



Case Summary: *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.*

On January 20, the Supreme Court ruled in *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.* that in reviewing a district court's resolution of factual disputes underlying a claim construction determination, the appellate court must apply a "clear error," not a *de novo*, standard of review. The opinion, which was authored by Justice Breyer and joined by Justices Roberts, Scalia, Kennedy, Ginsburg, Sotomayor, and Kagan, reverses the Federal Circuit's long-standing rule that all district court claim construction rulings are reviewed *de novo* on appeal.

In the district court, Sandoz argued that Teva's patent claim for a method of manufacturing Copaxone, a drug used to treat multiple sclerosis, was invalid for indefiniteness. Specifically, Sandoz argued that the term "molecular weight" might mean any one of three different things, and was thus indefinite. In construing "molecular weight" to refer to the "peak average molecular weight," and thereby finding the term definite and the claim valid, the district court accepted the opinion of Teva's technical expert concerning what a skilled artisan would understand the term to mean over the competing opinion of Sandoz's expert. The Federal Circuit, reviewing all aspects of the claim construction *de novo*, accepted instead the opinion of Sandoz's expert, who opined that a skilled artisan would understand Fig. 1 of the patent to reflect a different meaning of "molecular weight."

Reiterating its analysis in *Markman v. Westview*, the Supreme Court emphasized that while the ultimate construction of a claim term is always a legal question, judges often rely on subsidiary factual determinations in making the ultimate legal determination. The Court likened this to contract interpretation, in which factual questions concerning course of dealings and usage of trade, among others, inform the district court's legal determination of the meaning of the contract language. The Court held that just as Federal Rule of Civil Procedure 52(a)(6) prohibits appellate courts from setting aside a district court's determination of underlying factual issues in reviewing its ultimate legal determination of contract interpretation, appellate courts likewise must defer to a district court's resolution of factual disputes underlying the ultimate legal conclusion of patent claim construction absent clear error. Indeed, the Court found expressly that no exception to Rule 52(a)(6) exists in the context of claim construction. The Court further based its decision on practical considerations, including that patent law is a field where "so much depends upon familiarity with specific problems and principles not usually contained in the general storehouse of knowledge and experience"—knowledge with which the district court is likely to have better facility after presiding over the entirety of a proceeding. The Court made clear that determinations based on extrinsic evidence, such as judging witness credibility or attributing special meaning based on industry usage, are to be reviewed for clear error, while determinations based on the intrinsic record, such as the meaning of a term in light of the specification or prosecution history, are legal determinations to be reviewed *de novo* on appeal. The Court explained in this regard that where claim construction depends wholly on intrinsic evidence, "the judge's determination will amount solely to a determination of law, and the Court of Appeals will review that construction *de novo*." "In some cases, however, the district court will need to look

beyond the patent’s intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period. In cases where those subsidiary facts are in dispute, courts will need to make subsidiary findings about that extrinsic evidence. These are the ‘evidentiary underpinnings’ of claim construction that we discussed in *Markman*, and this subsidiary factfinding must be reviewed for clear error on appeal.” The Court emphasized, however, that even when extrinsic evidence, such as expert opinion, underlies the claim-construction determination, the ultimate question of the proper meaning of the claim terms in view of such evidence is always a legal determination subject to *de novo* review, even when the factual determination is close to dispositive of the ultimate legal question.

Applying its holding to the case at bar, the Court found that the Federal Circuit erred by failing to accept the district court’s finding concerning a skilled artisan’s understanding of “molecular weight” absent clear error. The Court vacated the Federal Circuit’s judgment and remanded the case for further proceedings consistent with its opinion.

Justice Thomas delivered a dissenting opinion, joined by Justice Alito. The dissent agreed that Rule 52(a) (6) provides no exception for claim-construction rulings, but found that claim construction is a wholly legal determination that does not involve underlying “findings of fact” as that phrase was understood at the time Rule 52 was adopted in 1937. The dissent analogized claim construction to statutory construction, in which “subsidiary evidentiary findings shape legal rules that apply far beyond the boundaries of the dispute involved.” The dissent found that the public stake in construing patent claim terms makes that analysis more like statutory interpretation than contract interpretation, in which only the intentions of the contracting parties are at issue. Thus, as a policy matter, “*de novo* review [of patent claim construction] on appeal helps to ensure that the construction is not skewed by the specific evidence presented in a given case.” The dissent also emphasized policy considerations, including a concern that reviewing factual determinations underlying claim-construction rulings for clear error will result in a lack of uniformity among district courts construing similar or identical claim language, warning that issue preclusion will not sufficiently prevent such disparate results. Justice Thomas concluded that “[b]ecause the skilled artisan inquiry in claim construction more closely resembles determinations categorized as ‘conclusions of law’ than determinations categorized as ‘findings of fact,’ I would hold that it falls outside the scope of Rule 52(a)(6) and is subject to *de novo* review.”

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