

The Impact of *Teva v. Sandoz*

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Topics for Today's Discussion

The Impact of *Teva v. Sandoz*

- I. Background of the Case
- II. The Supreme Court's Opinion
- III. Potential Effects

I. Background of the Case

- Legal Background
- Factual Background
- District Court's Claim Construction
- Federal Circuit's Decision

I. Background of the Case

- **Legal Background**
- Factual Background
- District Court's Claim Construction
- Federal Circuit's Decision

I. Background of the Case: Legal Background

Markman, Cybor, and FRCP 52(a)

- Legal issue in *Teva*: Whether factual findings made in the course of a trial court's claim construction decisions are reviewable *de novo* (as required by Federal Circuit precedent) or for clear error (under FRCP 52(a)(6)).
- *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996): Claim construction is a question for the trial judge rather than the jury.
- *Cybor Corp. v. FAS Techs., Inc.*, 122 F. 3d 1448, 1455 (Fed. Cir. 1998): A district court's claim construction decision should be treated as "a pure issue of law" subject to *de novo* review.
- Rule 52(a)(6): "Findings 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."

I. Background of the Case: Legal Background

Lighting Ballast

- Federal Circuit considered *de novo* review *en banc* four times.
 - › *Markman I*, 1995
 - › *Cybor*, 1998
 - › *Amgen*, 2006
 - › And most recently in 2014
- *Lighting Ballast Control LLC v. Philips Electronics N.A. Corp.*, 744 F.3d 1272 (Fed. Cir. 2014) (*en banc*): revisited and reaffirmed *Cybor*; claim construction still reviewed *de novo*.
 - › Held that adhering to *Cybor* rule of *de novo* review was warranted by *stare decisis* and “providing national uniformity, consistency, and finality to the meaning and scope of patent claims.” *Lighting Ballast*, 744 F.3d at 1276-77.
 - › Rejected position that *de novo* standard increased number of patent appeals, citing contrary empirical data from the 15 years since *Cybor*.

I. Background of the Case

- Legal Background
- **Factual Background**
- District Court's Claim Construction
- Federal Circuit's Decision

I. Background of the Case: Factual Background

Copaxone

- Parties:
 - › *Plaintiffs*: Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., Teva Neuroscience, Inc., Yeda Research & Development Co. Ltd.
 - › *Defendants*: (1) Sandoz, Inc. and Momenta Pharmaceuticals, Inc. (collectively, “Sandoz”); (2) Mylan, Inc., Mylan Pharmaceuticals Inc, and Natco Pharma Ltd. (collectively, “Mylan”).
- Sandoz and Mylan filed separate ANDAs seeking FDA approval to manufacture and sell a generic of Copaxone®.
- Copaxone is indicated for the treatment of relapsing forms of multiple sclerosis (“MS”), a disease affecting the central nervous system.
- The active ingredient in Copaxone® is copolymer-1, a complex mixture of synthetic polypeptides composed of four amino acids, glutamic acid, lysine, alanine, and tyrosine (GLAT).

I. Background of the Case: Factual Background

Copaxone®

- Copolymer-1 was discovered in the late-1960s by scientists at the Weizmann Institute of Science who were trying to synthesize compounds that would mimic myelin basic protein and that could induce experimental allergic encephalomyelitis, an animal model for MS.
- The Weizmann scientists surprisingly discovered that rather than induce EAE, the synthetic composition, copolymer-1, inhibited the development of that disease model.
- During later research and development in collaboration with scientists at Teva, it was discovered that copolymer-1 compositions with certain molecular weight characteristics have efficacy yet reduced toxicity as compared to the previously known higher molecular weight copolymer-1. Scientists at Teva also developed a new method of making the desirable low molecular weight copolymer-1 compositions.

I. Background of the Case: Factual Background

The Patents-in-Suit

- Teva asserted nine patents, which share a common specification and all claim priority to the same May 1994 application.
- The claims of the patents-in-suit pertain to copolymer-1 with particular molecular weight characteristics.
- The patents-in-suit describe the use of Size Exclusion Chromatography (SEC) to determine the molecular weight of copolymer-1.
- The claim construction at issue in the *Teva v. Sandoz* appeals was the district court's interpretation of the term "molecular weight."

