The Appellate Standard of Review for Patent Claim Construction

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An Article discussing the US Supreme Court's *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.* decision where the Court vacated the US Court of Appeals for the Federal Circuit's decision and clarified the appellate standard of review for patent claim construction. This Article examines the Court's decision and its practical implications.

In its decision in *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.*, the US Supreme Court:

- Vacated the US Court of Appeals for the Federal Circuit decision.
- Clarified the appellate standard of review for patent claim construction.

(*135 S. Ct. 831 (2015)*.)

The Court held that even though the ultimate issue of claim construction is reviewed de novo , the US Court of Appeals for the Federal Circuit must apply the more deferential clear error standard in reviewing subsidiary factual matters underlying the patent claim construction. The Court also provided guidance on how to apply the standard.

BACKGROUND

The petitioner and plaintiff, Teva Pharmaceuticals, owns a patent claiming a manufacturing method for Copaxone, a drug used to treat multiple sclerosis. The drug's active ingredient, copolymer-1, comprises molecules of different molecular weights. When Sandoz, Inc. and other defendants tried to market a generic version of the drug, Teva sued for patent infringement. Sandoz defended on the ground that the asserted patent claims are invalid.

THE DISPUTED PATENT CLAIM TERM

The parties' dispute concerned the claim term "molecular weight of 5 to 9 kilodaltons" for copolymer-1 (the drug's active ingredient). Both parties agreed that "molecular weight" as used in the claims means the average molecular weight, but disagreed over how a person of ordinary skill in the art would interpret the method for calculating that molecular weight.

Teva argued that a skilled artisan would understand that, as used in the asserted patent, "molecular weight" means the weight of the most prevalent molecule, known scientifically as the peak average molecular weight.

Sandoz disagreed with Teva. According to Sandoz, the term "molecular weight" can mean any of the following:

- The average peak molecular weight, which is the weight of the most prevalent molecules calculated from the chromatography plot.
- The average weight of all the different sized molecules, which is the weight calculated by the average weight of all molecules.
- The weight average molecular weight, which is the weight as calculated by an average in which heavier molecules count for more.

Each of these calculation methods yields a different molecular weight.

Sandoz argued that the patent claim does not say which method of calculation should be used and the claim's phrase "molecular weight" is therefore indefinite. Sandoz highlighted a discrepancy in a figure of the patent showing how the weights of a sample's molecules were distributed in three different samples. Specifically, Sandoz noted that the figure's legend indicates that the first sample's molecular weight is 7.7 kilodaltons. If Teva were correct, according to Sandoz, the molecules weighing 7.7 kilodaltons should be the most prevalent molecules in that sample. Instead, the plot itself showed the most prevalent molecules to be at about 6.8 kilodaltons.

In view of this discrepancy, Sandoz asserted that the claims were unduly ambiguous and therefore invalid as indefinite under *35 U.S.C. § 112*.

THE DISTRICT COURT DECISION

The district court held that the claim term "molecular weight" means average molecular weight as urged by Teva, and accordingly found the term definite, relying on:

- Citations to the intrinsic record, particularly the molecular weight distribution plots in the patent's specification.
- The prosecution history.
- Expert testimony.

Teva's expert testified that a skilled artisan would understand that converting chromatographic data to molecular weight distribution curves would cause the shift in weight value seen in the figures.

Sandoz's expert disagreed, testifying that such a shift would not occur, and that the weight value discrepancies in the patent figures would lead a person of ordinary skill to conclude that the term had multiple potential meanings.

The district court found Teva's expert's account credible and rejected Sandoz's expert's explanation.

Based on this subsidiary factual finding of how a skilled artisan would understand the plots and values in the patent specification, the district court concluded that:

- The patent claim term "molecular weight" referred to peak average molecular weight.
- The claims were not invalid under 35 U.S.C. § 112.

(*810 F. Supp. 2d 578 (S.D.N.Y. 2011)*.)

THE FEDERAL CIRCUIT DECISION

On appeal, the Federal Circuit followed its long-standing precedent that "any allegedly fact-based questions relating to claim construction . . . [are] reviewed de novo on appeal" (*Cybor Corp. v. FSA Techs., Inc., 138 F.3d 1448, 1456 (Fed. Cir. 1998)*).

