No. 13-854

IN THE
Supreme Court of the United States

TEVA PHARMACEUTICALS USA, INC., ET AL.,
Petitioners,

v.

SANDOZ, INC., ET AL.,
Respondents.

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

REPLY BRIEF FOR PETITIONERS

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RULE 29.6 STATEMENT

The Rule 29.6 statement included in the petition for a writ of certiorari remains accurate.

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REPLY BRIEF FOR PETITIONERS

The Federal Circuit overturned the district court's factual findings about matters of historical fact without deciding or even considering whether those findings were clearly erroneous. The Federal Circuit once again acted on the notion that every aspect of claim construction is a question of law to be reviewed "*de novo*," Pet. App. 7a, 10a, a position erroneously said to be compelled by this Court's decision in *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996). *See Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1455-56 (Fed. Cir. 1998).

That rule is ripe for reconsideration. This Court must examine it, because the Federal Circuit will not abandon it. On February 23, 2014, the Federal Circuit decided *Lighting Ballast Control LLC v. Philips Electronics North America*, the case that respondents urged this Court to await. In a closely-divided *en banc* opinion, the Federal Circuit, made it clear that it would continue to apply that rule as a matter of *stare decisis*. *See* App., *infra*, 1a-95a.

Respondents offer *not a single word* in defense of that rule on the merits. Rather, they urge this Court to grant review, if at all, only in *Lighting Ballast* or some subsequent case—once the decision in this case is safely final. But there is no reason to wait. Now that the Federal Circuit has decided *Lighting Ballast*, this Court has the benefit of that court's views, and of the dissenters'. Nothing about *Lighting Ballast* turned on the facts, and nothing makes it a superior vehicle to any other case. There is therefore no reason to wait for a petition in *Lighting Ballast* that may never come. As the Solicitor General pre-

viously advised the Court, the Federal Circuit's rule is wrong and this Court should review it in an appropriate case. Pet. 22-23, 27. This is such a case, and the Court should not pass it up.

Respondents maintain that they would still win *if* the Federal Circuit applied a clear-error standard of review. That speculation is unfounded and ignores the district court's sound, substantially unrebutted fact-finding.

Furthermore, the very question here—is claim construction a question of law or fact?—lies at the heart of *Nautilus, Inc. v. Biosig Instruments, Inc.*, No. 13-369, a case to be argued in this Court in April. In that case or this one, this Court should provide an answer.

I. This case is a proper vehicle because the proper standard of review is outcome-determinative.

Respondents insist that the standard of review made no difference in this case. They rely heavily (Opp. 2, 25-26) on the Federal Circuit's unexplained denial of rehearing, but nothing in that one-line order indicates that the panel reconsidered the case under clear-error review. On the contrary, it is now clear that the court denied rehearing and issued the mandate because it knew the *en banc* court had voted to reaffirm *Cybor*, making it pointless to hold this case in the Federal Circuit any longer.

Respondents also contend that the panel's view of the evidence was correct. And they seek to justify overturning the district court's contrary findings by insisting that the case does not turn on "'historical fact' evidence." *E.g.*, Opp. 22.

But respondents entirely miss the point. To demonstrate that applying the correct standard of review would not affect the outcome, respondents would have to show that the district court's findings in support of claim construction were "clearly erroneous." They do not even try to make *that* argument. Nor could they: a district court's findings are not clearly erroneous merely because the reviewing court would find the facts differently. *E.g.*, *Anderson v. City of Bessemer City*, 470 U.S. 564, 573 (1985). Indeed, respondents do not even *acknowledge* the district court's findings, understandably preferring the contrary "findings" made by the Federal Circuit on its *de novo* review of the record. They certainly do not refute or even address the substantial evidence supporting the district court's findings. *See* Pet. 24-26.

