No. 13-854

In The Supreme Court of the United States

TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES, LTD., TEVA NEUROSCIENCE, INC., AND YEDA RESEARCH AND DEVELOPMENT CO., LTD., PETITIONERS

v.

SANDOZ INC., MOMENTA PHARMACEUTICALS INC., MYLAN PHARMACEUTICALS INC., MYLAN INC., AND NATCO PHARMA LTD.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR RESPONDENTS IN OPPOSITION

ERIC D. MILLER
Counsel of Record
PERKINS COIE LLP
1201 Third Ave.,
Suite 4900
Seattle, Washington 98101
206.359.8000
EMiller@perkinscoie.com

Counsel for Respondents Mylan Pharmaceuticals Inc., Mylan Inc., and Natco Pharma Ltd.

DEANNE E. MAYNARD
Counsel of Record
BRIAN R. MATSUI
MARC A. HEARRON
NATALIE R. RAM
MORRISON & FOERSTER LLP
2000 Pennsylvania Ave., N.W.
Washington, D.C. 20006
202.887.8740
DMaynard@mofo.com

Counsel for Respondents Sandoz Inc. and Momenta Pharmaceuticals Inc.

[Additional Counsel Listed On Inside Cover]

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COCKLE LEGAL BRIEFS (800) 225-6964
WWW.COCKLELEGALBRIEFS.COM

SHANNON M. BLOODWORTH
PERKINS COIE LLP
700 13th Street, N.W.,
Suite 600
Washington, D.C. 20005
202.654.6200

EVAN R. CHESLER
CRAVATH, SWAINE &
MOORE LLP
825 Eighth Ave.
New York, New York 10019
212.474.1243

Additional Counsel for Respondents Mylan Pharmaceuticals Inc., Mylan Inc., and Natco Pharma Ltd.

DAVID C. DOYLE
ANDERS T. AANNESTAD
BRIAN M. KRAMER
MORRISON & FOERSTER LLP
12531 High Bluff Drive,
Suite 100
San Diego, California
92130
858.720.5100

Additional Counsel for Respondents Sandoz Inc. and Momenta Pharmaceuticals Inc.

QUESTION PRESENTED

Whether Federal Rule of Civil Procedure 52(a) requires an appellate court reviewing a district court's construction of patent claims to defer to conclusions that are based on a litigation expert's declaration that expressly contradicts the patent record.

CORPORATE DISCLOSURE STATEMENT

Sandoz Inc. is an indirect wholly-owned subsidiary of Novartis AG. No other publicly held company owns 10% or more of the stock of Sandoz Inc.

Momenta Pharmaceuticals Inc. is a publicly held corporation. No parent corporation or publicly held corporation owns more than 10% of its stock.

Mylan Inc. is a publicly held corporation. No parent corporation or publicly held corporation owns more than 10% of its stock. Defendant Mylan Pharmaceuticals Inc. is wholly owned by Mylan Inc.

Natco Pharma Ltd. is a publicly held corporation. No parent corporation or publicly held corporation owns more than 10% of its stock.

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INTRODUCTION

Petitioner makes the extraordinary request that this Court grant review to consider a question currently being considered by the en banc Federal Circuit. In the 30 years since that Circuit's creation, this Court has never preempted the Circuit's en banc review, and nothing about this case warrants doing so. There is no reason to presume (as Teva does) that this Court's intervention will be needed no matter how the en banc Circuit rules. And this case is not a suitable vehicle to review the question in any event.

Teva sued Sandoz and Momenta (together, Sandoz) and Mylan and Natco (together, Mylan) for infringement of multiple related patents covering Teva's multiple-sclerosis drug, Copaxone®. Most of those patents expire on May 24, 2014, but one would have expired on September 1, 2015. The district court held all of the asserted claims valid and infringed, but the court of appeals held certain of the asserted claims invalid as indefinite, including the sole claim of the patent that would have expired on September 1, 2015. At the same time, the court of appeals upheld the validity of certain claims expiring on May 24, 2014, and it affirmed the finding of infringement with respect to those claims. As a result of that decision, the district court's injunction was modified on remand so that Sandoz and Mylan are enjoined from entering the market until May 24, 2014, rather than September 1, 2015.

The question Teva poses in its petition—whether certain aspects of claim construction in patent cases are entitled to deferential review on appeal—does not warrant this Court's review, at least not at this time and in this case. That question is pending before the en banc Federal Circuit in *Lighting Ballast Control LLC v. Philips Electronics North America Corp.*, Nos. 2012-1014, -1015 (Fed. Cir. reargued Sept. 13, 2013). To the extent there is any conflict within the Federal Circuit, its resolution is appropriately left to that court.

Moreover, even if this Court were inclined to review the appellate standard-of-review question Teva poses, *Lighting Ballast*—or a case applying whatever rule the Federal Circuit adopts in *Lighting Ballast*—would be the appropriate vehicle for that review. In *Lighting Ballast*, the parties and numerous amici have focused on the standard of review and the effect it would have on the outcome of that case. Here, by contrast, Teva did not argue that the standard of review for claim construction should be changed (or even cite Rule 52) until its petition for rehearing. Thus, this case is no better vehicle than *any* claim-construction decision, and in fact is worse than most. The district court here held no evidentiary hearing and observed no live testimony before construing the claims and ruling on their indefiniteness.

