

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

BRIEF IN OPPOSITION

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QUESTIONS PRESENTED

1. Whether Baxter Corporation Englewood (Baxter) has forfeited its arguments by failing to present them below.
2. Whether 35 U.S.C. § 311(b) prohibits the citation of expert testimony in the course of a ruling that patent claims would have been obvious over a combination of prior art patents, despite 35 U.S.C. § 312(a)(3)(B) permitting the filing of “affidavits or declarations of supporting evidence and opinions, if the petitioner relies on expert opinions,” and 35 U.S.C. § 103 providing that obviousness is determined from the perspective of “a person having ordinary skill in the art.”
3. Whether the Federal Circuit’s case-specific decision to reverse after concluding that the Patent Trial and Appeal Board’s decision was not supported by substantial evidence was proper where Baxter never asked for a remand, the ultimate issue of obviousness is a question of law, and the Board already ruled that Baxter’s evidence of secondary considerations was “weak.”

CORPORATE DISCLOSURE STATEMENT

Respondent Becton, Dickinson and Company (BD) has no parent corporation. No publicly held company owns more than 10% of BD's stock.

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INTRODUCTION

Baxter's petition is not based on any issue that it argued before the Federal Circuit, either at the panel stage or in its petition for rehearing en banc. Instead, Baxter presents entirely new arguments to challenge the Federal Circuit's ruling that the claims of U.S. Patent No. 8,554,579 ('579 patent) would have been obvious in light of two prior art patents. Baxter's forfeiture of its arguments deprived the Federal Circuit of the opportunity to address them and is, by itself, fatal to Baxter's petition.

Moreover, had Baxter presented its current arguments below, the Federal Circuit undoubtedly would have explained that both arguments rest on a false premise because they misconstrue the basis for the Federal Circuit's ruling. Baxter's arguments are also unsupported by the legal authorities on which Baxter purports to rely. And although Baxter strains to identify larger legal questions, its arguments quickly devolve into a factbound challenge to a decision that involved no error and would, in any event, be a bad vehicle for addressing the questions presented.

First, Baxter's forfeited argument that Respondent Becton Dickinson (BD) improperly relied on expert testimony misunderstands both the Federal Circuit's decision and the statute. Baxter's claims were declared unpatentable "on the basis of prior art consisting of patents or printed publications." 35 U.S.C. § 311(b). Specifically, the Federal Circuit based its ruling on two prior art patents: Alexander and Liff. The Federal Circuit concluded that "the Board's determination that *Alexander* does not teach the verification limitation is not supported by substantial evidence." Pet. App. 10a (emphasis added). The Federal Circuit similarly

concluded that “the highlighting limitation would have been obvious to one of ordinary skill in the art in view of *Alexander and Liff*.” Pet. App. 15a (emphasis added).

Contrary to Baxter’s characterization, the Federal Circuit’s discussion of expert testimony did not exceed the proper bounds of an inter partes review (IPR). The Board cited un rebutted expert testimony simply to illustrate how a person of ordinary skill in the art would have understood the prior art and combined the Alexander and Liff patents using “ordinary creativity.” Pet. App. 14a (quoting *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007)). This was an appropriate use of such evidence. Indeed, Congress expressly provided for the use of expert testimony in IPRs. Section 312 of the Patent Act, which Baxter ignores, states that IPR petitioners may submit “affidavits or declarations of supporting evidence and opinions, if the petitioner relies on expert opinions.” 35 U.S.C. § 312(a)(3)(B). Section 103 of the Patent Act, which Baxter also ignores, provides that the obviousness of a patent claim must be determined from the perspective of “a person of ordinary skill in the art”—a standard that often requires expert testimony. 35 U.S.C. § 103. The Federal Circuit’s consideration of expert testimony in this case was in keeping with those statutory provisions. And, at a minimum, Baxter’s forfeiture of the argument and the Federal Circuit’s understanding of its own ruling as being based on the Alexander and Liff patents make this case a bad vehicle to address § 311(b).

Baxter’s second argument, that the Federal Circuit should have remanded to the Board rather than reversing, fares no better. Again, Baxter failed to raise this argument at any stage below even though BD clearly asked for reversal. Baxter thus deprived the Federal

Circuit of the opportunity to respond to its current arguments for remand.

