

January 22, 2015

On January 20, 2015, the Supreme Court issued a 7-2 decision in *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.*, No. 13-854, 574 U.S. \_\_\_ (2015), holding that the Federal Circuit must apply a "clear error" standard when reviewing subsidiary factual findings in patent claim construction. Under the previous standard and practice, the Federal Circuit would review all aspects of a district court's claim construction *de novo*. In *Teva* the Supreme Court held that, while the ultimate construction of a claim remains a legal conclusion that the Federal Circuit can review *de novo*, if that construction depends upon the resolution of underlying factual disputes the Federal Circuit may only set aside those factual findings if there was clear error in the district court's factual conclusion.

The Court also sought to explain "how" the clear error standard of review should be applied when reviewing subsidiary fact-findings in patent claim construction. In doing so, the Court delineated between the intrinsic and extrinsic record. The Court stated that when the district court reviews only intrinsic evidence—such as the patent claims, specification and file history—the claim construction will be solely a determination of law that is reviewed *de novo*. *Teva*, No. 13-854, slip. op. at 11-12 (2015). In contrast, where the district court makes factual findings from extrinsic evidence—such as to better understand "the background science" or the "meaning of a term in the relevant art during the relevant time period"—the fact-based conclusions are to be reviewed for clear error. *Id.* at 12. To illustrate the distinction, the Court provided an example of a factual dispute between experts regarding whether a "certain term of art had a particular meaning to a person of ordinary skill in the art at the time of the invention." *Id.* Once the district court resolved the factual issue regarding the meaning of the term, the Court explained that the ultimate construction of the claim term would then be legal analysis of whether that same meaning (i.e. the factual finding of the district court resolving the expert dispute as to the understanding of a person of skill in the art) properly applies in the context of the intrinsic record. *Id.*

The Court further explained that the importance of factual findings to the ultimate construction of claim terms will vary depending on the circumstances. While in some instances factual findings will play small or secondary roles in construing a claim term, in other instances factual findings "may be close to dispositive of the ultimate legal question of the proper meaning of the term in the context of the patent." *Id.* at 13. Nevertheless, even if a factual finding is dispositive of the ultimate legal question, the Court emphasized that such a situation does not "render the subsidiary [factual] question a legal one." *Id.*

Justice Thomas dissented, joined by Justice Alito. The dissent likened patent claim construction with statutory construction. Because statutory construction involves only questions of law, Justice Thomas reasoned that patent claim construction likewise involved pure questions of law subject to *de novo* review.

## Potential impacts

The Supreme Court's restructuring of the legal standard for appellate review of a district court's subsidiary factual determinations in the context of claim construction will substantially alter the landscape of this critical aspect of patent litigation. Claim construction is meant to occur from the perspective of one of ordinary skill in the art, and factual disputes regarding how one of ordinary skill in the art would view a particular claim term or interpret the intrinsic record are common. The Court's opinion provides some guidance on the distinction between fact and law in this context and notes that "Courts of appeal have long found it possible to separate factual from legal matters." *Id.* at 8. However, due to the inherent factual nature of construing claims from the perspective of one of ordinary skill in the art, district courts will likely encounter difficult questions trying to segregate questions of fact from questions of law within the analytical claim construction framework.

Overall, the increased deference afforded to district court factual findings under *Teva* should result in lower claim construction reversal rates at the Federal Circuit, and more finality in general at the district court level. District courts will be encouraged to provide greater justification for the factual findings underlying a particular claim construction to increase the likelihood that the constructions will withstand appeal. Additionally, the new standard may decrease the propensity for parties to enter stipulations of final judgment based on the likelihood of a completely *de novo* evaluation of claim construction before the Federal Circuit.

Since the perspective of one of ordinary skill in the art is most likely to arise in the context of highly technical fields, the Court's ruling is likely to have a greater impact on patents and patent claims in complex technical

areas that rely more heavily on specialized technical or scientific terms rather than patents that have language that is within the understanding of lay persons.

## Litigation strategy

The new deference afforded to a district court's factual findings in the context of claim construction raises significant strategic considerations. Litigants will have to consider more closely whether to rely on and how to emphasize extrinsic evidence in support of claim construction positions to generate or negate factual disputes regarding the understanding of one of ordinary skill in the art. Parties should, depending on the strength of their positions, seek to characterize claim construction disputes as either more factual or legal in nature, exploiting the potential ambiguity in segregating factual and legal matters.

## Background

Teva Pharmaceuticals sued Sandoz in the United States District Court for Southern District of New York for infringing various patents held by Teva related to Teva's drug for the treatment of multiple sclerosis, Copaxone. Sandoz and other defendants sought FDA approval to market generic formulations of Copaxone, triggering the filing of the district court infringement suit by Teva. The claim construction dispute involved the term "molecular weight." Sandoz argued that the term was indefinite, asserting that the term might mean one of three different things. The district court held that the term was definite, finding that the skilled artisan would understand that the term referred to one of the three methods identified by Sandoz. Reviewing the district court's claim construction *de novo*, a Federal Circuit panel reversed the district court's claim construction ruling and held the claim to be indefinite. The Supreme Court vacated the Federal Circuit's judgment and remanded for further proceedings consistent with the Court's clarified standard for appellate review of subsidiary factual findings in patent claim construction.

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