

Teva v. Sandoz: Supreme Court Rules That, In Reviewing Patent Claim
Constructions on Appeal, Factual Determinations Derived From
Extrinsic Evidence Must Be Given “Clearly Erroneous” Deference
by David R. Todd

On January 20, 2015, the U.S. Supreme Court issued its long-awaited decision in *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.* The Court concluded that when a district court’s claim construction is challenged on appeal, an appeals court must accept any factual determination by the district court that is derived from extrinsic evidence, unless the appeals court concludes that the determination is “clearly erroneous.” The decision overrules Federal Circuit *en banc* precedent first established twenty years ago in *Markman v. Westview Instruments, Inc.*^[1] and then reaffirmed in 1998 in *Cybor Corp. v. FAS Technologies, Inc.*^[2] and again just last year in *Lighting Ballast Control LLC v. Philips Electronics North America Corp.*^[3]

Teva owns a patent which covers a method for manufacturing Copaxone, a drug used to treat multiple sclerosis. The drug’s active ingredient, called “co-polymer 1,” is made up of molecules of varying sizes. Sandoz sought to market a generic version of Copaxone, and Teva sued Sandoz for infringement of Teva’s patent. The claims at issue require “co-polymer 1 having a molecular weight of about 5 to 9 kilodaltons.”^[4] The parties disagreed over the meaning of the phrase “molecular weight.” Disagreement over the meaning of claim terms is common in patent litigation, and those disagreements are resolved by the courts as a matter of “claim construction.” Claim construction is the process of determining what a person of ordinary skill in the art would understand to be the meaning employed by the patent applicant for a particular term in the claims of a patent. The focus is on “how the patentee used the claim term in the claims, specification, and prosecution history” (in the so-called “intrinsic evidence”).^[5] The law assumes that the patentee used the ordinary meaning in the relevant art unless the patent or its prosecution history shows otherwise.^[6] Evidence about “the ordinary meaning in the relevant art” can come from outside of the patent and is referred to as “extrinsic evidence.”

In 1996, the Supreme Court held in *Markman v. Westview Instruments, Inc.*^[7] that claim construction was a task properly allocated to judges rather than juries and that doing so did not run afoul of the Seventh Amendment. The Supreme Court in *Markman* did not expressly address the standard of review for claim construction decisions on appeal, and it used

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language that could be seen to support both a purely *de novo* approach as well as a more deferential approach. On one hand, the Supreme Court recognized that claim construction required “evidentiary underpinnings” and characterized it as a “mongrel practice,”^[8] falling “somewhere between a pristine legal standard and a simple historical fact.”^[9] On the other hand, the Supreme Court began by framing the issue before it as “whether the interpretation of a so-called patent claim...is a matter of law,”^[10] analyzed the issue by quoting with approval a treatise explaining that a court interpreting patent claims acts “as an arbiter of the law,”^[11] and concluded by observing that the advantage of “interjurisdictional uniformity” would be achieved by “*treating* interpretive issues as *purely legal*.”^[12]

Just last year, the Supreme Court also explained in *Nautilus, Inc. v. Biosig Instruments, Inc.*^[13] that “a patent’s claims, viewed in light of the specification and prosecution history, [must] inform those skilled in the art about the scope of the invention with reasonable certainty,” else the claims are invalid for being “indefinite.”^[14]

Against this backdrop, Sandoz argued that the phrase “molecular weight” caused the claims to be invalid for indefiniteness because that phrase could refer to any one of three different methods of calculation. The Court illustrated these three different meanings with an example:

“[I]magine we have a sample of copolymer-1...made up of 10 molecules: 4 weigh 6 kilodaltons each, 3 weigh 8 kilodaltons each, and 3 weigh 9 kilodaltons each. Using the first method of calculation, the ‘molecular weight’ would be 6 kilodaltons, the weight of the most prevalent molecule. Using the second method, the molecular weight would be 7.5 (total weight, 75, divided by the number of molecules, 10). Using the third method [a weighted average], the molecular weight would be more than 8, depending on how much extra weight we gave to the heavier molecules.”

Teva argued in the district court that the term “molecular weight” as used in the patent claims meant molecular weight calculated in the first way described above. Sandoz responded that Figure 1 of the patent showed that Teva could not be correct. Figure 1 shows

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how the weights of the molecules in three different batches of copolymer-1 were distributed. Figure 1 is reproduced below with the Court’s annotations:



As can be seen, the figure’s legend says that the “average molecular weight” of the first and second batches was 7.7 kilodaltons (kDa), whereas the “average molecular weight” for the third batch was 12.0 kilodaltons. According to Teva’s interpretation of “molecular weight,” molecules weighing 7.7 kilodaltons should be the most prevalent molecules in the first and second batches. But Sandoz pointed out that Figure 1 shows that the most prevalent molecule in the first and second batches weighs something less than 7.7 kilodaltons because the peak for those batches occurs at a value less than 7.7 kilodaltons. Therefore, Sandoz argued, the term “molecular weight” must mean something other than what Teva had asserted. However, Teva’s expert responded that a slight shift in the peak would have occurred when the data was converted from a chromatogram to the curves shown in Figure 1, and therefore Figure 1 was consistent with Teva’s proposed interpretation of the term “molecular weight.” In rebuttal, Sandoz’s expert testified that no such shift would occur. The district court credited Teva’s expert and concluded that Teva’s proposed interpretation of “molecular weight” was correct.[\[15\]](#)

On appeal, the Federal Circuit, conducting a *de novo* review, concluded that the phrase “molecular weight” was indefinite. The Federal Circuit relied on the fact that during the prosecution history of one of the patents-in-suit, the applicant had pointed to one method for determining molecular weight, but that during the prosecution history of another of the patents-in-suit, the applicant had pointed to another method. The Federal Circuit then concluded that, despite the testimony from Teva’s expert about how a skilled artisan would read Figure 1, “[t]he specification does not resolve the ambiguity.”[\[16\]](#) The Federal Circuit therefore held the claims invalid for indefiniteness. Teva petitioned for certiorari, arguing that by crediting Teva’s expert, the district court had made “findings of fact” and that the Federal Circuit was required by Federal Rule of Civil Procedure 52 to defer to those findings unless they were “clearly erroneous.”

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Federal Rule of Civil Procedure 52 reads in pertinent part: “Findings of fact, whether based on oral or other evidence, must not be set aside unless clearly erroneous, and the reviewing court must give due regard to the trial court’s opportunity to judge the witnesses’ credibility.” At the Supreme Court, both parties conceded that factual determinations are made during claim construction. However, the parties disagreed as to whether those factual determinations constitute “findings of fact” for purposes of Rule 52.

Justice Breyer wrote the opinion for the Court. The Court explained that its decision in *Markman* “concluded that it was proper to treat the ultimate question of the proper construction of the patent as a question of law in the way that we treat document construction as a question of law.” However, “this does not imply an exception to Rule 52(a) for underlying factual disputes.” The Court explained that it used the term “question of law” when pointing out that “a judge, in construing a patent claim, is engaged in much the same task as the judge would be in construing other written instruments, such as deeds, contracts, or tariffs.” Quoting from one its decisions interpreting an interstate tariff, the Court explained: “Construction of written instruments often presents a ‘question solely of law,’ at least when the words in those instruments are ‘used in their ordinary meaning.’ But sometimes, say when a written instrument uses ‘technical words or phrases not commonly understood,’ those words may give rise to a factual dispute. If so, extrinsic evidence may help to ‘establish a usage of trade or locality.’ And in that circumstance, the ‘determination of the matter of fact’ will ‘preced[e]’ the ‘function of construction.’ This factual determination, like all other factual determinations, must be reviewed for clear error.” The Court explained that this is what it was referring to in *Markman* when it stated that claim construction has “evidentiary underpinnings,”^[17] may require courts to make “credibility judgments,”^[18] and is a practice that “falls somewhere between a pristine legal standard and a simple historical fact.”^[19]

The Court next observed that precedent supported its conclusion. Specifically, the Court observed that before creation of the Federal Circuit, the Second Circuit had applied “clearly erroneous” deference to subsidiary factual questions in claim construction. The Court also

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observed that it had ruled in *Dennison Mfg. Co. v. Panduit Corp.*^[20] that “clearly erroneous” deference applies to subsidiary factual questions in determinations of obviousness.

Finally, the Court stated that “practical considerations” favor clear error review. Quoting its decision in *Graver Tank & Mfg. Co. v. Linde Air Products Co.*,^[21] the Court observed that “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.’” Therefore, “[a] district court judge who has presided over, and listened to, the entirety of a proceeding has a comparatively greater opportunity to gain that familiarity than an appeals court judge who must read a written transcript or perhaps just those portions to which the parties have referred.”

In response to a concern that “clear error” review might bring less uniformity, the Court stated that there had been no showing why “divergent claim construction stemming from divergent findings of fact (on subsidiary matters) should occur more than occasionally,” given that “the Federal Circuit will continue to review *de novo* the district court’s ultimate interpretation of the patent claims.” The Court opined that “subsidiary factfinding is unlikely to loom large in the universe of litigated claim construction.”

In dissent, Justice Thomas concluded that claim construction is more like construing statutes and land patents (where subsidiary factual questions are not considered “findings of fact” subject to Rule 52) and it is less like construing deeds, contracts, or tariffs (where subsidiary factual questions are considered “findings of fact”). Justice Thomas argued that treating subsidiary factual questions as “findings of fact” for deeds or contracts makes sense because construction of those instruments involves a search for intent that “ha[s] an existence outside the written instrument and that the instrument merely records.” On the other hand, patents, like statutes, have a “regulatory effect” that “restrain others” and “bind the public at large.” And a patent holder’s actual intentions “have effect only to the extent that they are expressed in the public record.” As such, Justice Thomas (joined by Justice Alito) would have concluded that subsidiary factual determinations in claim construction are “conclusions of law” rather than “findings of fact.”