Moreover, Baxter's argument that the Federal Circuit violated an established rule of procedure is belied by the cases on which it relies. The trio of immigration cases that Baxter cites all involved new questions that had never been addressed by the agency in the first instance and implicated its particular expertise. But here, there was no such issue for the Board to consider for the first time on remand, and Baxter's petition is notably vague on exactly what it thinks the Board needs to decide and why it would make any difference. The Board had already found that Alexander and Liff taught all the other claim limitations and that "one of ordinary skill in the art would have been motivated to combine Alexander and Liff." Pet. App. 4a. The Board had also ruled that Baxter's evidence of "secondary considerations" was "weak." Pet. App. 57a. Once the Board's errors on the verification and highlighting limitations were corrected, the invalidation of Baxter's claims was a foregone conclusion. Further, in contrast to issues that may arise in other contexts, "[t]he ultimate judgment of obviousness is a legal determination" that a court is competent to make. *KSR*, 550 U.S. at 427.

In any event, Baxter's disagreement about the decision to remand in this case is a factbound issue that does not warrant review. The Federal Circuit routinely remands where appropriate, and Baxter's attempt to fit this case into a larger pattern is unavailing and, if anything, illustrates why this case would not be a good vehicle for addressing Baxter's alleged concerns.

The petition should be denied.

STATEMENT

A. Telepharmacy Technology

A pharmacist's responsibilities can include preparing, compounding, packaging, and labeling medication. C.A.J.A. 1529(1:14-17). Where permitted by applicable regulations, pharmacy functions may be performed by a non-pharmacist, such as a pharmacy technician or registered nurse. "When a non-pharmacist performs such functions a pharmacist must generally verify their work." C.A.J.A. 1529(1:21-22).

Because having a pharmacist physically present is not always feasible or efficient, telepharmacy systems leverage computers and other technology to enable remote inspection and supervision of traditional pharmacy practices. As of the earliest claimed priority date of Baxter's '579 patent, telepharmacy was already practiced throughout the United States. C.A.J.A. 1478.

Prior art U.S. Patent No. 8,374,887 (Alexander) disclosed a "system and method for remotely supervising and verifying pharmacy functions performed by a non-pharmacist at an institutional pharmacy." C.A.J.A. 1519(Abstract). Alexander taught that a remote pharmacist can supervise the work of a non-pharmacist filling a medication dose based on images and "corresponding documentation" transmitted to the remote pharmacist's computer system. C.A.J.A. 1529(2:12-53). Alexander explained that the remote pharmacist may verify "the pharmacy work in various stages of completion." C.A.J.A. 1531(5:4-11). Of particular relevance, Alexander stated that "a remote pharmacist may verify each step as it is performed and may provide an indication to a non-pharmacist performing the pharmacy [work] that the step was performed correctly."

C.A.J.A. 1533(9:49-52). To enable such verification, “a pharmacist may remotely verify pharmacy work via a realtime collaboration tool” using “real-time” images. C.A.J.A. 1533(9:29-34); *see also* C.A.J.A. 1533(9:34-45).

U.S. Patent No. 6,581,798 (Liff) disclosed another telepharmacy system that “combine[d] computer hardware and software, a telecommunications capability, and a medication container dispensing cabinet to form a complete in-office dispensing system.” C.A.J.A. 1609(2:8-11). Liff’s system dispensed prepackaged drugs in response to remote commands from a “physician, pharmacist, or other licensed practitioner.” C.A.J.A. 1609(2:11-38). Liff taught an interactive user interface screen with multiple areas for the user to input information and to request more information by highlighting certain inputs on the screen. C.A.J.A. 1617(17:55-18:41); C.A.J.A. 1578.

B. Proceedings Below

1. The inter partes review

Baxter’s ’579 patent, titled “Management, Reporting and Benchmarking of Medication Preparation,” claims various methods and systems that can be used in conducting telepharmacy. C.A.J.A. 65. BD filed an IPR petition challenging claims 1-12 and 22 of the ’579 patent as obvious on multiple grounds, including most relevantly over the Alexander and Liff patents.¹ C.A.J.A. 5017.

¹ The Federal Circuit ultimately did not consider the Morrison published patent application because it found the patent obvious in light of Alexander and Liff. Pet. App. 15a.

In its final written decision, the Patent Trial and Appeal Board found that a skilled artisan would have been motivated to combine Alexander with Liff, Pet. App. 48a-51a, and that the combination of Alexander and Liff disclosed almost every contested limitation of the challenged claims. Pet. App. 61a-64a; Pet. App. 68a-73a. The Board also concluded that Baxter’s “evidence of secondary considerations,” such as commercial success and industry praise for the product, was “weak.” Pet. App. 57a. But the Board ultimately concluded that BD’s challenge fell short because the prior art allegedly did not teach two claim limitations: (1) the “verification” limitation, and (2) the “highlighting” limitation.

