

No. 21-819

---

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

---

**REPLY BRIEF FOR PETITIONER**

---

MICHAEL I. COHEN  
One Baxter Parkway  
Suite DF2-1E  
Deerfield, IL 60015

GABRIELLA MONTES  
GOODWIN PROCTER LLP  
620 Eighth Avenue  
New York, NY 10018

WILLIAM M. JAY  
*Counsel of Record*  
GOODWIN PROCTER LLP  
1900 N Street, NW  
Washington, DC 20036  
(202) 346-4000  
*wjay@goodwinlaw.com*

GERARD J. CEDRONE  
GOODWIN PROCTER LLP  
100 Northern Avenue  
Boston, MA 02210

April 5, 2022

*Counsel for Petitioner*

---

**RULE 29.6 STATEMENT**

The corporate disclosure statement included in the petition for a writ of certiorari remains accurate.

**TABLE OF CONTENTS**

Introduction.....	1
Argument.....	2
I. The Federal Circuit allows IPR challengers to circumvent § 311(b).....	2
A. Becton attacks a straw-man argument.....	3
B. Becton does not defend the Federal Circuit’s rule or challenge its certworthiness.....	4
II. The Federal Circuit does not follow the “ordinary remand rule.” .....	7
A. Becton fails to show that the Federal Circuit is following the law.....	7
B. Becton fails to show that a remand in this case would be futile.....	8
III. Baxter did not forfeit the questions presented. ....	10
IV. These issues are important.....	11
Conclusion .....	12

## TABLE OF AUTHORITIES

### Cases

<i>B/E Aerospace, Inc. v. C&amp;D Zodiac, Inc.</i> , 962 F.3d 1373 (Fed. Cir. 2020) .....	4
<i>Chemours Co. FC v. Daikin Indus., Ltd.</i> , 4 F.4th 1370 (Fed. Cir. 2021).....	9
<i>In re Comiskey</i> , 554 F.3d 967 (Fed. Cir. 2009) .....	8
<i>Graham v. John Deere Co. of Kansas City</i> , 383 U.S. 1 (1966) .....	2, 4, 5
<i>Koninklijke Philips N.V. v. Google LLC</i> , 948 F.3d 1330 (Fed. Cir. 2020) .....	3, 5
<i>KSR Int’l Co. v. Teleflex Inc.</i> , 550 U.S. 398 (2007) .....	4, 5
<i>Qualcomm Inc. v. Apple Inc.</i> , 24 F.4th 1367 (Fed. Cir. 2022).....	5, 6, 11

### Statutes

35 U.S.C. § 311(b).....	1, 2
35 U.S.C. § 312 .....	3
35 U.S.C. § 316 .....	3

## INTRODUCTION

Becton does not dispute that if the Federal Circuit follows either practice identified in the petition—*i.e.*, expanding the categories of prior art that litigants may use to attack duly issued patents in IPR proceedings, or failing to follow the “ordinary remand rule” in appeals from those proceedings—then those practices are wrong and this Court should correct them. Instead, Becton argues that the Federal Circuit is *not* following those practices—or, at least, that this case does not present them. But Becton’s contentions ignore both what the Federal Circuit said and what Baxter actually argues.

On the first question, for example, Becton stresses that Congress contemplated at least *some* role for expert testimony in IPRs. But Baxter has never argued otherwise. The issue is not whether IPR challengers may use expert testimony *at all*, but whether they may use such evidence to supply claim limitations that are necessary to invalidate a patent but are not found in “patents and printed publications.” 35 U.S.C. § 311(b). The Federal Circuit has unequivocally held that they may—and Becton did so here. On *that* question, the one actually presented, Becton fails to refute either the Federal Circuit’s general rule—that expert testimony may be used for that purpose “regardless of the tribunal,” eviscerating § 311(b)’s limitation—or its own improper reliance on expert testimony to invalidate Baxter’s patent.

