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Supreme Court to Consider Federal Circuit *De Novo* Review of Claim Construction in *Teva Pharmaceuticals USA Inc. v. Sandoz Inc.*

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On March 31, 2014, the Supreme Court granted writ of certiorari in *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.* to hear Teva's appeal of a Federal Circuit decision invalidating several patents on Teva's multi-billion dollar multiple sclerosis drug, Copaxone. The Supreme Court will address the Federal Circuit's standard of review of district court claim construction. On appeal, the standard of review determines the amount of deference an appeals court will give in reviewing a lower court's decision. Typically, an appeals court will review the lower court's factual findings for clear error, under Federal Rule of Civil Procedure 52(a). Under the "clearly erroneous" standard, an appeals court will not overturn the lower court decision unless definitely and firmly convinced that the lower court made a mistake. However, after its 1998 *Cybor Corporation v. FAS Technologies, Inc.* decision, the Federal Circuit reviews claim construction *de novo*. Under *de novo* review, the appeals court gives no deference to the lower court's findings, and will rule on the evidence and matters of law as if considering them for the first time. In *Cybor Corp.*, the Federal Circuit held that "as a purely legal question, we review claim construction *de novo* on appeal including any allegedly fact-based questions relating to claim construction." 138 F.3d 1448, 1456 (Fed. Cir. 1998).

In the *Teva* case, the Federal Circuit reversed the district court's claim construction determination on appeal. The district court had construed the term "molecular weight" to refer to the peak average molecular weight of the claimed synthetic polypeptide. The district court rejected defendants' argument that the claim term could refer to three different average molecular weight measures, and was therefore indefinite. Instead, the lower court credited Teva's expert's testimony that a person of ordinary skill in the art would know to use the peak average molecular weight. *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 876 F. Supp. 2d 295, 400 –01 (S.D.N.Y. 2012) *aff'd in part*, *rev'd in part*, 723 F.3d 1363 (Fed. Cir. 2013) *cert. granted,* 13-854, 2014 WL 199529 (U.S. Mar. 31, 2014).

On appeal, the Federal Circuit overturned the district court's finding of indefiniteness, noting that "[i] ndefiniteness is a question of law that we review *de novo*." *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 723 F.3d 1363, 1368 (Fed. Cir. 2013) *cert. granted*, 13-854, 2014 WL 199529 (U.S. Mar. 31, 2014). Accordingly, the Federal Circuit considered Teva's expert's testimony along with the patent-in-suit's prosecution history, and found "[o]n *de novo* review of the district court's indefiniteness holding…[the expert] testimony does not save Group I claims from indefiniteness." *Id.* at 1369.

Claim construction is a critical issue in almost every patent case. The Federal Circuit's *de novo* review of claim construction may add a level of uncertainty to patent litigation, as a change in the way the court construes asserted patent claims can completely reverse the outcome of infringement and validity analyses.

As Teva noted in its petition to the Supreme Court, the standard of review for claim construction is ripe for consideration after the Federal Circuit doubled down on *de novo* review by refusing to overturn the *Cybor Corp.* decision in *Lighting Ballast Control LLC v. Philips Electronics North America*. *See* Reply Brief for Petitioners, *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 723 F.3d 1363 (Fed. Cir. 2013) (No. 13-854), 2014 WL 768707, at *1. In *Lighting Ballast*, after a jury trial, the district court entered judgment of infringement and validity. On appeal, the Federal Circuit reversed, holding the claims invalid for indefiniteness. Plaintiffs petitioned for rehearing en banc, and the Federal Circuit granted the petition in order to address whether the *de novo* standard for appellate review of district court claim construction decisions from *Cybor Corp.* should be overturned.

In *Lighting Ballast*, both parties argued that the *Cybor Corp. de novo* standard of review is not appropriate for all aspects of claim construction in light of its fact-dependent nature. Lighting Ballast advocated for the Federal Circuit to abandon *de novo* review completely because claim construction is a mixed question of fact and law. Rehearing En Banc Response Brief of Plaintiff-Appellee, *Lighting*

Ballast Control LLC v. Philips Elecs. N. Am. Corp., 744 F.3d 1272 (Fed. Cir. 2014) (No. 2012-1014), 2013 WL 3423281, at *24–25. Universal Lighting argued that claim construction is a matter of law, and therefore *de novo* review is appropriate except where there are "disputed historical facts (if any)." Rehearing En Banc Reply Brief of Defendant-Appellant, *Lighting Ballast Control LLC v. Philips Elecs. N. Am. Corp.*, 744 F.3d 1272 (Fed. Cir. 2014) (No. 2012-1014), 2013 WL 3816455, at *5. The Federal Circuit heard oral argument on September 13, 2013, to determine whether it should overrule *Cybor Corp.* and afford deference to any aspect of a district court's claim interpretation.

On February 21, 2014, the Federal Circuit reconfirmed the *de novo* review standard for claim construction under *Cybor Corp.* in a fractured 6-4 decision. The Federal Circuit provided several reasons in support of upholding *Cybor Corp.*, noting that neither the Supreme Court nor Congress has provided authority post-*Cybor Corp.* to undermine its reasoning. *See Lighting Ballast Control LLC v. Philips Elecs. N. Am. Corp.*, 744 F.3d 1272, 1283 (Fed. Cir. 2014). In addition, the Federal Circuit found no evidence in the fifteen years since *Cybor Corp.* was decided that the *de novo* standard of review is "unworkable." *Id.* Furthermore, the Federal Circuit cited that the policy on uniformity concerns which underlies its *Cybor Corp.* decision remains in force, and no uniform proposal or alternative standard of review has been provided. *Id.* at 1286. The Federal Circuit stated that there is no evidence that deferential review would lead to "improved consistency" or "increased clarity" or that *Cybor Corp.* increased the burdens on the courts or litigants conducting claim construction. *Id.*

Given these reasons, the Federal Circuit upheld *Cybor Corp.* and the *de novo* standard of review. In dissent, Judge O'Malley, joined by Chief Judge Rader and Judges Reyna and Wallach, warned that "[c]onsiderations of *stare decisis*…do not justify adhering to precedent that misapprehends the Supreme Court's guidance, contravenes the Federal Rules of Civil Procedure, and adds considerable uncertainty and expense to patent litigation." *Lighting Ballast*, 744 F.3d at 1297 (O'Malley, J., dissenting). Instead, "[w]hen a district court makes fact-findings needed to resolve claim construction disputes, Rule 52(a) requires us to defer to those findings unless they are clearly erroneous." *Id.* at 1317.

While the parties in *Lighting Ballast* have yet to petition for writ of certiorari, the Supreme Court will hear the same issues in the *Teva* case next term in October or November 2014. In the meantime, Chief Justice John Roberts denied Teva's application for an order staying the Federal Circuit's ruling. Despite Teva's offer to post a $500 million bond if the Supreme Court would temporarily restore the district court's injunction, Chief Justice Roberts was "not convinced…that [Teva] has shown a likelihood of irreparable harm from denial of a stay" because Teva would be able to recover damages from the defendants for past patent infringement should it prevail in its appeal before the Supreme Court. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, No. 13A1003, 2014 WL 1516642 (U.S. Apr. 18, 2014). Chief Justice Roberts' order clears the way for drug makers to launch generic versions of Copaxone in May.