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# **Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.**

## **153 S. Ct. 831 (2015)**

RAHUL DEVNANI\*

### BACKGROUND

Plaintiff Teva Pharmaceuticals USA, Inc. (“Teva”) is a leader in the global market for pharmaceutical products. Teva’s patent portfolio includes more than a 1,000 molecules spanning across approximately sixty countries. Teva specializes in generic pharmaceutical products, but also holds the patents for numerous specialty drugs, including the disputed multiple sclerosis drug, Copaxone.

Defendant Sandoz, Inc. (“Sandoz”) is a competing global pharmaceutical company that specializes in manufacturing generic medical products. It is a subsidiary of Novartis International AG (“Novartis”), the world’s second largest pharmaceutical company.

The case debated the validity of a patent application submitted by Teva, regarding the scientific meaning of “molecular weight.” Teva submitted a patent application for Copaxone stating that the active ingredient in Copaxone had a molecular weight between five and nine kilodaltons. Following the successful sale of Copaxone, Sandoz attempted to produce and market a generic version of the drug. In response, Teva brought suit against Sandoz alleging patent infringement. Sandoz argued that it did not infringe on Teva’s Copaxone patent rights, because the patent was invalid for not meeting the appropriate specifications set out by the Patent Act. Sandoz argued that the term “molecular weight” was ambiguous due to the fact that there are various methods of calculating the molecular weight of an atom; therefore, the patent did not satisfy the requirement to clearly state the exact methodology that distinguishes this invention from others. Sandoz explained that there are three different methods of calculating molecular weight: (1) peak average molecular weight, (2) number average molecular weight, and (3) weight average molecular weight. Experts explained the methodology behind each measurement approach. Sandoz concluded that since Teva did not identify the specific methodology used to calculate the molecular weight of Copaxone, the patent should be considered invalid.

Specifically, the dispute between Teva and Sandoz discussed the validity of a patent claim construction. The U.S. Supreme Court does not rule on the validity of patents, but set out a standard of review that must be

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adhered to by appeals courts when reviewing such cases. The court of appeals concluded that the district court's factual findings of a patent construction claim must be reviewed under the "clear error" standard, instead of the *de novo* standard that was applied by the Federal Circuit.

### PROCEDURAL HISTORY

In its proceedings, the district court reviewed experts' statements and concluded that Teva provided enough information to meet the specifications of the Patent Act. The district court reasoned that in the context of a patent for a pharmaceutical product, "a skilled artisan"<sup>1</sup> would not consider the term indefinite and would calculate the molecular weight by using the first methodology: peak average molecular weight. The court ruled in favor of Teva and held the patent valid. Sandoz appealed.

Contrary to the findings of the district court, the Federal Circuit held that Teva's use of the term "molecular weight" was indefinite and the patent was invalid. In its proceedings, the court of appeals reviewed *de novo* and considered all aspects of the case, including subsidiary facts originally determined by the lower court. Upon review, the Federal Circuit held that Teva's patent was invalid, and, therefore, Sandoz did not infringe upon Teva's patent rights. Teva filed a writ for certiorari, and the U.S. Supreme Court granted review.

### ISSUE

The U.S. Supreme Court had to decide the standard of review for a court of appeals when reviewing factual findings and the construction of a patent claim.

### DECISION

The U.S. Supreme Court held that the Federal Circuit must apply the "clear error" standard of review, and not a review *de novo* of factual finding. In its decision, the Court set out the standard of review and remanded the case for further review to determine whether Teva's patent was valid. In addition, the Court stated that the interpretation of factual findings to determine a question of law, such as a patent claim construction, could be reviewed *de novo*.

