake. Given the limitations on discovery, the lack of live witnesses, and the tight time constraints, the Board is not equipped to referee expert disputes about what prior-art knowledge existed *outside* "patents and printed publications." So Congress reasonably decided to prevent the Board from relying on that type of extrinsic evidence.

To be clear, a challenger who wants to rely on other forms of prior art is free to do so in district court, where live testimony, meaningful discovery, and (potentially) factfinding by a jury allow a full ventilation of the disputes such evidence can trigger. A challenger may also rely on a full panoply of evidence in other proceedings before the PTO. The "post-grant review" mechanism—a close cousin of the IPR—allows a challenger to raise more invalidity grounds (including subject-matter eligibility under § 101 or written-description support under § 112) and to press an unlimited universe of prior art. But a post-grant review comes with strict time limitations—a petition for post-grant review must be filed within nine months of a patent's issuance. By contrast, *any* patent issued at *any* time is subject to an IPR. *See* AIA § 6(c)(2)(A),

125 Stat. at 304 (35 U.S.C. § 311 note). That is exactly why it made sense for Congress to limit challengers in an IPR to the teachings found on the face of a narrow class of written documents consisting of patents and printed publications.

### B. The Federal Circuit routinely allows challengers to rely on expert evidence to fill in gaps in "patents and printed publications."

Despite the plain text of § 311(b), the Federal Circuit has adopted a practice of allowing challengers in IPRs to rely on evidence beyond just "patents and printed publications." In particular, where the patents and printed publications identified in the IPR petition teach only *some* of the elements of the patented invention, the Federal Circuit routinely allows challengers to fill in the gaps with an expert's testimony that, in the expert's own view, the remaining elements would have been obvious. Indeed, in cases like this one, the Federal Circuit holds that it is reversible error *not* to credit such an expert—even though the expert's testimony should not be cognizable at all.

1. This case is emblematic of the Federal Circuit's improper approach. As in all IPRs, Becton—the party petitioning the Board—chose the references on which it wished to rely. With respect to the highlighting limitation, for example, it chose to hinge its argument on the teachings of Liff. But as Becton candidly acknowledged to the Federal Circuit, Liff does not "directly disclose highlighting to receive additional language *about a drug preparation step*." Pet. App. 12a (emphasis added) (quoting Becton C.A. Br. at 4). Instead, Becton argued that "Liff disclose[d] basic computer

functionality—*i.e.*, using prompts that can be highlighted by the operator to receive additional information." *Id.* (quoting Becton C.A. Br. at 4). To bridge the gap between Liff's more general disclosure and the specific limitations of the '579 patent, Becton offered the testimony of its expert, Dr. Young. According to Dr. Young, "[a] person of ordinary skill in the art would have understood" that Liff's interface could be modified to display "additional information"—such as drug-preparation information—"depending on the design needs and expected use of the software." Pet. App. 13a (quoting C.A. App. 1497).

The Federal Circuit blessed Becton's end-run around § 311(b). According to the Federal Circuit, the fact that Liff taught highlighting for a different purpose—*i.e.*, to display "patient characteristics when dispensing a prepackaged medication"—did not matter because "Dr. Young, without contradiction, testified . . . that a person of ordinary skill in the art would have found it obvious to include in the user interface taught by Liff a tab for the prescription order and information regarding the prescription order that the operator was fulfilling." Pet. App. 14a (quoting C.A. App. 1497).

Thus, the court quite literally reversed the Board for following the statute: in the court's view, "[t]he Board erred in looking to Liff as the only source a person of ordinary skill would consider for what 'additional information might be relevant.'" Pet. App. 14a (quoting Pet. App. 67a). Despite § 311(b)'s express limitation to "patents and printed publications," in other words, the court decided that those written documents did *not* need to be the "only source" (Pet. App. 14a). And it held that unless Baxter submitted *more*

extrinsic testimony to controvert Dr. Young's, the Board was *required* to credit Dr. Young.

