Teva Pharmaceuticals: Is It Time to Rethink How You Will Argue Claim Construction?

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The United States Supreme Court decided in Teva Pharmaceuticals USA Inc. v. Sandoz Inc. that the Federal Circuit must review all subsidiary factual findings in patent litigation claim construction proceedings that are on appeal for clear error. The January 20, 2015 decision overturned two long-standing Federal Circuit en banc decisions that previously held that all aspects of claim construction were to be reviewed de novo. See Cybor Corp. v. FAS Techs. Inc., 138 F.3d 1448 (Fed. Cir. 1993) and Lighting Ballast Control LLC v. Phillips Elecs. N. Am. Corp., 744 F.3d 1272 (Fed. Cir. 2014). The Court found that while the district court’s ultimate ruling should continue to be reviewed on appeal de novo, the resolution of any subsidiary factual disputes must be reviewed for clear error.

Claim construction (interpretation of the meaning of the words in a patent claim) is the most important analysis in any patent dispute because it is the first step toward determining (1) whether the patent is invalid for failing to meet the conditions and requirements of patentability and (2) whether the patent is infringed. In 1996, the Supreme Court decreed that claim construction is to be carried out by judges – not juries – because the interpretation of patent claims is a legal exercise. See generally Markman v. Westview Instruments Inc., 517 U.S. 370 (1996). Following Markman, the Federal Circuit consistently reviewed all claim construction determinations de novo because they are legal exercises.

In claim construction, the district court first looks to intrinsic legal evidence (the claims, specification, and prosecution history) to construe the meaning of the claim. The district court may resort to extrinsic factual evidence, but only when the intrinsic evidence is insufficiently clear to construe the meaning of the claim to determine if the conditions and requirements of patentability have been satisfied or the claim is infringed. Extrinsic factual evidence often plays an important role in claim construction – whether received informally through a tutorial at the start of the claim construction proceeding or as formal evidence – because it can shed light on the true meaning of the intrinsic evidence.

The dispute in Teva Pharmaceuticals concerned the meaning of the words “molecular weight”. The petitioners, Teva Pharmaceuticals, asserted a patent that claimed a manufacturing method for a drug used to treat multiple sclerosis. The claims language at issue described the active ingredient in the drug as having “a molecular weight of 5 to 9 kilodaltons” (emphasis added). When the respondents, Sandoz, Inc., tried to market a generic version of the drug, it was sued by Teva for patent infringement. Sandoz argued the claim was invalid because it failed to meet a condition of patentability in that it failed to “particularly point[ed] out and distinctly claim[ed] the subject matter...regard[ed] as [the] invention.” 35 U.S.C. § 112, ¶ 2.

Sandoz argued that the term “molecular weight” as used in the patent claim might mean any one of three different things. Sandoz argued that because the term might mean any one of three different things the claim failed to state the exact method of calculation to be used. According to Sandoz, the term “molecular weight” was therefore indefinite and the claim invalid.
The district court accepted extrinsic evidence from experts at the claim construction hearing as to the meaning of the term to one of ordinary skill in the art and concluded that the claim was sufficiently definite. It found an artisan would have understood the term “molecular weight” to be calculated one way (not one of three), namely by the weight of the most prevalent molecule. It further found that this common understanding was the same meaning of the term as used in the disputed claim. On appeal, the Federal Circuit reviewed de novo every aspect of the district court’s claim construction determination including its finding as to the ordinary meaning of the term “molecular weight” and overturned the district court finding the term “molecular weight” could have meant any of three different calculations.

The Supreme Court took the case to decide whether the Federal Circuit applied the correct legal standard in reviewing the decision of the district court. The Supreme Court relied heavily on Federal Rule of Civil Procedure 52(a)(6), which states that a court of appeals “must not...set aside” a district court’s “[f]indings of fact” unless they are “clearly erroneous” and distinguished the ultimate construction by the district court (based on the intrinsic legal evidence) from the subsidiary factual findings and held that the subsidiary fact finding must be reviewed for clear error. The Court’s decision upheld the underpinnings of the Markman decision – allowing judges to perform claim construction – by clarifying that the ultimate issue of proper construction within the context of an asserted patent remains a question of law to be reviewed de novo, while at the same time providing greater deference to the findings of district court judges by ruling that pre-requisites questions relating to the customary meaning of claim terms are to be reviewed under the “clearly erroneous” standard. The Court favored a “clear error” review of subsidiary factual determinations on the basis that district court judges who preside over and listened to the entirety of a proceeding are presumed to have comparatively greater opportunity to gain familiarity with subsidiary factual findings than appellate judges.

The decision elevates the importance of building strong factual records to support artisan relied-upon constructions to insulate such findings on appeal. In contrast, advocates of constructions supported by the lexography or clear teachings of the applications – as opposed to artisan relied-upon meanings – may wish to forgo the building of strong factual records to save expense and avoid potential confusion that could be difficult to overturn.

Today, many district courts prefer to receive off-the-record informal tutorials instead of time consuming record evidence, but advocates of strong extrinsic evidence supported constructions will need to push past such judicial tendencies and demand formal evidentiary submissions. Factually supported subsidiary findings will now be harder to overturn on appeal increasing their value in litigation and settlement. The submission of proposed findings of fact, if adopted by the district court, could help insulate patentability and infringement determinations grounded in constructions supported by subsidiary factual determinations.

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