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U.S. Supreme Court Holds That Claim Construction Is A Question Of Law But Underlying Factual Questions Are Subject To Clear Error Review

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On January 20, 2015, the U.S. Supreme Court in *Teva Pharms. USA, Inc. v. Sandoz, Inc.* , No. 13-854, vacated and remanded the Federal Circuit's judgment related to the meaning of the term "molecular weight" in the patent-at-issue. The Supreme Court upheld its previous holding in *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996) that claim construction is a question of law for the judge to determine with a *de novo* standard of review, and clarified that this holding did not create an exception to Fed. R. Civ. P. 52(a). (Slip Op. at 5–6). Instead, any "underlying factual disputes" resolved by the judge in the course of claim construction must be reviewed for clear error. (*Id.*).

The patent-at-issue covers a method of manufacturing Teva's wide-selling drug Copaxone®, which is used to treat multiple sclerosis and has generated over $10 billion since its introduction in 1997. The sole claim of this patent requires the claimed agent to have a "molecular weight" within a certain range. On appeal, the Federal Circuit reversed the district court's finding that the patent was not indefinite, following a *de novo* review of the construction of "molecular weight." *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 723 F.3d 1363 (Fed. Cir. 2013). After looking to the specification and the prosecution history, the Federal Circuit explained that the testimony of Teva's expert did not save the claims from indefiniteness because that testimony was not supported by the specification, especially Figure 1. *Id.* at 1369.

In a 7-2 decision, the Supreme Court held that the Federal Circuit erred by not accepting Teva's expert's explanation as to how a skilled artisan would interpret Figure 1 of the patent-at-issue, without finding that explanation "clearly erroneous." (Slip Op. at 16). The Court explained that, although it established in *Markman* that claim construction "is not for a jury but 'exclusively' for 'the court' to determine," the "evidentiary underpinnings" of claim construction are still underlying factual questions subject to clear error review under Rule 52(a). (*Id.* at 1).

In addition to reviewing its holding in *Markman*, the Supreme Court explained that precedent—including its treatment of "obviousness" as a question of law with underlying questions of fact—as well as "practical considerations"—such as the district court's familiarity with the "specific scientific principles" at issue in the case—support clear error review.

The Supreme Court rejected the argument that it is difficult to separate the "factual"

questions from the "legal" ones, and then explained how to identify the "factual" questions that are entitled to deference. First, the Supreme Court explained that claim construction only involves subsidiary factual findings when the district court reviews extrinsic evidence, outside of the patent's claims, specification, and prosecution history. The Supreme Court gave examples of such underlying facts, including witness credibility, (*Id.* at 7 (citing *Markman*)) and the meaning of a term of art to a person of ordinary skill in the art at the time of the invention. The Supreme Court made sure to distinguish these subsidiary factual findings from the ultimate legal analysis: the meaning of the term at issue "*in the context of the specific patent claim under review*." (*Id.* at 12) (emphasis in original).

In a dissenting opinion, Justice Thomas, joined by Justice Alito, agreed with the majority opinion that there is no special exception to Fed. R. Civ. P. 52(a)(6) for claim construction, but disagreed that claim construction involves findings of fact. Thus, the dissent argued that the Federal Circuit properly applied a *de novo* standard of review. While the majority opinion likened a patent to a deed or a contract rather than a statute, the dissent took the opposite position and argued that because patents "provide rules that bind the public at large, patent claims resemble statutes," which do not involve subsidiary findings of fact. (Dissenting Op. at 3–7). The dissent also disagreed with the majority that the allocation of subsidiary evidentiary determinations to the district court will not impact uniformity in claim construction. (*Id.* at 13–15).

We will continue to follow this patent law development. In the meantime, please feel free to contact our attorneys regarding issues raised by this case.

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