The Federal Circuit reviewed the subsidiary factual findings under the *de novo* standard and rejected Teva's expert's testimony without finding that the district court's determination was clearly erroneous. Accordingly, the Federal Circuit reversed the district court's decision, holding the term "molecular weight" indefinite and the claims invalid (*723 F.3d 1363, 1369 (Fed. Cir. 2013)*).

THE SUPREME COURT DECISION

The Supreme Court granted the petition for *certiorari* to determine whether a district court's fact finding should be reviewed de novo, as the Federal Circuit requires, (and as the panel explicitly did in this case), or only for clear error under Federal Rule of Civil Procedure (FRCP) 52(a).

On January 20, 2015, the Supreme Court handed down its *Teva* decision vacating the Federal Circuit's decision and overturning that court's long line of precedent applying a *de novo* standard of review to the entirety of the district court's patent claim construction analysis and finding. In its 7-2 decision authored by Justice Breyer, the Court, although recognizing that the district court's claim construction itself should be reviewed *de novo*, held that when reviewing a district court's resolution of subsidiary factual matters made when construing a patent claim, the Federal Circuit must apply the clear error, not *de novo*, standard of review (*135 S. Ct. at 836-43*).

In reaching its decision, the Supreme Court relied on:

- The language of *FRCP 52(a)*, which instructs that a district court's factual findings must not be set aside unless clearly erroneous.
- Its own precedent, particularly its prior decision in *Markman v. Westview Instruments, Inc.* (*517 U.S. 370 (1996)*).
- Practical considerations based on the underlying factual findings in dispute.

RULE 52(A)

The Court first analyzed FRCP 52(a) and noted that it:

- Provides a clear command that a district court's factual findings must not be set aside unless clearly erroneous.
- Does not make exceptions or exclusions of certain categories of factual findings from the clearly erroneous standard of review, citing *Pullman-Standard v. Swint* (*456 U.S. 273, 287 (1982)*).
- Applies to both subsidiary and ultimate facts since there are no convincing grounds for creating an exception for facts subsidiary to a claim construction determination in patent cases.

SUPREME COURT PRECEDENT

The Court also discussed its opinion in *Markman*. In doing so, the Court reaffirmed that the ultimate claim construction decision:

- Falls exclusively within the court's province, not the jury's.
- Is a question of law.

However, the Court reasoned that *Markman* did not imply or create an exception to *FRCP 52(a)*. Although the ultimate conclusion on claim construction is a matter of law, the Court did not find any basis in *Markman* to support the argument that Rule 52(a) is inapplicable or that there is an exception to the rule.

The Court also determined that *Markman* recognized the necessity of subsidiary factual findings in claim construction, and referred to claim construction as a practice with an evidentiary underpinning. The Court analogized construction of a patent to construction of a written instrument, such as a contract or deed, reasoning that when a written instrument uses technical words or phrases not commonly understood, those words may give rise to a factual dispute. In that situation, extrinsic evidence may be needed to help clarify the meaning of those words. Therefore, according to the Court, in construing a written instrument that requires extrinsic evidence, the determination of the facts that are relevant to the disputed terms must be reviewed for clear error.

The Court also cited other precedent to support its conclusion, including *Harries v. Air King Products Co.*, where the US Court of Appeals for the Second Circuit explained that subsidiary issues underlying the patent claim construction were "plainly a question of fact" and that the Court would take the district court's findings as controlling unless they were clearly erroneous (*183 F.2d 158, 164 (2d Cir. 1950)*).

The Court noted that the fact pattern was a perfect example of the fact finding that underlies claim construction. The district court had to resolve issues of fact by evaluating competing interpretations of factual issues by each sides' experts, including:

- The factual dispute over the term "molecular weight."
- Competing expert views on how a skilled artisan would understand the way in which the plots in the patent reflected molecular weights.

PRACTICAL CONSIDERATIONS

The Court explained that clear error review is important in cases concerning patent claim construction because resolution of patent disputes depends on an understanding of specific scientific problems and principles, citing *Graver Tank & Manufacturing Co. v. Linde Air Products Co.* In *Graver Tank*, the Court explained that a district court judge is in a better position to evaluate complicated scientific evidence, which is not general knowledge. A district court judge presiding over the case in person had a better opportunity to become familiar with the case than an appeals court judge who read the written transcript or only the portions of the transcript to which the parties had referred (*339 U.S. 605, 610 (1950)*).

The Court concluded by vacating the Federal Circuit's judgment, remanding the case and noting that it should have accepted the district court's finding unless it was clearly erroneous (*135 S. Ct. at 843*).

