IN THE

Supreme Court of the United States

MERCK & CO., INC.,

Petitioner,

ν.

TEVA PHARMACEUTICALS USA, INC.,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF OF THE BOSTON PATENT LAW ASSOCIATION AS

AMICUS CURIAE IN SUPPORT OF MERCK & Co.'s

PETITION FOR CERTIORARI

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INTEREST OF AMICUS CURIAE

The Boston Patent Law Association ("BPLA") is an association of intellectual property professionals providing programs and forums for the exchange of ideas and information about patent and other intellectual property rights. The BPLA is neutral as between the litigants, Merck & Co. and Teva Pharmaceuticals USA, Inc.. But the BPLA is concerned how *de novo* review of claim construction affects patent litigation and the patent system generally. This case highlights the shortcomings of *de novo* review. ¹

SUMMARY OF ARGUMENT

The elephant in the room, which all patent professionals recognize but, in the wake of *Markman v. Westview Instruments*, hesitate to say aloud, is that claim construction involves factual inquiry. While a patent is certainly a legal document, it is also a technical document meant to be read and understood by artisans in the field of invention.

Thus, the standard for interpreting a patent is not how any reasonable person would read the document but rather how "one of ordinary skill in the art" would. Indeed, patents contain jargon that, while foreign to most of us, is readily understood by an inventor's fellow engineers, scientists, or mechanics. Judges thus rely on technical experts to inform them how an artisan would view the patented technology. In doing so, judges find facts and weigh credibility.

¹ Pursuant to Supreme Court Rule 37.6, no party or its counsel authored any part of this brief. No person or entity, other than the BPLA and its counsel, Bromberg & Sunstein LLP, contributed money for the preparation or submission of this brief. The parties have consented to the filing of this *amicus* brief. The consent letters have been lodged with the Court.

Claim construction, however, has lost its focus on the technology and has instead devolved into a war of semantics. Terms such as "on" or "or" or, as in this case, "about," control patent scope rather than the technology that the inventor invented. That cannot be the original intent of the Constitution, which was to preserve to inventors their inventions, not to tangle them up in words.

De novo review biases the Federal Circuit away from expert testimony that informs a trial judge's determination of how skilled artisans would have understood the patented invention. Instead, the Federal Circuit tends to substitute its own (lay) reading of the patent for that of the skilled artisan. As a result, claim construction has become less about the technology and more about semantics.

Moreover, de novo review denies to litigants the certainty that the Markman decision once promised. Indeed, patent cases are about twice as likely as other civil cases to go to trial. About 40% of all claim construction appeals are reversed or vacated. Litigants who might otherwise settle are more willing to risk trial knowing that, whatever happens, they have a good chance of winning on appeal. A standard of review that is more deferential to the trial judge will necessarily lower the reversal rate, force the court to consider the view of skilled artisans, and thus restore certainty and confidence in the patent system.

The BPLA does not advocate overturning *Markman*, allowing juries to construe claims, or any other extraordinary measures. Rather, the BPLA proposes a standard of review like one used in contract cases: when a judge relies on extrinsic evidence to aid claim construction, his or her factual findings — in the words of *Markman*, the "evidentiary underpinnings" of claim construction — should be reviewed for clear error, while the ultimate legal conclusion should be reviewed *de novo*.

ARGUMENT

De novo review for claim construction is not working. First, it is based on the fiction that there is no factual inquiry in claim construction. Second, it deprives litigants of their hefty investment in patent litigation, creates a "zone of uncertainty," and erodes confidence in the patent system.

The case at bar presents an excellent example of this problem. The trial judge expressly relied on expert testimony explaining how skilled artisans would have read the patent. But the Federal Circuit ignored this testimony and the judge's reliance on it. As such, the Federal Circuit did not view the patent through the eyes of one of ordinary skill. Reviewing the claim construction under a deferential standard would have caused the Federal Circuit to consider the expert testimony. Indeed, the dissenter, Circuit Judge Rader, would have deferred to the trial judge and thus would have affirmed.

