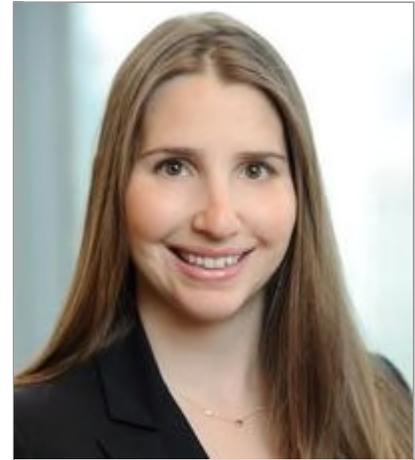


How High Court Teva Ruling Will Affect Patent Litigants

Law360, New York (January 21, 2015, 2:17 PM ET) -- In a 7-2 decision issued on Jan. 20, 2015, the U.S. Supreme Court, in *Teva Pharmaceuticals USA Inc. v. Sandoz Inc.*, held that the Federal Circuit must review factual findings underlying claim construction for clear error, pursuant to Federal Rule of Civil Procedure 52(a) (6). In so ruling, the Supreme Court rejected the Federal Circuit's en banc holdings in *Cybor Corp. v. FAS Techs. Inc.*, 138 F.3d 1448 (Fed. Cir. 1998), and *Lighting Ballast Control LLC v. Philips Elecs. N. Am. Corp.*, 744 F.3d 1272 (Fed. Cir. 2014), which had required de novo appellate review for all aspects of the Markman process.



Stacey L. Cohen

The court's decision to provide deference to the "evidentiary underpinnings" of district courts' claim construction rulings makes clear that factual determinations in patent cases should not be treated differently than those in other areas of the law. This ruling will also provide more certainty in instances where a lower court's claim construction is based, in part, on extrinsic evidence.

Procedural Background

The petitioners, several Teva Pharmaceutical entities and the Yeda Research and Development Corporation, market Copaxone, a treatment for multiple sclerosis. Respondents Sandoz, Momenta, Mylan and Natco are generic drug manufacturers who sought U.S. Food and Drug Administration approval to market generic versions of Copaxone. Pursuant to the Hatch-Waxman Act, the petitioners brought suit against the respondents in the Southern District of New York for patent infringement concerning the method of manufacturing the active ingredient of Copaxone with a low molecular weight in order to achieve therapeutic effectiveness with an improved side effect profile.

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 one of ordinary skill would understand the meaning of that phrase. The district court credited the petitioners' expert testimony in ultimately construing "average molecular weight" and rejecting the respondents' claim of indefiniteness.

On appeal, the Federal Circuit noted that "any allegedly fact-based questions relating to claim construction" are reviewed "de novo on appeal." Without affording any deference to the district court's findings, the Federal Circuit found that a person skilled in the art would not be able to discern the meaning of "average molecular weight" as used in the patent.

The Supreme Court granted certiorari to determine whether de novo review of factual matters underlying claim construction was appropriate, or whether such findings should be reviewed for "clear error."

The Supreme Court's Decision

Justice Stephen Breyer, writing for the seven-member majority, held that the Federal Circuit should review district courts' underlying factual determinations during claim construction for "clear error" pursuant to Federal Rule of Civil Procedure 52(a)(6), rather than using the de novo standard, which had been used to date. In support of its decision, the majority noted that Rule 52(a)(6) "sets forth a 'clear command'" that findings of fact be reviewed for clear error.

The court also held that this rule did not provide for any exceptions, and that even if exceptions were permitted, the court's seminal opinion on claim construction, *Markman v. Westview Instruments Inc.*, 517 U.S. 370 (1996), did not call for treating factual assessments in the claim construction context differently from other factual findings. The court also cited to a number of Federal Circuit dissents discussing the policy arguments in favor of changing the standard of review to highlight the importance of deferring to district court judges who have presided over the entirety of the claim construction proceedings.

