

**Claim Construction:
How Should the Supreme Court Weigh In?**

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Claim Construction: How Should the Supreme Court Weigh In?

The United States Supreme Court recently granted *certiorari* in the *Teva Pharmaceuticals USA, Inc. v. Sandoz Inc.* case to address whether appellate courts should afford any deference to a District Court's claim construction determination. This question has been a topic of heated debate since the Federal Circuit held that claim construction was purely a matter of law and thus subject to de novo review in an en banc decision in *Cybor Corp. v. FAS Technologies*, 138 F.3d 1448 (1998). Although the Federal Circuit has repeatedly refused to reconsider this holding – despite repeated requests from litigants, commentators and District Court judges – the Supreme Court appears to be ready to weigh in on this issue in an opinion that will have implications for nearly all patent cases.

I. How Did We Get Here? Cases Leading Up to *Teva v. Sandoz*

Tension has been brewing for many years over the proper standard of review for claim construction determinations. The following briefly summarizes the key cases that brought us to the Supreme Court's granting of *certiorari* in *Teva v. Sandoz*:

Markman I: A divided Federal Circuit held en banc for the first time that claim construction is purely an issue of law to be decided by the court, not the jury. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996). The court found:

The patent is a fully integrated written instrument. By statute, the patent must provide a written description of the invention that will enable one of ordinary skill in the art to make and use it. . . . It follows, therefore, from the general rule applicable to written instruments that a patent is uniquely suited for having its meaning and scope determined entirely by a court as a matter of law.

Id. at 978–79 (citations omitted).

Accordingly, the court held that claim construction would be subject to de novo review.

Id. at 979.

Markman II: On appeal of *Markman I*, the Supreme Court agreed that judges are better suited than juries to construe complex documents like patents. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388 (1996). The Court also found that reserving claim

construction for the court would promote certainty and uniformity. *Id.* at 390–91. Notably, the Supreme Court’s opinion in *Markman II* focused on whether there is a jury right to construction of a patent, and did not decide the proper standard of review for claim construction determinations. The Court seemed to recognize that claim construction involves both legal and factual determinations, however, describing claim-construction as a “mongrel practice” and “an issue “fall[ing] somewhere between a pristine legal standard and a simple historical fact.” *Id.* at 378, 388.

Following *Markman II*, some Federal Circuit panels reviewed claim construction de novo, while others granted deference to factual findings of District Courts. The Federal Circuit finally resolved this conflict in 1998.

Cybor: To resolve the conflicting standards of review applied by different Federal Circuit panels, the court in *Cybor Corp. v. FAS Technologies, Inc.* decided en banc that claim construction is a matter of law to be reviewed de novo. 138 F.3d 1448, 1451 (Fed. Cir. 1998). Relying heavily on its opinion in *Markman I*, the court stated:

Although the law is clear that the judge, and not the jury, is to construe the claims, this case presents the issue of the proper role of this court in reviewing the district court's claim construction. [¶] In *Markman I*, we held that, because claim construction is purely a matter of law, this court reviews the district court's claim construction de novo on appeal. In reaching this conclusion, we recognized that “[t]hrough this process of construing claims by, among other things, using certain extrinsic evidence that the court finds helpful and rejecting other evidence as unhelpful, and resolving disputes en route to pronouncing the meaning of claim language as a matter of law based on the patent documents themselves, the court is not crediting certain evidence over other evidence or making factual evidentiary findings. Rather, the court is looking to the extrinsic evidence to assist in its construction of the written document, a task it is required to perform. The district court's claim construction, enlightened by such extrinsic evidence as may be helpful, is still based upon the patent and prosecution history. It is therefore still construction, and is a matter of law subject to de novo review.” *Id.* at 981. [¶] After the Supreme Court's decision in *Markman II*, panels of this court have generally followed the review standard of *Markman I*. In some cases, however, a clearly erroneous standard has been applied to findings considered to be factual in nature that are incident to the judge's construction of patent claims. We ordered that this case be decided in banc to resolve this conflict, and we conclude that the de novo standard of review as stated in *Markman I* remains good law.

Id. at 1454-54 (citations and footnote omitted).

Concurring and dissenting opinions, however, undermined the majority opinion. For example, Judge Plager in concurrence wrote that “common sense dictates that the trial judge’s view will carry weight.” *Id.* at 1462. In dissent, Judge Rader argued that de novo review “has the potential to undercut the benefits of *Markman I*” by prolonging “uncertainty in the patent litigation process.” *Id.* at 1475.

