

No. 13-854

In the Supreme Court of the United States

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

v.

SANDOZ, INC., ET AL.

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

**BRIEF FOR THE UNITED STATES
AS AMICUS CURIAE SUPPORTING NEITHER PARTY**

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QUESTION PRESENTED

Whether, in reviewing a district court's determination that a patent claim is sufficiently clear to satisfy the definiteness requirement of 35 U.S.C. 112, ¶ 2 (2006), the court of appeals should apply a deferential clear-error standard of review to the district court's resolution of subsidiary questions of fact.

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INTEREST OF THE UNITED STATES

This case concerns the appropriate standard for appellate review of a district court’s determination that disputed patent claims were sufficiently clear to satisfy the definiteness requirement of 35 U.S.C. 112, ¶ 2 (2006). The United States Patent and Trademark Office (PTO) is responsible for “the granting and issuing of patents,” 35 U.S.C. 2(a)(1), as well as for advising the President on issues of patent policy, 35 U.S.C. 2(b)(8). The United States therefore has a substantial interest in the Court’s resolution of the question presented.

STATEMENT

1. a. A patent is a legal instrument that grants to the patentee “the right to exclude others” from prac-

ting the claimed invention “throughout the United States or importing the invention into the United States.” 35 U.S.C. 154(a)(1).¹ The patent document includes a specification and drawings. 35 U.S.C. 111(a)(2), 113, 154(a)(4). The specification must “contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains * * * to make and use the same.” 35 U.S.C. 112, ¶ 1. “The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.” 35 U.S.C. 112, ¶ 2.

Section 112, ¶ 2 requires that “a patent’s claims, viewed in light of the specification and prosecution history,” must be sufficiently definite to “inform those skilled in the art about the scope of the invention with reasonable certainty.” *Nautilus, Inc. v. Biosig Instruments, Inc.*, No. 13-369 (June 2, 2014), slip op. 11. An inventor’s failure to comply with the definiteness requirement renders the claim in suit invalid. See 35 U.S.C. 282(3).

b. In *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996), this Court held that, because a patent is a written legal instrument, “the construction of a patent, including terms of art within its claim[s], is exclusively within the province of the court” rather

¹ In the Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284, Congress amended several of the provisions implicated here. The amended versions are inapplicable to this case because the patents were filed before the Act’s effective date. See Pet. Br. 5 n.4. This brief’s citations to Title 35 of the United States Code refer to the 2006 edition.

than the jury. *Id.* at 372. The Federal Circuit subsequently construed *Markman* as mandating that a district court’s construction of disputed patent claims, “including any allegedly fact-based questions” resolved on the basis of expert testimony or other extrinsic evidence, is subject to de novo review by the court of appeals. *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1456 (1998). The en banc Federal Circuit recently considered whether it should overrule *Cybor*, but the court ultimately “confirm[ed] the *Cybor* standard of de novo review of claim construction” on *stare decisis* grounds. *Lighting Ballast Control LLC v. Philips Elecs. N. Am. Corp.*, 744 F.3d 1272, 1276-1277 (2014).

2. a. Petitioners are the owner and exclusive licensees of a family of nine patents related to Copaxone®, a drug used in treating multiple sclerosis. Pet. App. 27a-28a. The patents stem from a single patent application and share a common specification. *Id.* at 27a & n.2. Eight of the patents expired in May 2014. *Id.* at 79a-81a. Only the patent known as the ’808 patent remains in force; it will expire in September 2015. *Id.* at 81a.

The active ingredient in Copaxone® is “copolymer-1,” a mixture of polypeptide molecules of varying sizes. Pet. App. 28a, 31a. The ’808 patent recites a method of manufacturing “[c]opolymer-1 having a molecular weight of about 5 to 9 kilodaltons.” *Id.* at 5a (emphasis omitted); see *id.* at 3a n.2.

b. In 2008 and 2009, petitioners filed patent-infringement suits against respondents after respondents sought Food and Drug Administration approval to market a generic version of Copaxone®. Pet. App. 26a-28a; see 35 U.S.C. 271(e). As relevant here, re-

spondents argued that certain claims were indefinite because the claim term “molecular weight” has multiple possible meanings and was not defined in the patents’ shared specification. Pet. App. 28a.

The district court rejected that argument and held that the claims were not invalid. Pet. App. 26a-72a. The court first explained that, because a mixture like copolymer-1 contains molecules of varying weights, polymer chemists describe the mixture according to its “average molecular weight.” *Id.* at 41a. The court further explained that the term “average molecular weight” has no single ordinary meaning with respect to non-uniform compositions like copolymer-1, but instead may refer to any of several different measures, including: peak average molecular weight (M_p), or the molecular weight of the most abundant polymer molecule in the sample; number average molecular weight (M_n), or the arithmetic mean weight of the molecules in the sample; and weight average molecular weight (M_w), which is a weighted average value. *Ibid.*; see *id.* at 4a-5a. Because each measure of molecular weight typically will yield different values for non-uniform compounds, the choice among those alternative meanings dictates what polymer composition the patent claims encompass.

To determine which meaning the term “molecular weight” should be given in petitioners’ patent claims, the district court examined the claims, the specification, the prosecution history, and additional evidence, including declarations filed by the parties’ respective expert witnesses. Pet. App. 42a, 44a (citing *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314-1318 (Fed. Cir. 2005) (en banc), cert. denied, 546 U.S. 1170 (2006)). The court held, largely based on the declaration of peti-

tioners' expert, Dr. Grant, that a person of ordinary skill in the art would understand from the specification that, in the patents at issue, the claim term "molecular weight" means M_p . *Id.* at 43a-44a, 48a-49a.

