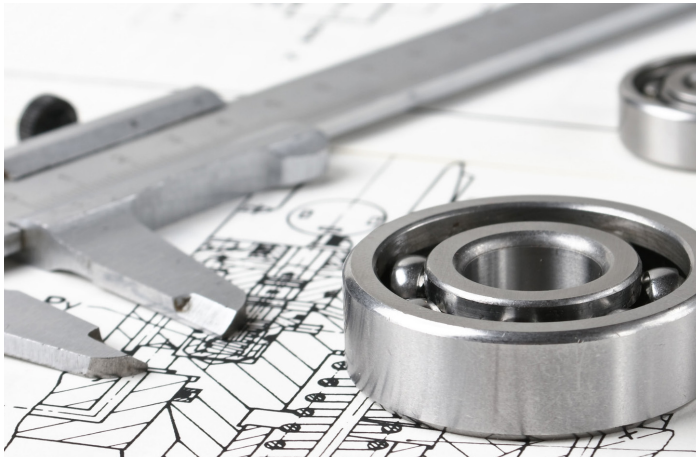


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IP LEGAL NEWS EDITORIAL BOARD

Paul E. Bain - Toronto Office
416.646.8364 • pbain@dickinsonwright.com

Joan Ellis, Ph.D. - Washington, D.C. Office
202.659.6929 • jellis@dickinsonwright.com

Christopher A. Mitchell - Ann Arbor Office
734.623.1906 • cmitchell@dickinsonwright.com

H. Jonathan Redway - Washington, D.C. Office
202.659.6946 • jredway@dickinsonwright.com

Robert L. Stearns - Troy Office
248.433.7382 • rstearns@dickinsonwright.com

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TEVA PHARMACEUTICALS: IS IT TIME TO RETHINK HOW YOU WILL ARGUE CLAIM CONSTRUCTION?

H. Jonathan Redway, Washington, D.C. Office

The United States Supreme Court decided in *Teva Pharmaceuticals USA Inc. v. Sandoz Inc.* that the Federal Circuit must review all subsidiary factual findings in patent litigation claim construction proceedings that are on appeal for clear error. The January 20, 2015 decision overturned two long-standing Federal Circuit *en banc* decisions that previously held that all aspects of claim construction were to be reviewed *de novo*. See *Cybor Corp. v. FAS Techs. Inc.*, 138 F.3d 1448 (Fed. Cir. 1998) and *Lighting Ballast Control LLC v. Phillips Elecs. N. Am. Corp.*, 744 F.3d 1272 (Fed. Cir. 2014). The Court found that while the district court's ultimate ruling should continue to be reviewed on appeal *de novo*, the resolution of any subsidiary factual disputes must be reviewed for clear error.

Claim construction (interpretation of the meaning of the words in a patent claim) is the most important analysis in any patent dispute because it is the first step toward determining (1) whether the patent is invalid for failing to meet the conditions and requirements of patentability and (2) whether the patent is infringed. In 1996, the Supreme Court decreed that claim construction is to be carried out by judges -- not juries -- because the interpretation of patent claims is a legal exercise. See generally *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996). Following *Markman*, the Federal Circuit consistently reviewed all claim construction determinations *de novo* because they are legal exercises.

In claim construction, the district court first looks to intrinsic legal evidence (the claims, specification, and prosecution history) to construe the meaning of the claim. The district court may resort to extrinsic factual evidence, but only when the intrinsic evidence is insufficiently clear to construe the meaning of the claim to determine if the conditions and requirements of patentability have been satisfied or the claim is infringed. Extrinsic factual evidence often plays an important role in claim construction -- whether received informally through a tutorial at the start of the claim construction proceeding or as formal evidence -- because it can shed light on the true meaning of the intrinsic evidence.