THE CLEARLY ERRONEOUS STANDARD

Under the Court's decision, a district court's claim construction that is based at least in part on subsidiary facts will be more difficult to overturn on appeal because review under the clearly erroneous standard is significantly deferential, requiring the appeals court to reach a definite and firm conviction that the district court made a mistake (see *Easley v. Cromartie, 532 U.S. 234, 242 (2001)*). This conviction of a district court's mistake may be based on a district court's factual findings that are illogical, implausible or without support in inferences drawn from the facts in the record (see *United States v. Hinkson, 585 F.3d 1247, 1263 (9th Cir. 2009) (en banc)*).

In addition, the clearly erroneous standard requires the appeals court to:

- Pay special deference to the trial court's credibility findings (see *Anderson v. City of Bessemer, 470 U.S. 564, 573 (1985)*).
- Not reverse the district court if the district court's account of the evidence is plausible in light of the entire record, even if the appeals court would have weighed the evidence differently (see *Husain v. Olympic Airways, 316 F.3d 829, 835 (9th Cir. 2002)*).
- Conclude that the factfinder's choice is not clearly erroneous where there are two permissible views of the evidence (see *United States v. Elliott, 322 F.3d 710, 715 (9th Cir. 2003)*).

APPLYING THE CLEARLY ERRONEOUS STANDARD

The Court provided guidance for determining the existence of a claim construction fact issue that would be subject to the clearly erroneous standard of review. Specifically, when the district court reviews no more than the intrinsic evidence (the patent claims, specification and the patent's prosecution history), the Federal Circuit should review the construction *de novo*.

However, where the district court looks beyond the patent's intrinsic evidence and consults extrinsic evidence, and the subsidiary facts in that analysis are in dispute, the subsidiary fact findings are reviewed on appeal using the clearly erroneous standard (*135 S. Ct. at 841*).

The following types of evidence are typically considered to be extrinsic, and therefore most likely to be subject to a clearly erroneous standard of review:

- The state of the art.
- The meaning of a technical term or terms of art.
- Scientific or technical background and relevant scientific principles.
- Dictionaries.
- Treatises and textbooks.
- Expert testimony.

DOES THE DECISION CREATE UNCERTAINTY FOR INVENTION AND INNOVATION?

In his dissenting opinion, Justice Thomas, joined by Justice Alito, argued that the majority decision, while correctly deciding that subsidiary facts are generally subject to *FRCP 52(a)*, incorrectly described the evaluation of specific expert opinions in the case to be resolving factual matters (*135 S. Ct. at 849*). Specifically, the dissent asserted that:

- There is no clear demarcation for facts and law in a claim construction determination.
- The majority was wrong to try to label determinations arising from the extrinsic record as findings of fact.

Justice Thomas also expressed his concern over the potential uncertainty the *Teva* decision may create, arguing that the decision will result in:

- Costly collateral litigation over the law and fact dividing line.
- Fewer claim construction decisions receiving precedential effect, which will create additional uncertainty.

(*135 S. Ct. at 852.*)

The majority dismissed these concerns, noting that:

- There is no evidence suggesting that different claim construction resulting from divergent findings of fact on subsidiary matters should occur more than occasionally.
- Subsidiary factfinding is unlikely to be a significant issue for litigated claim construction matters.

(*135 S. Ct. at 839.*)

PATENT LAW PRACTICE IN THE POST-TEVA WORLD

While it is premature to speculate whether the majority's views or dissent's concerns will become reality, the effect of the decision has been limited.

For example, the Federal Circuit has continued to use the *de novo* standard in several decisions because those claim constructions were based only on intrinsic evidence, requiring no deference. This has been the situation in at least the following exemplary Federal Circuit cases:

- *Shire Development, LLC v. Watson Pharmaceuticals, Inc.* (*No 13-1409, 2015 WL 3483245 (Fed. Cir. June 3, 2015)*).
- *Pacing Technologies, LLC v. Garmin Int'l, Inc.* (*778 F.3d 1021 (Fed. Cir. Mar. 18, 2015)*).

- *Eidos Display, LLC v. AU Optronics Corp.* (*779 F.3d 1360 (Fed. Cir. Mar. 10, 2015)*).
- *In re Papst Licensing Digital Camera Patent Litigation* (*778 F.3d 1255 (Fed. Cir. Feb. 2, 2015)*).

