Worth the Candle and a South African Yellow Canary

Will the Supreme Court Snuff *de novo* Review in *Teva Pharmaceuticals v. Sandoz*?

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INTELLECTUAL PROPERTY LAW

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The construction of written instruments is one of those things that judges often do and are likely to do better than jurors unburdened by training in exegesis.

--*Markman v. Westview Instruments*, 517 U.S. 370, 388

The used key is always bright.

--Benjamin Franklin, *Poor Richard's Almanac* (1744)

Outline

- Where have we been?
- *Teva v. Sandoz* Fed Circuit
- Briefs
- Oral argument
- What result?

Where have we been?

- *Markman I* (Fed Cir, *en banc*, 1995)
- *Markman II* (Supreme Ct, 1996)
- *Cybor v. Fas Technologies* (Fed Cir, *en banc,* 1998)
- *Lighting Ballast Control v. Philips Electronics* (Fed Cir, *en banc*, 2014)

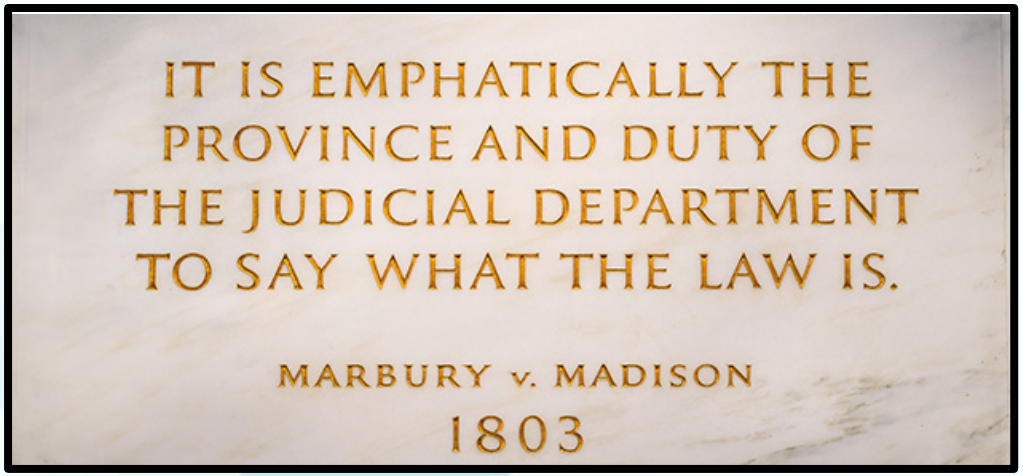
Markman I: At the Federal Circuit

- Held (1995): In jury trials, construction of patent claims is a matter of law exclusively for the court, and on appeal, is reviewed *de novo*.
- Not analogous to interpretation of contracts, deeds, wills
- Court looks to language of claims, specification, and prosecution history to interpret claim meaning
- Extrinsic evidence can be used to ascertain the true meaning of claim language
- After review of evidence, court pronounces meaning of claim language as a matter of law
- No violation of 7th Amendment in requiring the court to determine patent claim scope

Markman I, cont.

- "At its inception, the Federal Circuit held that claim construction was a matter of law" (citing *SSIH Equip. v. ITC*, Fed Cir, 1983)
- "[T]he Supreme Court as repeatedly held that the construction of a patent claim is a matter of law exclusively for the court" (citing to numerous 19th century decisions).
- "It . . . continues to be a fundamental principle of American law that the 'construction of a written evidence is exclusively with the court'" (quoting Chief Justice J. Marshall, 1805).
- "The patent is a fully integrated written instrument."
- "[I]t is only fair (and statutorily required) that competitors be able to ascertain to a reasonable degree the scope of the patentee's right to exclude."

Archer, C.J.



J. Marshall,
Chief Justice

Markman I, cont.