The district court "credit[ed] and accept[ed]" Dr. Grant's testimony that a skilled artisan would understand the patent to refer to M_p because the specification describes measuring the average molecular weight of a copolymer-1 sample using size exclusion chromatography (SEC). Pet. App. 44a. Dr. Grant explained that M_p can be determined directly from SEC-generated data because the "chromatogram" illustrating those data has curves whose "peaks" correspond to the peak average molecular weight for the sample. *Id.* at 43a. Although SEC-generated data can also be used to determine M_w or M_n , further calculations would be necessary. See *id.* at 48a. Dr. Grant further testified that, because the specification did not describe any additional calculations that would be performed to obtain the molecular weight values, a skilled artisan would understand the term "molecular weight" in the patent claims to "mean[] M_p ." *Id.* at 49a; see *id.* at 43a. The court "credit[ed]" that testimony. *Id.* at 44a.

The district court rejected respondents' argument that Dr. Grant's inference from the patents' disclosure of SEC was inconsistent with Figure 1 of the patent. Pet. App. 49a. Although Figure 1 depicted a molecular weight distribution curve whose peak values differed from the molecular weight values recited in the specification, the court "credit[ed] all of Dr. Grant's explanation" that converting data from a chromatogram into Figure 1 "would likely cause the peak on each curve to shift slightly." *Id.* at 45a. The court

therefore concluded that Figure 1 “would not dissuade” a skilled artisan from “concluding that [molecular weight] refers to M_p in the context of the patents-in-suit.” *Id.* at 49a.

Finally, the district court rejected respondents’ argument that the ’808 patent was indefinite because petitioners had “proffered contradictory definitions” of “average molecular weight” in prosecuting applications for two related patents. Pet. App. 50a; see *id.* at 45a-47a, 50a-53a. The PTO initially rejected claims in petitioners’ applications for what became the ’847 and ’539 patents on the ground that the term “average molecular weight” was “meaningless” by itself. *Id.* at 51a. Petitioners overcame the ’847 rejection by stating that “[o]ne of ordinary skill in the art could understand that kilodalton units implies a weight average molecular weight.” *Ibid.* (brackets in original). But petitioners overcame the ’539 rejection by representing that a skilled artisan “would understand that ‘average molecular weight’ refers to the molecular weight at the peak [M_p] of the molecular weight distribution curve shown in Figure 1.” *Id.* at 47a, 51a.

The district court credited the testimony of petitioners’ expert that, because the term “kilodalton” can be used in reference to any measure of molecular weight, a person of ordinary skill in the art would not infer that the use of the claim term in petitioners’ patents implies an M_w measure. Pet. App. 52a. The court concluded that a person of ordinary skill in the art therefore would instead credit the explanation given by petitioners in the prosecution history of the ’539 patent. *Ibid.*

3. The court of appeals reversed in relevant part, concluding that the term “molecular weight” was

indefinite. Pet. App. 1a-25a. Reviewing the issue of indefiniteness de novo, *id.* at 7a, the court explained that the claims' "plain language does not indicate which average molecular weight measure is intended," *id.* at 8a. The court concluded that nothing in the specification or prosecution history resolved that ambiguity. *Id.* at 8a-10a.

Reviewing the prosecution history, the court of appeals concluded that petitioners' contradictory representations to the PTO "render[ed] the ambiguity insoluble." Pet. App. 8a-9a. The court explained that petitioners had overcome identical indefiniteness rejections by providing the PTO with two different definitions of "molecular weight" that "cannot be reconciled." *Id.* at 9a.

The common specification of the patents, the court of appeals continued, did "not resolve the ambiguity." Pet. App. 9a. The court acknowledged Dr. Grant's testimony that a skilled artisan would understand that only M_p "can be read directly from a plot of SEC data." *Id.* at 9a-10a. But because it was undisputed that both M_n and M_w could be obtained from SEC data after further calculations, the court concluded that Dr. Grant's testimony did "not save [the] * * * claims from indefiniteness." *Id.* at 10a. The court also held that Figure 1 of the patent undermined the inference that "average molecular weight" means M_p . *Ibid.* The court emphasized that the peaks of the curves depicted in Figure 1 did not correspond to the values recited in the figure's legend as the relevant "average molecular weight" of the sample. *Ibid.*

SUMMARY OF ARGUMENT

I. A patent's claims establish the scope of the patentee's legal rights to exclude others from practicing

the invention. Because a patent is a written legal instrument, the ultimate interpretation of a patent claim—namely, how a person having ordinary skill in the relevant art at the time of the invention would understand the claim—is a question of law for the court. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372-373 (1996). Courts in patent cases can often resolve interpretive disputes solely by consulting the patent itself—its claims and specification—and its prosecution history. When the court’s claim construction is based on those sources alone, no part of its analysis is properly viewed as factual.

In order to understand the relevant science and the technical terms used in the patent, however, a district court often may need to receive additional evidence, such as expert testimony or scientific articles. When a predicate fact is both disputed and material to the court’s ultimate claim construction, the court may be required to make factual findings. The Court accordingly observed in *Markman* that, although it is appropriate to “treat[] interpretive issues as purely legal,” 517 U.S. at 391, and therefore to allocate interpretive responsibility to the judge, claim construction is a “mongrel practice” that has “evidentiary underpinnings,” *id.* at 378, 390.

The standard under which an appellate court should review a district court’s claim construction therefore turns on the nature of the district-court ruling under review. While a court’s ultimate interpretation of claim language is a legal question reviewed de novo, an appellate court may set aside the lower court’s subsidiary factual findings only if it concludes that they are clearly erroneous. See Fed. R. Civ. P. 52(a)(6). The justification for applying

clear-error review is particularly strong in the patent context, as adjudicating patent-law issues often requires familiarity with scientific and technical evidence. Accordingly, this Court has held in the obviousness context that a district court's factual findings—which include the kinds of technical inquiries that are also relevant to claim construction—are subject to Rule 52(a)(6). See *Dennison Mfg. Co. v. Panduit Corp.*, 475 U.S. 809, 810-811 (1986) (per curiam). The materially similar factual findings underlying claim construction should receive the same deference.

Applying Rule 52(a)(6) in the claim-construction context is both administrable and consistent with the need to foster uniform treatment of individual patents across multiple proceedings. Courts can distinguish between factual and legal conclusions by assessing the basis for the trial court's decision and the nature of the error asserted on appeal. Factual findings are those that are based at least in part on evidence outside the patent and its prosecution history, and that concern a matter that is in some sense distinct from the meaning or validity of the patent. A court's determination of what a particular claim term means in light of the patent document as a whole is a legal conclusion. Because the ultimate interpretive question remains one of law, there is no reason to think that deferentially reviewing underlying factual findings will lead to disuniformity.