Nor would the answer to the question Teva poses change the result in this case. Indeed, the Federal Circuit itself recognized as much, by repeatedly rebuffing Teva's requests to hold this case pending its en banc decision in *Lighting Ballast*. Even under

Teva's proposed standard, there were no factual findings in this case to which the Federal Circuit could properly have deferred. The "facts" as to which Teva seeks deference do not involve the historical meaning of any claim term. Rather, those "facts" are simply Teva's litigation expert's "interpretation" of the patent documents themselves—that is, the patents and their prosecution history. Indeed, deference would be particularly unwarranted here because Teva's expert simply labeled the patent documents mistaken wherever they did not support Teva's litigation position. Regardless of the standard of review, a reviewing court in a patent case should read the legal documents in the patent record for itself and disregard extrinsic evidence contrary to that record.

As a last resort, Teva asks this Court to hold its petition pending the resolution of *Nautilus, Inc. v. Biosig Instruments, Inc.*, No. 13-369 (cert. granted Jan. 10, 2014). But a hold is unwarranted. The question Teva presents is unrelated to the questions presented in *Nautilus*—which concern the substantive standard for indefiniteness, not the standard for appellate review. Having so framed its question, Teva is precluded from obtaining relief based on that case. Nor could *Nautilus* affect the outcome of this case in any event. In *Nautilus*, the petitioner contends that the Federal Circuit's substantive standard for indefiniteness—under which claims are invalid for indefiniteness only where "insolubly ambiguous" or "incapable of construction"—is too favorable to patentees and thus results in patent claims being

upheld that should be struck for indefiniteness. Given that Teva's claims could not even survive under the Federal Circuit's current indefiniteness standard, they *a fortiori* would not survive under any stricter standard this Court might adopt in *Nautilus*.

The petition should be denied.

STATEMENT

A. Statutory Framework

1. Congress enacted the Hatch-Waxman Act to facilitate entry of competitors in the marketplace for pharmaceutical drugs. *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585. The Act created an abbreviated new drug application (ANDA) process. This allows the Food and Drug Administration (FDA) to approve drugs that are biologically equivalent to already-approved pharmaceuticals without requiring additional evidence of safety and efficacy. *See* 21 U.S.C. § 355(j)(2)(A)(ii), (iv).

As part of the ANDA process, a drug maker must certify that its drug can be marketed without infringing certain patents related to the already-approved drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii)-(viii). As in this case, drug makers seeking ANDA approval often certify that the applicable patents are "invalid or will not be infringed by the manufacture, use, or sale of the [ANDA applicant's] drug." 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The Hatch-Waxman Act allows a patent holder to treat this "Paragraph IV

certification" as an act of infringement and immediately file a patent infringement suit in district court. 35 U.S.C. § 271(e)(2)(A). This process of certification and suit aims to allow drug manufacturers to launch competing products promptly upon the expiration or invalidation of patents protecting the approved drugs. *See Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 670-671 (1990).

2. The Patent Act requires that a patent include claims "particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention." 35 U.S.C. § 112(b) (2012) (formerly 35 U.S.C. § 112 ¶ 2). This ensures that the public has clear notice of what constitutes infringement. *United Carbon Co. v. Binney & Smith Co.*, 317 U.S. 228, 236 (1942); *Permutit Co. v. Graver Corp.*, 284 U.S. 52, 60 (1931).

This Court has explained that "[a] patent is a legal instrument, to be construed, like other legal instruments, according to its tenor." *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388 (1996) (internal quotation marks omitted). In construing patent claims, courts look to a hierarchy of sources informative of claim meaning. First, courts consider the claim language itself. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc). Second, courts look to a patent's specification and prosecution history, which together with the claims form the public record of the patent. *Id.* at 1313. This Court

has explained that "[t]he claims of a patent are always to be read or interpreted in the light of its specifications." *Schriber-Schroth Co. v. Cleveland Trust Co.*, 311 U.S. 211, 217 (1940). And "an invention is construed not only in the light of the claims, but also with reference to the file wrapper or prosecution history in the Patent Office." *Graham v. John Deere Co.*, 383 U.S. 1, 33 (1966); *see Phillips*, 415 F.3d at 1317.

Third, the en banc Federal Circuit has held that courts construing claim terms may consult extrinsic evidence, including expert testimony, dictionaries, and treatises. But use of these sources is limited. "[W]hile extrinsic evidence can shed useful light on the relevant art, * * * it is less significant than the intrinsic record in determining the legally operative meaning of claim language." *Phillips*, 415 F.3d at 1317 (internal quotation marks omitted). Moreover, courts "should discount any expert testimony that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent." *Id.* at 1318 (internal quotation marks omitted).

B. Factual Background

Teva markets Copaxone®, a drug used to treat multiple sclerosis. With no generic alternative on the market, the cost of treatment is roughly $40,000 per year. C.A. JA19635. Sandoz and Mylan each filed ANDAs seeking FDA approval to market their own

versions of the drug. In response, Teva sued Sandoz and Mylan on nine patents that share a common specification. Pet. App. 4a.