- Mayer, J., concurring:
  - "Today the court jettisons more than two hundred years of jurisprudence and eviscerates the role of the jury preserved by [the 7th Amendment]. . . ."
  - "[T]his is not just about claim language, it is about ejecting juries from infringement cases."
  - "[T]he effect of this case is to make of the judicial process a charade, for notwithstanding any trial level activity, this court will pretty much do what it wants under its *de novo* retrial."

Markman I, cont.

- Newman, J., dissenting:
  - "This holding not only raises a constitutional issue of grave consequence, but the court creates a litigation system that is unique to patent cases, unworkable, and ultimately unjust."
  - "By redesignating fact as 'law,' the court has eliminated the jury right from most trials of patent infringement."
  - "[W]hen the technologic issues are complex, appellate fact finding is probably the least effective path to accurate decisionmaking."

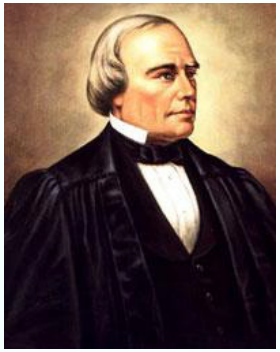
Markman II: US Supreme Court

- Held: (1996) Construction of a patent, including terms of art within its claim, is exclusively within the province of the court.
  - Patent infringement cases are properly tried before a jury
  - There is no direct antecedent of modern claim construction in historical sources
  - Judges, not juries, construed patent specification terms
  - Precedent, relative interpretive skills of judges and juries, and statutory policy considerations favor allocating construction issues to the court.
  - Judge is in best position to interpret highly technical subject matter for the jury
  - Uniformity favors claim construction by the court
- Not decided: The amount of deference owed to a trial court's claim construction on appeal

Justice Souter

Markman II, cont.

- No evidence in common law that 7th Amendment guarantee of trial by jury applied to claim construction.
- Therefore, look to precedent, relative interpretive skills of judge/jury, and policy considerations.
  - Justice Benjamin Curtis (1879): construing a patent is a matter of law, to be determined by the court; whether infringement occurred is a matter of fact, to be decided by the jury
  - Walker treatise (1895): matters of claim construction, even if aided by expert testimony, are questions for the court.
  - "Judges, not juries, are better suited to find the acquired meaning of patent terms."
  - "[W]e see the importance of uniformity in the treatment of a given patent as an independent reason to allocate all issues of construction to the court."



Justice Curtis

Cybor v. Fas Technologies

- Held (CAFC, en banc, 1998): Claim construction, as a purely legal issue, is subject to *de novo* review on appeal

- "[T]he Supreme Court endorsed this court's role in providing national uniformity to the construction of a patent claim, a role that would be impeded if we were bound to give deference to a trial judge's asserted factual determinations incident to claim construction."

Judge Archer

- "We conclude that the standard of review in *Markman I* . . . was not changed . . . in *Markman II*, and we therefore reaffirm that . . . we review claim construction *de novo* on appeal including any allegedly fact-based questions relating to claim construction"

Cybor v. Fas Technologies, cont.

Plager, J., concurring

- "This court's decision in *Markman I*, reaffirmed today, simply means that we do not spend our and appellate counsels' time debating whether the trial court's information base constitutes findings of "fact" or conclusions of "law," with verbally different standards of review. Instead both they and we can focus on the question that the trial court addressed, the question that counts: what do the claims mean? As we all recognize, that is not always easy to know, and much turns on the answer."

Bryson, J., concurring

- "[W]e approach the legal issue of claim construction recognizing that with respect to certain aspects of the task, the district court may be better situated than we are, and that as to those aspects we should be cautious about substituting our judgment for that of the district court."

Cybor v. Fas Technologies, cont.

Mayer, C.J., (with Newman), concurring

- "[The Supreme Court's decision in *Markman II*] was "a perilous decision of last resort. For juries regularly render verdicts in civil cases based on complex forensic and documentary evidence of equal or greater difficulty than seen in patent cases."

- "Wisely, the Supreme Court stopped short of authorizing us to find facts *de novo* when evidentiary disputes exist as part of the construction of a patent claim and the district court has made these findings without committing clear error."