II. These principles of claim construction apply with full force to respondents' contention that petitioners' patent claims using the term "molecular weight" are indefinite. Although the district court's ultimate determination that the claims were not indefinite (and therefore not invalid) was a legal ruling,

that determination was premised in part on findings that are properly characterized as factual.

The Federal Circuit reversed the district court's indefiniteness ruling after engaging in de novo review. Although de novo review was appropriate with respect to the district court's ultimate determination that the challenged claims were not indefinite, the court of appeals was required to accept the district court's factual findings unless it concluded that they were clearly erroneous. The Federal Circuit's indefiniteness analysis was in the main consistent with that requirement. In one respect, however, the court of appeals departed without justification from the district court's factual findings. Although it appears unlikely that this error affected the court of appeals' ultimate holding, this Court should vacate the judgment below and remand the case to allow the Federal Circuit to apply the correct standard of review in the first instance.

ARGUMENT

I. A DISTRICT COURT'S FACTUAL FINDINGS IN CONSTRUCTING A PATENT CLAIM, AND IN RESOLVING ISSUES OF DEFINITENESS, ARE ENTITLED TO DEFERENCE ON APPEAL

A patent is a legal instrument that grants to the patentee, for a limited term, the right to exclude others in the United States from practicing the claimed invention. *Markman*, 517 U.S. at 373. As with any other legal instrument, the ultimate meaning of a patent claim is a question of law. See *id.* at 372. But the proper construction of a patent claim can sometimes require consideration of evidence outside the patent and its prosecution history, such as expert testimony concerning relevant scientific or technical

principles or the accepted meaning of a specialized term in a particular industry at a particular time. When a district court examines such evidence and resolves disputed questions of fact in order to construe a patent claim, those factual findings “must not be set aside unless clearly erroneous.” Fed. R. Civ. P. 52(a)(6).

The same principles apply where, as here, the defendant in an infringement suit argues that a patent claim is invalid because it does not satisfy the definiteness requirement of 35 U.S.C. 112, ¶ 2. The district court’s ultimate determination that the claim is or is not indefinite is reviewed *de novo* on appeal. In conducting that review, however, the court of appeals must accept any subsidiary factual findings made by the district court unless it concludes that those findings are clearly erroneous.

A. The Proper Construction Of A Patent Claim Is An Issue Of Law, But Claim Construction May Involve The Resolution Of Subsidiary Factual Questions

1. Because a patent is a written legal instrument, its construction is ultimately a question of law

a. A patent is an integrated written legal instrument that defines the scope of the patentee’s exclusive right to exclude others from practicing the claimed invention. *Markman*, 517 U.S. at 373. The ultimate construction of a patent claim—that is, the determination of the boundaries of the patentee’s legal rights—is a question of law. See *id.* at 372; *Bates v. Coe*, 98 U.S. (8 Otto) 31, 38 (1878) (“the claims of the patent, like other provisions in writing, must be reasonably construed,” and the court must arrive at the “true legal construction”); *Winans v. The N.Y. & Erie R.R.*,

62 U.S. (21 How.) 88, 100-101 (1858). That principle is an application of the general rule that the proper interpretation of written instruments that set forth parties' legal rights, such as contracts or deeds, is a question of law. See *State-Planters Bank & Trust Co. v. Parker*, 283 U.S. 332, 336 (1931) ("construction of a clause of a deed of trust" is a question of law); *Philippine Sugar Estates Dev. Co. v. Government of the Philippine Islands*, 247 U.S. 385, 389 (1918) ("construction of a contract presents a question of law"). And because a patent is a technical document addressed to artisans skilled in the field of the invention, rather than to the "public generally," the ultimate legal question for the district court is how a person having ordinary skill in the relevant art at the time of the invention would understand the claims. *Carnegie Steel Co. v. Cambria Iron Co.*, 185 U.S. 403, 430, 437 (1902); see *Nautilus, Inc. v. Biosig Instruments, Inc.*, No. 13-369 (June 2, 2014), slip op. 8-9.

b. In conducting that inquiry, a court must construe a patent's claims "in light of the patent's specification and prosecution history." *Nautilus*, slip op. 8. Those sources constitute the publicly available record that a skilled practitioner would consult in order to ascertain the scope of the invention. See *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313-1314, 1317 (Fed. Cir. 2005) (en banc), cert. denied, 546 U.S. 1170 (2006). Courts in patent cases can often resolve interpretive disputes solely by consulting those sources as well as the claims themselves. When the court's claim construction is based on those sources alone, no aspect of the court's analysis is properly viewed as factual.

The specification describes the invention in more detail than do the claims, and it may resolve the prop-

er scope of a disputed claim term by defining a term or disavowing its ordinary meaning. See *Phillips*, 415 F.3d at 1316-1317; *Merrill v. Yeomans*, 94 U.S. (4 Otto) 568, 571-572 (1876) (using specification to resolve an ambiguity in the claim). When a court construes claim terms in light of the specification, it engages in the purely legal inquiry of interpreting claim terms in light of the patent document as a whole. See *Seymour v. Osborne*, 78 U.S. (11 Wall.) 516, 545-546 (1870) (interpretation of claims in light of specification is “purely a question of construction” for the court); see also *Markman*, 517 U.S. at 388-390 (courts, not juries, traditionally construe legal documents by applying the “standard construction rule” that term must be defined “in a way that comports with the instrument as a whole”).

The prosecution history likewise may resolve interpretive questions because a patent applicant’s representations to the PTO about the scope of the invention are generally binding in subsequent litigation. See, e.g., *Graham v. John Deere Co.*, 383 U.S. 1, 33 (1966). When an applicant narrows her claim or disclaims particular subject matter in response to an examiner’s rejection of the claim, the claim should no longer be construed to cover that subject matter. *Biogen Idec, Inc. v. GlaxoSmithKline LLC*, 713 F.3d 1090, 1094-1095 (Fed. Cir. 2013). In construing the claims in light of the prosecution history, a court conducts a legal analysis of the extent to which a patentee’s representations to the PTO should constrain the exclusive rights conferred on the patentee. See *id.* at 1095; see also *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 733-737 (2002).

