

## Intellectual Property Client Service Group

To: Our Clients and Friends

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## The Supreme Court Articulates a Dual Standard for Appellate Review of Claim Constructions

The Supreme Court has established a new dual standard for reviewing district court claim constructions. For the last nineteen years, since the Supreme Court's 1996 ruling in *Markman v*. *Westview Instruments*, *Inc.*, 517 U.S. 370, the Federal Circuit has reviewed district court claim construction rulings under the *de novo* standard (*i.e.*, the Federal Circuit reviewed claim constructions anew on appeal, granting no deference to district courts). On January 20, 2015, in *Teva Pharmaceuticals USA*, *Inc. v. Sandoz*, *Inc.*, the Supreme Court held that while the *de novo* standard of review remains applicable to claim construction rulings where there are no subsidiary findings of fact, if a district court's construction relies upon subsidiary findings of fact, such fact findings are subject to the *clear error* standard of review on appeal.

In *Teva*, the plaintiffs asserted patents relating to a method for manufacturing the drug Copaxone® against Sandoz and several other defendants. The drug is used in the treatment of relapsing forms of multiple sclerosis. In defense of a generic version of the drug, the defendants maintained that the claim limitation "a molecular weight of 5 to 9 kilodaltons" was indefinite, and the corresponding claims invalid, for failing to comply with 35 U.S.C. § 112 ¶ 2 (italic emphasis added). Central to the claim construction dispute was how a skilled artisan at the time of the alleged invention would have understood the limitation in light of the disclosure. The district court, *inter alia*, heard expert testimony (extrinsic evidence) on the issue, held that a skilled artisan would have understood the disclosure to teach a "peak average molecular weight," and concluded that the limitation was sufficiently definite and the patented claims were not invalid. 810 F.Supp.2d 578, 596 (SDNY 2011).

The Federal Circuit performed a *de novo*, non-deferential, review of the district court's claim construction analysis and ruling. In doing so, the Federal Circuit did not credit the district court's analysis and acceptance of Teva's expert's testimony regarding questions of fact. After its *de novo* review, the Federal Circuit reversed the district court's holding, found the claim term "molecular weight" indefinite, and held the patented claims invalid. 723 F.3d 1363, 1369 (Fed. Cir. 2013). On appeal, the Supreme Court held that a district court's *findings of fact* made in connection with its construction of disputed claim terms must be reviewed under the "clear error" standard - not *de novo* 

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review, vacated the Federal Circuit's judgment, and remanded the case for further proceedings consistent with its opinion.

The Supreme Court's decision is principally founded upon Federal Rule of Civil Procedure 52(a)(6), which provides that a court of appeals "must not...set aside" a district court's "[f]indings of fact" unless they are "clearly erroneous." The *Teva* decision highlights that Rule 52 neither makes exceptions for, nor categorically excludes, certain types of factual findings; it applies to both subsidiary and ultimate facts. As such, the Supreme Court held that subsidiary factual findings made by a district court in construing claim terms are only reviewable for *clear error*. The Supreme Court stated that this standard is consistent with and supported by: (i) its holding in *Markman*, which recognized claim construction's "evidentiary underpinnings"; (ii) precedent, including the treatment of subsidiary factfinding in the obviousness context; and (iii) practical considerations, such as the district court's "familiarity" with the record and specific scientific principles.

The Supreme Court recognized that its *Teva* holding applies to the appellate review of determinations of subsidiary facts "beyond the patent's intrinsic evidence" and including, for example, extrinsic evidence concerning "the background science or the meaning of a term in the relevant art during the relevant time period." Extrinsic evidence "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Phillips v. AWH Corp.*, 415 F. 3d 1303, 1317 (Fed. Cir. 2005) (internal citations omitted). In its decision, the Supreme Court stated that when considering only intrinsic evidence - "the patent claims and specifications, along with the patent's prosecution history" - a district court engages in no subsidiary factfinding and *de novo* appellate review is appropriate. The Court emphasized that while subsidiary factfinding should be reviewed for "clear error" under Rule 52(a)(6), the ultimate interpretation of a patent claim's meaning and scope is and remains a legal conclusion subject to *de novo* review.

Notably, the Supreme Court's analysis and holding in *Teva* continues the Court's nearly decade-long trend of aligning previously unique aspects of patent law with general principles applied in other areas of law. *See*, *e.g.*, *eBay Inc. v. MercExchange*, *L.L.C.*, 547 U.S. 388 (2006) (addressing the availability of injunctive relief in patent cases); *MedImmune*, *Inc. v. Genentech*, *Inc.*, 549 U.S. 118 (2007) (concerning declaratory judgment jurisdiction); and *Gunn v. Minton*, 568 U.S. 310 (2013) (regarding legal malpractice jurisdiction when the underlying claims relate to patent litigation).

The principles and directives articulated by the Supreme Court in *Teva* - and the Federal Circuit's consideration of those principles and directives on remand - will immediately bear on strategic choices and decisions in, for example, drafting new patent applications, the prosecution of patent applications, and how to prepare and argue claim construction in district court litigation and in adversarial proceedings before the Patent Trial and Appeal Board.

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