Cybor v. Fas Technologies, cont.

Mayer, C.J., (with Newman), concurring

- "If claim construction is only a question of law to be reviewed by this court *de novo*, then the absence of review as a matter of right over our claim constructions, which may be new and unsupported by legal analysis, or may never have been tested by the adversarial process, would transform this court into a trial court of first and usually last resort."

Cybor v. Fas Technologies, cont.

Rader, J., dissenting re claim construction

- "[T]his court has yet even to receive briefing and oral argument on the proper standard of review for a trial court's claim construction . . . To my eyes, this rejection of the trial process as the 'main event' will undermine, if not destroy, the values of certainty and predictability sought by *Markman I*."

Cybor v. Fas Technologies, cont.

Newman, J., concurring

- "The court states that it neither accepts the trial judge's findings of fact, nor accepts that there are factual issues in claim interpretation. With these strictures on evidence, witnesses, and findings, it is far from clear how the Federal Circuit proposes to reach the correct claim interpretation."

- "The court today not only rejects the opportunity to give normal appellate deference to the proceedings and findings of trial, but also rejects the opportunity to consider them at all."

Lighting Ballast Control v. Philips Electronics

- Held: (2014) Claim construction is a matter of law and is reviewed *de novo* on appeal
- 6-4 *en banc* decision
- Majority: Newman, joined by Lourie, Dyk, Prost, Moore, Taranto
- Dissent: O'Malley, joined by Rader, Reyna, Wallach

Lighting Ballast Control, cont.

- "After 15 years of experience with *Cybor*, we conclude that the court should retain plenary review of claim construction, thereby providing national uniformity, consistency, and finality to the meaning and scope of patent claims. The totality of experience has confirmed that *Cybor* is an effective implementation of *Markman II*, and that the criteria for departure from *stare decisis* are not met."

Lighting Ballast Control, cont.

- "The question now is not whether to adopt a *de novo* standard of review of claim construction, but whether to change that standard adopted fifteen years ago and applied in hundreds of decisions."

Lighting Ballast Control, cont.

- "[R]eversing Cybor or modifying it to introduce a fact/law distinction has a high potential to diminish workability and increase burdens by adding a new and uncertain inquiry, not only on appeal but also in the trial tribunal. No consensus has emerged as to how to adjust *Cybor* to resolve its perceived flaws . . . The principles of *stare decisis* counsel against overturning precedent when there is no evidence of unworkability and no clearly better resolution."

Lighting Ballast Control, cont.

O'Malley (dissenting):

- "[I]t appears that some members of today's 6-4 majority believe the pull of *stare decisis* is so strong that it prevents them from acting on their long-term convictions that *Cybor* was wrongly decided."
- "Considerations of *stare decisis* . . . do not justify adhering to precedent that misapprehends the Supreme Court's guidance, contravenes the FRCP, and adds considerable uncertainty and expense to patent litigation."

Teva v. Sandoz : Fed Cir

- Background
  - Sandoz et al. want to market generic versions of Copaxone®, file ANDA
  - Teva sues for patent infringement
  - Sandoz argues claims are indefinite because "mol. wt." is insolubly ambiguous
  - Dist. Ct.: "mol. wt." means "peak ave" mol. wt. (M_p); claims are not indefinite; generics infringe
  - Fed Cir: Group I claims are invalid for indefiniteness; Group II claims not proven indefinite (rev. in part)
    - Panel: C.J. Rader, J. Moore, District J. Benson

Teva v. Sandoz : Fed Cir

Group I claim:

1. Copolymer-1 having *a molecular weight of about 5 to 9 kilodaltons*, made by a process comprising the steps of:

reacting protected copolymer-1 . . . ; and

purifying said copolymer-1, to result in copolymer-1 *having a molecular weight of about 5 to 9 kilodaltons*.

Group II claim:

1. Copolymer-1 having over *75% of its mole fraction within the molecular weight range from about 2 kDa to about 20 kDa* . . . ."