The court relied on evidence beyond "patents and printed publications" with respect to the verification limitation, too. As discussed above, the '579 patent "requires that 'the system will not allow the operator to proceed to the next step until the prior step has been verified.'" Pet. App. 5a (quoting Pet. App. 38a). In Alexander, the reference Becton cited, the system does not prevent an operator from proceeding if a prior step is unverified. *See* Pet. App. 6a-7a, 59a-60a. To skirt this hole in Alexander's teachings, the court surmised that something not in Alexander or any written document—the fear of employee discipline—might prevent an employee from proceeding.[5]

At bottom, the Federal Circuit's reliance on these extrinsic considerations shows that the court allows parties to paper over the absence of a critical limitation in the "patents and printed publications" themselves—notwithstanding the plain text of § 311(b). And in light of the published decision *reversing* the Board despite the nominally deferential standard of review, there can be no doubt that future Board panels, petitioners, and patent owners will now feel constrained to engage in similar expert battles over gaps in the prior art.

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[5] The court raised that possibility itself, as a hypothetical at oral argument; counsel responded that an operator of Alexander's system might "possibly" be "disciplined" if he did not heed a pharmacist's instruction to stop. *See supra*, at 12. From there, the Federal Circuit took a substantial inferential leap and concluded that in the prior art, "[t]he remote operator *cannot* further process the work without authorization." Pet. App. 8a (emphasis added).

2. While particularly stark, the decision below is not exceptional. Other recent decisions have similarly allowed IPR challengers to fill gaps in the "patents and printed publications" with outside evidence. And they have explicitly rejected the foundational principle that a different rule applies in IPRs than in other forums. Rather, they have expressly—and unapologetically—held that the same rule applies "[r]egardless of the tribunal." *Koninklijke Philips N.V.* v. *Google LLC*, 948 F.3d 1330, 1337 (2020). In short, they have made § 311(b) a nullity.

*Philips* is a particularly plain example. There, the Federal Circuit acknowledged that the IPR challenger's asserted prior-art reference "did not disclose each and every element of the claimed invention." 948 F.3d at 1337. Yet the court thought it sufficient that, according to an expert, the missing claim limitations were "within the general knowledge of a skilled artisan." *Id.* at 1338. The patent owner protested that § 311(b) bars reliance on "general knowledge" in an IPR because it is neither a patent nor a printed publication. *Id.* at 1337. But the Federal Circuit rejected that argument and insisted that reliance on general knowledge is appropriate "[r]egardless of the tribunal." *Id.* (relying on cases from district court). The court briefly adverted to this Court's decision in *KSR*, but never acknowledged that *KSR*, too, arose from district court and never considered a statutory limitation on prior art like § 311(b) (which was enacted years later).[6]

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[6] The court also cited a case of its own, considering a now-repealed precursor to IPR called inter partes reexamination. But although the *Philips* court noted that the reexamination statute

The Federal Circuit committed a similar error in *B/E Aerospace, Inc.* v. *C&D Zodiac, Inc.*, 962 F.3d 1373 (Fed. Cir. 2020), again holding that the Board properly relied on expert testimony to "supply a missing claim limitation" not expressly found in the written prior art. *Id.* at 1380. The patent in *B/E* involved a space-saving design for aircraft enclosures, containing two "recesses"—upper and lower—fitting different parts of a passenger seat back. *Id.* at 1375. A challenger filed an IPR, arguing that the claimed invention was obvious in light of a prior-art patent containing only *one* recess, the upper one. *Id.* at 1376-1377, 1379. The Board agreed, relying on testimony by the challenger's expert that "lower recesses were a well-known solution to provide space for seat supports." *Id.* at 1380. And the Federal Circuit affirmed. Expressly analogizing to district-court litigation, the court held that outside evidence that "the claimed invention is simple" can "supply a missing claim limitation" not found on the face of the prior art. *Id.* Again, the analogy highlights the error: as discussed above (at 16), district courts are *not* subject to § 311(b), and however appropriate this type of proof may be in district court, Congress forbade it in IPRs.