The Federal Circuit’s holding in *Cybor* has engendered enormous commentary and criticism, including mounting frustration from District Court judges who were routinely seeing their hard work on patent cases reversed on appeal based on the Federal Circuit’s findings that their claim constructions were wrong. This has led certain judges of the Federal Circuit, as well as many District Court judges and commentators, to call into question the *Cybor* court’s holding. Most recently, the Federal Circuit decided to rehear en banc *Lighting Ballast Control, LLC v. Phillips Electronics N.A. Corp.* The court issued its opinion on February 21, 2014, just seven months after its opinion in *Teva v. Sandoz*. In a 6-4 decision, the *Lighting Ballast* court reaffirmed de novo review for claim construction orders, relying primarily on stare decisis to support its holding. The court heard from numerous amici, including the United States, which urged the court to adopt a hybrid review of claim construction orders. After “carefully consider[ing] the arguments for discarding or modifying *Cybor*,” the court concluded that “they do not justify departing from the now well-established principles and procedures.” *Lighting Ballast*, 744 F.3d 1272, 1285 (Fed. Cir. 2014). The court also reaffirmed the holding in *Cybor* that claim construction involved purely legal issues:

Claim construction is a legal statement of the scope of the patent right; it does not turn on witness credibility, but on the content of the patent documents. The court may indeed benefit from explanation of the technology and the instruction of treatises, but the elaboration of experts or tutorial explanation of technical sub-subject matter does not convert patent claim construction into a question of fact. The type of evidence that may assist a lay judge in determining what a technical term meant to one of skill in the art does not transform that meaning from a question of law into a question of fact. Reference to technical understanding and usage at the time of enactment does not convert statutory interpretation from law to fact. [¶] Courts routinely look to dictionaries and treatises to determine the meaning of a statute at the time it was written. [¶] Similarly, experts in the science or technology may assist the court in understanding the meaning and usage of a claim term, but this does not morph the question into one of fact.

Id. at 1284–85 (citations omitted).

In support of its opinion, the court relied on the fact that it is now common to have the same patent being litigated in multiple jurisdictions. The court reasoned that if claim construction orders were entitled to deference, the possibility of conflicting district court rulings could lead to the very “forum shopping that the Federal Circuit was created to avoid.” *Id.* at 1286.

The dissent authored by Judge O’Malley argued that the majority opinion conflicted with Supreme Court precedent, the Federal Rules of Civil Procedure, and the consensus of a “broad swath of the intellectual property community.” *Id.* at 1296.

It is against this backdrop that the Supreme Court is about to weigh in.

II. Overview of *Teva v. Sandoz*

A. Factual Background

The *Teva* case arose when Sandoz sought approval to market and sell Teva’s multiple sclerosis drug Copaxone[®]. Unlike drug products that are a single entity, such as a small molecule, the active ingredient of Copaxone[®] is copolymer-1 (or glatiramer acetate)—a mixture of polypeptide molecules. Specifically, the copolymer-1 polypeptides contain four different amino acids (alanine, glutamic acid, lysine, and tyrosine), but vary in their arrangement and number. Because the composition is not uniform, the asserted patents claimed copolymer-1 in terms of “average molecular weight.” The district court was therefore required to construe the term “molecular weight.”

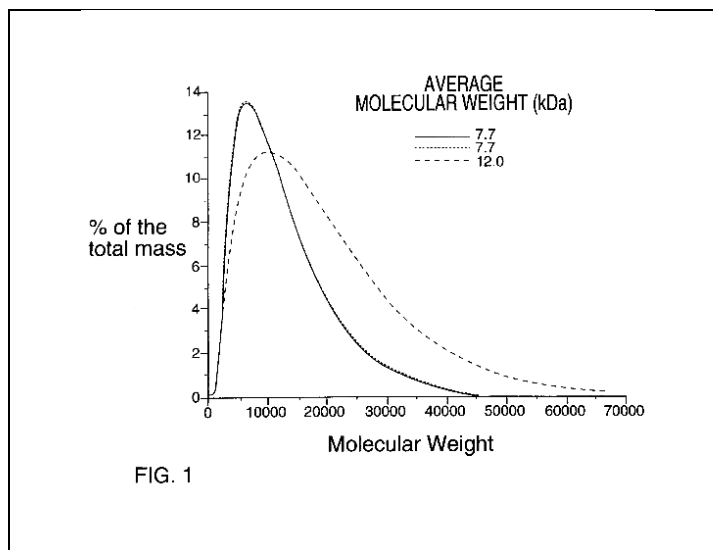
The dispute over the term “molecular weight” arose because, statistically speaking, there are at least three ways to calculate average molecular weight: peak average molecular weight (M_p), number average molecular weight (M_n), and weight average molecular weight (M_w). A common way to measure “molecular weight” is to use Size Exclusion Chromatography (“SEC”). A simplistic way to think about SEC is as a technique that utilizes a column “sieve” that allows different size (or weight) molecules to leave (elute) the column at different times. After the

column is calibrated, the size or weight of the molecules in question can be determined depending on when they elute from the column.