Generics: All claims must be indefinite b/c all recite "molecular weight"

Teva: Only peak MW can be determined directly from a chromatogram; Group II claim does not recite average MW values

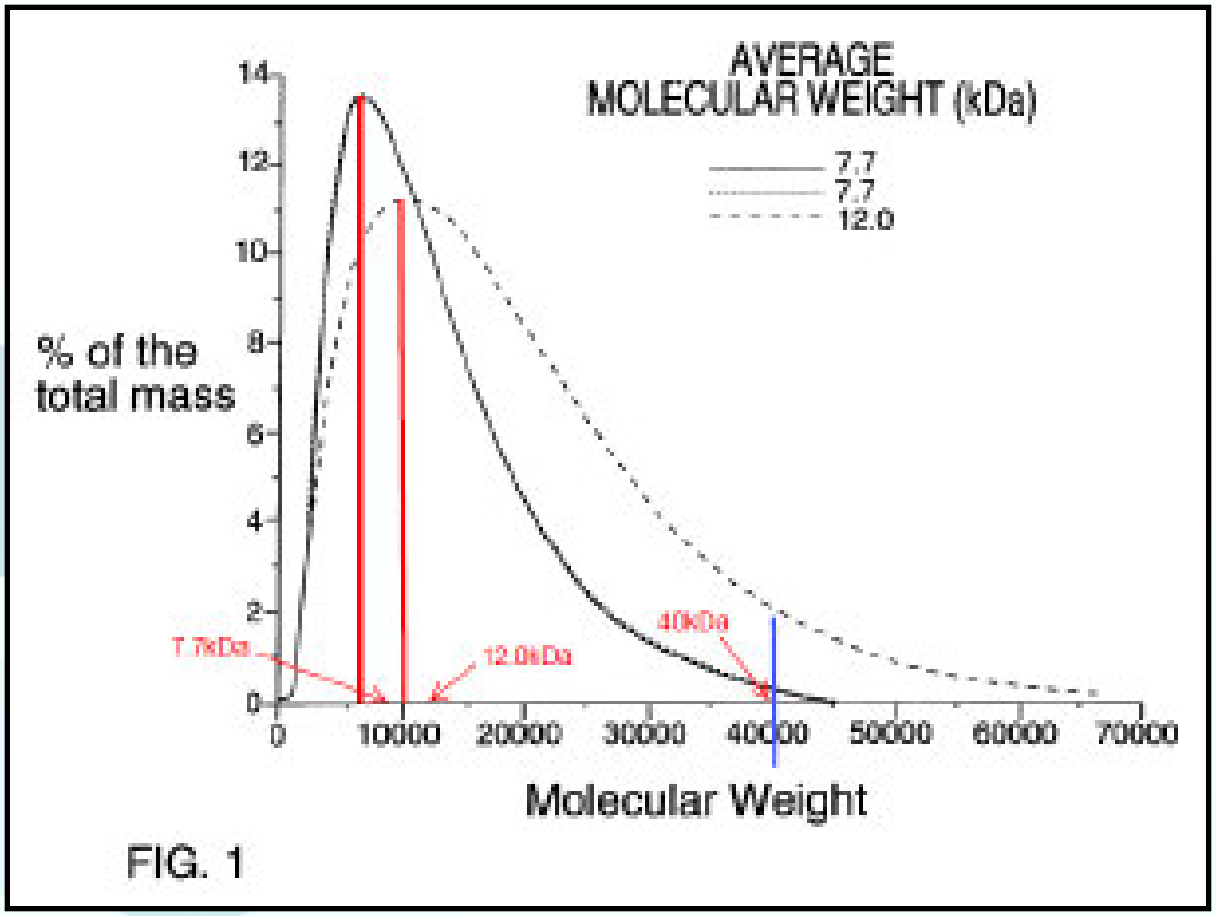


FIG. 1

Note:

Two superimposed curves at left (maximum ~6k Da)

Dotted curve is comparative

Teva v. Sandoz : Fed Cir

J. Moore:

- "We agree with Appellants that Group I claims are indefinite and with Teva that Group II claims are not."
- "In fact [re Group I], the 7.7 kDa value is closer to the M_w than to the M_p of the corresponding batch, which makes it difficult to conclude that M_p is the intended measure."
- "Group II claims . . . refer to exact values rather than statistical measures. The scope of Group II claims is thus readily ascertainable."