The verification limitation recites that “each of the steps must be verified as being properly completed before the operator can continue with the other steps of drug preparation.” C.A.J.A. 5044. BD argued that Alexander’s teaching that “a remote pharmacist may verify each step as it is performed and may provide an indication to a non-pharmacist performing the pharmacy [work] that the step was performed correctly” taught verification. C.A.J.A. 5028 (original emphasis omitted); C.A.J.A. 5044-5045 (original emphasis omitted). But relying on an argument that Baxter later abandoned on appeal and testimony from Baxter’s expert that did not even address the relevant passage in Alexander, the Board held that Alexander did not require verification before the operator can continue.

The highlighting limitation recites “prompts that can be highlighted by an operator to receive additional information relative to one particular step” in a drug preparation protocol. C.A.J.A. 5043. The ’579 patent gives the example of a “Detail button” and states that “the user can simply highlight this particular button

(as by “clicking” the box)” to receive more information. Pet. App. 10a (quoting the ’579 patent’s description of Figure 10). BD argued that the combination of Alexander and Liff taught this limitation because it would have been obvious to apply the highlighting from Liff’s user interface to the drug preparation steps in Alexander. C.A.J.A. 5025-5027; C.A.J.A. 1484-1485(¶36); C.A.J.A. 1494-1498(¶¶59-66). The Board agreed with BD that a skilled artisan combining Alexander and Liff “would have considered it obvious to provide a set of drug preparation steps on a computer.” Pet. App. 64a. The Board also acknowledged Liff’s disclosure of highlighting. Pet. App. 66a. But relying on the Liff reference in isolation, the Board held that Liff itself did not teach “highlight[ing] prompts in a drug formulation context.” Pet. App. 67a. The Board admitted, however, that “this presents a close case.” *Id.*

Both parties relied on expert testimony during the IPR to explain how a person of skill in the art would have viewed the prior art references. At no point did Baxter object to the use of expert testimony under 35 U.S.C. § 311(b).

2. The Federal Circuit’s decision

The Federal Circuit reversed, holding that the Board should have declared Baxter’s claims unpatentable. Pet. App. 1a. The Federal Circuit explained that the Board’s ruling on the verification limitation was not supported by substantial evidence. Pet. App. 10a. It disagreed with the Board’s attempt to draw a distinction between Alexander’s language that a remote pharmacist *may* verify each step and the ’579 patent’s language that the pharmacist *must* verify each step. Pet. App. 6a. Instead, the court held that it was “quite clear from the context of Alexander” that the term

“may” as used in the patent “does not mean ‘occasionally,’ but rather that one ‘may’ choose to systematically check each step.” *Id.* Therefore, there was “no significant difference between that teaching of Alexander and the ’579 patent’s verification requirement.” Pet. App. 7a.

The court rejected Baxter’s “attempts to sustain” the Board’s verification ruling on “grounds not adopted by the Board.” Pet. App. 8a. Baxter’s first argument depended on taking testimony of BD’s expert, Dr. Young, out of context to imply that Alexander’s system did not stop the operator from proceeding if a prior step was unverified. Pet. App. 6a; *see also* BD C.A. Br. 8-9 & n.1. But the Federal Circuit explained that “[r]equiring authorization before proceeding necessarily stops the work if the authorization is not forthcoming.” Pet. App. 8a. The court also noted that Baxter’s counsel had conceded at oral argument that a non-pharmacist who proceeded without authorization would likely be disciplined. Pet. App. 6a, 8a. The court further explained that Baxter was misreading the claims. Pet. App. 8a-9a.

Turning to the highlighting limitation, the Federal Circuit held that the “limitation would have been obvious to one of ordinary skill in the art in view of Alexander and Liff.” Pet. App. 15a. The Federal Circuit noted that the Board had found it obvious to provide a set of drug preparation steps on a computer, and that “[t]he Liff reference teaches highlighting in the pharmacy context.” Pet. App. 11a. The Federal Circuit then explained that although Liff itself did not directly disclose highlighting to receive additional information about a drug preparation step, the Board had “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. The Federal Circuit observed that BD was instead relying on a *combination* of prior art patents to teach highlighting by “argu[ing] that ‘Liff discloses basic computer functionality—i.e., using prompts that can be highlighted by the operator to receive additional information—that would render the highlighting limitation obvious when applied in combination with other references,’ primarily Alexander.” Pet. App. 13a (emphasis added).

Examining that combination, the Federal Circuit held that “[t]he Board’s determination that the highlighting limitation is not obvious over Alexander and Liff is not supported by substantial evidence.” Pet. App. 15a. Quoting this Court’s decision in *KSR*, the Federal Circuit stated that a person skilled in the art considering the combination of elements is a “person of ordinary creativity, not an automaton” and that the “combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” Pet. App. 14a (quoting *KSR*, 550 U.S. at 421, 426). The Federal Circuit also noted that BD’s expert, Dr. Young, had provided unrebutted testimony regarding a person of ordinary skill in the art’s perspective on the references, including a skilled artisan’s understanding that additional information regarding drug preparation steps could be displayed in the tabs of Liff’s computer interface. Pet. App. 15a.

