Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.: Where Does Claim Construction Go From Here?

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It is widely acknowledged that claim construction is an important phase in a patent litigation. Since the Federal Circuit's creation in 1982, the court has debated the proper standard of appellate review for the district court's construction of patent claims. In 1998, the Federal Circuit concluded *en banc* that claim construction should be reviewed *de novo*, giving no deference to any underlying findings of fact made by district courts. *Cybor Corp. v. FAS Technologies, Inc.*, 138 F.3d 1448 (Fed. Cir. 1998) (*en banc*). However, in January 2015 the Supreme Court stepped-in to resolve this long running dispute. In a 7-2 decision, the Court overturned the Federal Circuit's *de novo* standard of review for subsidiary findings of fact made during claim construction, holding "[w]hen reviewing a district court's resolution of subsidiary factual matters made in the course of its construction of a patent claim, the Federal Circuit must apply 'clear error,' not a *de novo*, standard of review." *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc., et al.* 135 S. Ct. 831 (2015) ("Teva Pharmaceuticals III").

PROGRESSION OF THE CLAIM CONSTRUCTION STANDARD OF REVIEW

Since its establishment, the Federal Circuit has wrestled with the question of whether claim construction was a purely legal issue or a mixed issue of law and fact. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (*en banc*) ("Markman I"). Along one line of cases, the Federal Circuit held claim construction may be "factual or mixed issue." *Markman I*, 52 F.3d at 976. An opposite line of cases held that claim construction was strictly a matter of law. *Id*. These two different lines of cases resulted in unpredictability in claim construction practice. *Id.*

In 1995, the Federal Circuit attempted to resolve "inconsistencies in [its] precedent." *Markman I*, 52 F.3d at 979. Sitting *en banc*, the court held claim construction is "properly viewed solely as a question of law" for the court, and on appeal "the construction given the claims is reviewed *de novo*." *Markman I*, 52 F.3d at 979, 983-84. On appeal, the Supreme Court agreed claim construction was a question of law, but did not directly address the standard of review. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 378, 388 (1996) ("*Markman II*") Instead, the Court merely noted that claim construction is a "mongrel practice," "fall[ing] somewhere between a pristine legal standard and simple historical fact." *Markman II*, 517 U.S. at 378, 388.

This ambiguity regarding the proper standard of review led to further debate amongst Federal Circuit judges. Some judges agreed with *Markman I* and felt that a district court's claim construction deserved no deference, while others continued to believe that "[w]here a district court makes findings of fact as part of a claim construction, we may not set them aside absent clear error." *Metaullics Systems Co. v. Cooper*, 100 F.3d 938 (Fed. Cir. 1996) (Mayor, J.); see also *J.T. Eaton & Co. v. Atlantic Paste & Glue Co.*, 106 F.3d 1563, 1577 (Fed. Cir. 1997) (Rader, J., dissenting).

Two years after *Markman II* in *Cybor Corp. v. FAS Technologies, Inc.* the Federal Circuit "resolved" this dispute by re-affirming the *de novo* standard of review, holding "we review claim construction de novo on appeal including any allegedly fact-based questions relating to claim construction," *Cybor*, 138 F.3d at 1456.

While *Cybor* established the *de novo* standard, over time a growing chorus of Federal Circuit judges started calling for its reconsideration. *See e.g. Philips v. AWH Corp.*, 415 F.3d 1303, 1330-35 (Fed. Cir. 2005) (*en banc*) (Mayer, J. dissenting, joined by Newman, J.); *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 469 F.3d 1039, 1040-46 (Fed. Cir. 2006) (Judges Dyk, Gajarsa, Linn, Michel, Moore, Newman and Rader indicated *Cybor* should be reconsidered); *Retractable Techs. v. Becton Dickinson & Co.*, 659 F.3d 1369; 1373 (Fed. Cir. 2011) (O'Malley, J., dissenting).

In January 2013, the Federal Circuit answered those calls for reconsideration in *Lighting Ballast Controls v. Philips Electronics North America Corp. et al.*, 498 Fed.Appx. 986, 2013 WL 11874, at *4-6 (Fed. Cir. Jan. 2, 2013). On February 21, 2014, a sharply divided (6-4) *en banc* panel re-affirmed the de novo standard. *Lighting Ballast Control LLC v. Philips Electronics North America Corp. et al.*, 744 F.3d 1272 (Fed. Cir. 2014).

TEVA PHARMACEUTICALS V. SANDOZ

Shortly after the Federal Circuit's *en banc* decision in *Lighting Ballast*, the Supreme Court granted certiorari in *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc., et al.*, No.13-854, 2014 WL 199529 (March 31, 2014) to address the standard of review issue. In *Teva Pharmaceuticals*, the issue before the district court was to construe the term "average molecular weight," and whether that term was indefinite. *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.*,723 F.3d 1363, at 1367-69 (Fed. Cir. 2013) ("Teva Pharmaceuticals II"). Both sides agreed the term had several potential meanings, including: (1) peak average molecular weight; (2) weight average molecular weight; and (3) number average molecular weight. Because the patent and prosecution history did not define how "average molecular weight" should be calculated, the district court relied on expert testimony to understand how a person of ordinary skill in the art would interpret that term. The district court credited Teva's expert to conclude that a person of ordinary skill in the art would understand the term meant "peak average molecular weight," and found the term sufficiently definite. *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc., et al.*, 810 F.Supp.2d 578, 587-96 (S.D.N.Y. Aug. 29, 2011) ("Teva Pharmaceuticals I").

On appeal, the Federal Circuit reversed the district court, finding the term indefinite because the patent did not resolve the ambiguity in its meaning. *Teva Pharmaceuticals II*, 723 F.3d at 1369. In accordance with *Cybor*, the Federal Circuit gave no deference to the district court's findings of fact regarding Teva's expert's testimony. *Id.* at 1368-69.