The dispute in *Teva Pharmaceuticals* concerned the meaning of the words "molecular weight". The petitioners, Teva Pharmaceuticals,

asserted a patent that claimed a manufacturing method for a drug used to treat multiple sclerosis. The claim language at issue described the active ingredient in the drug as having “a *molecular weight* of 5 to 9 kilodaltons” (emphasis added). When the respondents, Sandoz, Inc., tried to market a generic version of the drug, it was sued by Teva for patent infringement. Sandoz argued the claim was invalid because it failed to meet a condition of patentability in that it failed to “particularly poin[t] out and distinctly clai[m] the subject matter ... regard[ed] as [the] invention. 35 U.S.C. § 112, ¶ 2.

Sandoz argued that the term “molecular weight” as used in the patent claim might mean any one of three different things. Sandoz argued that because the term might mean any one of three different things the claim failed to state the exact method of calculation to be used. According to Sandoz, the term “molecular weight” was therefore indefinite and the claim invalid.

The district court accepted extrinsic evidence from experts at the claim construction hearing as to the meaning of the term to one of ordinary skill in the art and concluded that the claim was sufficiently definite. It found an artisan would have understood the term “molecular weight” to be calculated one way (not one of three), namely by the weight of the most prevalent molecule. It further found that this common understanding was the same meaning of the term as used in the disputed claim. On appeal, the Federal Circuit reviewed *de novo* every aspect of the district court’s claim construction determination including its finding as to the ordinary meaning of the term “molecular weight” and overturned the district court finding the term “molecular weight” could have meant any of three different calculations.

The Supreme Court took the case to decide whether the Federal Circuit applied the correct legal standard in reviewing the decision of the district court. The Supreme Court relied heavily on 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” and distinguished the ultimate construction by the district court (based on the intrinsic legal evidence) from the subsidiary factual findings and held that the subsidiary fact finding must be reviewed for clear error. The Court’s decision upheld the underpinnings of the *Markman* decision -- allowing judges to perform claim construction -- by clarifying that the ultimate issue of proper construction within the context of an asserted patent remains a question of law to be reviewed *de novo*, while at the same time providing greater deference to the findings of district court judges by ruling that pre-requisite questions relating to the customary meaning of claim terms are to be reviewed under the “clearly erroneous” standard. The Court favored a “clear error” review of subsidiary factual determinations on the basis that district court judges who preside over and listened to the entirety of a proceeding are presumed to have comparatively greater opportunity to gain familiarity with subsidiary factual findings than appellate judges.

The decision elevates the importance of building strong factual records to support artisan relied-upon constructions to insulate such findings on appeal. In contrast, advocates of constructions supported by the lexography or clear teachings of the application -- as opposed to artisan relied-upon meanings -- may wish to forgo the building of strong factual records to save expense and avoid potential confusion that could be difficult to overturn.

Today, many district courts prefer to receive off-the-record informal tutorials instead of time consuming record evidence, but advocates of strong extrinsic evidence supported constructions will need to push past such judicial tendencies and demand formal evidentiary submissions. Factually supported subsidiary findings will now be harder to overturn on appeal increasing their value in litigation and settlement. The submission of proposed findings of fact, if adopted by the district court, could help insulate patentability and infringement determinations grounded in constructions supported by subsidiary factual determinations.

DID TEVA ALTER THE STANDARD FOR INVALIDATING A PATENT FOR INDEFINITENESS?

Joan Ellis, Ph.D., Washington, D.C. office

As discussed in the concurrent article, prior to the Supreme Court’s decision in *Teva Pharmaceuticals v. Sandoz, Inc.*, 574 U.S. ___, No. 13-854, slip op. (2015), the Court of Appeals for the Federal Circuit (“Federal Circuit”) declined to give deference to district court judges’ findings of subsidiary facts made during claim construction, as required by Federal Rule of Civil Procedure § 52(a)(6). Although the parties’ dispute in *Teva* was whether the claims in Teva’s patent were indefinite under 35 U.S.C. § 112, second paragraph,¹ the question before the Court was whether the Federal Circuit employed the proper standard of review of a district court’s factual findings during claim construction.² The Court did not consider the underlying issue of indefiniteness, but rather it vacated the Federal Circuit’s decision and remanded with explicit instructions on how to apply the appropriate standard of review.

