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.,
Respondents.

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

BRIEF FOR *AMICUS CURIAE* HOUSTON INTELLECTUAL PROPERTY LAW ASSOCIATION IN SUPPORT OF NEITHER PARTY

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QUESTION PRESENTED

Whether a district court's factual finding in support of its construction of a patent claim term may be reviewed *de novo*, as the Federal Circuit requires (and as the panel explicitly did in this case), or only for clear error, as Federal Rule of Civil Procedure 52(a) requires?

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INTEREST OF *AMICUS CURIAE*

The Houston Intellectual Property Law Association ("HIPLA") is an association of over 400 lawyers and other professionals who predominately work in the Houston, Texas, area (see, generally, www.hipla.org). The practice of most of the HIPLA membership relates in substantial part to the field of intellectual property law. Founded in 1961, HIPLA is one of the largest associations of intellectual property practitioners in the United States.[1]

Consent to the filing of *amicus curiae* briefs in support of either party or of neither party was submitted to the Clerk by counsel for Respondent Mylan Pharmaceuticals, Inc., et al. Consent to the filing of HIPLA's *amicus curiae* brief in support of neither party was received from counsel of record for the Petitioners Teva Pharmaceuticals USA, Inc., et al., by letter dated June 10, 2014. And counsel for Sandoz, Inc., et al., consented to HIPLA's filing of its *amicus curiae* brief supporting neither party by letter dated June 13, 2014.

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[1] No counsel for a party in this case authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person or entity other than HIPLA, its members, or its counsel paid for this brief.

HIPLA has no stake in the outcome of this litigation. But HIPLA is interested in promoting consistency in the development of the law affecting patents and other forms of intellectual property.

SUMMARY OF ARGUMENT

The interpretation of patent claims, like that of other legal instruments, is ultimately a question of law. But claim interpretation can also depend on the resolution of underlying factual issues. Claim interpretation, thus, presents a hybrid mix of factual and legal issues that are resolved by a district court in determining the meaning of disputed claim terms. Having already recognized that claim construction can be a "mongrel practice," this Court should now mandate a hybrid fact/law approach for appellate review of claim constructions.

Under a hybrid approach, fact findings made by a district court judge would be reviewed for clear error under Rule 52(a). Legal conclusions as to the meaning of claim terms under established claim construction precedent would continue to be reviewed *de novo*. This approach is consistent with this Court's decisions on obviousness and the Federal Circuit's decisions on enablement (two other areas of mixed law and fact). Policy concerns of litigation efficiency and proper allocation of

judicial resources with national uniformity in the treatment of patents is also satisfied by such a hybrid approach.

This Court has recognized that distinguishing between fact findings and legal conclusions can be difficult. But adopting a hybrid review standard will require these distinctions to be made, and HIPLA urges this Court to provide additional guidance that facilitates implementation of this standard. Particularly, this Court should clarify that claim meaning, even when considered from the perspective of a skilled artisan at the time of invention, is a question of law subject to *de novo* review.

ARGUMENT

I. A district court's fact findings during claim construction should not be overturned unless clearly erroneous.

In *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996), this Court held that, as between a district court judge and a jury, the interpretation of claim terms falls within the exclusive province of the court. *Id.* at 376. Although this Court did not directly address in *Markman* the standard of review for claim construction, the Federal Circuit en banc held that a *de novo* standard is proper. *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1451

(Fed. Cir. 1998) (en banc) ("[C]laim construction, as a purely legal issue, is subject to *de novo* review on appeal."); *accord Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 723 F.3d 1363, 1373 (Fed Cir. 2013) ("Claim construction is an issue of law that we review *de novo*."). The en banc Federal Circuit recently reconsidered and, applying *stare decisis*, affirmed its holding in *Cybor*, holding that claim construction is a purely legal issue subject to *de novo* review. *Lighting Ballast Control LLC v. Philips Electronics N. Am. Corp.*, 744 F.3d 1272, 1276–77 (Fed. Cir. 2014) (en banc).

But the Federal Circuit's holdings conflict with this Court's recognition that claim construction, in at least some instances, can raise issues of both fact and law. *See Markman*, 517 U.S. at 378 (describing claim construction following receipt of evidence as a "mongrel practice"). This Court has further suggested that claim construction can fall "somewhere between a pristine legal standard and a simple historical fact." *Id.* at 388 (quoting *Miller v. Fenton*, 474 U.S. 104, 114 (1985)).

Moreover, a careful reading of the *Markman* opinion indicates that this Court defers to the district judge for answering factual questions that are subsidiary to claim construction (e.g., "credibility judgments . . . about the experts who testify in patent cases," 517 U.S. at 389). For example, this Court noted in *Markman* that:

> The decisionmaker vested with the task of construing the patent is in the better position to ascertain whether an expert's proposed definition fully comports with the specification and claims and so will preserve the patent's internal coherence. We accordingly think there is sufficient reason to treat construction of terms of art like many other responsibilities that we cede to a judge in the normal course of trial, notwithstanding its evidentiary underpinnings.