2. Courts in patent cases sometimes must resolve subsidiary factual issues in order to construe a claim

a. Because patent claims are construed from the perspective of a skilled artisan at the time of the invention, a district court may need to receive additional evidence, such as expert testimony or scientific articles, in order to understand the relevant science and the technical terms used in the patent claims, specification, and prosecution history. See *Seymour*, 78 U.S. at 546 (a patent may be “so interspersed with technical terms and terms of art that the testimony of scientific witnesses is indispensable to a correct understanding of its meaning”); see also *Markman*, 517 U.S. at 389-390; *Phillips*, 415 F.3d at 1317-1318. Often the background science is essentially uncontested, and the court may base its legal conclusions on agreed-upon scientific principles. But when a predicate fact is both contested and material to the court’s ultimate claim construction, a district court may be required to “choose between experts,” *Markman*, 517 U.S. at 389, and make appropriate factual findings.

For instance, a district court might need to resolve factual disputes about the accepted meaning in the relevant industry of a term found in a claim, or about the type of data that can be gleaned from a scientific experiment. In the context of obviousness under 35 U.S.C. 103, the Court has described similar issues as “basic factual inquiries.” *Graham*, 383 U.S. at 17 (factual questions include “the scope and content of the prior art,” “differences between the prior art and the claims at issue,” and “the level of ordinary skill in the pertinent art”). The Court has thus recognized that, although “the ultimate question of patent validity”—whether the invention’s advancement over the

prior art would not have been obvious to a skilled artisan—“is one of law,” that legal question must be answered against the “background” of subsidiary factual findings concerning the understanding of persons skilled in the art and the state of the prior art at a particular point in time. *Ibid.* Those predicate issues are no less factual when they arise in the context of a claim-construction dispute.

b. Although factual findings may “underpin[]” a district court’s interpretation of a patent claim, *Markman*, 517 U.S. at 390, they do not themselves determine the proper construction of the claim. It remains for the court to determine the significance of any factual findings in the context of the patent as a whole. *Id.* at 389. For instance, a court may find as a matter of fact that a disputed claim term had a certain meaning to a skilled artisan at the time of the invention. But the court must then undertake a legal analysis to determine whether a skilled artisan would ascribe the same meaning to the term in the specific context of the patent claim at issue. See *Corning v. Burden*, 56 U.S. (15 How.) 252, 270 (1853) (“Experts may be examined as to the meaning of terms of art * * * but not as to the construction of written instruments.”); *Vitronics Corp. v. Conception, Inc.*, 90 F.3d 1576, 1582-1583 (Fed. Cir. 1996) (patentee may serve as his own lexicographer). The court’s ultimate construction thus remains a question of law. See *Markman*, 517 U.S. at 389-390.

In that respect, claim construction resembles the interpretation of contracts and other written instruments. “When the words of a written instrument are used in their ordinary meaning, their construction presents a question solely of law,” but when “technical

words or phrases not commonly understood are employed,” “extrinsic evidence may be necessary to establish a usage of trade” or “peculiar meaning.” *Great N. Ry. Co. v. Merchants Elevator Co.*, 259 U.S. 285, 291-292 (1922) (construing a railroad tariff). In those cases where “the peculiar meaning of words, or the existence of a usage, is proved by evidence, the function of construction is necessarily preceded by the determination of the matter of fact.” *Id.* at 292; see *Cox v. Hart*, 145 U.S. 376, 387-388 (1892) (deed); *West v. Smith*, 101 U.S. (11 Otto) 263, 270 (1879) (contract); *FDIC v. First State Bank of Abilene*, 779 F.2d 242, 244 (5th Cir. 1985) (contract).

3. This Court did not hold in *Markman* that claim construction is a pure question of law

The Federal Circuit has described this Court’s decision in *Markman* as holding that “the totality of claim construction is a legal question to be decided by the judge.” *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1455 (1998); see *Lighting Ballast Control LLC v. Philips Elecs. N. Am. Corp.*, 744 F.3d 1272, 1276-1277 (2014) (en banc). That analysis reflects a misunderstanding of *Markman*. That decision did not hold that claim construction lacks any subsidiary factual components; it merely allocated the task of construing patent claims to the court rather than to a jury.

The Court in *Markman* addressed the question whether the Seventh Amendment’s jury-trial guarantee required that juries determine the meaning of “any disputed term of art about which expert testimony is offered,” or whether claim construction is “a matter of law reserved entirely for the court.” 517 U.S. at 372. The Court concluded that, in light of the relative skills of judges and juries, it is appropriate to

“treat[] interpretive issues as purely legal” and therefore to allocate interpretive responsibility to the judge. *Id.* at 391. The Court’s analysis was premised, however, on the recognition that claim construction is not a purely legal inquiry.

The Court thus observed that, although it had sometimes characterized the Seventh Amendment’s application as turning on whether the disputed issue was one of fact or law, the Seventh Amendment issue in *Markman* itself could not be resolved on that basis because “construing a term of art following receipt of evidence” is a “mongrel practice.” 517 U.S. at 378. After concluding that “history and precedent” provided “no clear answer[]” to the judge/jury allocation question, *id.* at 388, the Court explained that, “when an issue ‘falls somewhere between a pristine legal standard and a simple historical fact,’” decisionmaking responsibility has been allocated to the actor who is “better suited” to decide the question, *ibid.* (quoting *Miller v. Fenton*, 474 U.S. 104, 114 (1985)). The Court acknowledged that claim construction has “evidentiary underpinnings,” *id.* at 390, and that “credibility judgments have to be made about the experts who testify in patent cases,” *id.* at 389. The Court concluded, however, that judges were more capable than juries of “evaluat[ing] the testimony in relation to the overall structure of the patent.” *Id.* at 390. Accordingly, the Court held that “the construction of a patent, including terms of art within its claim, is exclusively within the province of the court.” *Id.* at 372.

