

**Keywords:** standard of review; claim construction; de novo; clear error; indefiniteness; 35 U.S.C. § 112 ¶2

**General:** When reviewing a district court's findings of subsidiary factual matters made in the course of its construction of a patent claim, the Federal Circuit must apply a "clear error," not a *de novo*, standard of review.

*Teva Pharms. USA, Inc. v. Sandoz, Inc.*  
No. 13-854 (U.S. Supreme Court)  
Decided Jan. 20, 2015

## **I. Facts**

The dispute in this case centers around the meaning of the words "molecular weight." Teva, with others, own a patent covering the manufacturing method for Copaxone, a drug used to treat multiple sclerosis. The drug's active ingredient, "copolymer-1," is made up of molecules of varying sizes. The relevant claim describes the ingredient as having "a molecular weight of 5 to 9 kilodaltons."

Sandoz tried to market a generic version of Copaxone and was subsequently sued by Teva. Sandoz's defense was that the phrase "molecular weight of 5 to 9 kilodaltons," was indefinite under 35 U.S.C. § 112 ¶2, and thus the patent was invalid. Sandoz contended that the term "molecular weight" could mean any one of three different things. The phrase could mean (1) molecular weight as calculated by the weight of the molecule that is most prevalent in the mix that makes up copolymer-1. This method is also known as "peak average molecular weight." The phrase might also refer (2) to molecular weight as calculated by taking all the different sized molecules in the mix that makes up copolymer-1 and calculating the average weight. This method is also known as "number average molecular weight." Or, the phrase might refer (3) to molecular weight as calculated by taking all the different-sized molecules in the mix that makes up copolymer-1 and calculating their average weight while giving heavier molecules a weight-related bonus when doing as. This method is also known as "weight average molecular weight."

The District Court, after taking evidence from experts to determine subsidiary facts, concluded that the patent claim was sufficiently definite. It found that, in context, a skilled artisan would understand that the term "molecular weight" referred to molecular weight as calculated by the "peak average molecular weight" method. On appeal, the Federal Circuit found otherwise. It found that the term "molecular weight" was indefinite and the patent invalid. In reaching this conclusion, the Federal Circuit reviewed *de novo* all aspects of the District Court's claim construction, including the determination of subsidiary facts. Teva petitioned for certiorari, which the Supreme Court granted.

## **II. Issue**

Did the Federal Circuit err in applying a *de novo* standard of review when reviewing a district court's resolution of subsidiary factual matters made in the course of its construction of a patent claim?

## **III. Discussion**

Yes. The Supreme Court found that the Federal Circuit should apply a "clear error" standard of review when reviewing a district court's resolution of subsidiary factual matters made in the course of its construction of a patent claim. In reaching this conclusion, the Supreme Court focused its analysis on whether an exception should be made to 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." The Supreme Court found that even if exceptions were permissible, there was no convincing ground for creating an exception here.

The Supreme Court started its analysis by turning to *Markman*. The Court found that *Markman* did not deal with a 52(a) exception, but rather a Seventh Amendment issue. The Court made clear that although a patent is a written instrument, like a contract, deed, or tariff, the technical words within a patent can still give rise to a factual dispute which precedes the “function of construction.” And, like all other factual determinations, it must be reviewed for clear error.

The Supreme Court continued its analysis by finding that both precedent and practical considerations favored clear error review. In 1950, before the Federal Circuit was created, the Second Circuit explained that the subsidiary question of how the art understood a term was a question of fact subject to the clearly erroneous standard of review. The Supreme Court also noted that subsidiary factual findings under obviousness issues are also subject to the clear error standard. As to the practical considerations, the Court reminded us that they previously pointed out, in *Graver Tank*, that clear error review is particularly important where patent law is at issue because patent law is “a field where so much depends upon familiarity with specific scientific problems and principles not usually contained in the general storehouse of knowledge and experience.”

Sandoz argued that claim construction mostly consists construing a set of written documents that do not give rise to subsidiary factual disputes, and that it is simpler for the Federal Circuit to review the entirety of the district court’s claim construction *de novo*. The Supreme Court remained unconvinced, concluding that Courts of appeals have long found it possible to separate factual from legal matters, and that treating factual findings and legal conclusions similarly has often been difficult as well. The Supreme Court also noted that “subsidiary factfinding is unlikely to loom large in the universe of litigated claim construction.”

The dissent argued that claim construction does not involve any factfinding, or, if it does, claim construction factfinding is more like the factfinding in statutory interpretation rather than the factfinding in a written instrument. The majority found that the first argument ran contrary to the recognition in *Markman* that claim construction has “evidentiary underpinnings” and that courts sometimes need to judge the credibility of witnesses. As to the dissent’s second argument, the majority found that claim construction is not similar to statutory interpretation because statutes generally address themselves to the general public, whereas patent claims concern only a small portion of that public.

#### **IV. Conclusion**

The Supreme Court found that the district court’s resolution of subsidiary facts in the course of claim construction is subject to a clear error standard of review.