To the Supreme Court

Question Presented

Teva:
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, or only for clear error, as FRCP 52(a) requires.

Sandoz:
Whether the court of appeals properly concluded that claim construction involves a pure question of law, and thus the standard of appellate review of the lower court's interpretation of a patent's claims is *de novo*.

Patent claims: More like a contract or a statute?

Teva:

- More like a contract
- Directed to skilled artisans, not the general public.
- May require intense fact-finding
- Best left to a jury
- Dist. court factual findings re claim construction are entitled to deference
- Reverse for clear error in accord with FRCP 52(a)

Sandoz:

- More like a statute
- Meaning binds the public
- Scientific facts are only rarely in dispute
- Best left to judges
- *De novo* review accords with *Markman I*
- FRCP 52(a) applies to other kinds of fact finding but not to claim construction

Teva brief

- FRCP 52(a) precludes appellate court from second-guessing dist. court's fact finding
  - District courts are well suited to make scientific determinations
- Claim construction entails fact finding
  - Skilled artisan perspective
  - Patent law treats closely related questions as factual
- Fed Circuit rationale for *de novo* review is unpersuasive
  - Fact finding resolves disputes when extrinsic evidence is used to interpret written instruments
  - Need for uniformity won't transform facts into law
  - Poor, costly decisions result when appeal courts engage in fact finding

Sandoz et al. brief

- Fed Cir correctly reviews all aspects of claim construction *de novo*
  - Factual underpinnings of claim construction are "legislative facts"
  - Supreme Court precedent supports *de novo* review
  - Okay to have different std./review in areas outside patent law
  - Uniform treatment of patents requires *de novo* review

- Outcome is the same even if not all aspects of claim construction are reviewed *de novo*
  - Any facts limited to extrinsic principles apart from the record
  - Fed Cir left the district court's factual findings alone
  - If the Supreme Court concludes that claim construction involves both fact finding and conclusions of law, it needs to tell us where to draw the line

U.S. Govt. brief

- Dist court's fact findings in construing patent claims are entitled to deference on appeal
  - Claim construction is a matter of law but it may require resolution of subsidiary fact questions
  - *Markman II* did not hold that claim construction is a pure question of law
  - Claim construction is a "mongrel practice" with "evidentiary underpinnings"
  - Rule 52(a) requires deference to subsidiary fact finding by district courts; no conflict with need for uniform treatment of patent claims
- Result here is likely the same under a "clear error" standard, but a remand is in order

The Amici Spectrum

Fresenius Kabi	IPO, AIPLA, law professors, Houston IPLA, US Gov't	ABA, FICPI
(Sandoz)		(Teva)
Pure *de novo* review	Hybrid approaches: Defer to trial court for fact findings incident to claim construction or only for fact findings related to extrinsic evidence.	Deference to all fact finding accords with FRCP 52(a)

Bardolph:

Why, sir, for my part I say the gentleman had drunk himself out of his five sentences.

Shakespeare,

*Merry Wives of Windsor (*I, i)

Oral Argument

- Teva's counsel (William M. Jay):
  - FRCP 52(a) requires Fed Cir (and all other appellate courts) to treat fact findings of a district court deferentially
  - Fed Cir failed to defer to dist. ct. meaning of "ave MW" as Mp and gave no weight to expert testimony re Fig 1
  - Meaning of terms of art to interpretive community (skilled artisans) is a fact question
  - Patent claims are more like contracts than statutes
  - Appeal courts have always deferred to district courts on matters of subsidiary findings
  - *De novo* standard encourages Fed Cir to "blow right by" skilled artisan's perspective.