Copaxone is a form of copolymer-1. The asserted patent claims cover copolymer-1 and methods of manufacturing it. Pet. App. 4a. Copolymer-1 is not new; it was invented in 1967 and first patented in 1974. C.A. JA49258; C.A. JA344; C.A. JA26052-26053. But the original patent expired before the inventors could market copolymer-1. To obtain new patent protection, Teva asserted that it had improved copolymer-1, making it less toxic but still efficacious, by selecting portions of copolymer-1 with particular "molecular weights" or "average molecular weights." To get that new patent coverage, Teva was required to define precisely the scope of its claimed improvement. *See* 35 U.S.C. § 112(b); *General Elec. Co. v. Wabash Appliance Corp.*, 304 U.S. 364, 369 (1938).

According to Teva, the effectiveness and reduced toxicity of the claimed substance depend on its precise molecular weight. C.A. JA18180, C.A. JA18199. An accurate determination of molecular weight thus was key to defining the claimed substance. But the molecular weight of any particular batch of copolymer-1 can be determined in multiple ways, including weight average molecular weight (M_w), number average molecular weight (M_n), and peak molecular weight (M_p). Pet. App. 4a. Because the "molecular weight" value differs depending on the type of average, a skilled artisan could not know the

bounds of the asserted claims without knowing which type was claimed.

Claim 1 of U.S. Patent No. 5,981,589 is representative of the claims with this "molecular weight" ambiguity:

> Copolymer-1 having *a molecular weight of about 5 to 9 kilodaltons*, made by a process comprising the steps of:
>
> reacting protected copolymer-1 * * * ; and
>
> purifying said copolymer-1, to result in copolymer-1 *having a molecular weight of about 5 to 9 kilodaltons*.

Pet. App. 5a (emphasis added by court of appeals).

Neither the patents' claims nor their common specification identifies the type of "molecular weight" or "average molecular weight" used in the claims. Indeed, the Patent Office twice rejected as indefinite claims reciting "average molecular weight" because that term is "meaningless as a limitation without specifying" the type of molecular weight. C.A. JA3220; C.A. JA3245. In response, Teva provided conflicting and irreconcilable answers, first telling the Patent Office that "average molecular weight" referred to "weight" average molecular weight (C.A. JA3229), and subsequently stating that "average molecular weight" referred to "peak" molecular weight (C.A. JA3258).

C. Proceedings Below

1. Proceedings in the district court

In the district court, Sandoz and Mylan contended that the asserted claims were invalid for indefiniteness because the patents' claims, common specification, and prosecution history provided no guidance as to which type of molecular weight was claimed, even though that information was critical to defining the claimed substance.

The district court nevertheless held that the asserted claims were not indefinite. Although the court acknowledged that the claims "are silent as to the meaning" of "average molecular weight," it construed "average molecular weight" as "peak molecular weight." Pet. App. 42a, 62a. In so doing, the district court relied on declarations of Teva's expert, Gregory Grant, that were prepared for this litigation and that purported to interpret the patents' specification and prosecution history. When the district court ruled, Teva's expert had not testified or been cross-examined in court. Indeed, the district court held no evidentiary hearing and observed no live testimony before construing the claims and ruling on their indefiniteness.

After a bench trial on infringement and other invalidity contentions, the district court held that the products proposed by Sandoz and Mylan would infringe the asserted claims. Pet. App. 75a-78a. The district court then enjoined Sandoz and Mylan from entering the market until expiration of U.S. Patent

No. 5,800,808 (the '808 patent) on September 1, 2015. Pet. App. 78a-81a.

2. Proceedings in the court of appeals

In a unanimous decision, a panel of the court of appeals held that a subset of the asserted claims (the "Group I" claims) were invalid for indefiniteness. Pet. App. 8a. The court recognized that it was "undisputed that Group I claims contain an ambiguity because their plain language does not indicate which average molecular weight measure is intended." Pet. App. 8a. And it rejected Teva's argument that the prosecution history and specification resolved that ambiguity.

As to the prosecution history, the court of appeals concluded that two of Teva's "prosecution statements directly contradict[ed] each other and render[ed] the ambiguity insoluble." Pet. App. 8a-9a. In particular, when prosecuting one patent, Teva overcame an indefiniteness rejection by asserting that one skilled in the art would understand "average molecular weight" to refer to "*peak*" molecular weight. Pet. App. 9a. Yet when prosecuting a related patent, Teva overcame the same objection by asserting that "average molecular weight" meant "*weight*" average molecular weight. Pet. App. 9a.

The court further held that "[t]he specification does not resolve the ambiguity." Pet. App. 9a. Citing Grant's declarations, Teva contended that the specification's reference to the Size Exclusion Chromatography (SEC) method for determining molecular weight implied "peak" molecular weight and that

Figure 1 of the patents confirmed this. Pet. App. 8a-10a. The court of appeals observed that all the experts, including Grant, agreed that "number" average molecular weight and "weight" average molecular weight also can be obtained from the data generated by the SEC method. Pet. App. 10a. Moreover, Figure 1 (reproduced below from the court of appeals' decision) actually contradicted Grant's declarations because "the peaks of the curves in Figure 1 do not correspond to the values denoted as 'average molecular weight' in the figure's legend." Pet. App. 10a. Indeed, the court noted Grant's concession that "the 7.7 kDa value [stated in Figure 1] is closer to the M_w than to the M_p of the corresponding batch," which refuted Teva's contention that peak molecular weight was the intended measure. Pet. App. 10a.