Finally, the Federal Circuit affirmed the Board’s finding that Alexander is prior art under 35 U.S.C. § 102(e)(2). Pet. App. 15a. It also noted that the finding of obviousness was not impacted by secondary considerations given that the Board found that Baxter’s evidence on this point was “weak,” and that “Baxter does not meaningfully argue that the weak showing of

secondary considerations here could overcome the showing of obviousness based on the prior art.” Pet. App. 17a.

Based on these holdings, the court reversed the Board’s decision. Pet. App. 17a. BD’s opening brief expressly sought this relief. *See* BD C.A. Br. 5, 40. But Baxter never argued in its responsive brief that out-right reversal would be the wrong remedy. Nor did Baxter ever object that the expert testimony cited by BD would violate 35 U.S.C. § 311(b).

3. Baxter’s petition for rehearing

Baxter filed a motion for rehearing en banc on two grounds. First, it argued that the panel had exceeded its authority by purportedly addressing a claim construction issue not appealed by either party, relying on evidence outside the record, and departing from the substantial review standard. C.A. Dkt. 34, at 3-13. Second, Baxter argued that the panel erred in holding that Alexander was prior art. *Id.* at 14-15.

Baxter’s petition did not raise either of the issues it now presents to this Court. The Federal Circuit denied the petition on September 1, 2021. Pet. App. 89a.

REASONS FOR DENYING THE PETITION

I. BAXTER’S FORFEITED SECTION 311 ARGUMENT DOES NOT WARRANT REVIEW

A. Baxter Forfeited Its Argument

In the years of proceedings in this matter—before the Board, the Federal Circuit panel, and in its en banc petition—Baxter never made so much as a passing mention of its argument that § 311(b) precludes reliance on expert testimony in IPRs. Far from objecting

to BD's use of expert testimony, Baxter made arguments before the Board that tried to read Dr. Young's testimony in a manner favorable to Baxter. *See* Pet. App. 8a. Baxter also introduced its own expert testimony by Dr. Jeffrey Brittain. Pet. App. 13a; Pet. App. 29a ("In support of its patentability challenges, Petitioner relies on the testimony of Dr. Marc Young ... Patent Owner relies on the testimony of Jeffrey R. Brittain."). In the course of making these arguments and introducing its own expert testimony, Baxter never took the position that the inclusion of this testimony in the record or reliance on it was improper.

Nor did Baxter present its argument that BD was using expert testimony to "fill in gaps" in the prior art to the Federal Circuit, despite BD's opening brief before the Federal Circuit citing Dr. Young's testimony for the same purpose for which the court ultimately relied on it. *See* BD C.A. Br. 31, 36. Baxter also failed to make this argument in its petition for rehearing en banc. As a result, the Federal Circuit had no opportunity to clarify the role that Dr. Young's testimony played in its decision-making process.

Where, as here, an "argument was never presented to any lower court," it "is ... forfeited." *OBB Personenverkehr AG v. Sachs*, 577 U.S. 27, 37 (2015); *see also Calhoun v. United States*, 568 U.S. 1206, 1207 (2013) (Sotomayor, J., concurring in the denial of petition for certiorari because petitioner's arguments "were forfeited when [he] failed to press them on appeal" before the court of appeals). The forfeiture is particularly egregious in this case because Baxter made other arguments about the Board's statutory authority in arguing that the Board should not have relied on Alexander as a prior art reference. The Federal Circuit properly rejected that challenge on the merits, and Baxter has

now abandoned it. *See* Pet. App. 16a. If Baxter had a legitimate argument under § 311, it should have raised it below as it did with other similar arguments.

For this reason alone, the Court should not grant certiorari to consider the Federal Circuit’s use of expert testimony.

B. Baxter’s Proposed Interpretation Of The AIA Is Unsupportable

Even if its argument were properly preserved, Baxter’s reading of § 311 cannot be reconciled with other provisions of the statute. In stark contrast to Baxter’s characterization, the Patent Act explicitly permits expert testimony in IPRs.