In its last term, however, the Supreme Court specifically addressed the issue of indefiniteness. *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 572 U.S. ___, 189 L. Ed. 2d 37(2014). In *Nautilus*, the parties disagreed over the meaning of the claim term “spaced relationship” used to describe the location of electrodes employed in an exercise apparatus. The accused infringer, Nautilus, argued that the term was indefinite when read in light of the specification and its accompanying drawings. The District Court agreed with Nautilus and concluded that the claim terms failed to inform one skilled in the art what the appropriate spacing was or how it should be determined. *Nautilus*, slip op. at 6-7.

On appeal, the Federal Circuit reviewed the district court’s claim construction *de novo*.³ The panel majority considered the intrinsic

evidence and found that there were “certain inherent parameters of the claimed apparatus, which to a skilled artisan may be sufficient to understand the metes and bounds of ‘spaced relationship.’” *Biosig Instruments, Inc. v. Nautilus, Inc.*, 715 F.3d 891, 897 (Fed. Cir. 2013). The majority also considered the extrinsic evidence of record and found that it supported the intrinsic evidence.⁴ Accordingly, the Federal Circuit reversed and remanded with instruction that the claims were not indefinite if they were “amenable to construction” and not “insolubly ambiguous.” *Nautilus* petitioned for *certiorari*.

The Supreme Court agreed to review the case and found that the Federal Circuit’s aforementioned standards were imprecise and diminished “the definiteness requirement’s public-notice function and foster[ed] the innovation-discouraging ‘zone of uncertainty.’” *Nautilus*, 572 U.S. slip op. at 12. The Court unanimously held that “[a] patent is invalid for indefiniteness if the patent’s specification and prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention [emphasis added].” *Nautilus*, 572 slip op. at 1. In reaching its conclusion, the Court acknowledged that the limitations of claim language must be balanced with the need to provide incentives for innovation and the ability of applicants to claim the full scope of their inventions. However, the Court also recognized that a check on indefiniteness was needed to counter any temptation a patent applicant might have “to inject ambiguity into their claims” and later impermissibly broaden their claims,” *Nautilus*, slip op. at 10. Specifically, the Court stated that “[e]liminating that temptation is in order, and ‘the patent drafter is in the best position to resolve the ambiguity in . . . patent claims.” *Nautilus*, slip op. at 10-11, quoting *Halliburton Energy Servs., Inc. v. M-I LLC*, 524 F.3d 1244, 1255 (Fed. Cir. 2008).

The Court vacated the Federal Circuit’s decision and remanded for determination of the claims indefiniteness under the new standard.

The Supreme Court’s holding that the claims, in combination with the intrinsic evidence, must inform the artisan of the scope of the invention with “reasonably certainty,” lowered the bar for invalidating a patent for indefiniteness. Thus, after *Nautilus*, it seemed as though patent practitioners were well advised to take care to draft both applications and claims with clear and precise language in order to preserve their patents’ validity.

In *Nautilus*, the Court emphasized the crucial role of intrinsic evidence; *i.e.*, the words of the claims, the specification, and the prosecution history, in determining whether claims satisfy the requirements of § 112, second paragraph, and focused on the need to reduce the temptation of patent drafters to inject ambiguity into the claims.⁵ The Court made no mention of the role extrinsic evidence plays in determining whether claims are indefinite.

In *Teva* however, the Court appears to sanction the introduction of extrinsic evidence to resolve ambiguous claim language. That is, rather than finding conflicting expert testimony on the meaning of

the terms in the claims at issue to be indicative of indefiniteness, the Court held that a district court judge’s use of extrinsic evidence during claim construction is to be given deference on appeal and only reviewed for clear error (Fed. R. Civ. Proc. 52(a)(6)). Thus, under *Teva*, it is not imperative that all claim terms be defined in the specification. Instead, experts can be employed to define terms in a manner that supports a party’s prosecution or litigation strategy.