I. Background of the Case: Factual Background

Molecular Weight

- Outside the context of the patents or copolymer-1, the term “molecular weight” generally refers to the sum of the atomic weights of the atoms making up a molecule.
- Because copolymer-1 is composed of hundreds of thousands of different polypeptides with varying molecular weights, its molecular weight would be understood to be reported as an average.
- At the time of the invention, there were at least three different types of “average” molecular weights known and used with polymers:
 - › “Peak average molecular weight” (or “peak molecular weight”),
 - › “Number average molecular weight,” and
 - › “Weight average molecular weight.”

I. Background of the Case

- Legal Background
- Factual Background
- **District Court's Claim Construction**
- Federal Circuit's Decision

I. Background of the Case: District Court's Opinion

Teva Pharm. USA, Inc. v. Sandoz Inc., 810 F. Supp. 2d 578 (S.D.N.Y. 2011)

- Defendants argued that the term “average molecular weight” was indefinite because the patent did not expressly define which “average molecular weight” was being reported, and due to certain statements during the prosecution of later-issued patents-in-suit.
- In construing the term “average molecular weight,” the district court noted that this term has no ordinary and customary meaning in the context of a polymer like copolymer-1. The district court thus looked to the specification, prosecution history, and extrinsic evidence to determine the meaning of average molecular weight.
- It was undisputed that the requisite level of skill for interpreting “average molecular weight” was very high, likely requiring a PhD in polymer and synthetic chemistry, and some experience in analytical chemistry and chromatography.

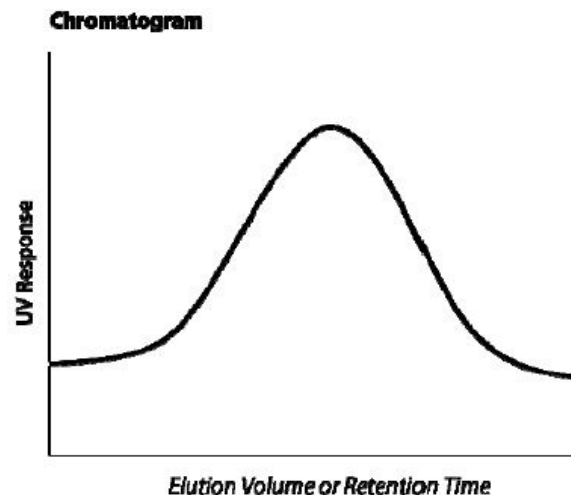
I. Background of the Case: District Court's Opinion

The '808 Patent's Specification and Teva's Expert Declaration

- Teva submitted testimony, in written form, from its expert, Dr. Gregory Grant.
- Dr. Grant provided background on the use of SEC, which is described in Example 1 of the specification to measure the average molecular weight of copolymer-1.
- Dr. Grant explained how a person of ordinary skill would understand the use of SEC and how that fact would lead the person of ordinary skill in the art to conclude that “peak molecular weight” was being reported.
- The district court “credit[ed] and accept[ed] all of Dr. Grant’s opinions regarding SEC.” *Teva*, 810 F. Supp. 2d at 588.

I. Background of the Case: District Court's Opinion **The '808 Patent's Specification and Teva's Expert Declaration**

- Dr. Grant further explained that a skilled artisan would understand that peak molecular weight can be determined using SEC and corresponds to the time (or weight) accounting for the largest amount of the polymer in the sample, i.e., the “peak” of a chromatogram.



I. Background of the Case: District Court's Opinion

The '808 Patent's Specification and Teva's Expert Declaration

- Dr. Grant further explained the relationship between a chromatogram and Figure 1 in the patent specification:

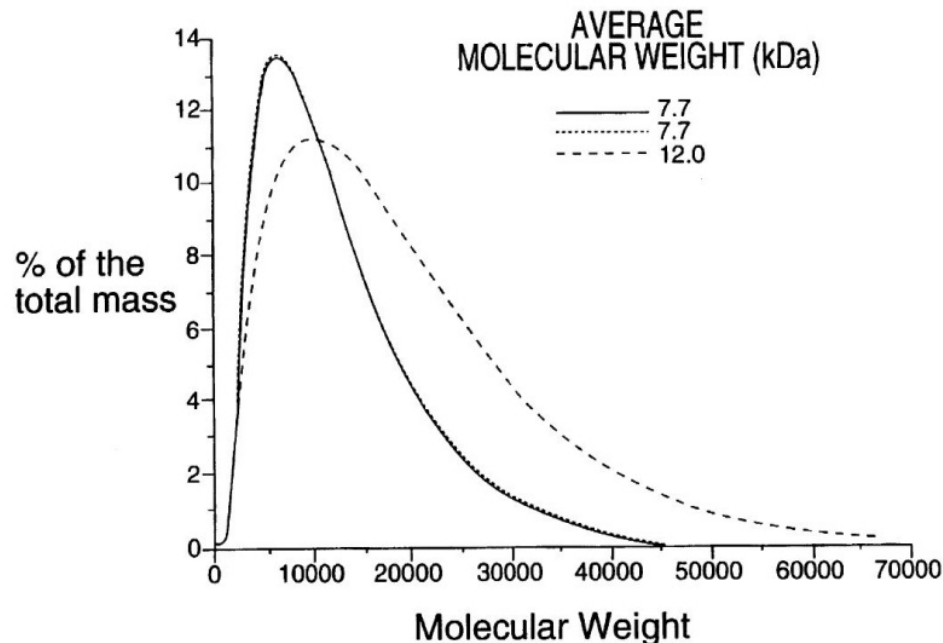


FIG. 1

- Dr. Grant explained how a person of ordinary skill in the field would understand that, during the transformation of the chromatogram into a graph like Figure 1, the peak would shift.

I. Background of the Case: District Court's Opinion

The '808 Patent's Specification and Teva's Expert Declaration

- An opposing expert testified that the peak would not shift.
- After evaluating Dr. Grant's and the competing experts' declarations about the knowledge of the person of ordinary skill in the art and the technology described in the specification, the district court credited Dr. Grant's explanations for what a skilled artisan would have understood from the specification.

I. Background of the Case: District Court's Opinion

Prosecution History of the Patents-in-Suit

- In addition to reviewing the specification, the Court also analyzed the prosecution history of the patents-in-suit.
- In examining another patent in the same family ('539), six years after the '808 patent issued, the patent examiner initially rejected the claims directed to “average molecular weight” as indefinite on the basis that the PTO could not determine what average was being claimed.
- In response to the rejection, Teva pointed to the specification, and stated that a skilled artisan would understand average molecular weight to mean “peak average molecular weight.”

I. Background of the Case: District Court's Opinion

Prosecution History of the Patents-in-Suit

- Defendants pointed to other statements made during prosecution of the patents-in-suit, and argued that the prosecution history was inconclusive on the whole.
- In particular, Defendants pointed to the prosecution of the application that issued as the '847 patent, where the patentee stated that “[o]ne of ordinary skill in the art could understand that kilodalton units implies a weight average molecular weight.”
- The District Court concluded that a person of ordinary skill in the art would understand that the statement during the prosecution of the '847 patent was erroneous, because all molecular weights are reported in “kilodalton.”

I. Background of the Case: District Court's Opinion

Prosecution History of the Patents-in-Suit

- The district court concluded that Teva's statement in prosecuting the '539 patent – that a person having ordinary skill in the art would understand average molecular weight to refer to peak molecular weight – was dispositive.
- The Court noted that this was the only statement in which “average molecular weight” was defined directly.
- As a result, based on the specification, Teva's expert declaration, and the prosecution history, the district court construed “molecular weight” to mean “peak molecular weight.”
- Following claim construction, there were two trials, resulting in verdicts that the patents were enforceable, infringed, and not invalid.

I. Background of the Case

- Legal Background
- Factual Background
- District Court's Claim Construction
- **Federal Circuit's Decision**

I. Background of the Case: The Federal Circuit's Opinion

Teva Pharm. USA, Inc. v. Sandoz, Inc., 723 F.3d 1363 (Fed. Cir. 2013)

- Defendants appealed the district court's claim construction determination, and the Federal Circuit applied *de novo* review to the issue.
- The Federal Circuit did not give any deference to the district court's factual findings and held that the term "average molecular weight" was indefinite.
- First, the Federal Circuit, focusing on Teva's statements with respect to the '539 and '847 patents, held that the two statements "cannot be reconciled." *Teva*, 723 F.3d at 1369.