Becton’s arguments on the second question fare no better. Its principal claim is that a remand would be futile because nothing is left for the Board to address. But that is not true: the Board did not have an oppor-

tunity to weigh the elements of obviousness (the *Graham* factors) in light of the Federal Circuit’s decision. And the case law makes clear that *the Board* was entitled to do so in the first instance. Moreover, if Becton were right, then Baxter would *never* receive one full and fair opportunity to appeal the issues that the Board decided against it; Baxter could not appeal the unfavorable-but-immaterial aspects of the Board’s now-reversed decision because Baxter *prevailed* before the Board.

Faced with these difficulties, Becton claims that, even if the issues are meritorious, Baxter forfeited them. But Baxter’s arguments below encompassed the questions presented—and, to the extent they were not specifically argued, that is because they were foreclosed by circuit precedent or the case’s posture. In short, nothing stands in the way of this Court’s review, which is urgently needed to correct two wayward lines of authority that, every time they recur, harm the inventive community and the public.

## ARGUMENT

### **I. The Federal Circuit allows IPR challengers to circumvent § 311(b).**

Consistent with the nature of IPR proceedings, which Congress designed as a streamlined alternative to district-court litigation, § 311(b) requires an IPR challenger to show that every limitation in a challenged patent claim can be found in “prior art consisting of patents or printed publications.” 35 U.S.C. § 311(b); Pet. 14-17. In that respect, Congress created a rule for IPRs that is different from the rule in other tribunals. Nevertheless, the Federal Circuit has expressly held that the same rule applies “[r]egardless

of the tribunal,” and has repeatedly allowed challengers to rely on other forms of evidence to supply claim limitations *not* found in patents or printed publications. Pet. 17-21 (quoting *Koninklijke Philips N.V. v. Google LLC*, 948 F.3d 1330, 1337 (Fed. Cir. 2020)). Becton fails to justify this departure from the plain text of § 311(b).

**A. Becton attacks a straw-man argument.**

Becton spends a substantial portion of its opposition arguing (at 12-14) that the Patent Act—specifically, 35 U.S.C. §§ 312 and 316—“explicitly permits expert testimony in IPRs.” That argument is a non sequitur: it does not respond to anything in the petition itself. Baxter has never suggested that the parties in an IPR may not use expert testimony *at all*. The problem in this case—and the others discussed in the petition—is not the use of expert testimony *in general*, such as to prove the knowledge of a person of ordinary skill in the art. Rather, it is the use of expert testimony *to supply a missing claim limitation*. See Pet. 15 (“[C]hallengers may not use extrinsic evidence *to supply claim limitations* that are not found in the ‘patents or printed publications’ themselves.” (emphasis added)). That specific type of gap-filling is what § 311(b) expressly prohibits—and what the Federal Circuit allowed here. See Pet. 14-21.

Becton arrives at its distorted presentation of Baxter’s argument only by misleadingly truncating quotations from the petition. According to Becton, “Baxter argues that ‘[g]iven the limitations on discovery, the lack of live witnesses, and the tight time constraints, the Board is not equipped to referee expert disputes.’” Br. in Opp. 13 (quoting Pet. 16). But what

the petition *actually* argues is that “[g]iven 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.’*” Pet. 16 (emphasis added). Becton changes Baxter’s argument by pretending the emphasized language does not exist.

Becton’s vigorous pummeling of its straw man should not distract from the fundamental point: even if expert testimony is proper for *some* purposes, it may not be used for *this* purpose—proving whether a particular claim limitation existed in the prior art.

**B. Becton does not defend the Federal Circuit’s rule or challenge its certworthiness.**

In the end, even Becton agrees: under § 311(b), “patents and printed publications are the only materials that can form the ‘basis’ for a claim of obviousness.” Br. in Opp. 12. Yet that is not the rule the Federal Circuit applies.

1. Becton conspicuously fails to dispute that the Federal Circuit has adopted a rule that leaves § 311(b) a nullity; it has no response to the cases cited in the petition, including *Philips* and *B/E Aerospace*. See Pet. 20-21.