Baxter points to the requirement in § 311 that a petitioner may request to cancel the claims of a patent as unpatentable “only on the basis of prior art consisting of patents or printed publications.” 35 U.S.C. § 311(b). The purpose of § 311(b) was not to exclude reliance on expert testimony but rather to avoid the complications that would come with relying on other categories of prior art defined in 35 U.S.C. § 102, such as evidence that an invention was in public use or on sale before the priority date. *See* S. Rep. No. 111-18, at 31 (2009) (“the amendment struck the language of the original bill that would have permitted a challenger to raise evidence that the claimed invention was in public use or on sale in the United States as a basis for invalidating the patent in an inter partes reexamination”).

Even though patents and printed publications are the only materials that can form the “basis” for a claim of obviousness, nothing in the statute prevents the use of expert testimony as a mechanism for explaining *how* these “patents or printed publications” render the

claims obvious to a person of skill in the art. To the contrary, the text of the next statutory provision shows that Congress intended petitioners to use expert testimony in IPR petitions.

Section 312, which Baxter never addressed in its petition, requires that petitions identify “the evidence that supports the grounds for the challenge to each claim, including ... affidavits or declarations of supporting evidence and opinions, if the petitioner relies on expert opinions.” 35 U.S.C. § 312(a)(3)(B). The patent owner is similarly required to include “through affidavits or declarations ... expert opinions on which the patent owner relies in support of the response.” *Id.* § 316(a)(8). Baxter does not explain why Congress would have included provisions explicitly discussing the inclusion of expert testimony in both IPR petitions and responses if it had intended that expert testimony would not be considered in these proceedings.

Other aspects of Baxter’s argument show similar logical gaps. For example, 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.” Pet. 16. But Congress clearly disagreed when it provided for expert testimony to be submitted in IPRs. Congress also instructed the Director to promulgate standards for “the deposition of witnesses submitting affidavits or declarations.” 35 U.S.C. § 316(a)(5)(A). Experts are deposed under oath, and relevant excerpts of their testimony are submitted to the Board. Moreover, the Board’s rules allow a party to request live testimony where appropriate, something Baxter never did here. *See, e.g., K-40 Elecs., LLC v. Escort Inc.*, IPR2013-00203, Paper 34, at 4 (PTAB May 21, 2014) (preceden-

tial) (granting motion to present live testimony).² If expert testimony could not be considered, Congress would not have included provisions directed at handling the manner in which this process would occur.

Finally, the statutory obviousness standard, set out in 35 U.S.C. § 103, reinforces the appropriateness of using expert testimony. The obviousness analysis focuses on whether the claimed invention would have been obvious to “a person of ordinary skill in the art.” Expert testimony is often necessary to provide that perspective on how a person of ordinary skill would think about the prior art and combine the references. Baxter’s depiction of IPRs as including only patents and printed publications is inconsistent with Congress’s intent and with the manner in which these proceedings have been conducted since their inception.

C. The Federal Circuit’s Consideration Of Expert Testimony And Other Evidence Was Consistent With The Statutory Requirements

Baxter’s petition misconstrues the way that the Federal Circuit used expert testimony in this case. The Federal Circuit cited expert testimony in the manner that the Patent Act contemplates—as evidence that supports, but is not itself the “basis” for, a challenge. Specifically, the Federal Circuit cited unrebutted expert testimony to shed light on how a person of ordinary skill would have viewed and combined the prior art Alexander and Liff patents.

² Indeed, Baxter’s own amicus argues that IPRs “embrace[] the vast majority of best practices that have been identified for any adjudication that requires an evidentiary hearing.” Vishnubhakat Br. 14.

The Alexander and Liff patents were clearly the “basis” for BD’s challenge and the Federal Circuit’s decision. On the verification limitation, the Federal Circuit concluded that “[t]here is no significant difference between th[e] teaching of *Alexander* and the ’579 patent’s verification requirement.” Pet. App. 7a (emphasis added). The Federal Circuit thus held that “the Board’s determination that *Alexander* does not teach the verification limitation is not supported by substantial evidence.” Pet. App. 10a (emphasis added). Similarly, for the highlighting limitation, the court based its holding on its conclusion that “the highlighting limitation would have been obvious to one of ordinary skill in the art in view of *Alexander and Liff*.” Pet. App. 15a (emphasis added). These rulings are expressly based on “prior art consisting of patents or printed publications.” 35 U.S.C. § 311(b).

Baxter’s characterization that the Federal Circuit used Dr. Young’s testimony to “fill in gaps” in the prior art is inaccurate. Baxter continues to focus on what the Liff reference teaches *in isolation*. Pet. 11. But BD’s challenge was based on the *combination* of Liff and Alexander. *See, e.g.*, Pet. App. 12a-13a; C.A.J.A. 5024-5025; C.A.J.A. 5336 (Baxter “repeatedly attacks the references individually and fails to address the combination as a whole”); C.A.J.A. 5337 (“Liff is cited for its user interface that shows well-known features such as prompts, highlights, and providing additional information. It is Alexander that is relied upon for drug preparation steps.” (citation omitted)).