I. Background of the Case: The Federal Circuit's Opinion

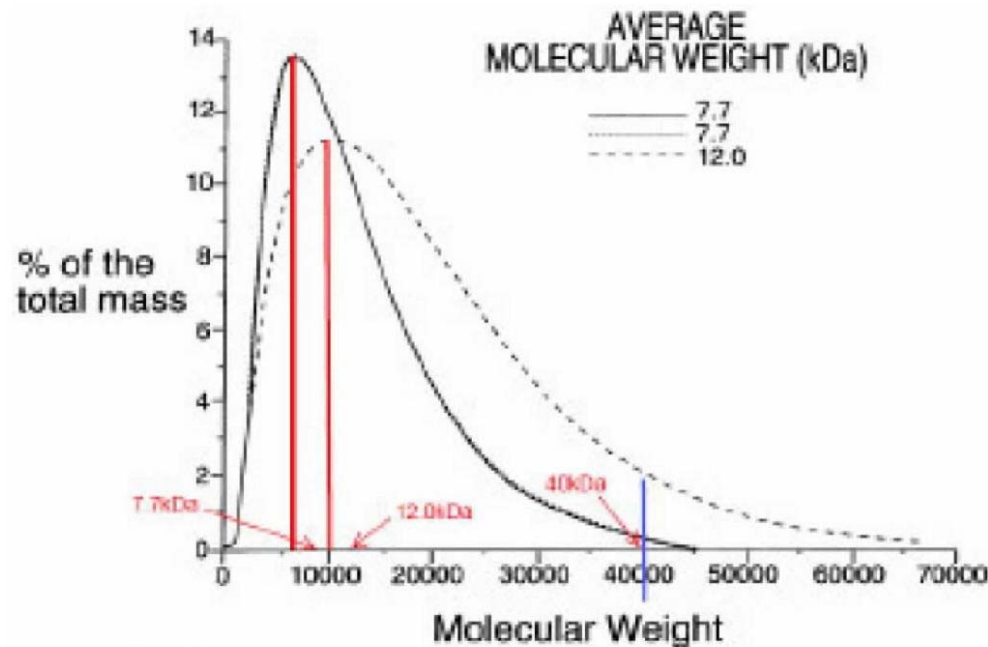
Teva Pharm. USA, Inc. v. Sandoz, Inc., 723 F.3d 1363 (Fed. Cir. 2013)

- Second, the Federal Circuit revisited Dr. Grant's declaration and the district court's interpretation of Figure 1 and Example 1 in the specification.
- The Federal Circuit held that, "[o]n *de novo* review," it did not agree with the district court's acceptance of Dr. Grant's statements about what a skilled artisan would understand about SEC or the specification. *Teva*, 723 F.3d at 1369.
- Instead, the Federal Circuit found it significant that SEC could also be used to calculate number average molecular weight and weight average molecular weight, and did not credit Dr. Grant's explanation that a skilled artisan would understand that only peak molecular weight could be determined without "further data manipulation or calculation."

I. Background of the Case: The Federal Circuit's Opinion

Teva Pharm. USA, Inc. v. Sandoz, Inc., 723 F.3d 1363 (Fed. Cir. 2013)

- The Federal Circuit also performed its own analysis of Figure 1 and emphasized that the peaks on Figure 1 do not perfectly align with the listed average molecular weights for each curve:



I. Background of the Case: The Federal Circuit's Opinion

Teva Pharm. USA, Inc. v. Sandoz, Inc., 723 F.3d 1363,(Fed. Cir. 2013)

- Based on its independent evaluation of Figure 1 and the specification, Dr. Grant's declaration, and the prosecution histories of the patents-in-suit, the Court held that the term "molecular weight" was indefinite.
- Teva filed a petition for certiorari, which was granted in March 2014.

I. Background of the Case: Supreme Court Proceedings

Briefs and Oral Argument

- Teva argued that Rule 52 applies equally to patent cases.
 - › Supported on the standard of review by amici such as the American Intellectual Property Law Association, American Bar Association, IPO.
- The federal government supported neither party.
 - › Supported Teva’s position on the standard of review.
 - › Concluded that the Federal Circuit erred with respect to Figure 1.
 - › Concluded that the other two issues were legal rather than factual.
- Sandoz/Mylan argued that patent cases are different.
 - › *Markman* / “Legislative facts.”
 - › “[T]he only answer [is] that claim construction is somehow different?” “Yes.”
 - › Supported by Intel, Google, and other tech companies.