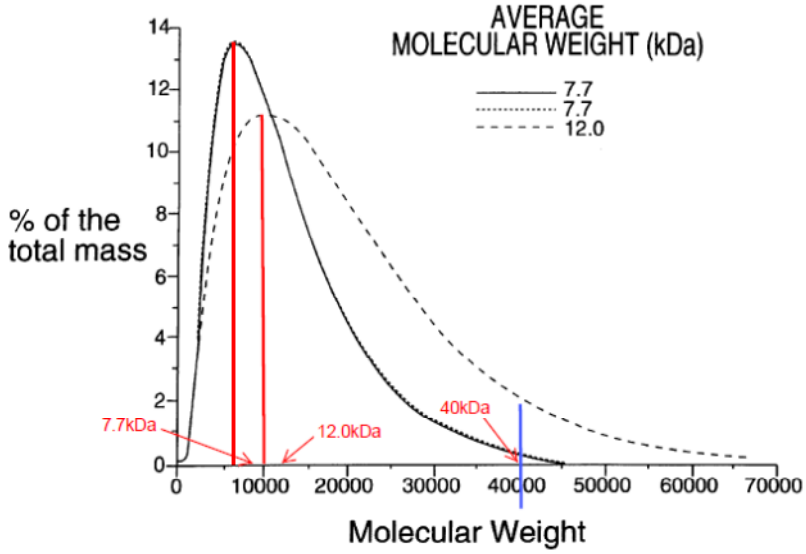

FIG. 1

Pet. App. 11a.

Because the patents and their prosecution history provided no indication as to which type of molecular weight Teva claimed, the court of appeals held indefinite and invalid the Group I claims, which include the only claim with a September 1, 2015 expiration date. The court of appeals went on, however, to affirm the validity and infringement of other ("Group II") claims, which the court held did not depend on average molecular weight. All of the Group II claims expire on May 24, 2014. Accordingly, the injunction has now been modified so that Sandoz and Mylan are barred from marketing copolymer-1 until May 24, 2014.

Teva sought rehearing and rehearing en banc. In that petition, Teva argued for the first time that the standard of review for claim construction should be changed, requesting that the Federal Circuit hold this case pending its decision in *Lighting Ballast*, in which it already had ordered en banc review. In *Lighting Ballast*, the en banc court is considering whether it should overrule its decision in *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448 (Fed. Cir. 1998) (en banc), which held that claim construction is a question of law subject to de novo review, and should instead "afford deference to any aspect of a district court's claim construction" and "[i]f so, which aspects should be afforded deference." *Lighting Ballast Control LLC v. Philips Elecs. N. Am. Corp.*, 500 F. App'x 951, 952 (Fed. Cir. 2013). The en banc Federal Circuit declined to hold this case pending *Lighting Ballast* and denied Teva's petition—without

dissent and without even calling for a response from Sandoz and Mylan.

Teva thereafter filed what it called a "motion to correct the judgment" (which repeated its rehearing petition arguments), as well as a motion to stay the mandate pending a certiorari petition. The Federal Circuit denied both motions, again without dissent or calling for a response.

3. Subsequent proceedings before the Patent Office

On August 12, 2013, Teva filed an application with the United States Patent and Trademark Office (Patent Office) asking that it reissue the '808 patent to correct the error in the claim language identified by the Federal Circuit. *See* Appl. No. 13/964,856, http://portal.uspto.gov/pair/PublicPair (search by application number). Reissue of patents to correct an error requires an oath by the applicant admitting the existence of the error to be corrected. 35 U.S.C. § 251; 37 C.F.R. §§ 1.63, 1.175; Manual of Patent Examining Procedure §§ 1402, 1414. The reissue application remains pending before the Patent Office.

4. Prior proceedings before this Court

Arguing that it faced imminent irreparable harm and that the question presented in its petition urgently required this Court's review, Teva asked the Chief Justice to recall and stay the mandate of the Federal Circuit. Appl. to Recall and Stay Mandate, *Teva Pharm. USA, Inc. v. Sandoz Inc.*, No. 13A458

(U.S. Nov. 4, 2013). The Chief Justice denied Teva's application. Teva then waited to file its petition until the ninetieth day after denial of rehearing.

ARGUMENT

A. Teva's Question Presented Does Not Warrant This Court's Review

Teva makes an extraordinary request: it seeks immediate review of the Federal Circuit's 16-year-old decision in *Cybor*, even though the en banc Circuit currently is reconsidering *Cybor*. There is no need for this Court's review.

1. Certiorari is not needed to review the correctness of the Federal Circuit's Cybor *decision*

Teva asserts that certiorari is warranted to review whether the Federal Circuit's decision in *Cybor*, which held that all aspects of claim construction are reviewed de novo on appeal, is consistent with Rule 52(a) of the Federal Rules of Civil Procedure. Pet. 3, 21-23. Teva describes what it considers to be an internal division within the Circuit, contending that "a majority of the Federal Circuit" has continued to insist that all aspects of claim construction are reviewed de novo, even in the face of a "growing number of Federal Circuit judges [who] have concluded that the standard of review their court applies is flawed or simply wrong." Pet. 3.