Markman thus indicates that the ultimate choice between competing interpretations of a patent claim is a question of law. 517 U.S. at 389-390. But the decision does not suggest that claim construction lacks

any factual component. To the contrary, the Court recognized that factual findings based on extrinsic evidence will sometimes be essential. If the Court had conceived of claim construction as a purely legal inquiry, it would have been unnecessary to examine the relative competence of judges and juries to determine how interpretive responsibility should be allocated. See *id.* at 388.

The Court's analysis in *Markman* focused on cases in which the parties espouse different interpretations of a particular claim term (in *Markman*, the term "inventory," see 517 U.S. at 375), and the district court is asked to choose between them. In this case, by contrast, respondents do not argue that the district court should have adopted a different construction of the claim term "molecular weight." Rather, respondents contend that the patent claims using that term were invalid because, even after consideration of all the relevant evidence, *no* particular construction of that term emerged with sufficient clarity to satisfy the definiteness requirement of 35 U.S.C. 112, ¶ 2. The principles set forth above, however, apply with full force to the resolution of respondents' definiteness challenge. Although the district court's ultimate determination that the claims were not indefinite (and therefore not invalid) was a legal ruling, that determination was premised in part on findings that are properly characterized as factual.

B. Rule 52(a)(6) Requires Deference To A District Court's Subsidiary Factual Findings In Claim Construction

The standard of appellate review of a district court's claim construction depends in part on the range of materials the district court consults. When

the court’s construction rests entirely on its assessment of the patent itself and its prosecution history, the court has engaged in a purely legal analysis, see pp. 12-13, *supra*, to which the appellate court owes no deference. But when a district court considers additional evidence and resolves a disputed issue of fact, the court of appeals may set aside that finding only if it concludes that the finding is clearly erroneous.

Rule 52(a)(6) of the Federal Rules of Civil Procedure provides that “[f]indings of fact, whether based on oral or other evidence, must not be set aside unless clearly erroneous, and the reviewing court must give due regard to the trial court’s opportunity to judge the witnesses’ credibility.” Fed. R. Civ. P. 52(a)(6). Rule 52(a)(6) “does not make exceptions or purport to exclude certain categories of factual findings from the obligation of a court of appeals to accept a district court’s findings unless clearly erroneous.” *Pullman-Standard v. Swint*, 456 U.S. 273, 287 (1982). The Court has accordingly held that, across all types of civil litigation, “review of factual findings under the clearly-erroneous standard—with its deference to the trier of fact—is the rule, not the exception.” *Anderson v. City of Bessemer City*, 470 U.S. 564, 575 (1985).

Nothing in the Patent Act suggests that district-court factual findings in patent cases are entitled to less deference than Rule 52(a)(6) requires in other contexts. To the contrary, the Court has recognized that the justification for applying clear-error review is particularly strong in the patent context. *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 609-610 (1950). That is because adjudicating patent-law issues sometimes depends on the “testimony of experts or others versed in the technology” and

requires “familiarity with specific scientific problems and principles not usually contained in the general storehouse of knowledge and experience.” *Ibid.*

Accordingly, the Court has held in the obviousness context that a district court’s factual findings—which include inquiries that are also relevant to claim construction, see pp. 14-15, *supra*—“ought to be subject to the Rule.” *Dennison Mfg. Co. v. Panduit Corp.*, 475 U.S. 809, 811 (1986) (per curiam); see *Graver Tank*, 339 U.S. at 609-611 (in applying doctrine of equivalents, reviewing district court’s findings concerning scientific issues and the content of the prior art for clear error). There is no reason that factual findings made by a district court in choosing between competing constructions of a disputed claim, or in determining whether the claim is sufficiently clear to satisfy 35 U.S.C. 112, ¶ 2, should be given less deference on appeal than the same findings would receive in a validity challenge based on obviousness.²

² Contrary to the Federal Circuit’s view, see *Lighting Ballast*, 744 F.3d at 1279-1280, historical practice does not support de novo appellate review of factual findings underlying claim construction. This Court did not directly address the standard of review for claim-construction decisions either before or after Rule 52(a)(6) was promulgated in 1937. And even when it reversed or disagreed with aspects of lower-court interpretations, the Court did not suggest that it did so on the ground that the district court had made erroneous fact-findings about extrinsic evidence. See, e.g., *Universal Oil Prods. Co. v. Globe Oil & Ref. Co.*, 322 U.S. 471, 473, 482-483 (1944) (affirming lower courts’ claim construction based on patent and prosecution history); *United Carbon Co. v. Binney & Smith Co.*, 317 U.S. 228, 233-237 (1942) (reinstating district court’s indefiniteness ruling based on specification and undisputed inventor testimony); *Exhibit Supply Co. v. Ace Patents Corp.*, 315 U.S. 126, 134-137 (1942) (affirming claim construction but reversing application of doctrine of equivalents); *Schriber-Schroth Co. v.*

C. Applying Rule 52(a)(6) To Factual Findings Underlying Claim Construction Is Administrable And Consistent With The Need For Uniformity

The Federal Circuit has articulated two primary policy rationales for de novo review of factual findings underlying claim construction. See *Lighting Ballast*, 744 F.3d at 1283-1286. Those rationales are inconsistent with Rule 52(a)(6)'s clear command and are unpersuasive on their own terms.

1. a. Applying Rule 52(a)(6) in reviewing district-court claim-construction decisions would not, as the Federal Circuit believed, “diminish workability.” *Lighting Ballast*, 744 F.3d at 1283-1284. While discerning the “distinction between questions of fact and questions of law” can be “vexing,” *Pullman-Standard*, 456 U.S. at 288, federal courts have extensive experience applying the standard, see *First Options of Chi., Inc. v. Kaplan*, 514 U.S. 938, 947-948 (1995); *Albemarle Paper Co. v. Moody*, 422 U.S. 405, 424 (1975) (standard is “familiar”). In patent cases as elsewhere, courts can distinguish between factual and legal conclusions by assessing the basis for the trial court’s decision and the nature of the error asserted on appeal.