The court relied on Dr. Young’s testimony simply to shed light on this combination by explaining how “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 regard-

ing the prescription order that the operator was fulfilling.” Pet. App. 14a (quoting C.A.J.A. 1497). Using expert testimony in this way constitutes a direct application of *KSR*, cited by the court in its analysis, which held that the “combination of familiar elements according to known methods” is generally obvious. Pet. App. 14a (quoting *KSR*, 550 U.S. at 416). Citing expert testimony to determine what a person using “ordinary creativity” would have done when combining two references, *KSR*, 550 U.S. at 420, does not amount to impermissibly using expert testimony to supply missing claim elements. It is a core part of the obviousness analysis when combining prior art references.

Indeed, the Court has, on multiple occasions, approved of the use of expert testimony for similar purposes. See *KSR*, 550 U.S. at 427 (courts “can and should take into account expert testimony, which may resolve or keep open certain questions of fact” when determining obviousness); *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 25 (1966) (relying on expert testimony about whether a particular aspect of the invention was “a significant feature of the patent” in determining whether the patent was obvious). Far from “revers[ing] the Board for following the statute,” Pet. 18, as Baxter asserts, the Federal Circuit was required by the plain text of § 103 to consider what an artisan exercising reasonable creativity would find obvious based on the prior art patents and printed publications.

The notion that the Federal Circuit is blatantly disregarding § 311 is also belied by its recent decision in *Qualcomm Inc. v. Apple Inc.*, 24 F.4th 1367 (Fed. Cir. 2022). In *Qualcomm*, the Federal Circuit explained that Applicant Admitted Prior Art—i.e., background statements made in the challenged patent about the state of the prior art—do not qualify as a “patent[] or

printed publication[.]” and could not form the “basis” of an IPR challenge. *Id.* at 1374-1375. But, as the court noted, there is a difference between evidence forming the basis for a petition and evidence merely being considered in the proceeding.

Moreover, Baxter’s long discussion about other cases in which the Federal Circuit allegedly used expert testimony to supply a missing claim limitation is irrelevant to the Court’s consideration of whether to grant certiorari in this case, given that the court did not do so here. *See* Pet. 20-21. Even assuming, hypothetically, that there had been an error in some other case, this would not be an appropriate vehicle for correcting it. Indeed, between Baxter’s forfeiture of its § 311 argument and the Federal Circuit’s express statements that its decision was based on prior art patents, this would be a terrible case in which to explore the relationship between § 311 and expert testimony.

Baxter’s argument regarding its attorney’s concession at oral argument fares no better. Contrary to Baxter’s allegation that the Federal Circuit used its counsel’s statement to “skirt” a “hole in Alexander’s teachings,” Pet. 19, the Federal Circuit had already concluded based on the plain text of Alexander that “[t]here is no significant difference between ... Alexander and the ’579 patent’s verification requirement” before it mentioned Baxter’s concession. Pet. App. 7a. After all, the very notion of “verify[ing] each step *as it is performed*,” C.A.J.A. 1533(9:49-52) (emphasis added), indicates that the operator cannot proceed without verification. Baxter’s concession that a pharmacist who proceeded without authorization would likely be disciplined was just additional support. The Federal Circuit cited it in direct response to Baxter’s attempt to rely on out-of-context expert testimony. Pet. App. 8a. Baxter

can hardly fault the court for relying on “extrinsic considerations,” Pet. 19, to respond to an argument that was itself based on expert testimony. Moreover, Baxter’s argument regarding its attorney’s concession would be a particularly poor way to explore the contours of § 311 given the complication that, in an adversarial system, courts are expected to rely on the issues as they are presented—and conceded—by the parties.

As the above discussion demonstrates, there was no error in the Federal Circuit’s decision. In any event, Baxter’s challenge turns on factbound issues regarding the details of the prior art patents and the expert testimony in this case, making this case both unworthy of review and a bad vehicle for addressing § 311. *See* S. Ct. R. 10 (petitions rarely granted for “erroneous factual findings or the misapplication of a properly stated rule of law”).

II. BAXTER’S FORFEITED REMAND ARGUMENT DOES NOT WARRANT REVIEW

A. Baxter Forfeited Its Argument By Failing To Object To BD’s Request For Reversal

Baxter had ample opportunity to argue before the Federal Circuit that this case should be remanded rather than reversed. BD made clear throughout its opening brief that it sought outright reversal as its primary request. *See* BD C.A. Br. 5, 23, 25, 40. Despite this, Baxter made no mention of the so-called “ordinary remand rule” at any point in its briefing before the panel, nor did it suggest that remand would be preferable to reversal more generally. *See* Baxter C.A. Br.