Granted, the Supreme Court stated that “subsidiary fact finding is unlikely to loom large in the universe of litigated claim construction.” *Teva*, slip op. at 10. To that end, the Court envisions the use of extrinsic evidence to be limited to background scientific information and the explanation of technical terms. *Teva*, slip op. at 12. However, the *Teva* opinion invites courtroom behavior to the contrary. That is, after *Teva*, litigants are more likely to use expert testimony to challenge the definiteness of even the simplest claim terms if they can obtain a claim construction that is favorable to their client. And, district court judges wanting to ensure that their claim construction is not reversed on appeal, will now be motivated to permit entry of such testimony during *Markman* (claim construction) hearings. However, the more a district court finds it necessary to rely on extrinsic evidence to construe claims, the less likely it is that a patent’s specification and prosecution history inform, with reasonable certainty, those skilled in the art about the scope of the invention. See *Nautilus*, slip op. at 1. Should the *Teva* decision lead district courts to permit the entry of more extrinsic evidence in claim construction, then perhaps the Federal Circuit’s original test of indefiniteness (*i.e.*, “amenable to construction” or not “insolubly ambiguous”) was more judicious than the Supreme Court recognized.

¹ 35 U.S.C. § 112, second paragraph, requires that the claims particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

² The issue before the Supreme Court in *Teva* was:

Whether a district court’s factual finding in support of its construction of a patent claim term may be reviewed *de novo* as the Federal Circuit requires (and as the panel explicitly did in this case) or only for clear error, as Rule 52(a) requires?

³ The District Court held a *Markman* hearing and construed the *Biosig* patent claims. Following the claim construction, *Nautilus* filed a motion for summary judgment arguing that based on the district court’s construction of “spaced relationship,” the claims were indefinite. The District Court agreed and granted the motion. *Biosig* appealed. The issue before the Federal Circuit was whether the District Court erred in holding the patent invalid for indefiniteness and, consequently, in granting the motion for summary judgment. *Biosig Instruments, Inc. v. Nautilus, Inc.*, 715 F.3d 891, 897 (Fed. Cir. 2013).

⁴ The extrinsic evidence of record included a declaration (1) submitted by the inventor (Mr. Lekhtman) during a reexamination proceeding before the USPTO describing some or his own tests as well as tests performed by another laboratory (Dr. Galiana) and; (2) to support the opposition to the motion for summary judgment (Dr. Yanulis) which supported Mr. Lekhtman’s and Dr. Galiana’s test results and reports.

⁵ The Supreme Court also acknowledged that another relevant inquiry was the perspective or understanding of the claims by one skilled in the art at the time the patent application was filed.

Dickinson Wright Offices

Detroit

500 Woodward Ave.
Suite 4000
Detroit, MI 48226
Phone: 313.223.3500

Washington, D.C.

1875 Eye St., NW
Suite 1200
Washington, DC 20006
Phone: 202.457.0160

Columbus

150 E. Gay St.
Suite 2400
Columbus, OH 43215
Phone: 614.744.2570

Ann Arbor

350 S. Main St.
Suite 300
Ann Arbor, MI 48104
Phone: 734.623.7075

Las Vegas

8363 West Sunset Rd.
Suite 200
Las Vegas, NV 89113
Phone: 702.382.4002

Grand Rapids

200 Ottawa Ave., NW
Suite 1000
Grand Rapids, MI 49503
Phone: 616.458.1300

Lexington

300 W. Vine St.
Suite 1700
Lexington, KY
Phone: 859.899.8700

Lansing

215 S. Washington Square
Suite 200
Lansing, MI 48933
Phone: 517.371.1730

Nashville

424 Church St.
Suite 1401
Nashville, TN 37219
Phone: 615.244.6538

Music Row

54 Music Square East
Suite 300
Nashville TN 37203
Phone: 615.577.9600

Phoenix

1850 North Central Ave.
Suite 1400
Phoenix, AZ 85004
Phone: 602.285.5000

Saginaw

4800 Fashion Square Blvd.
Suite 300
Saginaw, MI 48604
Phone: 989.791.4646

Toronto

199 Bay St., Suite 2200
Commerce Court West
Toronto ON M5L 1G4
Phone: 416.777.0101

Troy

2600 W. Big Beaver Rd.
Suite 300
Troy, MI 48084
Phone: 248.433.7200