A holding by this Court that Rule 52(a)(6) applies, moreover, may have salutary effects that reduce the

Cleveland Trust Co., 311 U.S. 211, 220-223 (1940) (reversing construction based on prosecution history); *Smith v. Snow*, 294 U.S. 1, 10-16 (1935) (reversing court of appeals’ claim interpretation and agreeing with district court after reviewing specification in light of “scientific fact”); *Coupe v. Royer*, 155 U.S. 565, 574-577 (1895) (reversing construction based on claim language). The Court thus has had no occasion to address the proper standard of reviewing factual findings underlying claim construction.

difficulty of “disentangling” the factual and legal components of district-court claim-construction decisions. *Lighting Ballast*, 744 F.3d at 1284. Under the Federal Circuit’s current practice of independently reviewing all aspects of claim construction, district courts have little reason to clearly distinguish factual findings from legal conclusions. District courts are more likely to “disentangl[e]” fact from law in their own decisions if doing so has some operative effect.

b. In order for a finding in this context to qualify as “factual,” two criteria must be satisfied. First, the finding must be based at least in part on evidence outside the patent and its prosecution history. Second, the finding must concern a matter that is in some sense distinct from the meaning or validity of a patent claim. For instance, when a district court based on expert testimony finds that a skilled practitioner would understand a term to have a particular meaning when it is used in the relevant field, the court has made a finding of fact. But if the court then determines that the term bears the same meaning in the claim as it does in the field, the court has rendered a legal conclusion. In many cases the legal ruling about the term’s meaning in the claim will entail only a small inferential step from the factual finding about its meaning outside the document. Yet the ultimate claim-construction determination remains one of law because it reflects the court’s construction of a legal instrument in light of the document as a whole.

Whether a factual or legal challenge is presented will often be readily discernible from the appellant’s arguments on appeal. Taking the example just discussed, if the appellant contends that key language in the specification supports a construction of a claim

term different from the term's usual meaning in the field, and that the district court failed to appreciate the significance of that specification language, the appeal will turn on purely legal questions. But if the appellant argues that the court erred in its assessment of historical industry practice, *e.g.*, by crediting an expert whose testimony was unworthy of belief, its appeal will present a factual challenge subject to Rule 52(a)(6).

The instances in which the Federal Circuit must apply clear-error review in this context should be relatively infrequent. Claim construction ordinarily turns on disputes about the correct legal inferences to be drawn from the patent's language and prosecution history rather than disputes about scientific facts. See *Lighting Ballast*, 744 F.3d at 1285. Clear-error review is appropriate only to the extent that the district court has considered additional evidence and rendered clearly identifiable factual findings. And because expert witnesses may "be examined as to the meaning of terms of art * * * but not as to the construction of written instruments," *Corning*, 56 U.S. at 270, a district court's ultimate construction of a patent claim remains legal even if the court purports to credit an expert witness's testimony that a skilled artisan would understand the claim in a particular way.

c. The Federal Circuit was also incorrect in suggesting that, because applying Rule 52(a)(6) in claim construction is unlikely to alter the outcomes of a substantial number of cases, any benefit would be outweighed by the burden of distinguishing between factual and legal questions. See *Lighting Ballast*, 744 F.3d at 1285-1286. Even apart from the court's over-

estimation of the difficulty involved, the fact that applying Rule 52(a)(6) might not alter the outcome of many cases does not justify ignoring its clear command. See *Salve Regina Coll. v. Russell*, 499 U.S. 225, 237-238 (1991). The Rule reflects the recognition that district courts are institutionally better placed than appellate courts to make factual findings, and that on balance, deferential appellate review furthers accuracy and conserves judicial and litigant resources. See *Anderson*, 470 U.S. at 574-575.

2. The Federal Circuit has also expressed concern that applying Rule 52(a)(6) will undermine the “uniformity in the treatment of a given patent’ that [this] Court sought to achieve in *Markman*.” *Lighting Ballast*, 744 F.3d at 1286 (quoting *Markman*, 517 U.S. at 390). There is no reason to think that reviewing subsidiary factual findings for clear error would often result in the Federal Circuit’s affirming “differing district court rulings” construing a single patent. *Ibid.* The Federal Circuit would continue to review de novo the district court’s resolution of the legal questions, including questions as to the inferences that should be drawn from factual findings in light of the patent as a whole, that generally predominate in claim construction.³ See pp. 15-16, *supra*. The court may also overturn clearly erroneous findings.

³ In addition, issue-preclusion principles will “ordinarily foster uniformity” by preventing “evidentiary questions of meaning” from being “wide open in every new court in which a patent might be litigated.” *Markman*, 517 U.S. at 391 (citing *Blonder-Tongue Labs., Inc. v. University of Ill. Found.*, 402 U.S. 313 (1971)).

II. APPLYING THE CLEAR-ERROR STANDARD IN THIS CASE WOULD LIKELY NOT ALTER THE COURT OF APPEALS' INDEFINITENESS HOLDING, BUT THIS COURT SHOULD REMAND TO PERMIT THE COURT OF APPEALS TO CONSIDER THE QUESTION IN THE FIRST INSTANCE

The district court construed the claim term “molecular weight” in the '808 patent to mean peak average molecular weight. The court further held that, “[b]ecause the term ‘average molecular weight’ is amenable to construction and not insolubly ambiguous, [respondents’] motion for summary judgment on the basis of indefiniteness is DENIED.” Pet. App. 62a (brackets and some internal quotation marks omitted); see *id.* at 47a-62a. The Federal Circuit reversed, holding that the relevant claim was indefinite because a skilled artisan would not be able to determine which definition of “average molecular weight” the '808 patent incorporates.⁴ *Id.* at 6a-10a. The court of appeals explicitly engaged in “*de novo* review of the district court’s indefiniteness holding.” *Id.* at 10a.