But any internal division concerning the continued validity of *Cybor* soon will be addressed by the

full Federal Circuit itself. In *Lighting Ballast*, the en banc Federal Circuit already is reconsidering whether and to what extent a district court's claim-construction ruling is entitled to deference on appeal. And "[i]t is primarily the task of a Court of Appeals to reconcile its internal difficulties." *Wisniewski v. United States*, 353 U.S. 901, 902 (1957).

Circumstances thus have changed significantly since two Terms ago when, Teva says, this "Court might well have taken up this question" in *Retractable Technologies, Inc. v. Becton, Dickinson & Co.*, No. 11-1154 (cert. denied Jan. 7, 2013). Pet. 27. While the petitioner there urged that this Court's review was needed because the Federal Circuit had "steadfastly refused to reconsider its decision in *Cybor*," that is no longer the case. Pet. for Writ of Cert. at 3, *Retractable Techs.*, *supra*. The en banc Circuit is expressly considering whether to "overrule *Cybor*" in whole or in part. *Lighting Ballast*, 500 F. App'x at 951. Moreover, when the Solicitor General suggested in *Retractable Technologies* that the standard-of-appellate-review issue might warrant this Court's review in some future case, that suggestion was based on his view of *Cybor*. U.S. Amicus Br. at 19-21, *Retractable Techs.*, *supra*; *contra* Pet. 23. But that view is now being considered by the en banc Federal Circuit, where the United States has both filed an amicus brief and presented oral argument.

With *Lighting Ballast* fully briefed, argued, and under submission to the full Federal Circuit, the issue posed by Teva is not worthy of this Court's

review. This Court recently has refused to review the same question presented. *See, e.g.*, *Saffran v. Johnson & Johnson*, No. 13-405 (cert. denied Jan. 27, 2014). There is no reason for a different result here.

2. There is no reason to presume that this Court's review will be needed regardless of the outcome of Lighting Ballast

Teva contends that this Court's immediate review is needed despite the pendency of *Lighting Ballast* and regardless of the outcome of the en banc court's review. More specifically, Teva argues that "a decision by today's Federal Circuit judges, no matter what it may be, cannot provide a sure and certain answer to this question" and each time the Circuit has attempted to clarify the law, "the dissenters have vowed to keep up the fight." Pet. 28-29.

But there is no reason to presume that this Court's intervention will be needed no matter how the en banc Federal Circuit resolves the issue. This Court does not review every en banc decision from that Circuit, or any other. And it would be an affront to the Federal Circuit to preempt the en banc court's consideration by granting review here. This is not a case in which a "sole outlier court of appeals had already granted rehearing en banc whether to overrule its precedent and eliminate the circuit split." Pet. 28 n.10. It is a case where there is no circuit conflict and the court of appeals with exclusive jurisdiction is reconsidering its position en banc based on extensive briefing and argument.

Nor is there reason to assume that *Lighting Ballast* will not resolve any intra-circuit division concerning *Cybor*. The changed composition of the Federal Circuit, which Teva identifies as a reason for granting review, actually cautions against review. *Contra* Pet. 29-30. Only three members of the Federal Circuit who decided *Cybor* (and just one in the majority) are participating in the en banc review in *Lighting Ballast*. *See Cybor*, 138 F.3d 1448. If anything, the Circuit's new membership is reason to allow that court, which reviews hundreds of claim-construction rulings each year, to resolve *Lighting Ballast*—and to allow the rule of *Lighting Ballast* to percolate in future cases before this Court decides whether to step in. *See* Pet. 31 (noting that the Circuit decides "dozens" of claim-construction cases each month).

Teva speculates that the Circuit is unlikely to revisit *Cybor* because it did not reach the question in *Phillips*. Pet. 5-6, 28. But in *Phillips* the en banc court was faced with multiple issues, and it resolved the case by establishing the substantive framework used to construe a patent's claims. *Phillips v. AWH Corp.*, 376 F.3d 1382, 1383 (Fed. Cir. 2004) (ordering rehearing en banc and identifying issues for en banc briefing and review); *Phillips*, 415 F.3d at 1312 ("The principal question that this case presents to us is the extent to which we should resort to and rely on a patent's specification in seeking to ascertain the proper scope of its claims."). Unlike *Phillips*, the only issue before the en banc court in *Lighting Ballast* is

whether *Cybor* should be overruled and the level of deference, if any, that should be afforded a district court's claim construction. *Lighting Ballast*, 500 F. App'x at 951-952.

Finally, Teva demonstrates no urgent need for this Court's review. Teva's own actions belie any such claim: it chose not to file its petition in time for it to be heard on the merits this Term. *Cybor* has been the rule for 16 years. If *Lighting Ballast* announces a rule of law warranting this Court's consideration, the Court can grant review in that case—or in one of the other innumerable claim-construction cases that will apply it.

B. This Case Is An Unsuitable Vehicle To Consider The Appellate Standard Of Review

1. Lighting Ballast*, or a case applying its rule, would be a better vehicle to review the question presented*

If this Court wishes to consider the standard of appellate review for claim-construction rulings, *Lighting Ballast*, or a case applying the rule of *Lighting Ballast*, would be the appropriate vehicle to do so. *Contra* Pet. 29-31. The Federal Circuit's en banc decision will explore fully what deference, if any, should be accorded to which aspects of a district court's claim-construction ruling. A petition following *Lighting Ballast* would permit this Court to review the considered views of the en banc Federal Circuit and any percolation of those views that has occurred since that decision. This Court may then consider whether

review is warranted in a case in which, unlike this one, the court of appeals has addressed the application of the rule of *Lighting Ballast* to the facts presented.

