

TEVA PHARMACEUTICALS USA, INC. v. SANDOZ, INC., Appeal No. 13-854. (U.S. Supreme Court, January 20, 2015). Opinion by Breyer; Thomas and Alito, dissenting. Appealed from Court of Appeals for the Federal Circuit.

Background:

Teva owns a patent directed to a method of manufacturing Copaxone, a drug used to treat multiple sclerosis. Teva sued Sandoz for infringement, and Sandoz alleged that Teva's patent was invalid for indefiniteness because "molecular weight" as recited in the claims was not defined, and may refer to (1) the peak average molecular weight, (2) number average molecular weight, or (3) weight average molecular weight.

After taking expert testimony, the District Court determined that one of ordinary skill in the art would have understood that "molecular weight" in the patent means the peak average molecular weight, and interpreted the patent claims accordingly. The District Court thus found Teva's claims definite. On appeal, the Federal Circuit reviewed the District Court's resolution of "molecular weight" *de novo*, and found the term "molecular weight" indefinite. The Federal Circuit thus invalidated Teva's patent for indefiniteness. Teva filed a petition for certiorari.

Issue/Holding:

What is the proper standard of review of subsidiary factual matters during claim construction? Subsidiary factual matters in claim construction must be reviewed for "clear error." Vacated and remanded.

Discussion:

Federal Rule of Civil Procedure 52(a)(6) states that a court of appeal must not set aside a district court's findings of fact unless it is "clearly erroneous." In reviewing Rule 52(a)(6), the Supreme Court found no exceptions in the rule with respect to claim construction. In addition, Supreme Court precedent indicated that this rule applies to both subsidiary facts and ultimate facts.

The Supreme Court also reviewed its opinion in *Markman v. Westview Instruments, Inc.*, (517 U.S. 370 (1996)). The Supreme Court found that while *Markman* held that the ultimate issue of claim construction was an issue of law, that decision did not create an exception to Rule 52(a)(6) regarding any subsidiary facts needed to construe a patent claim.

The Supreme Court also likened patents to contracts and deeds in that finding of facts are made if there is a dispute as to the meaning of a term in the contract or deed, which findings are reviewed for clear error.

Therefore, the Supreme Court held that during claim construction, if the claims are construed relying only on intrinsic evidence, only then may claim construction be reviewed *de novo*. However, if extrinsic evidence is needed to construe a claim (i.e., there is an underlying subsidiary factual dispute about a claim term), the findings of fact are reviewed for "clear error," even if that finding of fact is the determining issue for how a claim is construed, while the ultimate claim construction is reviewed *de novo*.

The dissent argued that patents are more akin to statutes and land patents. The dissent argued that when construing a statute or land patent, any subsidiary factual findings are reviewed *de novo*, and that the same standard should apply in patent cases.