The most Becton can offer is a citation to two of this Court’s obviousness decisions to argue that the Court has approved the use of expert testimony to show “what an artisan exercising reasonable creativity would find obvious.” Br. in Opp. 16 (citing *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007); *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966)).



As Baxter explained, however, those decisions arose in appeals from district-court actions well before § 311(b) was enacted. Pet. 20. That cuts *against* Becton’s argument. Congress, well aware that *KSR* and *Graham* allowed *district courts* to consider all types of prior art as the basis of an obviousness challenge, chose to limit *the Board* to a narrow category of “patents and printed publications.” Indeed, that is the sole purpose of that statutory language—to apply a more limited set of prior art in this tribunal specifically. Yet the Federal Circuit has deprived it of any effect and insisted that the same rule applies “[r]egardless of the tribunal.” *Philips*, 948 F.3d at 1337.

The recent *Qualcomm* decision confirms that the Federal Circuit continues to commit this same error. Becton cites that decision as supposed proof that the Federal Circuit understands that statements that “do not qualify as a ‘patent[] or printed publication[]’” cannot “form the ‘basis’ of an IPR challenge.” Br. in Opp. 17 (quoting *Qualcomm Inc. v. Apple Inc.*, 24 F.4th 1367, 1374-1375 (2022)). But Becton ignores the opinion’s pivotal passage. Citing *Philips*, the court made clear that it thought the challenger in that case *could* use the background statements at issue (which were not themselves “patents or printed publications”) to “supply[] a missing claim limitation.” *Qualcomm*, 24 F.4th at 1376. And to say that evidence can supply a missing claim limitation *is* to treat the evidence as a “basis” of the obviousness determination—exactly what § 311(b) prohibits.

Thus, *Qualcomm* confirms the persistence of the Federal Circuit’s statutory defiance. This case is just one of many in which the Federal Circuit has allowed

IPR challengers to use evidence that is *not* a patent or printed publication—like the background statements in *Qualcomm*, or the expert testimony in *Philips*—to “supply[] a missing claim limitation.” *Id.*

2. Unable to defend the Federal Circuit’s general rule, Becton seeks to shoehorn this case into the permissible scope of an IPR. In particular, Becton argues (at 15) that the Federal Circuit was not citing Dr. Young’s testimony to “fill in the gaps” of the Liff reference in violation of § 311(b), but rather that it was using his testimony merely to elucidate the “*combination* of [limitations contained in] Liff and Alexander.” But that characterization conflicts with what the Federal Circuit actually said and did.

The Court need look no further than the Federal Circuit’s opinion. The panel began by acknowledging that Liff does not “directly disclose[]” the highlighting limitation. Pet. App. 12a. The court then faulted the Board for “looking to Liff as the *only* source a person of ordinary skill would consider for what ‘additional information might be relevant.’” Pet. App. 14a (emphasis added). What other sources did the Federal Circuit consider relevant? Its opinion identified just one: Dr. Young’s testimony about what “a person of ordinary skill in the art would have understood.” Pet. App. 13a-15a.

In short, neither the relevant passages of the Federal Circuit’s opinion (Pet. App. 13a-15a) nor the relevant paragraphs of Dr. Young’s testimony (C.A. App. 1497) discussed the contents of Alexander or the manner in which a skilled artisan would have combined Alexander and Liff. Becton’s argument to that effect

is just a post hoc recharacterization of the decision below.<sup>1</sup>

## **II. The Federal Circuit does not follow the “ordinary remand rule.”**

After concluding that the prior art taught all the patent’s limitations, the court should have remanded for the Board to make the ultimate obviousness determination in the first instance. Yet the Federal Circuit consistently ignores this ordinary remand rule. *See* Pet. 24-33. Becton offers two arguments why the Court need not address the Federal Circuit’s departure from this fundamental principle of administrative law. Both miss the mark.