By contrast, this case is not a suitable vehicle. The Federal Circuit's decision here contains *no* discussion of what should be the standard of appellate review for claim-construction rulings. Indeed, Teva did not argue that the standard of review for claim construction should be changed (or even raise Rule 52) until its petition for rehearing. As such, nothing about this case makes it a more suitable vehicle than *Lighting Ballast* (or a case following *Lighting Ballast*).

2. The standard of review made no difference in the outcome of this case

In fact, this is a particularly unsuitable vehicle because the court of appeals correctly held a subset of the claims at issue invalid for indefiniteness, and that outcome would be the same regardless of the standard of review.

Teva conceded below that the patent claims at issue were ambiguous on their face because they did not specify which type of molecular weight was claimed. Pet. App. 8a ("It is undisputed that Group I claims contain an ambiguity because their plain language does not indicate which average molecular weight measure is intended."). On appeal, the court of appeals looked solely to the patent instruments

themselves and their prosecution history to hold the terms indefinite. Pet. App. 8a-10a.

First, the court observed that, during prosecution of these related patents before the Patent Office, Teva gave two flatly contradictory definitions of "average molecular weight." Pet. App. 9a. As discussed above, while prosecuting one patent, Teva informed the Patent Office that one of ordinary skill in the art would understand "average molecular weight" to mean "peak" molecular weight. Pet. App. 9a (quoting C.A. JA3258). Yet in prosecuting another, Teva told the Patent Office that "average molecular weight" meant "weight average molecular weight." Pet. App. 9a (quoting C.A. JA3229). No matter what an expert might later say in litigation, "Teva's two definitions cannot be reconciled." Pet. App. 9a.

Second, the court of appeals looked to the common specification of the asserted patents and determined that it too provided no guidance regarding the meaning of "average molecular weight." Pet. App. 9a-10a. The court recognized that Figure 1 of the patent contradicted the declaration of Teva's expert that the figure referred to "peak" molecular weight. Pet. App. 9a-10a. Even a cursory examination of the patent instrument demonstrated that "the peaks of the curves in Figure 1 do not correspond to the values denoted as 'average molecular weight' in the figure's legend." Pet. App. 10a. Indeed, those reported "average molecular weight" values were closer to "weight average molecular weight" than to "peak" molecular

weight—as even Teva's expert admitted. Pet. App. 10a; *see* C.A. JA5824-5825.

Simply put, the court of appeals properly refused to allow a litigation expert to determine the ultimate meaning of the patent instruments. That outcome would not change under any standard of review.[1]

3. The nature of the extrinsic "evidence" in this case makes this a poor vehicle to explore the contours of any deference

Given the square contradiction between the intrinsic record and Teva's expert's declarations, this is an especially poor vehicle for considering what deference, if any, should be accorded to a district court's claim-construction rulings under Rule 52, and what the contours of any such deference should be.

The expert "testimony" Teva cites consisted solely of written declarations of its paid expert. *See* Pet. 9, 14, 25. The purported "facts" on which Teva relies were its expert's litigation-driven "interpretation" of the asserted patents themselves and their prosecution history. *See* C.A. JA1016-1018, JA7097-7101 (Grant declarations discussing "average molecular weight"). Contrary to Teva's assertion, these were not declarations about "the *historical* meaning of a claim term to one of ordinary skill in the art at the time of

[1] Indeed, in its pending reissue application to the Patent Office, Teva has conceded that the '808 patent claim as written is erroneous.

the invention." Pet. 23 (quoting U.S. En Banc Amicus Br. at 15, *Lighting Ballast*, *supra*) (emphasis added). Nowhere did these expert declarations contend that "average molecular weight" had an established meaning at the time of the invention. In fact, Teva admitted that the term was ambiguous and had no fixed meaning. Pet. App. 8a.

As such, the "evidence" Teva cites is not the kind of "historical fact" evidence that the United States has contended could support findings warranting deference on appeal. *Contra* Pet. 23. Quite the opposite: the United States has explained that courts "must exercise care to distinguish relevant and probative expert testimony (e.g., testimony about the accepted meaning of a claim term in the relevant art at the time of the invention) from irrelevant opinion (e.g., an expert's present, subjective understanding of a patent claim)." U.S. En Banc Amicus Br. at 20, *Lighting Ballast*, *supra*; *see Phillips*, 415 F.3d at 1318. Teva's expert declarations offered only the latter.

More significantly, the court of appeals properly refused to defer to the district court's decision to "credit" Teva's expert's declarations that directly contradicted what the legal documents actually said. Where the patents and their prosecution history did not support his argument, Grant simply opined that those documents—the public record of the asserted invention—were wrong. For example, as to one of the two irreconcilable definitions of "average molecular weight" in the prosecution history, Grant contradicted

the public record by saying that one of skill in the art reading the prosecution history "would have understood that to be a misstatement." C.A. JA7100. Moreover, because Grant's readings of the "peaks" in Figure 1 of the specification did not correspond to the "average molecular weight" values denoted in that figure's legend, Grant opined that Figure 1 was in error and that his calculation fell within an unspecified "margin of error." C.A. JA3115-3116.