Baxter’s failure to raise the issue of remand before the panel is confirmed by the Federal Circuit’s opinion, which pointed out that “Baxter [did] not meaningfully

argue [before it] that the weak showing of secondary considerations here could overcome the showing of obviousness based on the prior art.” Pet. App. 17a. Yet this is the issue that Baxter now contends must be considered by the Board on remand. Pet. 28. Likewise, after the panel’s decision, Baxter filed a petition for panel rehearing and rehearing en banc that raised only other issues and did not argue that the panel should have remanded. *See* C.A. Dkt. 34.

By failing to raise the question of remand earlier, Baxter forfeited this argument. *See Jenkins v. Anderson*, 447 U.S. 231, 234 n.1 (1980) (“Ordinarily, we will not consider a claim that was not presented to the courts below.”); *Ryder v. United States*, 515 U.S. 177, 184 n.4 (1995) (declining to reach arguments that party “did not raise below”).

This failure is not merely technical. Baxter’s omission denied the Federal Circuit an opportunity to explain its reasoning and clarify that there were no new questions of law or fact for the Board to address in the first instance. The Federal Circuit’s analysis would have been particularly helpful here because the “ordinary remand rule” is not an inexorable command. Other courts of appeals have emphasized that remand is not necessary where “the issue does not require finding new facts,” “nothing remains for the agency to investigate or explain,” or “no alternative determination is possible.” *Ghebremedhin v. Ashcroft*, 392 F.3d 241, 243 (7th Cir. 2004); *see also Zhao v. Gonzales*, 404 F.3d 295, 311 (5th Cir. 2005) (reversing rather than remanding when there were no new issues for the agency to consider). Courts have similarly declined to remand when the agency “had opportunities to consider specific factual or legal issues but elected to rule ‘on the basis of an

erroneous application of the law.” *Siwe v. Holder*, 742 F.3d 603, 612 (5th Cir. 2014).

The question whether to remand in a particular case thus turns on a number of factors, such as whether the agency already considered or had an opportunity to consider the legal issue. Baxter’s failure to preserve its argument on this case-specific question has deprived this Court of an express discussion of those issues to review. The Court “normally decline[s] to consider a legal claim” when it does not have the benefit of “a lower court opinion on the legal issue.” *NLRB v. Sears, Roebuck & Co.*, 421 U.S. 132, 163-164 (1975).

The petition should be denied due to Baxter’s forfeiture.

B. The Federal Circuit’s Case-Specific Decision To Reverse Rather Than Remand Does Not Warrant Review

Even if it were not forfeited, Baxter’s argument would not warrant review. The Federal Circuit unquestionably has the power to review the Board’s decision to assess its “compliance with governing legal standards de novo and its underlying factual determinations for substantial evidence.” *Oil States Energy Servs., LLC v. Greene’s Energy Grp., LLC*, 138 S. Ct. 1365, 1371 (2018) (quoting *Randall Mfg. v. Rea*, 733 F.3d 1355, 1362 (Fed. Cir. 2013)). That is what the Federal Circuit did here, and once it completed that review, there was nothing left for the Board to decide on remand.

The Board had already found that Alexander and Liff disclosed all of the other claim limitations and that “one of ordinary skill in the art would have been motivated to combine Alexander and Liff.” Pet. App. 4a.

The Board had also ruled that Baxter’s evidence of “secondary considerations” was “weak.” Pet. App. 57a. Once the Federal Circuit had addressed the Board’s errors on the verification and highlighting limitations, no further action by the Board was required.

Baxter’s discussion of reweighing factors ignores that “[t]he ultimate judgment of obviousness is a legal determination” that the Federal Circuit is competent to make. *KSR*, 550 U.S. at 427; *see also Graham*, 383 U.S. at 17 (“[T]he ultimate question of patent validity is one of law[.]”).³ With no outstanding factual questions or new developments for the Board to address, reversal was the appropriate remedy.

Indeed, it is not clear what Baxter intends to argue on remand or how it would make any difference. Baxter vaguely asserts that the Board should be allowed to “correct its factual determinations” in light of the Federal Circuit’s “findings regarding the verification and highlighting limitation[s].” Pet. 30. But Baxter never even attempts to explain how the Federal Circuit’s ruling would cause the Board to reconsider other findings that the Board had made. That silence speaks volumes, and the fact of the matter is that nothing in the Federal Circuit’s opinion ruling *in favor of BD* would cause the Board to abandon its other findings *in favor of BD*.