From the Justices (for Mr. Jay)

- JUSTICE GINSBURG: "What are the facts to which the Federal Circuit should have applied the clearly erroneous rule?"

- JUSTICE ALITO: "Do you think that the average person on the street has any idea what Tier 1 capital [from the Dodd-Frank Act] is?"

- JUSTICE KENNEDY: "[T]he court's construction is X, Y, Z. Could that determination by the district judge . . . involve some subsidiary questions of fact as to which he must be given deference?"

From the Justices (for Mr. Jay)

- JUSTICE SOTOMAYER: "If you and the government can't agree, why should we defer to a district court?"
- CHIEF JUSTICE ROBERTS: "What do you mean by a subsidiary fact?"
- JUSTICE GINSBURG: "If these are truly fact questions, then what happened to the Seventh Amendment?"
- JUSTICE KAGAN: "[W]hen an expert . . . gives testimony about what . . . a skilled artisan . . . would understand to be the meaning of a particular patent term . . . how is that different from the ultimate legal question?"

From the Justices (for Mr. Jay)

- JUSTICE BREYER: "The statute might use the word 'South African yellow canary.' But we are not certain whether that is a South African yellow canary. If we call in a bird expert . . . that is a question of fact. If we call in a lawyer to say how these words are being used in the statute and does that fit within it, then it is a question of law."

- JUSTICE ALITO: "In a recent law review article . . . the authors . . . couldn't find any case in which this fascinating legal debate had any practical significance. Now, you want to introduce a level of complication to this. . . you want the Federal Circuit now to struggle to determine which are factual questions as to which there's clear error review, which ones get *de novo* review . . . Is it worthwhile as a practical matter?"

Oral Argument

- Office of the Solicitor General (Ginger D. Anders):
  - Factual findings can be based on evidence outside the patent and its prosecution history; those findings applied to claim construction involves making legal inferences
  - Dist Ct found that SEC data provides Mp; legal inference: patentee meant Mp. Fed Cir disagreed with the legal inference from the Dist Ct fact findings
  - Legal inquiry needed following fact finding based on patent spec, claims, prosecution history
  - Different courts reaching different conclusions is "unlikely"; in the patent system, other values supersede uniformity
  - Fact finding allows district court to assume the perspective of the skilled artisan and then decide what the claims mean

From the Justices (for Ms. Anders)

- JUSTICE GINSBURG: "Why do you reject what Mr. Jay tells us were also fact-findings?"
- JUSTICE KAGAN: "[S]uppose an expert just says . . . molecular weight means the following . . . Is that a factual determination in your view?"
- CHIEF JUSTICE ROBERTS: "[T]wo different district courts construing the same patent could come out to opposite results based on a subsidiary fact finding, and neither of those would be clearly erroneous, and yet on a public patent . . . people won't know what to do . . . What happens then?"

From the Justices (for Ms. Anders)

- JUSTICE BREYER: "I can think of examples in antitrust . . . corporate law [where] different factual things have enormous public implications."

- JUSTICE SCALIA: "[A] deed is a private document that has public effect . . .and could be construed in the various courts that reach different results. So the mere fact that this binds the public is not conclusive."

- JUSTICE ALITO: "It sounds like you're saying that anything that is a factual issue is subject to clear error review. But I thought you were saying something less than that."

Oral Argument

- Sandoz et al.'s counsel (Carter G. Phillips):
  - *De novo* review follows from *Markman II*
  - Patent claims are unique; other fact-based inquiries, such as obviousness determinations, are distinguishable from claim construction
  - Not "worth the candle" to try to distinguish between facts entitled to deference or not ("cottage industry" problem)
  - *Markman II* says treat claim construction as a pure matter of law to guarantee uniformity and provide adequate notice
  - Expert testimony will rarely help a court decide how to construe claims
  - Patents are more like statutes than contracts: binding on the public, so we need *de novo* review for uniformity
  - Fed Cir should give only "Skidmore deference" to district courts

From the Justices (for Mr. Phillips)

- JUSTICE BREYER: "[W]hy should you treat fact matters here any different than any other case? . . . In technical cases, there are all kinds of facts. And the traditional reason is you've seen the witnesses . . . and in a technical case . . . that makes an enormous difference."

