

Supreme Court Clarified Standard of Review for Patent Claim Construction – Subsidiary Factual Findings are to be Reviewed for Clear Error Not De Novo

Articles January 22, 2015

In a recent case, *Teva Pharmaceuticals USA, Inc. Et Al. V. Sandoz, Inc. Et Al.*, the Supreme Court of the United States clarified that subsidiary issues of fact determined by a District Court during patent claim construction are to be reviewed for clear error and not *de novo*.

Teva owns a patent covering a method for manufacturing Copaxone, which is a drug used to treat multiple sclerosis. Sandoz marketed a generic version of Copaxone, and Teva sued for patent infringement. Sandoz countered that the Patent was invalid under 35 U.S.C. §112 as indefinite[1]. Specifically, Sandoz argued that the language disclosing that the active ingredient has a “molecular weight of 5 to 9 kilodaltons” was indefinite because the Patent did not disclose the method for calculating molecular weight. Sandoz argued that there were three possible methods that could be used to calculate molecular weight: (1) weight of the most prevalent molecule, (2) weight as an average weight of all molecules, and (3) weight as an average of all molecules but where heavier molecules count for more.

After considering evidence presented by experts from both sides, the District Court held that the Patent was sufficiently definite (and not invalid) where the term “molecular weight” would be understood by one of skill in the art to mean the weight of the most prevalent molecule. On appeal, the Federal Circuit found the term to be indefinite and the Patent invalid, reviewing the District Court’s findings of fact and claim construction *de novo*.

The issue before the Supreme Court was whether or not the Federal Circuit erred in reviewing the District Court’s resolution of subsidiary factual matters *de novo*. In analyzing the issue, the Supreme Court cited Federal Rule of Civil Procedure 52(a)(6), which states that a court of appeals “must not...set aside” a district court’s “findings of fact unless there are clearly erroneous” and compared the construction of patent claims to the construction of other written instruments, such as contracts or deeds[2].

When written instruments can be construed based solely on evidence intrinsic to the document, a judge’s determination is purely a question of law which may be reviewed *de novo*. However, in more complicated situations where a written instrument uses terms or phrases not commonly known, extrinsic evidence (such as expert testimony) must be considered. Here, there is first a factual matter that must be resolved. These subsidiary issues of fact are to be reviewed only for clear error. Ultimate construction of the written instrument remains a question of law.

The Teva case presented a subsidiary issue of fact (what method is understood to be used to calculate molecular weight) before the ultimate question of law (claim construction) could be addressed. Extrinsic evidence in the form of expert testimony was needed to understand technical terms used in the Patent. In such a situation, the Federal Circuit must review the factual issue only for clear error while reviewing the legal conclusion regarding claim construction *de novo*.

[1]The Patent Act requires a claim particularly point out and distinctly claim the subject matter the applicant regards as their invention. See 35 U.S.C. §112, 2nd paragraph.

[2] Federal Rule of Civil Procedure 52(a)(6) states, “findings of fact, whether based on oral or other evidence, must not be set aside unless clearly erroneous, and the reviewing court must give due regard to the trial court’s opportunity to judge

the witnesses' credibility.”