II. The Supreme Court's Opinion

- Summary of Holding
- The Court's Reasoning

II. The Supreme Court's Opinion

- **Summary of Holding**
- The Court's Reasoning

II. The Supreme Court's Decision: Summary of Holding

Teva Pharm. USA, Inc. v. Sandoz, Inc., 135 S. Ct. 831 (2015)

- On January 20, 2015, the Supreme Court (7-2) vacated and remanded the Federal Circuit's *Teva v. Sandoz* decision.
- The Court held that Rule 52(a)'s clear error standard of review applies to a district court's findings of fact regarding "evidentiary underpinnings" of claim construction decisions. *Teva*, 135 S. Ct. at 835.
- The Court clarified that while the "ultimate issue of the proper construction of a claim" is still a question of law subject to *de novo* review, "subsidiary factfinding" determinations by the should be reviewed for clear error. *Id.* at 838, 841.

II. The Supreme Court's Decision: Summary of Holding

Teva Pharm. USA, Inc. v. Sandoz, Inc., 135 S. Ct. 831 (2015)

- The Supreme Court listed several examples of “subsidiary factfinding” decisions that should be considered issues of fact subject to clear error review, including:
 - › Credibility decisions, *Teva*, 135 S. Ct. at 838, 840;
 - › Resolving issues of fact regarding which competing experts disagree, *id.* at 840; and
 - › “The background science or the meaning of a term in the relevant art during the relevant time period.” *Id.* at 841.
- In the context of the case, the Supreme Court noted that the district court’s decision regarding how a skilled artisan would understand the variation of the listed molecular weights in Figure 1 from the true peaks of the depicted curves was a decision of fact. *Id.* at 842-43.

II. The Supreme Court's Decision: Summary of Holding

Teva Pharm. USA, Inc. v. Sandoz, Inc., 135 S. Ct. 831 (2015)

- The Court also provided guidance on the circumstances in which *de novo* review still applies to claim construction.
- For example, “when the district court reviews only evidence intrinsic to the patent (the patent claims and specification, along with the patent's prosecution history), the judge’s determination will amount solely to a determination of law” and is reviewable *de novo*. *Id.* at 841.
- Similarly, once a factual determination has been made – for example, “resolv[ing] a dispute between experts and mak[ing] a factual finding that, in general, a certain term of art had a particular meaning to a person of ordinary skill in the art at the time of the invention” – the resulting “legal analysis[–]whether a skilled artisan would ascribe that same meaning to that term *in the context of the specific patent claim under review*” – is reviewable *de novo*. *Id.* (emphasis in original).

II. The Supreme Court's Opinion

- Summary of Holding
- **The Court's Reasoning**

II. The Supreme Court's Decision: The Court's Reasoning

Teva Pharm. USA, Inc. v. Sandoz, Inc., 135 S. Ct. 831 (2015)

- The Supreme Court criticized *Cybor* and *Lighting Ballast* as misguided “efforts to treat factual findings and legal conclusions similarly.” *Teva*, 135 S. Ct. at 839.
- In support of its holding, the Court pointed to “practical considerations” that “favor clear error review” of factual underpinnings of claim construction, *id.* at 838:
 - › “[C]lear error review is particularly important where patent law is at issue because patent law is a field where so much depends upon familiarity with specific scientific problems and principles not usually contained in the general storehouse of knowledge and experience.” *Id.* (internal quotation marks omitted).
 - › In this context, a trial judge has a “greater opportunity to gain that familiarity than an appeals court judge.” *Id.*

II. The Supreme Court's Decision: The Court's Reasoning

Teva Pharm. USA, Inc. v. Sandoz, Inc., 135 S. Ct. 831 (2015)

- The Court also rejected Sandoz's argument that it would be "simpler for th[e] appellate court to review the entirety of the district court's claim construction de novo rather than to apply two separate standards." *Teva*, 135 S. Ct. at 839.
- To the contrary, the Supreme Court noted that "[c]ourts of appeals have long found it possible to separate factual from legal matter," and noted that separating underlying factual issues from legal determinations is already required in appellate review of obviousness determinations. *Id.* at 838, 839, 840.

II. The Supreme Court's Decision: The Court's Reasoning

Teva Pharm. USA, Inc. v. Sandoz, Inc., 135 S. Ct. 831 (2015)

- The *Teva* majority also addressed the concern that clear error review would result in less uniformity by noting that several considerations minimized this potential problem, including:
 - › Issue preclusion;
 - › Consolidating discovery among cases asserting the same claims;
 - › Continued *de novo* review of the “ultimate issue of the proper construction of a claim;” and
 - › The relatively small role of subsidiary fact finding in “the universe of claim construction.” *Teva*, 135 S. Ct. at 839-40.