- JUSTICE GINSBURG: "I thought in our Seventh Amendment cases we have rejected the notion that if an issue is difficult, technical, the judge can decide it even though it's a fact."

- JUSTICE KAGAN: "Is it your argument that there are no subordinate factual determinations in these kinds of cases or . . . we can come up with a zillion of them, but it's not worth the candle to figure out which is which?"

From the Justices (for Mr. Phillips)

- JUSTICE BREYER: "Are we going to have the 3 people from the Federal Circuit . . . second-guessing the judge without giving him any weight on that kind of factual question . . . ?"

- JUSTICE KAGAN: "Rule 52(a) sets out the very blanket rule. It doesn't say except where it's not worth the candle."

- JUSTICE BREYER: "It isn't that I like [Rule 52(a)] better. It is that Rule 52(a) says that fact-finding of the district court should be overturned only for clear error. And once I start down this road . . . I don't see where the stopping place is."

From the Justices (for Mr. Phillips)

- JUSTICE SCALIA: "Do you want the district court . . . even though what it finds is not going to be given any deference, do you want them to listen to live witnesses?"

- JUSTICE ALITO: "If a patent is like public law . . . Then factual findings regarding the meaning of that patent are not entitled to clear error review . . . [O]n the other hand, if a patent is a private law, if it's like a deed or . . . contract, then Rule 52(a) comes into play."

- JUSTICE KAGAN: "[A]re you saying that there aren't similar things that could arise within the context of claim construction, just different people's views of what the facts on the ground are?"

What Result?

- On the Court for *Markman II*:
  - Justices Breyer, Scalia, Kennedy, Ginsburg, Thomas
- New since *Markman II*:
  - Justices Kagan, Sotomayer, Roberts, Alito
- Departed since Markman II:
  - Justices Souter, Rehnquist, Stevens, O'Connor

What if the *Markman II* group stayed together?

"*De novo* review is consistent with our earlier decision in *Markman II*"?!:






May also favor *de novo* review:

May favor deference:

A "hybrid" ruling?

- Court could decide to rule consistent with the amicus briefs supplied by the U.S. government, IPO, AIPLA, and others:
  - Claim construction is ultimately a matter of law, to be decided by the court, not a jury, as held in *Markman II*.
  - Contrary to the holdings in *Cybor* and *Lighting Ballast Control*, the Fed Cir must, consistent with Rule 52(a), defer to a trial judge's factual findings "incident to claim construction" and reverse only for clear error.
  - Or: defer to trial court for fact findings regarding extrinsic evidence only re claim construction
  - Ruling is consistent with *Markman II* because Court was silent regarding the proper standard of review.

Based on Justice Queries for Counsel, who might favor a "hybrid"?

May favor only *de novo* review



May favor a hybrid approach



May favor pure deference


Who knows?

Time to Cast Your Vote!

- What result?
  1. *De novo* review wins! Cybor upheld!
  2. Deference to trial court wins! Respect Rule 52(a)!
  3. Quash *Cybor!* Hybrid wins!
  4. Beats me!

Conclusion

- Federal Circuit precedent favors *de novo* review of claim construction, but there are good arguments that the Federal Circuit should defer to a trial court's findings of fact to be consistent with Rule 52(a).
- Five Justices from *Markman II* remain on the Court. However, the precise issue of standard of review on appeal was not expressly addressed in *Markman II*.
- Justice Breyer favors deference; it is more challenging to predict how the other Justices are leaning.
- A Teva win would send yet another message about how *little* deference the Supreme Court is inclined to give the Federal Circuit.
- A "hybrid" ruling appears most likely.

I have lost more than a friend, I have lost an inspiration. She would rather light candles than curse the darkness and her glow has warmed the world.

--Adlai E. Stevenson, 11-7-1962
(regarding Eleanor Roosevelt)

Thanks for your attention!

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