

# 1 Year Later, Teva Providing Less Certainty Than Expected

Law360, New York (January 19, 2016, 12:50 PM ET) -- One year ago, in *Teva Pharmaceuticals USA Inc. v. Sandoz Inc.*, 135 S. Ct. 831 (2015), the U.S. Supreme Court held that the Federal Circuit must review factual findings underlying claim construction for clear error. At the time, many commentators believed that the availability of the heightened standard of review would lead to fewer reversals and thus would provide greater predictability for litigants. However, over the past year, the Federal Circuit has reaffirmed that de novo review plays an integral role in claim construction jurisprudence, even where district courts have considered extrinsic evidence. In fact, post-Teva, the clear error standard of review has been applied only in very limited circumstances. As a result, little of the certainty anticipated by the Supreme Court's decision has come to pass.

## Procedural Background — Teva

Petitioners in Teva, several Teva Pharmaceutical entities and the Yeda Research and Development Corporation, market Copaxone to treat multiple sclerosis. When respondents Sandoz, Momenta Pharmaceuticals Inc., Mylan Pharmaceuticals Inc. and Natco Pharma Ltd. sought approval from the U.S. Food and Drug Administration to market generic versions of Copaxone, the petitioners brought suit for patent infringement pursuant to the Hatch-Waxman Act.



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At issue in the district court was the meaning of the claim term "molecular weight." Though the parties agreed that this term referred to "average molecular weight," they disagreed over whether a person of ordinary skill would understand this term. In construing the claim term, the district court credited the petitioners' expert testimony and rejected the respondents' claim of indefiniteness.

On appeal, the Federal Circuit applied a de novo standard of review to the district court's claim construction, including all fact-based questions relating to that claim construction. Under the de novo standard, the Federal Circuit reversed the district court, finding that the meaning of "average molecular weight" could not be discerned and holding the patent invalid due to indefiniteness. The Supreme Court granted certiorari to determine whether the Federal Circuit's de novo review of factual matters underlying claim construction was appropriate.

## The Supreme Court's Decision In Teva

In a 7-2 decision, the Supreme Court held that the Federal Circuit should review a district

court's factual determinations underlying a claim construction under the "clear error" standard of review rather than under the de novo standard. Justice Stephen Breyer, writing for the majority, noted that while a court's ultimate conclusion regarding the construction of a claim term is a matter of law that is subject to de novo review, factual findings that underlie such a construction are to be reviewed under a clear error standard.

In articulating how to delineate between factual and legal determinations, the court confirmed long-standing Federal Circuit precedent that assessments of intrinsic evidence, such as the interpretation of the patent's claims, specification and prosecution history, remain legal determinations to be reviewed de novo. It is extrinsic evidence, the court held, such as a dispute between experts, in which a district court's factual findings should be reviewed for clear error.

## **The Federal Circuit's Continued Use of De Novo Review Post-Teva**

While the Supreme Court held in Teva that the introduction of extrinsic evidence can lead to review under a clear error standard, the Federal Circuit has since clarified that inclusion of extrinsic evidence in the record does not guarantee that the clear error standard will be applied. In *Shire Development LLC v. Watson Pharmaceuticals Inc.*, 787 F.3d 1359 (Fed. Cir. 2015), the Federal Circuit applied de novo review to the district court's claim constructions and ultimately reversed the lower court's ruling, even though the district court had heard evidence from experts regarding the claim constructions at issue. Noting that "[t]he [Supreme] Court did not hold that a deferential standard of review is triggered any time a district court hears or receives extrinsic evidence," the Federal Circuit found "no indication that the district court made any factual findings that underlie its constructions" and thus declined to apply the clear error standard of review.

The Federal Circuit again applied de novo review in *CardSoft LLC v. VeriFone Inc.*, 807 F.3d 1346 (Fed. Cir. 2015), even though the district court had made factual findings based upon extrinsic evidence. Here, the court reasoned that regardless of the extrinsic evidence considered, the Federal Circuit "may nevertheless review the district court's constructions de novo if the intrinsic record fully determines the proper scope of the disputed claim terms." In effect, if extrinsic evidence is deemed unnecessary to construe a claim term by the Federal Circuit, de novo review will be applied, whether or not the district court based its ruling on extrinsic evidence.

Likewise, in *Vasudevan Software Inc. v. MicroStrategy Inc.*, 782 F.3d 671 (Fed. Cir. 2015), the Federal Circuit discussed, and then discounted, extrinsic evidence of record, including (1) expert testimony of Vasudevan's expert, (2) a claim construction to which Vasudevan had stipulated in a prior case, and (3) marketing materials that Vasudevan claimed informed the plain and ordinary meaning of a disputed term. Deeming such extrinsic evidence irrelevant to the construction of the disputed claim term, the Federal Circuit applied a de novo standard of review and upheld the construction.

Once again, in *Enzo Biochem Inc. v. Applera Corp.*, 780 F.3d 1149 (Fed. Cir. 2015), the Federal Circuit reviewed a claim construction de novo and reversed even after acknowledging that the district court had relied upon expert testimony to reach its conclusion. Here too, the Federal Circuit found that the patent specification alone was instructive and thus that reliance on expert testimony was not necessary for claim construction.

In *Info-Hold Inc. v. Applied Media Technologies Corp.*, 783 F.3d 1262 (Fed. Cir. 2015), the Federal Circuit also reviewed de novo and reversed a district court's interpretation of three claim terms. In making its determination, the district court had relied upon a notice of allowability of a related patent, which the district court referred to as extrinsic evidence. In applying de novo review, the Federal Circuit noted that it need not classify the notice of allowability as "'intrinsic' or 'extrinsic'" because the "public record presents no disputed

issue of fact as to the notice's existence or content; the district court made no findings about it; and what remains is what, if any, significance it might have for the ultimate claim construction, which is a question of law."

The Federal Circuit has, however, applied the clear error standard post-Teva in certain cases. In *Lighting Ballast Control LLC v. Philips Electronics North America Corp.*, 790 F.3d 1329 (Fed. Cir. 2015), petition for cert. filed, No. 15-893 (U.S. Jan. 11, 2016), the Federal Circuit applied the clear error standard for reviewing the district court's findings of fact based on expert evidence and ultimately affirmed the claim construction ruling. In so ruling, the Federal Circuit found that the extrinsic evidence was "not used to contradict claim meaning that is unambiguous in light of the intrinsic evidence", and therefore "defer [red] to these factual findings." And, in *Imaginal Systematic LLC v. Leggett & Platt Inc.*, 805 F.3d 1102 (Fed. Cir. 2015), the Federal Circuit referred to Teva's clear error standard before discussing the district court's reliance on dictionary definitions in claim construction. However, in upholding the district court's claim construction, the Federal Circuit focused on its determination that the construction was consistent with the claim language and specification and simply dismissed the appellant's argument concerning the dictionary definitions as "unfounded" without discussing a particular standard of review.

## **Implications For Patent Litigants**

While many commentators expected the clear error standard to be applied frequently by the Federal Circuit after Teva, the Federal Circuit has since made clear that the majority of claim construction appeals remain entrenched in de novo review. Nevertheless, since the court has indicated a willingness to afford more deference to district courts' factual findings in at least certain circumstances, Teva will likely continue to incentivize litigants to introduce extrinsic evidence to be considered along with the intrinsic evidence during the claim construction process. As a result, parties can expect additional disputes as to whether the extrinsic evidence of record is consistent or conflicts with the intrinsic evidence as well as disputes on appeal as to the extent to which the lower court relied upon the extrinsic evidence.

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