### **A. Becton fails to show that the Federal Circuit is following the law.**

Once again, Becton fails to address the specific decisions identified in the petition—here, decisions showing the Federal Circuit’s pattern of refusing to remand cases to the Board. *See* Pet. 30-32. Instead, Becton argues (at 23) that the Federal Circuit has *sometimes* remanded to the Board, showing (Becton says) that the court is properly making case-by-case determinations about whether to remand. But at best Becton has shown discord in the Federal Circuit’s case

---

<sup>1</sup> Similarly, Becton’s discussion of counsel’s supposed concession below recasts the Federal Circuit’s decision. In Becton’s telling (at 17-18), the court merely used counsel’s statement as supplemental support for a conclusion already supported by the evidence. But the court’s opinion shows otherwise: the “concession” was the *only* thing that allowed the court to bridge the gap between the language of Alexander (“*may* verify”) and that of the challenged claim (“*must* be verified”). Pet. App. 5a-8a.

law. And that entrenched confusion would be reason alone to grant certiorari.

But there is more than just discord. As Baxter explained, the Federal Circuit has elevated its disregard of administrative-law principles from entrenched practice to formal doctrine. In fact, the Federal Circuit has held that it can disregard the basis for the agency's decision altogether, resolving cases on its own alternative grounds. *See* Pet. 32 (discussing *In re Comiskey*, 554 F.3d 967 (Fed. Cir. 2009)). Becton has no response—it fails to discuss *Comiskey* at all. That decision makes it impossible for Becton to brush aside the cases in which the Federal Circuit has violated the ordinary remand rule as “outliers.” Br. in Opp. 24. The Federal Circuit has all but announced its view that it can ignore these foundational administrative-law principles.

**B. Becton fails to show that a remand in this case would be futile.**

Becton also argues (at 20-21) that a remand would be futile because the Board already deemed Baxter's evidence of secondary considerations “weak,” and the ultimate determination of obviousness is a question of law. But those arguments disregard both controlling decisions and the posture of this case.

As Baxter explained, the ordinary remand rule applies to questions of law—including mixed questions of law and fact and pure questions of law on which the agency receives deference. Pet. 27. So Becton's observation that the *ultimate* question of obviousness (as opposed to the factual findings that underlie it) is a legal determination is irrelevant. Under the ordinary

remand rule, the agency is supposed to have the first opportunity to address *all* relevant questions.

Becton is also wrong that a finding of obviousness would be a foregone conclusion on remand in this case. True, the agency opined that Baxter’s evidence of objective indicia of nonobviousness was “weak.” Pet. App. 57a. As an initial matter, however, the Board’s entire discussion of these objective indicia was unnecessary to its decision. It never had to decide whether the objective indicia could make the difference in showing the claims patentable. Once the Federal Circuit disagreed with the Board’s decision, however, the Board was required to do exactly that type of weighing. Pet. 28-30; *Chemours Co. FC v. Daikin Indus., Ltd.*, 4 F.4th 1370, 1380 (Fed. Cir. 2021) (Dyk, J., concurring in part and dissenting in part). Becton argues (at 22 n.4) that the objective indicia could not possibly move the needle *here* because the Federal Circuit found Becton’s prima facie showing of obviousness to be “strong,” but that is incorrect. The Federal Circuit used the term “strong showing of obviousness” only in its general statement of the law—not in its discussion of this particular case. Pet. App. 17a.<sup>2</sup>

In any event, even if the Board reached the same conclusion on remand, that still does not mean a remand would be futile. First, remand would give the agency the opportunity to bring its expertise to bear on the ultimate question of obviousness in light of the Federal Circuit’s legal conclusions—exactly as the ordinary remand rule intends. Second, a remand would

---

<sup>2</sup> And if the Federal Circuit *did* make its own judgment that Becton’s prima facie showing was comparatively “strong,” that is just another example of the Federal Circuit making a determination that was reserved to the Board in the first instance.

also allow Baxter to challenge factual and legal determinations that went against it in the Board's first decision. For example, given the way this case has unfolded, Baxter has *never* had a chance to appeal the Board's assessment of objective indicia and the Board's conclusion that they were "weak." *See* Pet. 29. Becton does not dispute the point. A remand would give Baxter the opportunity to appeal those issues that, to date, it has never had one full and fair opportunity to appeal.<sup>3</sup>

### **III. Baxter did not forfeit the questions presented.**

Unable to dispute that the Federal Circuit has gone astray in two ways that warrant this Court's review, Becton argues that the Court should nevertheless decline to take this case because Baxter has forfeited the questions presented. But Becton's forfeiture theories have no support in the law or the record.