As this string of decisions shows, the Federal Circuit will persist in treating IPRs just like district-court proceedings—"[r]egardless of the tribunal"—unless this Court steps in to vindicate the statute.

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had included a similar patent-or-printed-publication requirement, 948 F.3d at 1337, the cited case never discussed it. *See Randall*, 733 F.3d at 1362-1363.

### C. The Federal Circuit's persistent violation of § 311(b) warrants this Court's attention.

The Federal Circuit's excision of this important limitation on IPRs will harm both the inventive community and the public, making IPRs more expensive and less accurate. This Court's intervention is needed.

There is no doubt that one of the central goals of the IPR system is to provide a cheaper and less time-consuming avenue to challenge the validity of an issued patent. The Congressional report accompanying the AIA explained that the act's amendments were designed to "provid[e] quick and cost effective alternatives to litigation." H.R. Rep. No. 112-98, pt. 1, at 78. The PTO recognizes that the IPR mechanism should "create a timely, cost-effective alternative to litigation." 77 Fed. Reg. 48,680, 48,680 (Aug. 14, 2012). And this Court has echoed those observations, noting that "[b]y providing for inter partes review, Congress, concerned about overpatenting and its diminishment of competition, sought to weed out bad patent claims efficiently." *Thryv*, 140 S. Ct. at 1374.

The Federal Circuit's approach undermines this central purpose. By bending § 311(b)'s limitations, the Federal Circuit confronts the Board with evidentiary questions not presented by "patents and printed publications." Is a particular expert's testimony credible? Is the expert right that "common sense" would have led a skilled artisan to an undisclosed claim limitation? These are exactly the types of questions that the Board was not meant to answer on a cold record with limited discovery. Yet these are exactly the types

of questions the Board now *has* to answer. The Federal Circuit's decision turns the PTAB into a mini-district court, one that lacks the necessary factfinding tools. Burden and expense will go up; accuracy and reliability will go down.

And the harm will fall on inventors whose patents should not be subject to IPR challenge, much less invalidation. As this Court has observed, when it comes to patent rights, "clarity is essential to promote progress, because it enables efficient investment in innovation." *Festo Corp.* v. *Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 730-731 (2002). "A patent holder should know what he owns, and the public should know what he does not." *Id.* at 731. Inter partes review already raises the risks, given its lower burden of proof—a mere preponderance will do—and the constraints on its factfinders. *See Thryv*, 140 S. Ct. at 1379 (Gorsuch, J., dissenting). The Federal Circuit's approach increases the risk that strong patents—patents that the Board would not invalidate based on printed publications alone—will be cancelled in hasty fashion based on evidence that Congress excluded from these streamlined proceedings. That result, in turn, creates uncertainty for patentees and the public, undermining confidence in the validity of patents duly issued by the PTO and discouraging innovation and investment.

The Federal Circuit's recent spate of precedential decisions, capped by the reversal in this case, sends an unmistakable message: despite § 311(b), any type of evidence is fair game for a patent challenger. More patents will fall as the Board internalizes the Federal Circuit's instructions—unless this Court steps in.

## II. The Federal Circuit is persistently failing to follow the "ordinary remand rule" in appeals of inter partes review proceedings.

The Board is part of the PTO, and the PTO is an administrative agency. That may seem self-evident, but the Federal Circuit has historically been reluctant to *treat* the Board like an agency by following the substantive and procedural standards of agency review. Accordingly, this Court has had to underscore that the Federal Circuit must review the PTO and its components as it would any other agency. And one of the ordinary elements of judicial review is the "ordinary remand rule": if an agency errs, a court should correct the error and remand, not substitute its own judgment for the agency's. It is time to apply the same rule to the PTAB.