This cavalier contradiction of the intrinsic record did not merit consideration in claim construction, much less deference on appeal. *See U.S. Indus. Chems., Inc. v. Carbide & Carbon Chems. Corp.*, 315 U.S. 668, 678 (1942) ("It is inadmissible to enlarge the scope of the original patent by recourse to expert testimony * * * ."). Indeed, in *Phillips*, the en banc Federal Circuit instructed that courts "should discount any expert testimony that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent." *Phillips*, 415 F.3d at 1318 (internal quotation marks omitted). The court of appeals explained that "conclusory, unsupported assertions by experts as to the definition of a claim term are not useful to a court." *Ibid*. And it is the job of neither an expert nor the district court to correct "misstatements" in the intrinsic record to preserve patent validity. *Ibid*.

Teva does not challenge *Phillips*' elevation of the intrinsic patent record above the extrinsic evidence of

expert testimony, and that elevation fully comports with this Court's precedent. Yet for Teva to prevail, this Court would need to set aside that well-settled framework. That is further reason to deny review here, as those unchallenged claim-construction principles could preclude the Court from even reaching the question presented.

For similar reasons, Teva is wrong in suggesting that certain amici in *Lighting Ballast* advocate Teva's approach. Pet. 23 & n.8. None of those associations has argued that extrinsic expert testimony should trump a patent record that it squarely contradicts. *See* ABA En Banc Amicus Br. at Add. 1, *Lighting Ballast*, *supra* (ABA resolution advocating that expert testimony may not be used to contradict a patent's intrinsic record); AIPLA En Banc Amicus Br. at 14, *Lighting Ballast*, *supra* ("Where, for example, the district court determines a factual issue based on expert testimony, this Court must 'discount [such] expert testimony "[if] that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history * * * ."'") (quoting *Phillips*, 415 F.3d at 1318); FCBA En Banc Amicus Br. at 10-11, *Lighting Ballast*, *supra* (explaining that no deference is due to extrinsic evidence that contradicts the intrinsic evidence or that does not inform questions of historical fact).

In short, regardless of the standard of review, there were no factual findings here that warranted deference. At the very least, the square contradiction between the intrinsic record and the expert's

declarations make this a poor vehicle to assess which, if any, factual findings relating to claim construction should receive deference on appeal.[2]

4. The court of appeals' actions confirm that a different standard of review would not change the outcome

The court of appeals' repeated rebuffs of Teva's attempts to have this case stayed pending *Lighting Ballast* further demonstrate that the standard of review was not outcome determinative.

The panel issued its unanimous decision in this case while *Lighting Ballast* was pending before the en banc court. The entire court of appeals then denied Teva's rehearing petition (which was based primarily on *Lighting Ballast*), declined to hold the case for *Lighting Ballast*, and refused Teva's plea to stay issuance of the mandate pending the outcome in *Lighting Ballast*. *See* Pet. App. 84a, 87a. Those repeated rejections demonstrate that the court of appeals did not deem the standard of review dispositive of the

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[2] *Great Northern Railway Co. v. Merchants' Elevator Co.*, 259 U.S. 285, 291-292 (1922), does not help Teva's cause. *Contra* Pet. 19-20. There, this Court simply affirmed the general rule that construction of tariffs "presents ordinarily a question of law which does not differ in character from those presented when the construction of any other document is in dispute." *Great Northern Railway*, 259 U.S. at 291. Although the Court observed that an issue of fact might arise where resort to extrinsic evidence was necessary for construction, *id.* at 292, the Court did not address whether deference could be afforded to an expert's reading of the legal instrument itself.

outcome here. Given that the same legal question is pending before the en banc court, that court's assessment warrants this Court's deference.

Respect for the court of appeals' assessment is particularly appropriate here, as the Federal Circuit judges on the panel in this case were Chief Judge Rader and Judge Moore, two of the most vocal judges calling for a deferential standard of review of claim-construction rulings. *See, e.g.*, *Retractable Techs., Inc. v. Becton, Dickinson & Co.*, 659 F.3d 1369, 1373 (Fed. Cir. 2011) (Moore, J., and Rader, C.J., dissenting from denial of rehearing en banc); *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 469 F.3d 1039, 1040-1041 (Fed. Cir. 2006) (Michel, C.J., and Rader, J., dissenting from denial of rehearing en banc); *id.* at 1044-1045 (Rader, J., dissenting from denial of rehearing en banc); *id.* at 1045-1046 (Moore, J., dissenting from denial of rehearing en banc). Indeed, Teva prominently relies on opinions by those two judges. Pet. 3 n.2, 5, 21. Nevertheless, Judge Moore authored, and Chief Judge Rader joined, the decision holding a subset of the claims indefinite and then repeatedly declined to hold this case for *Lighting Ballast*. That further confirms that the standard of review did not affect the outcome here.

C. There Is No Reason To Hold The Petition

In the alternative, Teva suggests (Pet. 32-35) that the Court hold its petition pending the resolution of *Nautilus, Inc. v. Biosig Instruments, Inc.*, No. 13-369 (cert. granted Jan. 10, 2014). But Teva's question

presented does not invoke the questions presented in *Nautilus*, and that alone should preclude Teva from obtaining any relief under that decision. In any event, because the result in *Nautilus* should not affect the disposition of this case, there is no reason to hold the petition.