Respondents are simply incorrect in asserting that Dr. Grant offered only his own subjective understanding and that the district court's findings therefore should be disregarded. *E.g.*, Opp. 21-22. For example, the panel placed crucial reliance on Figure 1 of the patent specification (as annotated in red by respondents' counsel), Opp. 11, Pet. App. 10a-11a; respondents assert that a "cursory examination" of that figure was enough to undermine the district court's claim construction. Opp. 20-21, 23. But Dr. Grant—who had far better than a "cursory" understanding of the relevant science—specifically addressed that very argument and explained why, given the data conversions needed to produce Figure 1, M_p would not necessarily appear at the peak of that figure. Pet. App. 118a, 126a-27a. Dr. Grant did not contradict the patent; he explained the science that it taught. Dr. Grant's evidence on that scientific, fac-

tual issue was unrebutted, and the district court properly credited it. *Id.* at 49a. The panel needed a highly compelling reason to set aside the finding. It gave *no* reason, and respondents give none here.

Respondents' complaint that Dr. Grant gave no "live testimony" (Opp. 2, 9) is a red herring. There was no live testimony in *Lighting Ballast* either. Pet. 27 & n.9. That fact does not eliminate the need for deference, in either case. Pet. 26-27. And in any event, respondents cross-examined Dr. Grant and submitted that testimony during the summary-judgment proceedings. They could have called him, or their own expert, to testify at trial if they had wished. They simply had no evidence to counter Dr. Grant's explanation.

If the Federal Circuit had credited the district court's findings, it would have been required to reject the indefiniteness defense. Despite respondents' attempt to create ambiguity using the prosecution history, *see* Opp. 20, 22-23, those materials are "less useful" in claim construction than the patent specification itself, which is the "best" and "primary basis for construing the claims." *Philips v. AWH Corp.*, 415 F.3d 1303, 1317 (Fed. Cir. 2005) (*en banc*) (citations omitted). And the district court's findings leave no doubt that a person of ordinary skill in the art, reading the specification, would have discerned the meaning of average molecular weight.

Changing the standard of review thus would change the outcome.[1] The panel gave no indication

[1] Even if that were not so, this Court has reviewed unsettled standard-of-review issues even where the answer ultimately did not affect the outcome of the particular case. *See, e.g.*, *Russell*

that it considered the district court's findings clearly erroneous; to the contrary, the panel made clear that it reviewed *de novo* in making findings inconsistent with those of the district court. Pet. App. 7a, 10a.[2]

Under the standard of review this Court has specified in Fed. R. Civ. P. 52(a)(6), the substantial evidence—indeed, one-sided evidence—supporting the district court's findings should have led to affirmance. This case therefore squarely presents the question of what the proper standard of review should be.[3]

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v. Salve Regina Coll., 938 F.3d 315, 315-16 (1st Cir. 1991) (reaching same result after this Court reversed on standard-of-review issue).

[2] Respondents' other vehicle argument—that Teva did not ask the panel to apply clear-error review, Opp, 2, 12, 19—is both factually wrong, *see* Teva C.A. Br. 26, and legally irrelevant. The panel could not have overruled *Cybor*, and the *en banc* court has now declined to do so in any event.

[3] The "concession" to which respondents allude (Opp. 21 n.1) refers to a submission to the Patent Office seeking reissuance of the patent. Teva made that submission following the Federal Circuit's decision and, on February 13, 2014, updated its submission with the required oath acknowledging that an "error" has caused the patent to be "inoperative or invalid," 37 C.F.R. § 1.175(a). The Patent Office is still considering Teva's reissue application, however, and indeed, respondents have vigorously and repeatedly urged the Patent Office not to reissue the patent, relying in part on arguments that have nothing to do with the issues addressed by the Federal Circuit.

II. This Court should not deny the petition in anticipation of a petition in *Lighting Ballast*, because that case may never reach this court and this case is a suitable vehicle for resolving the issue.

