

Supreme Court Rules that the “Clear Error” Standard Applies When Factual Determinations Underlying Claim Construction Are Reviewed on Appeal in *Teva v. Sandoz*

On January 20, 2015, the Supreme Court, in a 7-2 decision, held in *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, that an appellate court must apply a “clear error” standard of review when assessing a trial judge’s resolution of underlying factual disputes in claim construction. Justices Thomas and Alito dissented, arguing that claim construction does not involve findings of fact and, as such, *de novo* review is proper.

Plaintiff Teva markets Copaxone®, a drug used in the treatment of multiple sclerosis. Copaxone® is a form of copolymer-1, a mixture of polypeptide molecules.

Teva sued Defendants for patent infringement under 35 U.S.C. § 271(e)(2)(A) after they submitted Abbreviated New Drug Applications seeking to market generic versions of Copaxone®. Teva asserted nine patents listed in the FDA Orange Book as covering Copaxone® against Defendants. The patents claim copolymer-1 of specific molecular weights or ranges (the active ingredient of Copaxone®), and methods of making copolymer-1.

The District Court construed the asserted claims and found them definite and infringed. On appeal, the Federal Circuit reviewed *de novo* the claim construction and definiteness of the asserted claims. In doing so, it rejected the District Court’s factual findings related to conflicting expert testimony regarding interpretation of a patent figure and how one of ordinary skill would understand the claim term “molecular weight.” Based on this rejection, the Federal Circuit reversed the District Court’s ruling and held that a number of the asserted patent claims are indefinite.

Teva appealed, arguing that the Federal Circuit erred in failing to review the District Court’s findings of fact only for clear error as required by Fed. R. Civ. P. 52(a).

The majority of the Supreme Court sided with Teva, applying Federal Rule of Civil Procedure 52(a)(6), which instructs that a court of appeals must not set aside a district court’s findings of fact unless they are clearly erroneous. Citing *Pullman-Standard v. Swint*, 456 U.S. 273, 287, (1982), the majority explained that Rule 52(a)(6) applies “to both subsidiary and ultimate facts” and explained why, even if the Rule permitted exceptions, no exception was warranted in the claim construction context.

The majority then proceeded to explain how the Supreme Court’s decision in *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996), did not create an exception to Rule 52(a), but rather resolved a Seventh Amendment question – whether a judge or a jury should construe patent claims. The *Markman* opinion reasoned that because claim construction primarily involves the construction of written instruments, a task that is better matched to a judge’s skills, claim construction should be done exclusively by a judge.

Although *Markman* “treated the ultimate question of the proper construction of the patent as a question of law,” the majority stated, it is “a question of law in the way that we treat document construction as a question of law” when interpreting written instruments such as deeds, contracts, and tariffs. The majority then relied upon a nearly century-old case, *Great Northern R. Co. v. Merchants Elevator Co.*, 259 U.S. 285, 291 (1922), to explain that factual disputes may arise when a court is resolving a question of law such as construction of a written instrument where that instrument “uses ‘technical words or phrases not commonly understood.’” In

such circumstances, the Court explained, the “determination of the matter of fact’ will ‘preced[e]’ the ‘function of construction’” and, “like all other factual determinations, must be reviewed for clear error.”

Notably, the majority also reached outside of Federal Circuit case law to find precedential support for its determination, citing a 1950 Second Circuit case authored by Judge Learned Hand and its own cases to analogize the “subsidiary facts” in the claim construction context to those in the obviousness context.

The majority also took into consideration practical considerations, such as the fact that appellate courts must rely on the written record and lack the tools available to district courts that aid in resolving factual disputes fairly and accurately. The majority summarily dismissed the concern noted by the dissent that “clear error” review would bring about less uniformity, explaining that the Federal Circuit will still review the district court’s ultimate claim construction *de novo* and, where the same claims are tried in different district courts, those cases could either be consolidated or, if not tried concurrently, issue preclusion may apply.

The crux of the dispute between the majority and the dissent in this case is whether claim construction of a patent is more analogous to construction of written instruments or to statutory construction. The dissent’s disagreement walks through the origination of patent rights in English law through the Framers’ inclusion of Article I, Section 8, clause 8 in the Constitution to explain that patents are “governmental dispositions” that “provide rules that bind the public at large” such that “patent claims resemble statutes.” The dissent also argues that the need for uniformity weighs heavily in favor of *de novo* review. According to the majority, patent construction is more akin to written instruments because the Court has repeatedly compared patent claim construction to the construction of written instruments. The majority also observed that patents, like written instruments, are likely only to be considered by a smaller audience: private parties, experts, and administrators. Statutes, on the other hand, are addressed to the general public and are subject to congressional consideration of general facts.

The Court’s decision vacated the Federal Circuit’s finding of indefiniteness after clarifying the standard of review for claim construction. On remand, the Court instructed the Federal Circuit to consider whether the District Court’s factual findings underlying its claim construction were clearly erroneous. While the majority did not explicitly resolve the issue of whether the District Court clearly erred in resolving the subsidiary factual dispute here, it did use the facts at issue in this case to explain how the Federal Circuit should apply clear error review of subsidiary facts in claim construction. In so doing, the Court implied that the Federal Circuit may have difficulty supporting any determination that the District Court clearly erred in this instance.

Going forward, this decision does not require district courts to change their approach to claim construction. At the appellate stage, however, litigants should take care to delineate between underlying findings that are questions of fact and those that are questions of law in order to better assist the Court in deciding the appropriate standard of review to be applied.

A copy of the Supreme Court’s *Teva Pharms. USA, Inc. v. Sandoz, Inc.* decision is available [here](#). To discuss further the potential impact of *Teva v. Sandoz* or the Court’s other decisions related to claim construction, please contact your usual Ropes & Gray attorney or one of the Ropes & Gray attorneys listed below.

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