The patents at issue contained an ambiguity with regard to which of the three average molecular weight calculations was intended. Some of the asserted claims (which the Federal Circuit referred to as “Group I claims”) described molecular weight without specifying which of the three measures should be used. For example, claim 1 of U.S. Patent 5,981,589 claims: “Copolymer-1 having a molecular weight **of about 5 to 9 kilodaltons**” and a process that would “result in copolymer-1 having a molecular weight **of about 5 to 9 kilodaltons**” (emphasis added).

B. The Claim Construction Hearing and Order

During claim construction, Teva argued that the asserted claims were not indefinite and that they referred to peak average molecular weight (M_p). Teva pointed to the specification’s discussion of SEC technology and a chromatogram that the SEC process would produce (Figure 1 in the patent, reproduced below) to support its argument:



See Teva Pharm.v. Sandoz Inc., Case No. 1:08-cv-0711, Dkt. 273 at 20 (Aug. 29, 2011 S.D.N.Y.) (Claim Construction Order).

According to Teva and its expert, Dr. Grant, a person of ordinary skill in the art would understand that the SEC process, without further data manipulation, can produce only M_p , not any other measure for average molecular weight. *Id.* Teva further pointed to the prosecution history of one of the asserted patents, in which Teva responded to a rejection by arguing that a person of ordinary skill in the art would understand “average molecular weight” to mean “average weight at the peak of the molecular weight distribution curve shown in Figure 1.” *Id.* at 22 (quoting prosecution history of U.S. Patent 6,939,539).

Sandoz pointed out two substantial problems with Teva’s argument.¹ First, Sandoz argued that Figure 1 does not in fact support interpreting “average molecular weight” to mean “peak average molecular weight.” Figure 1 “does not show peaks of either 7.7 kDa or 12.0 kDa,” as the figure’s legend claims. *Id.* at 25. Thus, Sandoz argued, Figure 1 cannot be a representation of peak average molecular weight.

Second, Sandoz identified contradictory statements by Teva during the prosecution of some of the asserted patents. Although, as discussed above, Teva at one point told the PTO that “average molecular weight” meant “peak average,” in the prosecution of a related patent, it stated that “[o]ne of ordinary skill in the art could understand that kilodalton units implies a weight average molecular weight.” *Id.* at 28 (quoting prosecution history of U.S. Patent 6,620,847).

The court sided with Teva, relying heavily on the testimony of its expert, Dr. Grant. First, regarding the SEC process described in the specification, the court stated that it “credit[ed] and accept[ed] all of Dr. Grant’s opinions regarding SEC.” *Id.* at 20. As to the discrepancy in the peaks of the curves in Figure 1, the court agreed with Dr. Grant that a person of ordinary skill in the art would understand ““that the process of transferring the data from the chromatogram would likely cause the peak on each curve to shift slightly” and that “any

¹ The case actually involves two defendants, Sandoz Incorporated and Mylan Pharmaceuticals Inc. For the sake of simplicity, this summary refers to both defendants simply as “Sandoz.”

discrepancy between the peak values read from the chromatogram (7.7 kDa and 12.0 kDa) and the peak of Figure 1 is merely a by-product of the process by which the data from the chromatogram would have been used to generate Figure 1.” *Id.* at 21 (quoting Dr. Grant’s testimony). The court further found that Sandoz relied on “unsubstantiated attorney-argument” that was “insufficient to cast doubt on Dr. Grant’s opinions, which, as explained above, the Court credits and accepts.” *Id.* at 26.

As to the conflicting prosecution history statements, Teva admitted that the statement “was incorrect.” *Id.* at 29. “Because the statement was incorrect,” the court concluded, “a person of ordinary skill in the art would not rely on it.” *Id.* Accordingly, the court found that the claims that included the “average molecular weight” terms were not indefinite.