Even though this case squarely presents the standard-of-review question, respondents insist that *only Lighting Ballast*, or a later one, can be a proper vehicle. While convenient for respondents, that notion is not based on this Court's certiorari criteria. Nor is it based on anything making *Lighting Ballast* a superior vehicle. *See* Pet. 27 & n.9. Indeed, the *en banc* opinions in *Lighting Ballast* do not even discuss the facts of that case. Nothing about *Lighting Ballast* makes it a uniquely suitable vehicle. The Court can read the *en banc* opinions for itself, whether it grants review in this case or any other case. And waiting for a petition in *Lighting Ballast* specifically may be in vain because the losing patentee may not seek certiorari. *See* Pet. 31. [4]

Furthermore, because Federal Circuit decided in *Lighting Ballast* to continue to follow *Cybor* irrespective of its merits and notwithstanding its flaws, there is a compelling need for review by this Court without further delay. A bare majority of the Federal Circuit has declined to change its collective mind after a fourth *en banc*, despite changes in membership (Opp. 17) and a barrage of criticism from everyone ranging

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[4] Respondents incorrectly assert (Opp. 16) that the Court has denied certiorari in a similar posture. That is incorrect—the *Saffran* case would not have been a suitable vehicle because the district court made no factual findings, and in any event, the posture has changed now that the Federal Circuit has reaffirmed the rule Teva challenges.

from the United States to its own former Chief Judge. Respondents' plea for further "percolat[ion]" (Opp. 17, 18) is absurd: the Federal Circuit has declared that it will simply continue to brew exactly the same bitter product that it has brewed for well over a decade.

Indeed, the concurring and dissenting opinions in *Lighting Ballast*, confirm Teva's argument that the answer to the question presented turns on what this Court meant in *Markman*. Although the *Lighting Ballast* majority relied on principles of *stare decisis*, Judge Lourie's concurrence defended the *Cybor* rule on the merits primarily as a logical consequence of this Court's ruling in *Markman* that claim construction was a matter for the trial court, and not a jury, in the first instance. By contrast, Judge O'Malley's dissent for herself and three colleagues concluded upon a close analysis that *Markman* did not compel *de novo* review but instead "repeatedly acknowledged the factual component of claim construction." App., *infra*, at 51a. Only this Court can resolve which of these conflicting views of *Markman* is correct.

The *Lighting Ballast* majority, which included the author of the decision below and other judges who had previously criticized the *Cybor* rule, tacitly acknowledged this point. By basing the decision to uphold the *Cybor* rule on *stare decisis* grounds without even attempting to resolve the issue on the merits, a majority of the Federal Circuit essentially threw up its hands, despairing that it could reach consensus on the meaning of *Markman* and the proper standard of review. The message is clear: only this Court, which is decidedly *not* bound by Feder-

al Circuit precedent (especially incorrect precedent), can definitively resolve the issue.

The standard of review plainly is "an important question of federal law that has not been, but should be"—and can only be—settled by this Court." Sup. Ct. R. 10(c).

III. Because there is a reasonable likelihood that resolution of the issues accepted for review in *Nautilus* will determine what standard of review applies to claim construction, this Court may wish to hold the petition in this case pending its decision in *Nautilus*.

The Court already has granted review in *Nautilus,* to review questions that will require this Court to decide whether "claim construction is purely legal," as the Federal Circuit held in *Cybor*, 138 F.3d at 1456, or may turn on underlying factual issues, as Teva contends. If this Court holds in *Nautilus* that claim construction is not a pure question of law, the basic premise of the Federal Circuit's rule of *de novo* review would be fatally undermined. *See* Pet. 32-35. That is more than sufficient to justify holding Teva's petition until *Nautilus* is decided and, depending on the outcome, may justify directing the Federal Circuit to reconsider this case in light of *Nautilus*. In arguing against a hold, respondents simply ignore the specific questions presented in *Nautilus* and their relevance to this case.

The defense of indefiniteness under 35 U.S.C. § 112, at issue in *Nautilus*, invariably turns on the meaning of patent claims and whether that meaning is expressed clearly enough. In *Nautilus*, the Feder-

al Circuit upheld patents against an indefiniteness challenge, because they contained sufficient information to allow a person of ordinary skill in the art to discern the boundaries of the relevant claim term and, therefore, the claims were not "insolubly ambiguous."

This Court granted review on both questions presented by the *Nautilus* petition. The first concerns whether the Federal Circuit's standard for indefiniteness accurately implements the requirement of § 112 that claims be "distinct." The second question is whether "the presumption of validity dilute[s]" that requirement. Pet. for Cert. at i, *Nautilus, supra*.