The district court’s ultimate determination that the challenged claims were not indefinite was subject to

⁴ The court of appeals used the formulations of indefiniteness that this Court recently discountenanced in *Nautilus*. Compare Pet. App. 6a (claim is indefinite if it is “insolubly ambiguous”), with *Nautilus*, slip op. 11-13 (claim is indefinite if it does not “inform those skilled in the art about the scope of the invention with reasonable certainty”). Because the “insolubly ambiguous” standard “tolerate[s] [more] imprecision” than the *Nautilus* standard, *id.* at 12, and the Federal Circuit found that the claim was indefinite even under the more forgiving standard, the court’s use of the incorrect formulation in this case did not affect the outcome.

de novo review on appeal. For the reasons set forth above, however, the court of appeals was required to accept the district court's factual findings unless the appellate court concluded that particular findings were clearly erroneous. For the most part, the Federal Circuit's indefiniteness analysis was consistent with that requirement. In one respect, however, the court of appeals departed without justification from the district court's factual findings. Although it appears unlikely that this error affected the court of appeals' ultimate indefiniteness holding, the Court should vacate the judgment below and remand the case to allow the Federal Circuit to apply the correct standard of review in the first instance.

A. The Federal Circuit's Decision Rested Primarily On Its Rejection Of The District Court's Legal Inferences

Petitioners assert (Br. 53-58) that the Federal Circuit effectively overturned without justification three factual findings made by the district court: (1) that petitioners' statement about the meaning of "kilodalton" in prosecuting the '847 patent was scientifically incorrect; (2) that a skilled artisan would infer from the patent's reference to SEC that M_p is the relevant measure of "average molecular weight"; and (3) that any discrepancy between Figure 1's value and M_p was a technical artifact. In evaluating petitioners' claims of error, it is essential to distinguish the district court's factual findings from its subsequent legal inferences. In the government's view, the court of appeals violated Rule 52(a)(6) by relying on Figure 1 in a way that was logically inconsistent with a district-court factual finding. Petitioners' other claims of error lack merit (or at least do not implicate Rule 52(a)(6)), however, because the challenged aspects of

the Federal Circuit’s analysis take issue with the legal inferences drawn by the district court rather than with that court’s factual findings.

1. The court of appeals did not overturn, or reach a conclusion logically inconsistent with, the district court’s factual finding that petitioners’ prosecution-history statement about the word “kilodalton” was inaccurate.

a. In the district court, respondents contended that petitioners’ inconsistent prosecution-history statements about the meaning of “molecular weight” in related patents demonstrated that a skilled artisan would be unable to discern which measure of “molecular weight” the claims contemplated. Pet. App. 50a-51a. In responding to an initial rejection of the ’847 patent application, petitioners told the examiner that “[o]ne of ordinary skill in the art could understand that kilodalton units implies a weight average molecular weight [M_w].” *Id.* at 51a (first set of brackets in original). The district court found (and the parties do not dispute) that this statement was scientifically “incorrect,” and that a person skilled in the art would know it was incorrect, because the term “kilodalton” is used in reference to each different measure of molecular weight. *Id.* at 52a. That is a finding of fact concerning scientific principles and understandings as they exist in the field, outside the patent document.

The district court then concluded that, because the ’847 prosecution-history statement was scientifically incorrect, a person skilled in the art would disregard the statement entirely, “would not conclude that” the claim term “molecular weight” “implies” M_w , and would instead conclude that the term referred to M_p on the basis of “the ’539 patent prosecution state-

ment.” Pet. App. 52a (internal quotation marks omitted). Those conclusions are legal, because they concern the relative weight that a skilled artisan *interpreting the patent claims* would accord each prosecution-history statement in light of the fact that one of the statements contained a scientific inaccuracy. The legal nature of that conclusion is not negated by the district court’s characterization of its conclusion as a “finding” based on Dr. Grant’s assertions about how a skilled artisan would understand the claim term. *Ibid.* The ultimate interpretive significance of representations in the prosecution history is a matter of law for the court to decide—even if, as here, the parties offer their preferred interpretations through the opinion testimony of expert witnesses. *Winans*, 62 U.S. at 100-101; see p. 23, *supra*.

b. The court of appeals, without mentioning the district court’s finding about the inaccuracy of the ’847 statement, held that petitioners’ “prosecution statements directly contradict each other and render” the ’808 patent indefinite. Pet. App. 8a-9a. The court emphasized that the “plain language [of the patents] does not indicate which average molecular weight measure is intended.” *Id.* at 8a. The court then explained that the “only basis upon which the Examiner could have agreed that the ’539 patent claims were not indefinite was that ‘molecular weight’ means M_p ,” while the “only basis for the Examiner’s withdrawal of the indefiniteness rejection of the ’847 patent claims was that the same term means M_w .” *Id.* at 9a. The court observed that these alternative explanations of the same term “cannot be reconciled.” *Ibid.*

In the court of appeals’ view, the salient point for indefiniteness purposes was that the PTO had issued

two patents based on petitioners' irreconcilable representations about what "molecular weight" meant in the claims. It is unclear whether the Federal Circuit overlooked the district court's finding that the '847 prosecution-history statement was erroneous, or whether it simply regarded that fact as ultimately insignificant to the indefiniteness inquiry. In either event, there is no sound reason to conclude that the Federal Circuit rejected, or analyzed the case in a manner logically inconsistent with, the district court's factual finding. In particular, nothing in the Federal Circuit's opinion suggests that the court decided the case on the misunderstanding that the term "kilodalton" actually implies M_w . Petitioners appear to argue (Br. 57-58) that, in light of the district court's finding that one of petitioners' prosecution-history statements was scientifically incorrect, the court of appeals should have attached less weight to the existence of the inconsistent statements. But arguments concerning the significance of particular facts to the overall legal analysis, whatever the merits of those arguments, have nothing to do with Rule 52(a)(6) or with the standard-of-review question on which this Court granted certiorari.