Baxter’s only other argument is that it should have another opportunity to argue that “secondary considerations” support non-obviousness. Pet. 29. But, again, Baxter is tellingly silent on the substance of what it intends to argue. The Board already analyzed Baxter’s

³ Baxter’s amicus also ignores the classification of the ultimate question of obviousness as an issue of law when it raises separation-of-powers concerns. *Vishnubhakat Br.* 4.

arguments at length in its initial decision, Pet. App. 52a-57a, and, as noted, already determined that the “Patent Owner’s evidence of secondary considerations [was] weak,” Pet. App. 57a. Baxter does not explain why the analysis would be different the second time around. Nor does Baxter explain how “reweigh[ing]” this “weak” evidence could possibly lead to a different outcome if this case were remanded.⁴ Finally, Baxter’s argument that it had no occasion to challenge the Board’s assessment that its evidence was “weak” should be rejected because Baxter had—and forfeited—an opportunity to respond when BD asked for reversal.

The cases on which Baxter hinges its arguments are easily distinguished. In *INS v. Orlando Ventura*, “both sides asked that the Ninth Circuit remand” for the Board of Immigration Appeals to consider a changed circumstances argument it had never addressed, but the Ninth Circuit instead addressed “a highly complex and sensitive matter” regarding “the significance of political change in Guatemala” based on an “ambiguous” State Department report. 537 U.S. 12, 13, 17 (2002). Similarly, in *Gonzales v. Thomas*, the Court held that remand was necessary because the agency had “not yet considered whether” the asylum applicant’s family “present[ed] the kind of ‘kinship ties’ that constitute ‘a particular social group,’” a question

⁴ Baxter’s contention that “no adjudicator, including the Federal Circuit, ever found that there was” “a strong showing of obviousness,” Pet. 29, is puzzling. That is exactly what the Federal Circuit was indicating when it noted the weakness of Baxter’s argument and said: “[W]eak evidence of secondary considerations ... cannot overcome the strong showing of obviousness.” Pet. App. 17a (quoting *ZUP, LLC v. Nash Mfg, Inc.*, 896 F.3d 1365, 1375 (Fed. Cir. 2018)).

that “require[d] determining the facts and deciding whether the facts as found fall within a statutory term.” 547 U.S. 183, 186 (2006). Finally, in *Negusie v. Holder*, the Court held that remand was warranted for the BIA to undertake an “initial determination of the statutory interpretation question” because the decision would be entitled to *Chevron* deference, the agency had a better understanding of “how practical, or impractical, the standard would be,” and it might be necessary to “conduct additional factfinding based on the new standard.” 555 U.S. 511, 523-524 (2009).

At bottom, Baxter is raising nothing more than a factbound dispute about whether a particular decision should have been remanded. There was no error in the Federal Circuit’s decision to reverse on the facts before it, but even if there had been, this type of case-specific question would not remotely justify review by this Court.

Baxter’s attempt to invoke a “long line of decisions in which the court of appeals has usurped the agency’s authority,” Pet. 30-32, is unavailing. In other cases, when there has been reason to remand, the Federal Circuit has regularly done so. *See, e.g., MaxLinear, Inc. v. CF CRESPE LLC*, 880 F.3d 1373, 1377 (Fed. Cir. 2018) (remanding in light of intervening event that could affect the Board’s decision and collecting other cases doing the same); *Vivint v. Alarm.com Inc.*, 754 F. App’x 999, 1005 (Fed. Cir. 2018) (remanding for Board to construe term after vacating previous construction); *Dell Inc. v. Accelaron, LLC*, 818 F.3d 1293, 1300 (Fed. Cir. 2016) (remanding for Board to apply legal test in the first instance); *Singh v. Brake*, 222 F.3d 1362, 1371 (Fed. Cir. 2000) (remanding because “[t]he Board explicitly did not reach any of the parties’ section 112, paragraph 1 arguments ... and we consider that such

issues should be first decided by the Board”).⁵ And Baxter’s invocation of a few cases that it sees as outliers does not mean that review is appropriate in this case, which was decided on different facts.

There was and is no reason to remand in this case and, at the very least, it would be a particularly bad vehicle to address Baxter’s second question presented because the ultimate question before the court of appeals was one of law and Baxter has not articulated a clear theory of why a remand would make any difference.

CONCLUSION

The petition for a writ of certiorari should be denied.

⁵ These cases, and many more like them, refute the claim that the Federal Circuit “has, in practice, categorically exempted a particular agency from the ordinary remand rule.” Vishnubhakat Br. 7. The Federal Circuit often remands. It simply made a case-specific and entirely correct decision that a remand would serve no purpose in this particular case.

Respectfully submitted.

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