In *Nautilus*, this Court is considering the standard for declaring a patent indefinite under 35 U.S.C. § 112(b), which requires that a patent contain "one or more claims particularly pointing out and distinctly claiming the subject matter which the [applicant] regards as the invention." Under Federal Circuit precedent, a patent is not indefinite as long as it is "amenable to construction, however difficult that task may be," even if "the conclusion may be one over which reasonable persons will disagree." *Exxon Research & Eng'g Co. v. United States*, 265 F.3d 1371, 1375 (Fed. Cir. 2001). Under that standard, a court may invalidate a claim for indefiniteness only if the claim is "insolubly ambiguous, and no narrowing construction can properly be adopted." *Ibid.*

According to Teva, the parties to *Nautilus* are "likely to argue" that case "in a way highly relevant to this case." Pet. 32. But neither the questions presented nor any of the petition-stage briefs in *Nautilus* mentions the standard of appellate review of indefiniteness determinations. Instead, the parties have focused on the underlying substantive issue of what standard of indefiniteness should be applied, in the first instance, to determine the validity of a patent claim. That issue is not relevant to the question

presented as framed by Teva, which concerns only the *appellate* standard of review. Thus, regardless of the outcome of *Nautilus*, Teva should not be entitled to any relief under that decision. *Yee v. City of Escondido*, 503 U.S. 519, 535 (1992) ("The framing of the question presented has significant consequences, however, because under this Court's Rule 14.1(a), '[o]nly the questions set forth in the petition, or fairly included therein, will be considered by the Court.' "). That alone is sufficient reason not to hold the petition.

Moreover, the issues in *Nautilus* are not relevant to this case in any way that could possibly help Teva. The petitioner in *Nautilus* has argued that the Federal Circuit's substantive indefiniteness standard makes it too difficult to establish indefiniteness and that the Federal Circuit is wrongly upholding ambiguous patent claims. Pet. for Writ of Cert. at 2-5, *Nautilus*, *supra*. The respondent, by contrast, has argued that the Federal Circuit's substantive indefiniteness standard is correct. Br. in Opp. at 26-28, *Nautilus*, *supra*. Neither party, however, has suggested that this Court should adopt a substantive indefiniteness standard that is *more* favorable to patentees. Indeed, it is difficult to see how *any* standard could be more deferential than that currently applied by the Federal Circuit, which upholds patent claims as long as they are not "insolubly ambiguous" and thus incapable of construction. *Exxon Research*, 265 F.3d at 1375; *accord Enzo Biochem, Inc. v. Applera Corp.*, 605 F.3d 1347, 1348 (Fed. Cir. 2010) (Plager, J.,

dissenting from denial of panel rehearing) ("[T]he general conclusion from our law seems to be this: if a person of ordinary skill in the art can come up with a plausible meaning for a disputed claim term in a patent, that term, and therefore the claim, is not indefinite.").

Here, applying that "insolubly ambiguous" test, the Federal Circuit held that a subset of the patent claims at issue were invalid for indefiniteness. Pet. App. 6a-11a. Because Teva's claims could not survive under the current indefiniteness standard, they will, *a fortiori*, be unable to survive under any more rigorous standard this Court might adopt in *Nautilus*. That is yet another reason not to hold the petition.

In a last-ditch effort to delay final resolution of this case, Teva asks in a footnote that its petition also be held pending the disposition of *Highmark Inc. v. Allcare Health Management Systems, Inc.*, No. 12-1163, and *Octane Fitness, LLC v. Icon Health & Fitness, Inc.*, No. 12-1184 (both to be argued Feb. 26, 2014). Pet. 34 n.18. But those cases involve the standards that trial and appellate courts should apply in determining whether a case is "exceptional" and warrants an award of attorney's fees under 35 U.S.C. § 285. Those cases have no relevance here, where no award of attorney's fees is at issue.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

ERIC D. MILLER
Counsel of Record
PERKINS COIE LLP
1201 Third Ave.,
Suite 4900
Seattle, Washington 98101
206.359.8000
EMiller@perkinscoie.com

SHANNON M. BLOODWORTH
PERKINS COIE LLP
700 13th Street, N.W.,
Suite 600
Washington, D.C. 20005
202.654.6200

EVAN R. CHESLER
CRAVATH, SWAINE &
MOORE LLP
825 Eighth Ave.
New York, New York 10019
212.474.1243

Counsel for Respondents
Mylan Pharmaceuticals Inc.,
Mylan Inc., and
Natco Pharma Ltd.

DEANNE E. MAYNARD
Counsel of Record
BRIAN R. MATSUI
MARC A. HEARRON
NATALIE R. RAM
MORRISON & FOERSTER LLP
2000 Pennsylvania Ave., N.W.
Washington, D.C. 20006
202.887.8740
DMaynard@mofo.com

DAVID C. DOYLE
ANDERS T. AANNESTAD
BRIAN M. KRAMER
MORRISON & FOERSTER LLP
12531 High Bluff Drive,
Suite 100
San Diego, California
92130
858.720.5100

Counsel for Respondents
Sandoz Inc.
and Momenta
Pharmaceuticals Inc.

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