### A. The PTO is subject to the same rules of agency review as any other administrative agency.

*Dickinson* v. *Zurko*, 527 U.S. 150 (1999), is the leading case establishing that the Federal Circuit should review the PTO as other courts review other agencies. The Federal Circuit had long been reviewing factfinding by the PTAB's predecessor under a less deferential standard (clear error), rather than the "ordinary APA court/agency standards" (substantial evidence). *Id.* at 153. This Court rejected that aberrant approach, explaining that because "the PTO is an 'agency' subject to the APA's constraints," and because the agency's "finding[s] constitute[] 'agency action,'" the Federal Circuit "must apply the APA's court/agency review standards." *Id.* at 154; *see also Cuozzo Speed Technologies, LLC* v. *Lee*, 136 S. Ct.

2131, 2143-2144 (2016) (noting that "inter partes review is less like a judicial proceeding and more like a specialized agency proceeding").

There are strong reasons to apply the ordinary principles of agency review to the PTAB. For one thing, there is the "importance of maintaining a uniform approach to judicial review of administrative action." *Dickinson*, 527 U.S. at 154. As this Court has explained, "[t]he APA was meant to bring uniformity to a field full of variation and diversity," and "[i]t would frustrate that purpose to permit divergence on the basis of" anything less than a clear statutory indication. *Id.* at 155. Moreover, the history of the PTO's governing statute in particular suggests that the agency is subject to ordinary judicial review: a prior version of the Patent Act gave a reviewing court the power "to take additional evidence and to substitute its judgment for that of the Commissioner," but the statute has since been amended to make clear that the court of appeals is "confined to the record made in the Patent Office." *Brenner* v. *Manson*, 383 U.S. 519, 525 (1966); *see* 35 U.S.C. § 144.

### B. The "ordinary remand rule" applies to Federal Circuit appeals from IPRs.

Under the "ordinary remand rule," a court that has rejected the stated basis of an agency's decision should typically return the matter to the agency to address any outstanding questions in the first instance. *See, e.g.*, *INS* v. *Orlando Ventura*, 537 U.S. 12, 16-18 (per curiam). That rule applies with equal force to the Federal Circuit's review of the PTAB's decisions in IPR cases.

This remand rule stems from decades of this Court's precedent. In *SEC* v. *Chenery Corp.*, 332 U.S. 194 (1947), for example, the Court made clear that "a reviewing court, in dealing with a determination or judgment which an administrative agency alone is authorized to make, must judge the propriety of such action solely by the grounds invoked by the agency." *Id.* at 196. "If those grounds are inadequate or improper," the Court explained, "the [reviewing] court is powerless to affirm the administrative action by substituting what it considers to be a more adequate or proper basis." *Id.* From *Chenery*'s starting point, the Court has refined and reiterated the principle over the years: once a court has rejected the stated basis for an agency's decision, the proper course is to return the matter for the agency to resolve any outstanding issues in the first instance. *See, e.g.*, *Fed. Power Comm'n* v. *Idaho Power Co.*, 344 U.S. 17, 20 (1952) ("[T]he function of the reviewing court ends when an error of law is laid bare. At that point the matter once more goes to the Commission for reconsideration."); *Fla. Power & Light Co.* v. *Lorion*, 470 U.S. 729, 744 (1985) ("If the record before the agency does not support the agency action . . . , the proper course, except in rare circumstances, is to remand to the agency for additional investigation or explanation.").