In Markman v. Westview Instruments, 517 U.S. 370 (1996), this Court labeled claim construction a "mongrel practice" with "evidentiary underpinnings." Id. at 378, 390. This Court also recognized that "credibility judgments have to be made about the experts who testify in patent cases." Id. at 389. While this Court held that this mixed question of law and fact is ultimately for a court alone to decide, it did not specify the standard for reviewing the trial court's decision.

No statute or Supreme Court precedent requires that claim construction must be reviewed purely *de novo*. Just the opposite. This Court's *per curium* decision in *Dennison Mfg. Co. v. Panduit Corp.*, 475 U.S. 809, 811 (1986), recognizes that when ultimate questions of law (in that case, the question of obviousness) are based on subsidiary findings of fact (such as what the prior art discloses to one of ordinary skill), those subsidiary findings should be reviewed for clear error.

Accordingly, the BPLA urges this Court to review this case, which provides an excellent opportunity to reconsider the Federal Circuit's *de novo* review standard. First, as argued in Section I, claim construction, like the obviousness inquiry, involves subsidiary facts. But *de novo* review allows the Federal Circuit to lose sight of the facts underlying claim construction and thus to depart from how the relevant industry would read a patent. Second, as argued in Section II, *de novo* review causes uncertainty and increases the cost of litigation. Thus, this case presents (a) questions that call for this Court to exercise its supervisory power over the Federal Circuit and (b) important questions of federal law. *See* Supreme Court Rules 10(a) and (c).

I. CLAIM CONSTRUCTION DEPENDS ON FACTS

Invention takes place in the lab. Or in the factory, amidst the hum and clank of machinery. Or even in the weekend inventor's garage workshop, sawdust and oil stains on the floor. Invention involves beakers, soldering irons, lathes, drill presses, calculators, and microscopes. Invention does not take place in a lawyer's office or in the halls of the United States Patent & Trademark Office.

Correspondingly, the primary audience for a patent is the inventor's competitor or fellow artisan — e.g., the white-coated chemist, surrounded by test tubes and Bunsen burners; the machine shop foreman, blueprints spread out before him on the workbench; or even the grease-stained mechanic, wrench and socket in hand. The intended audience is not first and foremost a lay judge or an appellate court:

Patent documents are written for persons familiar with the relevant field; the patentee is not required to include in the specification information readily understood by practitioners, lest every patent be required to be written as a comprehensive tutorial

and treatise for the generalist, instead of a concise statement for persons in the field

Verve, LLC v. Crane Cams, Inc., 311 F.3d 1116, 119 (Fed. Cir. 2002). See also Carnegie Steel Co. v. Cambria Iron Co., 185 U.S. 403, 437 (1902) (patent directed to steel-making process was "not addressed to lawyers, or even to the public generally, but to the manufacturers of steel"). Thus, a court will most strongly satisfy the notice function of a patent by defining its scope as it would be understood in the relevant industry. In order to do so, a judge must step out of the courtroom, so to speak, and into the lab or workshop.

The Federal Circuit has likened claim construction to statutory construction. Markman v. Westview Instruments. Inc., 52 F.3d 967, 987 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996). That analogy, however, encourages reference to the real world of invention and technology: "judicial construction ought not to be torn from its wider, non-legal context." Felix Frankfurter, Some Reflections on the Reading of Statutes, 47 Colum. L. Rev. 527, 528 (1947). Thus, as Justice Frankfurter wrote in the context of statutory construction, "to understand or at least get the feeling of great painting, one does not go to books on the art of One goes to the great masters." Id. at 530. Likewise, to understand patented technology, one must go to artisans in the field of invention. Whether a statute or a patent, if it is "addressed to the specialist, [it] must be read by judges with the minds of the specialist." *Id.* at 536.

Patents are typically filled with terms of art — the jargon of the mechanics, engineers, chemists, scientists, and other artisans who form the core audience for patents. But "words of art bring their art with them. They bear the meaning of their habitat whether it be a phrase of technical significance in the scientific or business world." *Id.* at 537. To isolate a

word from its real-world, technological context strips the term of all relevant meaning.