First, Becton argues (at 7, 10-12) that Baxter did not challenge Becton's use of Dr. Young's testimony below. But Becton relies on the same straw-man characterization discussed above—it suggests, erroneously, that Baxter is seeking to wholly exclude expert testimony from IPRs. *See supra*, at 3-4. Since that is not Baxter's argument *anywhere*, Becton scores no points by showing that Baxter did not argue it *below*. And as to Baxter's *actual* argument—that Becton used expert testimony to supply claim limitations—it was foreclosed by circuit precedent, especially *Philips*,

---

<sup>3</sup> For these same reasons, Becton's argument (at 19) that the ordinary remand rule is "not an inexorable command" and its citation (at 19-20) of decisions that have declined to remand where there was no further work for the agency are inapplicable here.

holding that an IPR petitioner can use evidence like expert testimony to supply elements not found in the prior-art reference itself. *See supra*, at 4-5. Indeed, as discussed above, the Federal Circuit recently confirmed in *Qualcomm* that it meant what it said in *Philips*. *See supra*, at 5-6. Baxter was not required to make an argument that was foreclosed by circuit precedent.

Second, Becton argues (at 10, 18-20) that Baxter did not cite the “ordinary remand rule” in response to Becton’s request that the Federal Circuit reverse the Board. But Becton’s own brief repeatedly acknowledged the potential need for a remand—a point Becton now glosses over. *See* Becton C.A. Br. 5, 25, 28, 40. In any event, Baxter’s brief made clear that it thought no remand was warranted because *the Federal Circuit should have affirmed*. Again, Baxter had no opportunity to cross-appeal those aspects of the Board’s decision that went *against* Baxter, because it ultimately prevailed before the Board. *See supra*, at 9-10. In the posture of this case, it was plain that a remand was necessary if the Federal Circuit disagreed with the Board’s reading of Liff.

Finally, Becton repeatedly argues (at 10-12, 19) that Baxter did not raise the questions presented in its rehearing petition in the Federal Circuit. That argument is insubstantial. Filing a petition for a panel rehearing or rehearing en banc is not a prerequisite to seeking certiorari in this Court.

#### **IV. These issues are important.**

Both questions presented merit the Court’s attention. The Federal Circuit’s distortion of § 311(b) harms both the inventive community and the broader

public. *See* Pet. 22-23. And the Federal Circuit’s failure to follow the ordinary remand rule impedes judicial review of agency decisions and violates separation-of-powers principles. *See* Pet. 33-34; Amicus Br. 7-17. Becton does not dispute these points—it instead argues that the Federal Circuit has not actually committed these errors. As discussed, however, the Federal Circuit has gone astray both in this case and many others. This Court’s review is urgently needed.

### CONCLUSION

The Court should grant the petition.

Respectfully submitted.

MICHAEL I. COHEN  
One Baxter Parkway  
Suite DF2-1E  
Deerfield, IL 60015

GABRIELLA MONTES  
GOODWIN PROCTER LLP  
620 Eighth Avenue  
New York, NY 10018

WILLIAM M. JAY  
*Counsel of Record*  
GOODWIN PROCTER LLP  
1900 N Street, NW  
Washington, DC 20036  
(202) 346-4000  
*wjay@goodwinlaw.com*

GERARD J. CEDRONE  
GOODWIN PROCTER LLP  
100 Northern Avenue  
Boston, MA 02210

April 5, 2022

*Counsel for Petitioner*