

SHIRE DEVELOPMENT, LLC v. WATSON PHARMACEUTICALS, INC., Appeal No. 13-1409 (Fed. Cir. June 3, 2015). Before Prost, Chen, and Hughes. Appealed from S.D. Fla. (Judge Middlebrooks).

Background:

Shire sued Watson for infringement of its patent directed to a controlled-release oral pharmaceutical composition for treating inflammatory bowel diseases, marketed under the brand name LIALDA®, after Watson filed an Abbreviated New Drug Application (ANDA) seeking approval to sell the bioequivalent of LIALDA®. The Federal Circuit previously reversed the district court's construction of two claim terms and remanded the case for further proceedings. Following *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831 (2015), which clarified the standard of review for a district court's claim construction, the Supreme Court vacated and remanded the case for further consideration.

Issue/Holding:

Applying the standard of review set forth in *Teva*, did the district court err in construing Shire's patent claims? Yes, reversed and remanded.

Discussion:

In *Teva*, the Supreme Court held that determinations by the district court based on intrinsic evidence, such as the patent claims, specification, and prosecution history, amount to a determination of law that should be reviewed de novo. However, a district court's underlying factual determinations based on evidence extrinsic to the patent in the ultimate claim construction analysis should be given deference on appeal and reviewed for clear error.

In this case, the Federal Circuit found that the intrinsic evidence completely determined the proper claim construction and, thus, the Federal Circuit reviewed the district court's claim construction de novo. The Federal Circuit held that the district court's construction of "inner lipophilic matrix" and "outer hydrophilic matrix," as meaning a matrix including at least one lipophilic excipient and a matrix of at least one hydrophilic excipient located outside the inner lipophilic matrix, respectively, were overly broad and did not reflect the ordinary and customary meaning of the claim terms in light of the intrinsic evidence.

Based on a review of the intrinsic evidence as a whole, the Federal Circuit held that the district court's construction erroneously focused on the lipophilic/hydrophilic properties of an excipient in each of the matrices as opposed to the properties of each of the matrices themselves. The Federal Circuit opined that, based on the claim language, "lipophilic" is an adjective that modifies "matrix," and, as such, the matrix, and not just an excipient within the matrix, must exhibit lipophilic characteristics. The Federal Circuit also opined that a logical reading of the claims, in view of the specification and prosecution history, requires that the matrices be separate, as the matrices are defined by mutually exclusive spatial characteristics and mutually exclusive compositional characteristics, thereby excluding a single matrix in which hydrophilic and lipophilic substances are mixed together.

The Federal Circuit rejected Shire's arguments that because the district court heard testimony from numerous expert witnesses, the Federal Circuit must defer to the district court's constructions of the claim terms, stating that the Supreme Court did not hold that a deferential standard of review is triggered any time a district court hears or receives extrinsic evidence.