Moreover, many patents involve complex technology beyond the ken of lay people. As the saying goes, "[a]ny sufficiently advanced technology is indistinguishable from magic." Arthur C. Clarke, Profiles of the Future: An Inquiry into the Limits of the Possible (1973). Thus, to decipher that magic, judges need experts. Arti K. Rai, Specialized Trial Courts: Concentrating Expertise on Fact, 17 Berkeley Tech. L.J. 877, 882 (2002) ("In most cases involving technically complex invention, the judge would be well-advised to turn to the testimony of experts in the relevant scientific or technological community").

Accordingly, litigants present experts, as Merck and Teva did in this case, to help the trial judge understand the technology from the point of view of the skilled artisan. Indeed, statistics show that trial judges admit extrinsic evidence into the claim construction analysis 83% of the time. See Cheryl L. Johnson, The False Premise and Promise of Markman's Decision to Task Judges with Claim Construction and the Judicial Scorecard, 837 PLI/Pat 9, 61 (2005) (citing ABA Section of Intell. Prop. L. 1999, Markman Survey, Intell. Prop. L. Newsletter, Spring 2000, at 12). And 80% of those cases admitted expert testimony. Id. Finally, 49% of the resulting claim construction rulings in those cases expressly relied on that expert testimony. Id.

Thus, in the course of construing claims, trial judges necessarily credit one expert's translation over another's. But judges are well situated to make such credibility determinations:

It may of course occur that persons experienced in a technologic field will have divergent opinions as to the meaning of a term, particularly as narrow distinctions are drawn by the parties or warranted by the technology. Patent disputes often raise close questions requiring refinement of technical definitions in light of particular facts. The judge will then be obliged to decide between contending positions; a role familiar to judges.

Verve, 311 F.3d at 1119–20; see also Anderson v. City of Bessemer City, 470 U.S. 564, 574 (1985) (recognizing the trial judge's role and superiority in assessing credibility and determining facts).

Although trial judges rely on expert testimony and other extrinsic evidence in their claim construction opinions, the Federal Circuit has largely ignored this evidence when reviewing claim construction. See Eric M. Dobrusin, Post-Cybor: Can Past Performance Dictate Future Practice?, IP Litigator, Sept.—Oct. 1998, at 9–10 (1998) (noting that in a study of all claim construction rulings over a certain period, the Federal Circuit mostly confined its review to the intrinsic evidence and rarely considered extrinsic evidence).

This pattern is alarming in two ways. First, it suggests that the Federal Circuit is replacing a specific finding on how one of ordinary skill would read a patent (the correct standard) with its own assumptions on how one of ordinary skill would read the patent. But the judges of the Federal Circuit are neither skilled artisans nor experts on how one of ordinary skill would read patents in every field of invention. Indeed, most Federal Circuit judges do not even have scientific or engineering backgrounds. Kimberly A. Moore, Markman Eight Years Later: Is Claim Construction More Predictable?, 9 Lewis & Clark L. Rev. 231, 245 (2005).

Second, it suggests that claim construction today depends more on the unintended meanings of a patent author's word choice than on the actual technology invented. As this Court recognized, "the nature of language makes it impossible to capture the essence of a thing in a patent application." Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 731 (2002). As a result, the "conversion of machine to words allows for unintended idea gaps." Id. (citation omitted). But expert testimony explaining how artisans in the relevant industry would understand a given patent helps fill in those idea gaps and thus restores to the patent a better representation of the "machine."

This pattern of ignoring the district court's careful sifting of extrinsic evidence also conflicts with the Federal Circuit's practice in validity disputes. For example, the relevant inquiry for the "anticipation" defense is what the alleged prior art patent or reference discloses to one of ordinary skill in the art. *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1349 (Fed. Cir. 2001). The outcome of that inquiry is reviewed with deference to the fact-finder. *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1323 (Fed. Cir. 2002). It is curious, therefore, that the Federal Circuit says in one instance (validity) that what a patent discloses is a question of fact, reviewed with deference, and in the other instance (claim construction), that what a patent discloses is a question of law reviewed *de novo*.