517 U.S. at 390.

As Professors Jonas Anderson and Peter Menell have detailed, the Federal Circuit appears not to have sufficiently considered that this Court in *Markman* is expressing its appreciation that claim construction rulings are analogous to other "rulings that a trial judge routinely resolves during the course of trial, which are not subject to *de novo* review." J. Jonas Anderson & Peter S. Menell, *Informal Deference: A Historical, Empirical, and Normative Analysis of Patent Claim Construction*, 108 NW. U. L. REV. 1, 66 (2014). Professors Anderson and Menell maintain:

> Thus, the more plausible interpretation of the full passage is that the Supreme Court is inclined toward a deferential standard of review of claim construction determinations reflecting the inherently "mongrel"—mixed

> fact and law—character of claim construction.

Id.

Justifying its plenary *de novo* review standard in *Cybor*, the Federal Circuit characterized this Court's *Markman* opinion as providing "only prefatory comments demonstrating the Supreme Court's recognition that the determination of whether patent claim construction is a question of law or fact is not simple or clear cut." *Cybor*, 138 F.3d at 1455. While *Markman* does give various precedential and historical reasons for concluding that claim construction is a question of law, it does not mandate sacrificing a district court's fact findings at the altar of the Federal Circuit's plenary *de novo* review standard. *See Markman*, 517 U.S. at 384–88. Rather, the most natural reading of this Court's decision in *Markman* is that the process of construing a claim term may indeed depend on the resolution of underlying fact questions. To the extent that *Cybor* and *Lighting Ballast* hold otherwise, they should be overruled.

Another area of patent law having a similar mix of factual and legal questions is obviousness under 35 U.S.C. § 103. Although the ultimate conclusion of whether a claim is obvious is a question of law, this conclusion is founded upon underlying facts. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 427 (2007); *Graham v. John Deere Co. of Kansas City*,

383 U.S. 1, 17–18 (1966). These underlying facts include the scope and content of the prior art, the differences between the prior art and claims at issue, the level of ordinary skill in the art, and any secondary considerations (e.g., commercial success, long-felt but unsolved needs, and failure of others). *KSR Int'l*, 550 U.S. at 427; *Graham*, 383 U.S. at 17.

Once these factual determinations are made, the district court then determines, as a matter of law, whether a claim at issue is obvious. And this Court long ago concluded that factual determinations underlying the obviousness inquiry are subject to Rule 52(a) and must be reviewed deferentially under the clear error standard. *Dennison Mfg. Co. v. Panduit Corp.*, 475 U.S. 809, 811 (1986) ("the subsidiary determinations of the District Court, at the least, ought to be subject to the Rule.").

Dennison is consistent with this Court's other decisions indicating that Rule 52(a)'s clear error standard is broadly applicable to fact findings. *See* Eileen M. Herlihy, *Appellate Review of Patent Claim Construction: Should the Federal Circuit Be Its Own Lexicographer in Matters Related to the Seventh Amendment*, 15 MICH. TELECOMM. & TECH. L. REV. 469, 499 (2009) (noting the consistency of the decisions regarding the broad applicability of Rule 52(a) in *Dennison*, *Pullman–Standard v. Swint*, 456 U.S. 273 (1982), and *Bose Corp. v.*

Consumers Union of United States, Inc., 466 U.S. 485 (1984)).

In the context of enablement determinations, that is, whether a patent's specification provides enough detail to explain how the claims work to a person of ordinary skill in the relevant art, the Federal Circuit also applies a clear error analysis to a district court's fact findings. *See Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1369–70 (Fed. Cir. 1999) ("Whether undue experimentation would have been required to make and use an invention, and thus whether a disclosure is enabling under 35 U.S.C. § 112, ¶ 1, is a question of law that we review *de novo*, based on underlying factual inquiries that we review for clear error. *See Johns Hopkins Univ. v. Cellpro, Inc.*, 152 F.3d 1342, 1354 (Fed. Cir. 1998) (citing *Wands*, 858 F.2d at 736–37)."); *see also ALZA Corp. v. Andrx Pharms., LLC*, 603 F.3d 935, 940 (Fed. Cir. 2010) ("The district court's determination of the hypothetical person of ordinary skill in the relevant art is a finding of fact we review for clear error. *Graham v. John Deere Co. of Kan. City*, 383 U.S. 1, 17 (1966).")

Rule 52(a) should equally apply to appellate review of claim construction rulings. The factual underpinnings of claim construction orders should be reviewed deferentially and not overturned unless clearly erroneous.