III. Potential Effects

- Subsequent Cases Applying *Teva v. Sandoz*
- Likely Future Developments

III. Potential Effects

- **Subsequent Federal Circuit Cases**
- Likely Future Developments

III. Potential Effects: Subsequent Federal Circuit Cases

Cuozzo and Papst

- Since the Supreme Court's decision, the Federal Circuit has applied *Teva v. Sandoz* in two precedential cases:
 - › *In re Cuozzo Speed Technologies, LLC*, No. 2014-1301, 2015 WL 448667 (Fed. Cir. Feb. 4, 2015)
 - › *In re Papst Licensing Digital Camera Patent Litig.*, No. 2014-1110, 2015 WL 408127 (Fed. Cir. Feb. 2, 2015)
- In both cases, the Federal Circuit concluded that *de novo* review applied in full, as the claim construction determinations were based entirely on intrinsic evidence:
 - › *Cuozzo*, 2015 WL 448667, at *8 (“[T]here is no issue here as to extrinsic evidence”)
 - › *Papst*, 2015 WL 408127, at *3 (“[T]he district court relied only on the intrinsic record, . . . and neither party challenges that approach.”)

III. Potential Effects: Subsequent Federal Circuit Cases

Cuozzo and Papst

- Following *Teva*, the Federal Circuit has indicated that claim construction determinations based solely on interpreting the specification, prosecution history, and the internal logic of the claim language are subject to *de novo* review:
 - › In *Cuozzo*, the Patent Trial and Appeal Board construed the disputed claims by referring to the specification and the internal logic of the claim language. 2015 WL 448667, at *8.
 - › In *Papst*, the district court based its claim construction on the “phrasing in the claim” and the written description, and the prosecution history of the patents-in-suit. 2015 WL 408127, at *5, *6, *8.

III. Potential Effects: Subsequent Federal Circuit Cases

Impact on Claim Construction Opinions

- The Federal Circuit has yet to establish what claim construction determinations it considers to be factual and therefore subject to clear error review.
- However, the *Papst* Court noted that the district court did not rely on “any testimony about skilled artisans’ understandings of claim terms in the relevant field,” suggesting that this is the type of factual determination that would receive clear error review. 2015 WL 408127, at *3.
- The Federal Circuit also noted in *Papst*, after overturning the district court’s claim construction, that “it is worth reiterating that a district court may (and sometimes must) revisit, alter, or supplement its claim constructions (subject to controlling appellate mandates) to the extent necessary to ensure that final constructions serve their purpose of genuinely clarifying the scope of claims for the finder of fact.” *Id.* at *4.

III. Potential Effects

- Subsequent Federal Circuit Cases
- **Likely Future Developments**

III. Potential Effects: Likely Future Developments

Impact on Claim Construction Opinions

- *Teva v. Sandoz* is likely to affect claim construction opinions in district courts and before the Federal Circuit.
- Following *Teva*, a district court seeking to avoid reversal can rely heavily on extrinsic evidence in its claim construction in an effort to ensure clear error review on appeal.
- Conversely, by stating that the intrinsic record is dispositive of the construction of the disputed term, the Federal Circuit may be able to effectively still apply *de novo* review even in cases where the district court relied on extrinsic evidence.

III. Potential Effects: Likely Future Developments

Impact on Claim Construction Litigation

- Parties seeking to inject more finality into the district court's claim construction can strategically use expert witnesses to frame the issues as extrinsic to the patent-in-suit, both before the trial court and on appeal.
 - › Conversely, parties seeking to overturn a claim construction determination will likely argue that the intrinsic evidence is dispositive and that factual decisions are unnecessary.
- Following *Teva*, expert testimony and declarations will be more important to the parties' strategy regarding claim construction.
- The use of experts may also lead to a corresponding increase in the importance of motions challenging experts and their declarations.

III. Potential Effects: Likely Future Developments

Impact on Claim Construction Litigation

- Following *Teva*, it will also be critically important for the parties to create a full record during *Markman* proceedings and to engage with that record on appeal.
 - › These proceedings may begin to more closely resemble trial.
 - › Appellants will need to be able to point specifically to how the district court erred in order to dispute factual determinations.
- Live testimony might also become more important, if the district court will permit it.

III. Potential Effects: Likely Future Developments

Impact on Claim Construction Litigation

- Additionally, now that claim construction is less likely to be modified on appeal, settlement rates may increase immediately preceding and following the district court's claim construction opinion.
 - › Increased finality following claim construction provides greater incentive to settle.

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