This Court reaffirmed that principle most recently in a trio of cases: *Orlando Ventura*, *Gonzales* v. *Thomas*, 547 U.S. 183, 185 (2006) (per curiam), and *Negusie* v. *Holder*, 555 U.S. 511 (2009). As these three cases make clear, this well-established rule—which the Court referred to as the "ordinary 'remand' rule," *Orlando Ventura*, 537 U.S. at 18—applies to all manner of agency determinations. *Id.* at 16-17 (applying

"the basic legal principles that govern remand") (citing agency cases from various contexts).[7] Those include contested questions of fact, *id.* at 16; application of law to fact in the first instance, *Thomas*, 547 U.S. at 186; and resolution of a pure question of law on which the agency was owed *Chevron* deference, *Negusie*, 555 U.S. at 523. *See generally* Christopher J. Walker, *The Ordinary Remand Rule and the Judicial Toolbox for Agency Dialogue*, 82 Geo. Wash. L. Rev. 1553, 1575-1579 (2014) (discussing these cases).

All of the considerations that supported the application of the ordinary remand rule in those cases apply with equal force here. Like the agency determinations in those cases, "statutes place" the determination of obviousness or anticipation in IPR proceedings "primarily in agency hands." *Orlando Ventura*, 537 U.S. at 16 (2002). Like the agency determinations in those cases, the PTAB "can bring its expertise to bear upon the matter; it can evaluate the evidence; it can make an initial determination; and, in doing so, it can, through informed discussion and analysis, help a court later determine whether its decision exceeds the leeway that the law provides." *Id.* at 17. And like the agency determinations in those cases, the question of obviousness or anticipation "requires determining the facts and deciding whether the facts as found fall within a statutory term." *Thomas*, 547 U.S. at 186. In short, as in those cases, there are "no special cir-

[7] Courts of appeals have likewise understood that these principles apply to agency review generally, not immigration specifically. *E.g.*, *Stone & Webster Construction, Inc.* v. *U.S. Dep't of Labor*, 684 F.3d 1127, 1137 (11th Cir. 2012).

cumstance[s] here that might have justified the [Federal Circuit's] determination of the matter in the first instance." *Id.* at 187.[8]

### C. The Federal Circuit is consistently failing to follow the ordinary remand rule.

1. The decision below is emblematic of the Federal Circuit's failure to follow the ordinary remand rule. As discussed above, the Board in an IPR is required to make factual findings regarding the four *Graham* factors—(1) the scope and content of the prior art, (2) the differences between the prior art and the claims at issue, (3) the level of ordinary skill in the pertinent art, and (4) any objective indicia of non-obviousness—and then to weigh those factors against one another. *See supra*, at 12. Here, the Federal Circuit held that substantial evidence did not support the Board's reading of the prior art, including Alexander and Liff, and whether the challenged claims differ from it (matters that go to the first and second *Graham* factors). But that was not the end of the case: there were other issues for the Board to resolve in the first instance.

a. Most notably, the Board should have had the opportunity to reweigh the four *Graham* factors—including any objective indicia of non-obviousness—in the first instance. That weighing is exactly the type of decisionmaking that the ordinary remand rule was designed for. It involves, as *Thomas* put it, "determining the facts and deciding whether the facts as found fall within a statutory term." 547 U.S. at 186. And it

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[8] Indeed, the case for remanding is even stronger in IPR appeals because—unlike in most agency cases—the government usually is not a party. So when the Federal Circuit decides issues without remanding, it does so without the benefit even of briefing from the agency's counsel.

presents, as *Orlando Ventura* observed, an opportunity for the agency to "bring its expertise to bear upon the matter" and to "help a court later determine whether its decision exceeds the leeway that the law provides." 537 U.S. at 17. The Federal Circuit improperly deprived the PTAB of that opportunity.

The Federal Circuit concluded that a remand was not necessary here because the Board had already described Baxter's evidence of objective indicia as "weak," and because Baxter "d[id] not argue [on appeal] that the Board's determination in this respect was in error." Pet. App. 17a. But, for two reasons, the Board's logic only underscores why a remand was appropriate in this case.