Even where claim construction involved consideration of extrinsic evidence, the Federal Circuit has indicated that it will employ a *de novo* standard of review where there is a clear intrinsic record. Therefore, in *Enzo Biochem Inc. v. Applera Corp.*, decided on March 16, 2015, where the extrinsic evidence at issue was expert evidence and testimony, the Federal Circuit reversed the district court's claim construction ruling. The Federal Circuit reached this conclusion because it determined that it was unnecessary to go beyond the intrinsic record, even though the parties did so, and therefore, a *de novo* standard of review was still proper (*780 F.3d 1149, 1156 (Fed. Cir. 2015)*).

Chief Judge Prost, writing for the majority, reasoned that:

> "[E]ven if we were to consider the district court's finding, which would be subject to review for clear error under *Teva*, this sole factual finding does not override our analysis of the totality of the specification, which clearly indicates [otherwise]."

In her dissenting opinion, Judge Newman criticized the majority for:

- Not identifying any contrary evidence.
- Ignoring the testimony, the district court's findings and the jury verdict based on the evidence.

She also noted that the district court's decision considered the conflicting testimony and concessions on cross-examination at trial, which should have resulted in deference by the Federal Circuit to the district court's claim construction decision, in accordance with *Teva*'s teaching (*Enzo Biochem, 780 F.3d at 1159*).

The Federal Circuit's March 10, 2015 decision in *Eidos Display, LLC v. AU Optronics Corp.* similarly suggests that it will continue with *de novo* review in cases where the intrinsic evidence is clear, even though the district court may have considered extrinsic evidence (*779 F.3d 1360 (Fed. Cir. 2015)*).

One reason that the Federal Circuit seems to be sidestepping the *Teva* decision by relying solely on the intrinsic record is the inherent tension between the new more deferential standard applied only to findings concerning extrinsic evidence and its view that extrinsic evidence should carry less weight than intrinsic evidence. The Federal Circuit traditionally has viewed extrinsic evidence skeptically because of its belief that this evidence is not as reliable or useful in claim construction as the patent itself and its prosecution (see *Phillips v. AWH Corp., 415 F.3d 1303, 1317-19 (Fed. Cir. 2005)*). This tension may result in more decisions like *Enzo Biochem* and *Eidos Display*, where the Federal Circuit may avoid the issue altogether by concluding that the intrinsic evidence alone warrants a certain construction.

In line with *Enzo Biochem* and *Eidos*, the Federal Circuit similarly side stepped the clearly erroneous standard when it recently decided the *Teva* case itself on remand. Despite the remand from the Supreme Court, the appellate court again reversed the district court's decision (*2012-1567, 2012-1568, 2012-1569, 2012-1570, 2015 WL 3772402 (Fed. Cir. June 18, 2015)*).

While it did apply the clearly erroneous standard to the factual findings, finding no clear error, the Federal Circuit nevertheless still ruled the claims indefinite based on the specification and the prosecution history. In its view, the construction of the term "molecular weight" is a legal conclusion based on the intrinsic record that is not entitled to deference even in view of the Supreme Court decision. Notably, the Federal Circuit stated that "a party cannot transform into a factual matter the internal coherence and context assessment of the patent simply by having an expert offer an opinion on it."

Although initially it appears that the *Teva* decision has not significantly changed patent law, the decision may ultimately impact the patent law practice, for example, in the following ways:

- Litigants may be more likely to rely on extrinsic evidence in support of a claim construction.
- Reliance on expert witnesses, already a common practice in claim construction, may be even more heavily emphasized.
- *Markman* briefs, aside from emphasizing the above types of evidence, may also be more likely to articulate extrinsic or intrinsic factual underpinnings for each evidentiary argument.
- Appeal briefs may become more complicated as different reviewing standards need to be applied, perhaps even in the same brief.
- Patent applications should be drafted in consideration of the benefits and risks of developing a clear intrinsic evidence, for example, by:
  - defining claim terms;
  - providing background information in the specification; and
  - making statements to the USPTO.

The *Teva* decision should not have much impact on appeals from the Patent Trial and Appeal Board. The standard of review for a PTAB decision has not changed, as it is governed by a separate statute, the Administrative Procedure Act (APA) (see *Dickinson v. Zurko, 527 U.S. 150, 152 (1999)*). The APA provides a *de novo* standard of review with no deference for questions of law and a more deferential substantial evidence standard for questions of fact. Therefore, the standard for PTAB reviews was already similar to the new standard mandated by *Teva*.

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