Moreover, a rule for deferential review of fact findings is consistent with this Court's recent decision in *Highmark Inc. v. Allcare Health Mgmt. Sys., Inc.,* 572 U.S. ___ (2014). Although founded upon exceptional case determinations under 35 U.S.C. § 285, this Court in *Highmark* clearly stated:

> As in *Pierce* [*v. Underwood,* 487 U.S. 552 (1988)], "as a matter of the sound administration of justice," the district court "is better positioned" to decide whether a case is exceptional, *id.*, at 559–560, because it lives with the case over a prolonged period of time. And as in *Pierce*, the question is "multifarious and novel," not susceptible to "useful generalization" of the sort that *de novo* review provides. . . .

Id., slip op. at 5.

II. The ultimate determination of claim term meaning is a question of law that is reviewed *de novo*, but such a determination should only be reversed if the fact findings upon which it is based are clearly erroneous, or if the district court misapplied established Federal Circuit or Supreme Court precedent.

Patents are legal documents, and the interpretation of legal documents is a question of

law. *See Markman*, 370 at 388 ("'A patent is a legal instrument, to be construed, like other legal instruments, according to its tenor.'" (quoting 2 W. C. ROBINSON, THE LAW OF PATENTS FOR USEFUL INVENTIONS § 732 (1890))); *Levy v. Gadsby*, 7 U.S. (3 Cranch) 180, 186 (1805) (Marshall, C.J.) ("in this case the question arises upon, a written instrument, and no principle is more clearly settled, than that the construction of a written evidence is exclusively with the court"); *Eddy v. Prudence Bonds Corp.*, 165 F.2d 157, 163 (2d Cir. 1947) (Learned Hand, J.) ("[A]ppellate courts have untrammelled power to interpret written documents.").

On appeal, questions of law are reviewed *de novo*. *Pierce*, 487 U.S. at 558. Thus, while fact findings underlying claim construction should be reviewed for clear error, the final conclusion as to the proper meaning of a claim term is a question of law that should be reviewed *de novo*—claim terms are part of a legal document, a patent.

By analogy, this Court mandates a hybrid approach when reviewing a district court's obviousness determination. *See Dennison*, 475 U.S. at 810–11; *KSR Int'l*, 550 U.S. at 427; *Graham*, 383 U.S. at 17. A district court's fact findings during an obviousness analysis includes its review of the scope and content of the prior art, the differences between the prior art and the asserted claims, and the level of ordinary skill in the pertinent art. *KSR*

Int'l, 550 U.S. at 427; *Graham*, 383 U.S. at 17. Upon appellate review, this Court requires that the district court's fact findings be reviewed under Rule 52(a) for clear error. *Dennison*, 475 U.S. at 810–11. But the ultimate question of obviousness—whether a claim would have been obvious to one of ordinary skill in the art at the time of invention—is a question of law that is reviewed *de novo*. *KSR Int'l*, 550 U.S. at 427; *Graham*, 383 U.S. at 17.

The ultimate question in claim construction is the meaning that is attributed to a claim term by a person of ordinary skill in the relevant art at the time of the invention. And that meaning may be informed by subsidiary fact findings. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1332 (Fed. Cir. 2005) (Mayer, J., dissenting) ("While this court may persist in the delusion that claim construction is a purely legal determination, unaffected by underlying facts . . . a claim should be interpreted from the perspective of one of ordinary skill in the art and in view of the state of the art at the time of invention. . . . These questions, which are critical to the correct interpretation of a claim, are inherently factual.")

Thus, like obviousness determinations, this Court should require the Federal Circuit to apply a similar hybrid fact/law standard of review when reviewing claim construction rulings. Under this standard, the Federal Circuit could not reverse a district court's claim construction unless the court's

factual basis is clearly erroneous, or the district court misapplied established appellate claim construction precedent under a *de novo* review.

III. The meaning that a person of ordinary skill in the art would have given a claim term at the time of invention is not a historical fact.

The Federal Circuit in *Lighting Ballast* aptly noted that Rule 52(a) prescribes the standard of review for questions of fact. *Lighting Ballast*, 744 F.3d at 1290. The Federal Circuit further stated that courts must look outside the Rule to decide if a question is properly characterized as one of fact. *Id.* As this Court has recognized, drawing lines between questions of law and fact can be difficult: "Rule 52(a) does not furnish particular guidance with respect to distinguishing law from fact. Nor do we yet know of any other rule or principle that will unerringly distinguish a factual finding from a legal conclusion." *Pullman–Standard*, 456 U.S. at 288; *Cooter & Gell v. Hartmarx Corp.*, 496 U.S. 384, 401 (1990) ("The Court has long noted the difficulty of distinguishing between legal and factual issues."); *Miller*, 474 U.S. at 113–14 ("Perhaps much of the difficulty in this area stems from the practical truth that the decision to label an issue a 'question of law,' a 'question of fact,' or a 'mixed question of law and fact' is sometimes as much a matter of allocation as it is of analysis."). This

Court has also made clear that the "vexing nature" of distinguishing law from fact "does not, however, diminish its importance, or the importance of the principles that require the distinction to be drawn in certain cases." *Bose*, 466 U.S. at 501.