2. The court of appeals next concluded that the patent's reference to SEC did not "resolve the ambiguity" created by the prosecution history. Pet. App. 9a-10a. Contrary to petitioners' contention (Br. 56-57), the court did not overturn or implicitly reject the district court's factual findings concerning SEC.

a. The district court concluded that a skilled artisan would understand the patent's reference to SEC to indicate that "molecular weight" means M_p . Pet. App. 43a-45a. The court first credited Dr. Grant's

testimony, which respondents did not dispute (*id.* at 48a-49a), that “ M_p can be read from the chromatogram generated by SEC without any further calculation.” *Id.* at 43a (internal quotation marks omitted). The court further found, based on the testimony of both parties’ experts, that SEC “can also provide M_w and M_n ” if further calculations are performed. *Id.* at 48a. Those determinations are findings of fact about the types of data that can be generated by particular methods of measurement.

Ultimately, the court “credit[ed] Dr. Grant’s representation” that, because the specification does not disclose additional calculations, “a person of ordinary skill in the art would understand that [molecular weight] means M_p ” in the claims. Pet. App. 48a-49a. That conclusion, though phrased as a credibility finding, is a legal determination of how a skilled artisan would interpret the claim’s use of “molecular weight” in light of the specification’s reference to SEC. See p. 23, *supra*.

b. The court of appeals acknowledged Dr. Grant’s testimony that “only M_p * * * can be read directly from a plot of SEC data.” Pet. App. 10a. But the court additionally took note of the undisputed fact that “ M_n and M_w can also be obtained from the data generated by the SEC method after some calculations.” *Ibid.* The court concluded that “Dr. Grant’s testimony does not save [the] claims from indefiniteness.” *Ibid.*

That reasoning is not inconsistent with the district court’s finding that only M_p can be gleaned from SEC without further calculations. A skilled artisan could accept that SEC generates M_p directly but conclude that, because SEC data can also be used to calculate

M_n and M_w , the specification's reference to SEC does not resolve the ambiguity concerning the claim term "molecular weight." The district court concluded that Dr. Grant's testimony concerning the data that SEC can generate, *combined with* the absence of any reference in the patent to the additional calculations that would be needed to determine M_n or M_w , indicates that "molecular weight" in the claims means M_p . Pet. App. 48a-49a. But determinations concerning the appropriate inferences to be drawn from other portions of the patent itself are legal rather than factual in nature. Even assuming, *arguendo*, that the court of appeals unjustifiably disregarded the absence of any reference within the patents to additional calculations, its error had nothing to do with the standard of review that applies to district-court factual findings.

3. Finally, the court of appeals did engage in impermissible *de novo* fact-finding with respect to Figure 1 of the patent. Pet. App. 10a.

a. In the district court, respondents argued that Dr. Grant's assertion that the patent referred to M_p was inconsistent with the molecular weight distribution curve depicted in Figure 1 of the patent, the peak values of which do not correspond to the molecular weight values recited in the body of the specification. Pet. App. 49a. The court rejected that argument, "credit[ing] all of Dr. Grant's explanation" that converting data from a chromatogram to a molecular weight distribution curve, such as that shown in Figure 1, "would likely cause the peak on each curve to shift slightly." *Id.* at 44a-45a. That explanation of how a skilled artisan would understand a distribution curve created from chromatogram data is a finding of fact. The court then reached the legal conclusion that

a person skilled in the art, considering Figure 1 in light of the knowledge that the curves would have shifted, “would not [have been] dissuade[d] * * * from concluding that [molecular weight] refers to M_p in the context of the patents-in-suit.” *Id.* at 49a.

b. The court of appeals, however, observed 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,” and stated that it was therefore “difficult to conclude that M_p is the intended measure.” Pet. App. 10a. The court thus relied on Figure 1 in a way that was logically inconsistent with the district court’s factual finding that a skilled artisan would understand that the peaks of a distribution curve would have shifted in the data conversion process. If the court of appeals had accepted that finding, it could not have concluded on the basis of the discrepancy alone that Figure 1 undermined the case for M_p .

B. Although Applying Clear-Error Review Would Likely Not Alter The Court Of Appeals’ Holding That The Patent Is Indefinite, Remanding To The Federal Circuit Would Be Consistent With This Court’s Ordinary Practice

The court of appeals’ disregard of the district court’s factual finding concerning Figure 1 likely did not affect its ultimate conclusion that the claim of the ’808 patent is indefinite. The court of appeals’ indefiniteness holding appeared to rest primarily on its conclusion that petitioners’ prosecution-history statements “render[ed] * * * insoluble” the ambiguity created by the patent’s failure to define “molecular weight.” Pet. App. 8a-9a. The court then held that the specification—its reference to SEC and Figure

1—did “not resolve the ambiguity” created by the prosecution history. *Id.* at 9a.

Even if the court of appeals had accepted the district court’s findings about Figure 1, the court would not likely have concluded that the specification shed any light on the meaning of “molecular weight.” The court of appeals appears to have viewed Figure 1’s failure to illustrate M_p values as an *additional* reason to conclude that the specification’s reference to SEC did not resolve the ambiguity concerning the claim term “molecular weight.” See Pet. App. 10a (“Furthermore, * * * the peaks of the curves in Figure 1 do not correspond” to M_p .). Even if the court had accepted the district court’s finding as not clearly erroneous, then, it is unlikely that this finding alone would have led the Federal Circuit to hold that a skilled artisan would understand with reasonable certainty that the patent claim referred to M_p .

When a court of appeals has applied an incorrect legal standard, however, this Court’s “ordinary practice” is to remand so that the court of appeals “can reconsider” its decision “under the proper standard.” *Nautilus*, slip op. 14. Although it appears likely that the Federal Circuit will ultimately reaffirm its conclusion that the patent is indefinite, the Court should remand in order to permit the Federal Circuit to consider in the first instance whether deferring to the district court’s factual findings affects its ultimate decision.⁵

⁵ Remanding could have the effect of depriving respondents of any practical benefit of a judicial ruling that the claim of the ’808 patent is invalid. When the ’808 patent expires in September 2015, respondents will be able to market their generic versions of Copaxone® regardless of whether the patent is valid. See Br. in Opp.

CONCLUSION

The judgment of the court of appeals should be vacated and the case remanded for further proceedings.

Respectfully submitted.

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1. It is uncertain whether any remand proceedings could be completed substantially before September 2015.