The majority reaffirmed, however, that district courts' assessments of intrinsic evidence, such as the interpretation of the patent's claims, specification and prosecution history, are legal determinations which will continue to be reviewed de novo, as will the court's ultimate claim construction ruling. In attempting to delineate between determinations of fact and law in a claim construction dispute, the court made clear where a court looks beyond the intrinsic evidence, it is moving beyond the legal documents, and making a factual determination. As a result, "if a district court resolves a dispute between experts and [finds that] ... a certain term of art had a particular meaning to a person of ordinary skill," that assessment is considered a factual finding to be reviewed for clear error.

By contrast, the court suggested that "whether a skilled artisan would ascribe that same meaning to that term in the context of the specific patent claim under review," is a legal question, to be reviewed de novo. For this reason, "[t]he Federal Circuit should have accepted the District Court's finding [regarding Teva's expert] unless it was 'clearly erroneous.'" In failing to do so, the majority held that "the Federal Circuit was wrong," and vacated for further consideration of the facts in dispute.

In a lengthy dissent, Justice Clarence Thomas, joined by Justice Samuel Alito, agreed that "there is no special exception to Federal Rule of Civil Procedure 52(a)(6)" for determinations in the patent law context, but maintained that claim construction determinations do not involve any subsidiary factual determinations, and thus that Rule 52(a)(6) does not apply. Describing patent claims as "governmental dispositions [that] provide rules that bind the public at large," and thus akin to statutes, rather than private documents, such as contracts or deeds, the dissent stated that the interpretation of the "intent" behind drafting is a purely legal conclusion. As legal conclusions are to be reviewed de novo on appeal, the dissent disagreed with the majority's mandate to review assessments of extrinsic evidence for clear error.

Implications for Patent Litigants

Although the impact of the Teva decision on the reversal rates of claim construction determinations by the Federal Circuit remains to be seen, the ruling is a clear rejection of the Federal Circuit's existing practice of reviewing all matters related to claim construction de novo. The court's decision is likely to have at least the following implications for patent litigants:

- By ensuring that factual determinations be reviewed for clear error under Federal Rule of Civil Procedure 52(a)(6), just as factual determinations are outside of the patent context, the Supreme Court has reaffirmed its message that patent cases should not be treated differently than other types of civil litigation.
- The Supreme Court has now made it clear that claim construction rulings relying solely on intrinsic evidence are reviewed de novo whereas district court's factual findings concerning extrinsic evidence, such as expert testimony, will be reviewed for clear error. This will likely affect the strategy of litigants at the trial court level when deciding when, and if, to argue that proper claim construction requires the court to consider extrinsic evidence.
- The use of clear error review will likely provide additional certainty to litigants in cases where the claim construction ruling relied upon extrinsic evidence. This increase in predictability has the potential to lead to fewer appeals, and shorter and less costly patent litigations. Moreover, additional predictability may increase the likelihood of early settlements after a district court's Markman ruling. However, there may be an increase in disputes at the lower court level as to the appropriateness of including extrinsic evidence in claim construction arguments, as well as an increase in disputes at the appellate level as to the extent to which the lower court's claim construction ruling turned on its assessment of extrinsic evidence.
- The Federal Circuit has noted that "there is an 'unbounded universe' of potential extrinsic evidence having differing levels of relevance." *Vehicle IP LLC v. AT&T Mobility LLC*, 2014 U.S. App. LEXIS 21960, at * 17-18 (Fed. Cir. Nov. 18, 2014) (unpublished). Given the current uncertainty in the state of the law on the use of extrinsic evidence in claim construction, it is likely that the courts — both at the district court and appellate levels — will now be asked to clarify or revise the standards for including extrinsic evidence in the claim construction process.

—By Stacey L. Cohen and Devin A. Kothari, Skadden Arps Slate Meagher & Flom LLP

Stacey Cohen is a counsel and Devin Kothari is an associate in Skadden's New York office.

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