C. The Federal Circuit’s Opinion

The Federal Circuit did not agree with the District Court’s reasoning. In a short opinion, the court held that “[o]n *de novo* review of the district court’s indefiniteness holding, we conclude that Dr. Grant’s testimony does not save Group I claims from indefiniteness.”² *Teva Pharm.*, 723 F.3d 1363, 1369 (Fed. Cir. 2013). Instead, the Federal Circuit reviewed the specification and prosecution history for itself and found them not to be as clear as the District Court believed. As to the apparent inconsistency in Figure 1, the court stated: “as illustrated in the figure below, the peaks of the curves in Figure 1 do not correspond to the values denoted as ‘average molecular weight’ in the figure’s legend.” *Id.* In fact, said the court, the figures in the legend corresponded more closely to weight average molecular weight (M_w) than to peak average molecular weight (M_p), “which makes it difficult to conclude that M_p is the intended measure.” *Id.*

The court also rejected the District Court’s rationale for reconciling Teva’s apparently contradictory prosecution history statements. “[T]wo of [Teva’s] prosecution statements directly

² A second group of claims, which expressed molecular weight in terms of percentage of copolymer-1 molecules that fell within a range rather than as a statistical measure, were upheld as not indefinite. These claims should not be at issue before the Supreme Court.

contradict each other and render the ambiguity insoluble.” *Id.* The court gave no indication whether the outcome would have been different under a different standard of appellate review.

D. Certiorari: The Question Presented

On March 31, 2014, the Supreme Court granted certiorari on Teva’s appeal. The sole issue on appeal to the Supreme Court was encapsulated by the question presented:

Rule 52(a) of the Federal Rules of Civil Procedure provides that in matters tried to district court, the court’s “[f]indings of fact ... must not be set aside unless clearly erroneous.”

The question presented is as follows:

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 Rule 52(a) requires.

The way the question reads makes it seem likely that the Supreme Court will reverse the Federal Circuit. Indeed, over the past few months, the Supreme Court has issued four opinions, in each case rebuking the Federal Circuit on other patent-related issues. Specifically, in *Octane Fitness LLC v. Icon Health & Fitness Inc.*, 134 S. Ct. 981 (2014), the Court found that the Federal Circuit’s test for awarding attorneys’ fees in patent cases was too stringent. The same day, in *Highmark Inc. v. Allcare Health Management Systems Inc.*, 134 S. Ct. 1051 (2014), the Court in a 9-0 opinion found that District Court decisions on attorneys’ fees deserve deference on appeal and that the Federal Circuit erred in reviewing such determinations *de novo*. The Court vacated the Federal Circuit opinion and remanded the case. In *Nautilus Inc. v. Biosig Instruments Inc.*, 134 S. Ct. 896 (2014), the Court rejected the Federal Circuit’s standard for indefiniteness. In another unanimous opinion, the Court in *Limelight Networks Inc. v. Akamai Technologies Inc.*, 133 S.Ct. 2879 (2013) reversed a Federal Circuit holding expanding liability for induced infringement.³

³ The Court did uphold at least one recent Federal Circuit ruling. In yet another unanimous opinion in *Alice Corp. v. CLS Bank International*, the Court agreed with the Federal Circuit and

The Supreme Court granted *certiorari* in *Teva* against this backdrop of recent rejections of Federal Circuit holdings and continued dissent from District Court judges, the academic community, and numerous Federal Circuit judges who have all called for at least some form of deference to District Courts in their claim construction determinations.

E. Possible Outcomes Of The Supreme Court’s Opinion

It seems that the Supreme Court is likely to arrive at one of three outcomes in *Teva*. The positions are summarized in the Federal Circuit’s opinion in *Lighting Ballast* as follows:

1. Reject Cybor and Apply “Clear Error” Review: The proponents of this position, *Lighting Ballast* among them, point out that *Markman II* did not touch on the proper standard of review for claim construction opinions. They argue that claim construction is most reasonably classified as a question of fact, despite the Supreme Court’s decision designating the court as the proper entity to construe claims.

2. Apply De Novo Review to Legal Questions, and Clear Error Review to Factual Questions: The proponents of this position, including the United States as amicus in *Lighting Ballast*, argue that claim construction involves both legal and factual questions. Accordingly, different standards of review should apply depending on what evidence the court relies on for any particular aspect of its decision. In its amicus papers, the United States drew an analogy to the ruling in a regulatory tariff case, in which the Supreme Court held that “when ambiguity arises in the construction of certain legal instruments, the ambiguity is resolved as a question of fact.” *Lighting Ballast*, 744 F.3d at 1278 (citing United States amicus brief).⁴ Under this approach, district court decisions based entirely on intrinsic evidence (the patent and its

reaffirmed that abstract ideas cannot be patented simply by including a computer element in the claims.