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In response to Justice Thomas’s dissent, the majority provided the following reasoning as to why patents should not be treated like statutes: “Statutes, in general, address themselves to the general public; patent claims concern a small portion of that public. Statutes typically (though not always) rest upon congressional consideration of general facts related to a reasonably broad set of social circumstances; patents typically (though not always) rest upon consideration by a few private parties, experts, and administrators of more narrowly circumscribed facts related to specific technical matters. The public, and often an adversarial public, typically considers and discusses the relevant general facts before Congress enacts a statute; only private parties, experts, and administrators likely consider the relevant technical facts before the award of a patent.” Given these differences, the Court observed, “it is not surprising that this Court has never previously compared patent claim construction...to statutory construction,” whereas the Court “has repeatedly compared patent claim construction to the construction of other written instruments such as deeds and contracts.”[\[22\]](#) The majority did not supply any specific response to Justice Thomas’s argument that patents were also analogous to land patents.

After explaining *why* “clear error” review must be applied, the Court endeavored to explain *how* to apply it. It began by recognizing that “a district court’s construction of a patent claim, like a district court’s interpretation of a written instrument, often requires the judge only to examine and to construe the document’s words without requiring the judge to resolve any underlying factual disputes.” Thus, “when the district court reviews only evidence intrinsic to the patent (the patent claims and specifications, along with the patent’s prosecution history), the judge’s determination will amount solely to a determination of law, and the Court of Appeals will review that construction *de novo*.” “In some cases, however, the district court will need to look beyond the patent’s intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period.” “In cases where those subsidiary facts are in dispute, courts will need to make subsidiary factual findings about that extrinsic evidence. These are the ‘evidentiary underpinnings’ of claim construction that we discussed in *Markman*, and this subsidiary factfinding must be reviewed for clear error on appeal.”

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“For example, if a district court resolves a dispute between experts and makes a factual finding that, in general, a certain term of art had a particular meaning to a person of ordinary skill in the art at the time of the invention, the district court must then conduct a legal analysis: whether a skilled artisan would ascribe that same meaning to that term *in the context of the specific patent claim under review*....This ultimate interpretation is a legal conclusion. The appellate court can still review the district court’s ultimate construction of the claim *de novo*. But, to overturn the judge’s resolution of an underlying factual dispute, the Court of Appeals must find that the judge, in respect to those factual findings, has made a clear error.”

“In some instances, a factual finding will play only a small role in a judge’s ultimate legal conclusion about the meaning of the patent term. But in some instances, a factual finding may be close to dispositive of the ultimate legal question of the proper meaning of the term in the context of the patent. Nonetheless, the ultimate question of construction will remain a legal question. Simply because a factual finding may be nearly dispositive does not render the subsidiary question a legal one.”

The Court then addressed the specific dispute between Teva and Sandoz over Figure 1. The Court noted that the district court had credited the explanation given by Teva’s expert (and had rejected the testimony given by Sandoz’s expert) about why the peak in Figure 1 was not located exactly at 7.7 kilodaltons. As a result, “the District Court’s finding about this matter was a factual finding—about how a skilled artisan would understand the way in which a curve created from chromatogram data reflects molecular weights.” Based on that factual finding, the district court reached “the legal conclusion” that Figure 1 “did not undermine Teva’s argument.” As the Supreme Court viewed the case, the Federal Circuit “recognized that the peak of the curve did not match the 7.7 kilodaltons listed in the legend of figure 1,” but it “did not accept Teva’s expert’s explanation as to how a skilled artisan would expect the peaks of the curves to shift” and did so “without finding that the District Court’s contrary determination as ‘clearly erroneous.’” The Court concluded: “Our holding today makes clear that, in failing to do so, the Federal Circuit was wrong.”

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On remand, it remains to be seen whether the Federal Circuit will conclude that Teva’s expert was “clearly erroneous.” Or whether the Federal Circuit will feel free to determine as part of a “legal conclusion” that even after crediting Teva’s explanation of Figure 1, the applicant’s promotion of one definition in the prosecution history of one patent-in-suit but of another definition in the prosecution history of another patent-in-suit results in a lack of “reasonable certainty” and therefore indefiniteness under *Nautilus v. Biosig*. It also remains to be seen whether the Supreme Court’s ruling will have an effect on how the Federal Circuit views the substantive law of claim construction. The only thing that is clear is that the lower courts and litigants will be grappling with the implications of the Court’s ruling for some time to come.