### REASONING

The Court first turned to the Federal Rules of Civil Procedure, specifically examining Rule 52(a)(6). This rule explains that a court of appeals does not have authority to set aside findings of fact by district courts unless the findings of fact are clearly erroneous. Furthermore, precedent makes it clear that the role of a court of appeals is to accept a

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1 Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc., 135 S. Ct. 831, 836 (2015).

district court's factual findings as true, and most importantly, not to make exceptions to this standard of review. The Court explained that a judge is in an ideal position to determine whether a written legal instrument, such as a patent, was valid. For most cases, a judge has the requisite knowledge and expertise, more so than a panel of jurors, to determine whether such legal instruments are valid. However, with regard to patents, a judge may require additional assistance and subsidiary fact-finding is necessary (i.e., gathering of extrinsic evidence). The Court reasoned that a district court judge is in the best position to make factual determinations because they are present during court proceedings and have a better understanding of the necessary scientific and technical information. District court judges are able to witness testimonies and evidentiary hearings first-hand, while a court of appeals judge only has access to transcripts. In conclusion, the Court determined that a court of appeals must apply the "clear error" standard of review when reviewing subsidiary facts.

Second, the Court struck down Sandoz's argument that a court of appeals has difficulty separating "factual" and "legal" issues, and therefore should review the patent claim construction *de novo*. In response to this argument, the Court cited several cases that proved a court of appeals can untangle factual and legal issues. These cases covered several claim constructions where the courts successfully differentiated factual and legal issues. Further, the Federal Circuit claimed that the "clear error" standard of review might lead to inconsistent applications in patent claim construction disputes. In response, the Court stated that there was no basis for lesser standard of uniformity when applying this standard of review and found this argument to be unpersuasive, due to the lack of evidence.

Third, the Court considered and struck down an argument made by the dissent. The dissent asserted that the fact-finding required in claim construction is similar to the interpretation of statutes. This is contrary to the *Markman* decision where the Court acknowledged that claims constructions have "evidentiary underpinnings." In *Markman*, the Court explained that when examining and construing legal instruments, especially ones that involve technical and scientific products, judges might have to make "credibility judgments." In this context, the Court did not find similarities between fact finding for statutory interpretation and claims construction. For the most part, statutes require congressional approval and must be understood by the general public, therefore broad understanding of statutes is a fair conclusion. Whereas in a patent's claim construction, there are only a small group of private parties (including administrators and experts) that understand the specific and technical aspects of filing and prosecuting a valid patent. The Court reasoned that due to these differences, patent claim construction has been compared to other written legal instruments, which require a court of appeals to apply a "clear error" standard of review when considering factual findings. However, the interpretation of such findings and determination of the validity of a patent claim construction is a question of law and can be reviewed *de novo*.

Fourth, the Court provided some guidance on how the “clear error” standard of review should be applied and when an issue is considered a question of law, versus a subsidiary factual finding. The Court recognized that, more often than not, construing a written legal instrument requires examining intrinsic evidence as opposed to resolving factual disputes. Therefore, a court of appeals has the opportunity to perform a *de novo* review because this is considered a purely legal determination. However, when a district court judge consults extrinsic evidence, as in the case of patent claim construction, a court of appeals must apply the “clear error” standard of review for subsidiary factual findings. Accordingly, a court of appeals may interpret a claim construction considering subsidiary factual findings; however, it remains a question of law reviewed *de novo*.

Finally, the Court explained its holding by considering expert testimonies explaining the meaning of “molecular weight” and respective methodologies for calculation. Sandoz argued that the molecular weight distribution curve showed that Teva did not use the first method of calculation, peak average molecular weight; therefore, Teva’s patent could not be valid. However, the district court judge did not accept Sandoz’s argument, determining that a skilled artisan, in interpreting molecular weight data, understands that there are slight errors made when converting chromatogram data to a molecular weight distribution curve. The Court continued to explain that the Federal Circuit rejected this factual finding without determining that the finding was “clearly erroneous.” Here, the Federal Circuit should have accepted the factual finding and by not doing so, it did not meet the “clear error” standard of review.

In conclusion, the Court set forth the “clear error” standard of review in patent claim construction for appellate courts and rejected a *de novo* review of factual determinations.

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