The second question arose because the Federal Circuit deemed the statutory presumption of validity, 35 U.S.C. § 282(a), to inform the standard of indefiniteness. The standard allows some degree of ambiguity, so long as the patent claim's meaning can be discerned using the traditional canons of claim construction. *See Biosig Instruments, Inc. v. Nautilus, Inc.*, 715 F.3d 891, 902 (Fed. Cir. 2013) (*Nautilus* Pet. App. at 14a, 21a-22a). Thus, this Court will consider the nature of the presumption of validity and its relevance in determining the meaning of a patent claim that is challenged for indefiniteness.

But the presumption of validity set out in Section 282(a) creates an "evidentiary standard of proof" that applies only to questions of *fact*. *Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238, 2253 (2011) (Breyer, J., joined by Scalia and Alito, JJ., concurring). Accordingly, to determine how the presumption of validity affects the indefiniteness defense, this Court will have to address whether the claim-construction

issues on which indefiniteness turns are questions of fact (to which the presumption applies) or of law (as to which it is irrelevant). As Teva has described, the parties in *Nautilus* have already squared off on this point, with the petitioner insisting that the presumption of validity plays no role because "there are no factual determinations in claim construction," and the patentee arguing that claim construction involves fact questions and the presumption applies to those questions. Pet. 32-33. Both sides invoke this Court's decision in *Markman*, as do the concurring and dissenting opinions in *Lighting Ballast*.

Respondents insist that the questions presented in *Nautilus* do not mention "the standard of appellate review," Opp. 27-28, but that is a *non sequitur*. If this Court accepts the patentee's argument in *Nautilus* that claim construction is not "purely legal," that holding will undo the very premise on which the Federal Circuit has based its standard of appellate review. Such a decision by this Court would, at a minimum, be an "intervening development[] . . . reveal[ing] a reasonable probability that the decision below rests upon a premise that the lower court would reject if given the opportunity for further consideration," and warranting a GVR. *Lawrence v. Chater*, 516 U.S. 163, 167 (1996) (per curiam).[5]

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[5] The test for GVRs is not, as respondents would have it, whether the questions presented in Teva's petition and Nautilus's are the same. Dozens of recent GVRs show that respondents' same-question-presented test is wrong. *See, e.g.*, *Giovanniello v. ALM Media, LLC*, 133 S. Ct. 159 (2012) (No. 11-1411) (GVRing petition presenting statute-of-limitations question in light of opinion on jurisdictional question). And the standard for a *hold* is not whether a GVR is certain, but whether it is reasonably likely.

Respondents also contend (Opp. 28-29) that the Court has only two options in *Nautilus*: ratify the Federal Circuit's current indefiniteness doctrine or make the test "more rigorous." The Court faces no such constraint: unlike the Federal Circuit, this Court need not (and should not) conform its holding to *Cybor*. In answering the presumption-of-validity question presented in *Nautilus*, therefore, this Court is free to give an answer that the Federal Circuit panel in *Nautilus* was not: that the presumption of validity sometimes applies to claim construction *because claim construction sometimes turns on factual issues*. And *that* holding would require the Federal Circuit to reconsider its rule reviewing findings on those factual issues *de novo*—the rule that allowed respondents to prevail on appeal. Crediting the district court's findings would defeat respondents' indefiniteness defense, under *any* indefiniteness standard.

Thus, this case and *Nautilus* share a common pivotal question: is claim construction purely legal? Given the substantial possibility that *Nautilus* will answer that question, or at least shed light on it, there is certainly no reason to follow respondents' urging and hurriedly deny the petition before *Nautilus* is even briefed, much less decided.

* * * * *

This case amply illustrates why this Court should bring to an end the Federal Circuit's practice of reviewing factual issues in claim construction *de novo*: the panel relied on its own "cursory" understanding (Opp. 20) of highly complex and technical scientific matters and concluded that because *the panel* could

not discern the meaning of the patent, neither could a skilled artisan. The district court's factual findings squarely refute that notion, and because those findings are not clearly erroneous, they should have been the end of the case. These facts starkly present the question that has long demanded an answer by this Court and that the Federal Circuit itself has given up trying to resolve on the merits. The Court should take this opportunity and resolve the matter.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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