Various fact issues may be resolved during the process of interpreting the meaning of claim terms. These fact issues may include the pertinent field of invention and the level of ordinary skill in the art for that field. In the present case, the different ways that skilled artisans could have characterized the average molecular weight of polypeptide mixtures (e.g., peak average, number average, or weight average) in the patent claims is an example of a fact issue that the district court would have resolved. How skilled artisans could have measured the different average molecular weights, and the relative ease or difficulty with which these different averages could be obtained are also fact issues for the district court's resolution. And the district court's findings for such fact issues should only be reversed if clearly erroneous under Rule 52(a).

Some, including the petitioners in this case, have suggested that the meaning that would have been given to a claim term by a person of ordinary skill in the art at the time of invention is a "historical fact." Pet. for Writ of Cert. at 23. And that a district court's ultimate conclusion as to this meaning should also be treated as a fact finding subject to clear error review under Rule 52(a). *Id.*

The Federal Circuit in *Lighting Ballast* vigorously rejected this suggestion:

> This is not a question of fact; it is the very inquiry which determines the claim construction in nearly all cases. Claim terms are given their ordinary meaning to one of skill in the art, unless the patent documents show that the patentee departed from that meaning. . . . Treating the ordinary meaning to a skilled artisan as requiring deference would mean deference on the controlling question of claim construction in nearly every case.

Lighting Ballast, 744 F.3d at 1289 (internal citations omitted).

One could argue that determining the meaning of a claim term from the perspective of a "person of ordinary skill in the art at the time of invention" requires forming a baseline understanding of the technology in dispute. *See* Pet. for Writ of Cert. at 18–19. One could also argue that viewing claim meaning through the lens of a person of ordinary skill in the art justifies clear error review.

But viewing a claim term's meaning through the lens of a person of ordinary skill in the art should not characterize that inquiry as a pure question of fact; it should lead to a hybrid fact/law review of a district court's claim construction.

IV. Policy considerations further support a hybrid approach to appellate review of claim construction rulings.

The private and public costs of the Federal Circuit's current *de novo* review of final claim construction definitions are high. Professor Peter Menell summarizes these costs as including:

- lower quality decision-making at both the district and appellate levels;
- higher costs of litigation resulting from too many appeals and retrials following reversals;
- greater litigation uncertainty;
- fewer and delayed settlements resulting from longer case pendency and litigation;
- the distraction and disruption of [extended] litigation on the technology marketplace; and
- unnecessarily added burdens on judges and the judicial system.

Brief of Professor Peter S. Menell as *Amicus Curiae*, *Lighting Ballast Control, LLC v. Philips Elecs. N. Am. Corp.*, 744 F.3d 1272 (Fed. Cir. 2014) (en banc), at 16–17, available at:

http://www.grayonclaims.com/storage/Menell%20Amicus%20Brief%20Dkt.%20No.%20278.pdf.

In contrast, advantages of a "balanced, structurally sound, legally appropriate, hybrid standard of appellate review" (i.e., a standard toward which this Court's *Markman* decision points) would promote "more accurate, efficient patent dispute resolution." *Id.* at 3. Specific advantages include:

- fewer reversals and remands;
- less fear of reversal due to factual disagreements at the Federal Circuit;
- more complete and thorough claim construction orders detailing fact findings for the parties and for Federal Circuit's review;
- improved utilization of district court resources; and
- increased settlements.

Id.

This Court has long-recognized the importance of uniformity in the treatment of patents as an additional reason for allocating claim construction issues to the district judge, and for reviewing final claim term definitions *de novo*, but with deference

to the district court's fact findings. Professor Menell's assessments provide this Court additional, prudential reasons for requiring a hybrid fact/law approach when reviewing claim construction rulings.

CONCLUSION

HIPLA respectfully asks this Court to rule that: (1) a district court's fact findings during claim construction is entitled to deferential review under the clearly erroneous standard of Rule 52(a); (2) a district court's final claim term definition is subject to *de novo* review; (3) a claim term definition should not be overturned unless the fact findings upon which the definition is based are clearly erroneous, or unless the district court misapplied settled claim construction precedent; and (4) the meaning attributable to a claim term by one of ordinary skill in the art at the time of invention is not a historical fact entitled to deferential review.

Respectfully submitted,

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