⁴ In its Petition for Writ of Certiorari, *Teva* cited the same authority as the United States and argued the point more broadly: “In a contract case, for example, ‘extrinsic evidence may be necessary to determine the meaning of words appearing in the document. This is true where technical words or phrases not commonly understood are employed’ *Great N. Ry. Co. v. Merchants’ Elevator Co.*, 259 U.S. 285, 291-92 (1922). The construction of a contract is undoubtedly a question of law. But ‘the function of construction is necessarily preceded by the determination of the matter of fact.’ *Id.* at 292.” Pet. for Cert. at 19–20.

prosecution history) would be reviewed de novo, but decisions based on extrinsic evidence such as witness testimony would be reviewed for clear error. This outcome seems consistent with Federal Rule of Civil Procedure 52(a), but may be difficult to implement in practice.

3. *Uphold Cybor and Apply De Novo Review*: The Federal Circuit adopted this outcome in *Lighting Ballast*. As discussed above, it relied mostly on stare decisis and the need for uniform claim constructions to support its holding.⁵ It seems unlikely that the Supreme Court will adopt this approach.

⁵ Summaries of these three positions can be found at *Lighting Ballast*, 744 F.3d at 1278–81.

III. Arguments For and Against a New Standard of Review

Over the years, numerous arguments have been made both for and against the *Cybor* court’s holding. These arguments are summarized below:

<u>FOR DE NOVO REVIEW</u>	<u>AGAINST DE NOVO REVIEW</u>
<p>De novo review maintains national uniformity, consistency, and finality to the meaning of claim terms</p> <ul style="list-style-type: none"> • particular concern with multi-district litigation where differing rulings on close questions of claim construction could warrant affirmance on appeal of differing constructions with deferential standard of review • would restore forum shopping Federal Circuit was designed to avoid 	<p>District Court judges are best able to devote the time and resources necessary to effectively construe claims, can weigh credibility, etc.</p> <ul style="list-style-type: none"> • Federal Circuit is confined to bare “record” and has limited time for argument • is there really only a single “correct” construction? does de novo review lead to unnecessary reversals? • forum shopping is already alive and well in patent litigation • possible inconsistent claim construction rulings in multi-district litigation not a reason to ignore Rule 52(a)
<p>In practice, reversal rates have dropped significantly since <i>Phillips</i> / the Federal Circuit is already affording “informal deference” to District Courts</p> <p>The vast majority of patent cases still settle and parties are not focused on the standard of review</p>	<p>De novo review has led to a high reversal rate, less certainty, less predictability, a waste of judicial resources and increased litigation costs as parties unwilling to settle until after appeal</p> <ul style="list-style-type: none"> • unhappy District Courts • problem exacerbated by Federal Circuit’s refusal to hear interlocutory appeals re claim construction • even if reversal rate has dipped since <i>Phillips</i>, it is still high compared to other areas
<p>De novo review is an effective implementation of the Supreme Court’s <i>Markman</i> opinion, which recognized claim construction as a legal issue</p>	<p>The Supreme Court recognized in <i>Markman</i> that claim construction is a “mongrel” practice that involves both legal and factual determinations / Rule 52(a) expressly requires deference be afforded for factual determinations</p>
<p>It is impossible to separate “legal” and “factual” issues, so best to treat everything as legal issue (“claim construction is a legal statement of the scope of the patent right”) and afford no deference to district court</p>	<p>While it may be difficult to separate “legal” and “factual” issues, Rule 52(a) expressly requires deference be afforded for factual determinations</p> <ul style="list-style-type: none"> • fact issues include whether claim term has specialized meaning to POSITA; who

<u>FOR DE NOVO REVIEW</u>	<u>AGAINST DE NOVO REVIEW</u>
<ul style="list-style-type: none"> • <i>Teva</i> case is perfect example of difficulty of sorting out “legal” and “factual” determinations • Rule 52(a) therefore does not apply 	<p>qualifies as POSITA; whether to credit one party’s expert testimony over another party’s; what would POSITA glean from prior art, etc.</p>
<p>Analogous to statutory construction</p>	<p>Analogous to contract interpretation and obviousness determinations where District Courts given deference on fact issues</p>
<p>Federal Circuit was established as “specialist” court to handle patent appeals / achieving uniformity, consistency and finality in claim construction is consistent with its core function</p>	<p>De novo review is product of an activist Federal Circuit which has helped create an out of whack patent system</p>
<p>Changing the standard of review will affect only a small number of decisions and will create peripheral litigation over what is a “legal” vs. “factual” determination</p>	<p>Changing the standard of review will affect a large number of decisions and ultimately lead to more cases settling and fewer cases being appealed</p>
<p>The real problems are poorly drafted claims and contradictory claim construction methodologies / abandoning the de novo standard of review will make these problems worse</p>	