Teva sought Supreme Court review and the Court decided to review Federal Circuit's *en banc* decisions to finally resolve the debate concerning the proper standard of appellate review for district court claim constructions.

SUPREME COURT'S DECISION

The issue before the Supreme Court was "[w]hether a district court's factual finding in support of its construction of a patent claim term may be reviewed *de novo*, as the Federal Circuit requires (and as the panel explicitly did in this case), or only for clear error, as Rule 52(a) requires." *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc., et al.*, No.13-854, 2014 WL 199529 (March 31, 2014). Writing for the majority, Justice Breyer held the Federal Circuit "must apply a 'clear error,' not a *de novo*, standard of review" to subsidiary factual findings made in district court claim constructions. *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc., et al.* 135 S. Ct. 831 (2015) ("Teva Pharmaceuticals III").

The Court premised its decision on four points.

First, the Court found Rule 52(a) sets forth a "clear command," that "[i]n our view, this rule and the standard it sets forth must apply when a court of appeals reviews a district court's resolution of subsidiary factual matters made in the course of its construction of a patent claim." The Rule "applies to both subsidiary and ultimate facts." *Id.* at 836.

Second, the Court stated that its decision in *Markman II* "neither created, nor argued for, an exception to Rule 52(a)." *Teva Pharmaceuticals III*, 135 S. Ct. at 837. The Court clarified that *Markman II* concerned whether "a judge or jury [should] construe patent claims," and found the "task is better matched to a judge's skills." *Id.* The Court noted that, while *Markman II* found the final construction of patent claims was a question of law, it "pointed out that a judge, in construing a patent claim, is engaged in much the same task as the judge would be in construing other written instruments, such as deeds, contracts, or tariffs." *Id.* at 838. Like the construction of contractual terms, when words are "used in their ordinary meaning" then that presents a "question solely of law." But if a contract uses "technical words or phrases not commonly understood," the construction of "those words may give rise to a factual dispute," to which extrinsic evidence may be used and clear error review is required. *Id.* at 837-38.

Third, the Court explained that pre-Federal Circuit cases and current Supreme Court precedent in other areas of patent law, namely obviousness, supported clear error review. *Id.* For example, obviousness has underlying factual determinations, but the ultimate conclusion is a legal issue.

Fourth, the Court found that "practical considerations" favored clear error review, particularly in the field of patent law: "where so much depends on familiarity with specific scientific problems . . . [A] district court judge who has presided over, and listened to, the entire proceeding has a comparatively greater opportunity to gain the necessary 'familiarity with specific scientific problems and principles than an appeals court judge who must read a written transcript or perhaps just those portions referenced by the parties.'" *Id.* at 838-39.

SUPREME COURT'S GUIDANCE

Following its legal analysis, the Court provided guidance regarding how the new standard of review should be applied. The Court made clear the new standard did not alter two other longstanding precedents: (1) that district court claim constructions based on intrinsic evidence ("[th]e patent claims and specifications, along with the patent's prosecution history") are reviewed de novo; and (2) the actual construction of patent claims, even if it involves findings of fact based on extrinsic evidence, is ultimately a question of law—subject to de novo review. *Teva Pharmaceuticals III*, 135 S. Ct. at 840-41.

The Court then explained that if a district court needs to look beyond the intrinsic record and consult extrinsic evidence (e.g. dictionaries, treatises, and expert testimony), to understand for example "the background science or the meaning of a term in the relevant art during the relevant time period," in those cases subsidiary factual findings based on that evidence, "must be reviewed for clear error." *Id.* at 831.

After a court has made a factual finding or "decid[ed] a factual dispute" based on extrinsic evidence, the court then "conduct[s] a legal analysis" by "interpret[ing] the patent claim in light of the facts as he has found them." *Id.* For example, "if a district court resolves a dispute between experts and makes a factual finding" regarding the meaning of a claim term to a person of skill in the art at the time of the invention, the court would then construe the term based on "whether a skilled artisan would ascribe that same meaning to that term *in the context of the specific patent claim under review*." *Id.* (emphasis original).

The Court noted that extrinsic evidence and subsidiary factual findings will play varying roles in claim construction, stating "in some instances, a factual finding 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 841-42. Nevertheless, "the ultimate construction will remain a legal question. Simply because a factual finding may be nearly dispositive does not render the subsidiary question a legal one." *Id.* at 842.

FUTURE IMPLICATIONS ON PATENT LITIGATION

The decision reached in *Teva v. Sandoz* is likely to affect how litigants and courts approach claim construction issues in several ways.

Use of Extrinsic Evidence: The *Teva* decision will likely result in an increase use of extrinsic evidence by litigants in attempt to avail themselves of the clear error standard. In particular, litigants likely will rely more on expert testimony. Likewise, district courts may begin to more frequently hold evidentiary hearings on claim construction issues in order to evaluate the credibility of the experts.

Application of Extrinsic Evidence: *Teva v. Sandoz* likely will play a key role in future appeals from lower court claim construction rulings. While the Court's decision provides guidance regarding the application of this new standard, there likely will be future debates concerning its implementation. Indeed, in at least one decision shortly after *Teva*, the Federal Circuit reviewed the lower court's claim construction *de novo* "because intrinsic evidence fully determines the proper constructions." *In re Papst Licensing Digital Camera Patent Litigation*, No. 2014-1110, 2015 WL 408127, *3 (Fed. Cir. Feb. 2, 2015).

Time & Resources: Finally, the *Teva* decision will likely result in more time and resources being devoted to claim construction. Expanded use of expert witnesses will likely increase the time needed to prepare for and costs associated with *Markman* hearings.