First, Baxter did not challenge the Board's assessment of objective indicia on appeal because *it had no occasion to do so*. Becton's appeal did not present (and its brief did not even mention) the issue. Nor could Baxter properly cross-appeal the Board's decision in its favor. *See, e.g.*, *Droplets, Inc.* v. *E*Trade Bank*, 887 F.3d 1309, 1321-22 (Fed. Cir. 2018) (rejecting a cross-appeal that challenged only an "alternative finding" in an otherwise favorable IPR decision).

Second, even if the objective indicia were "weak," that does not lead inexorably to the conclusion that the claims-in-suit are obvious. The Federal Circuit reasoned that "weak evidence of secondary considerations . . . cannot overcome [a] strong showing of obviousness." Pet. App. 17a. But here there was *not* a strong showing of obviousness (and no adjudicator, including the Federal Circuit, ever found that there was). And, again, weighing the strength of one argument against the weakness of another is exactly the

type of weighing that is reserved to the Board in the first instance.

b. A remand would also allow the Board to review and correct its factual determinations related to the first three *Graham* factors with the benefit of the Federal Circuit's interpretation. For example, the Board analyzed the other disclosures of Liff and Alexander—and a skilled artisan's motivation to combine those two references—against the backdrop of its findings regarding the verification and highlighting limitation. *See* Pet. App. 30a-31a. Now that the latter findings have been vacated, the Board should have the opportunity to address antecedent or interconnected findings in the first instance.

2. The Federal Circuit has never acknowledged the need to follow the ordinary remand rule in PTAB appeals. The decision below is part of a long line of decisions in which the court of appeals has usurped the agency's authority.

In *Corning* v. *Fast Felt Corp.*, 873 F.3d 896 (Fed. Cir. 2017), for example, the PTAB held that all of the elements of the challenged claims were taught in several discrete prior-art references, but that a person of ordinary skill in the art would not have been motivated to combine those references. *See id.* at 899-900. On appeal, the Federal Circuit held that the Board's decision rested on a flawed claim construction. *See id.* 901. And, as relevant here, the court concluded that it was "not necessary or appropriate to remand for the Board to reassess the evidence in light of the correct claim construction." *Id.* In the court's view, its rejection of the Board's claim construction meant "there [was] only one permissible factual finding—a skilled artisan would be motivated to combine the prior-art

references." *Id.* at 903. As here, the court rested its decision in part on the fact that the *appellee* had not "challenge[d]" or "show[n] error" in an aspect of the Board's decision—namely, that all the elements of the claim were taught in the asserted references. *See id.* at 899 & n.3.

The Federal Circuit likewise reversed a judgment of the PTAB and decided contested issues in the first instance *In re Hodges*, 882 F.3d 1107 (Fed. Cir. 2018). There, the Board held that a patent was anticipated by a prior-art reference. *Id.* at 1111. The panel majority concluded that the Board's reading of the reference was not supported by substantial evidence and reversed outright, on the view that there was "only [one] permissible" reading of the reference. *Id.* at 1113. The partial dissent, for its part, agreed with the panel majority that the PTAB misread the reference, but "believe[d] that the majority [went] too far in reversing the PTAB's anticipation finding." *Id.* at 1118 (opinion of Wallach, J.). The partial dissent reasoned that "the majority exceed[ed] its appellate authority by making an unsupported factual finding in the first instance and by failing to demonstrate that no other factual finding would be 'permissible.'" *Id.* at 1119.

Other decisions abound in which the Federal Circuit has reversed a PTO decision outright, rather than remanding to allow the agency to resolve any remaining issues in the first instance. *See, e.g.*, *Canfield Scientific, Inc.* v. *Melanoscan, LLC*, 987 F.3d 1375, 1383 (Fed. Cir. 2021) (reversing the Board's finding of patentability and reaching the ultimate conclusion that certain patent claims would have been obvious); *PlaSmart, Inc.* v. *Kappos*, 482 Fed. Appx. 568, 574

(Fed. Cir. 2012) (in appeal of inter partes reexamination before PTAB's predecessor, reversing outright the agency's determination that certain claims are not obvious in part based on the court's view of what "would have been a common sense alternative design choice").

3. Not only has the Federal Circuit decided that it may resolve contested issues not passed upon by the agency *after* addressing the basis of the Board's decision—the court has also declared that it sometimes need not address the basis of the Board's decision *at all*. In *In re Comiskey*, 554 F.3d 967 (Fed. Cir. 2009), the Federal Circuit decided that it did not need to "reach the ground relied on by the Board below—that the claims were unpatentable as obvious over [the prior art]—because [the court] conclude[d] that many of the claims [were] barred at the threshold by § 101." *Id.* at 973 (quotation marks omitted). The court attempted to reconcile that view with the *Chenery* principle on the ground that "*Chenery* not only permits [a court] to supply a new legal ground for affirmance, but encourages such a resolution." *Id.* at 975. The Federal Circuit has subsequently applied *Comiskey* to affirm PTO decisions on alternative grounds not addressed by the agency. *See, e.g.*, *In re Aoyama*, 656 F.3d 1293, 1298-1301 (Fed. Cir. 2011). Needless to say, that is inconsistent with how this Court has understood and applied the *Chenery* principle. *See, e.g.*, *Department of Homeland Security* v. *Regents of the University of California*, 140 S. Ct. 1891, 1909 (2020) (reiterating the rule "[r]equiring a new decision before considering new reasons").

The Federal Circuit's practice of reaching new legal grounds goes hand-in-glove with the court's violation of the ordinary remand rule. As this Court made

clear in *Dickinson*, however, the Federal Circuit is not entitled to create sui generis carve-outs to the ordinary operation of administrative law. *See* 527 U.S. at 153. And as this Court made clear in the *Orlando Ventura* trilogy, the ordinary remand rule applies to all manner of agency decisions. The Federal Circuit is simply flouting these rules.

### D. The Federal Circuit's approach warrants the Court's attention.

Not only does the Federal Circuit's practice run afoul of decades of clear case law, but it also leads to unwelcome and anomalous results.

Most notably, the Federal Circuit's failure to remand effectively requires prevailing parties in PTO proceedings to brief all possible alternative grounds for affirmance—including grounds on which they lost before the agency but which ultimately proved not to make a difference to the agency's decision. After all, if an appellee does *not* raise those alternative issues in the Federal Circuit, it runs the risk that the court will reverse the PTAB's decision outright, resolving all remaining issues against the appellee. Yet it is precisely those type of arguments that *Chenery* disfavors in appeals from agency decisions. *See supra*, at 26. Nor can the prevailing party raise them in a cross-appeal. *See supra*, at 29. In short, the Federal Circuit's approach requires a party to either engage in extensive (and potentially needless) briefing, or else forfeit its chance to raise an issue on which the Federal Circuit might later rely.

This case demonstrates the conundrum. As discussed above, obviousness turns on a consideration of the four *Graham* factors. *See supra*, at 12. Here, the

Federal Circuit reversed the agency as to two of those factors—the scope and content of the prior art and the difference between the prior art and the claimed invention. But by reaching out and weighing the factors and deciding the ultimate question of obviousness, the court deprived Baxter of its opportunity to appeal issues decided adversely to it—*e.g.*, the determination that the objective indicia of non-obviousness were "weak." Future litigants who find themselves in Baxter's position will understand the need to brief every possible issue on appeal. Yet it was that sort of ever-expanding litigation that the AIA and IPRs were designed to avoid in the first place.

* * * *

Congress constrained both the scope of an IPR and the scope of an appeal from an IPR. The Federal Circuit is persistently disregarding those constraints and improperly applying standards drawn from district-court appeals, "[r]egardless of the tribunal." And the cost is paid primarily by innovators like Baxter, whose patents survive IPR only to have the Federal Circuit declare them invalid. This Court should restore the boundaries that Congress drew.

## CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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