In summary, "facts are often central to the ultimate disposition of patent cases," including to claim construction. Rai, *supra*, at 878. But *de novo* review biases the Federal Circuit away from the underlying facts that help inform the understanding in the art. Accordingly, this *de novo* standard needs reform.

II. DE NOVO REVIEW INCREASES UNCERTAINTY AND THE COST OF LITIGATION

In Markman, this Court sought in part to shrink the "zone of uncertainty" in the patent system. 517 U.S. at 390 (citing General Elec. Co. v. Wabash Appliance Corp., 304 U.S. 364, 369 (1938)). When disputes arise over the metes and bounds of patent claims, litigants look to trial judges to construe the disputed claims and reduce uncertainty.

Yet since *Markman*, and particularly since the Federal Circuit solidified its *de novo* standard of review in *Cybor Corp. v. FAS Techs. Inc.*, 138 F.3d 1448 (Fed.Cir. 1998) (en banc), uncertainty as increased. In particular, the reversal rate has actually <u>increased</u> since the *Cybor* ruling, contrary to Markman's intent. Kimberly A. Moore, *Markman Eight Years Later: Is Claim Construction More Predictable?*, 9 Lewis & Clark L. Rev. 231, 246–47 (2005).

De novo review of claim construction makes district court rulings little more than costly (and often temporary) "first takes" at claim construction. Various studies have shown that the Federal Circuit's reversal rate for claim construction rulings is at least 30% to 40%, depending on the statistical method used. See, e.g., See Cheryl L. Johnson, The False Premise and Promise of Markman's Decision to Task Judges with Claim Construction and the Judicial Scorecard, 837 PLI/Pat 9, 64-66 (2005) (summarizing various empirical studies showing the reversal rate hovers near 40%); Christian A. Chu, Empirical Analysis of the Federal Circuit's Claim Construction Trends, 16 Berkeley Tech. L.J. 1075, 1104 (2001) (claim construction modified in 44% of cases in the study); Moore, Eight Years Later, supra, at 233 (finding that the Federal Circuit reversed 34.5% of the claims construction cases between 1996 and 2003).

These reversal rates are the highest by far in the federal court system. In comparison, only about 8% of all civil appeals are reversed. See Admin. Office of the U.S. Courts, U.S. Courts of Appeals—Appeals Terminated on the Merits, By Circuit, During the 12-Month Period Ending December 31, 2004 1 (2005). Some might interpret this contrast to suggest that trial judges do not understand patents—that they are not listening to the Federal Circuit, following its canons of claim construction, or seeing enough patent cases to gain experience in claim construction.

The BPLA, however, observes that trial judges do understand patents, work hard at doing so, and, importantly, understand when to defer to the expertise of those of ordinary skill in translating patented technology. Indeed, statistics show that a significant number of all patent cases arise in just ten district courts. Arti K. Rai, Specialized Trial Courts: Concentrating Expertise on Fact, 17 Berkeley Tech. L.J. 877, 880 (2002) (citing Kimberly A. Moore, Forum Shopping in Patent Cases: Does Geographic Choice Affect Innovation?, 79 N.C. L. Rev. 889 (2000)). This statistic suggests that the judges in these courts see enough cases to gain experience and thus facility with patents.

De novo review of claim construction does nothing to promote certainty among property owners or to diminish disputes. Early settlements become less likely when litigants know that an adverse claim construction in the trial court can be argued anew to the Federal Circuit. As such, de novo review creates little incentive to settle before trial. Kimberly A. Moore, Are District Court Judges Equipped to Resolve Patent Cases?, 15 Harv. J.L. & Tech. 1, 27-28 (2001); Johnson, supra, at 18. Not surprisingly, patent disputes go to trial at nearly twice the rate of general civil litigation. James Bessen & Michael J. Meurer, Lessons For Patent Policy From Empirical Research On Patent Litigation, 9 Lewis & Clark L. Rev. 1, 3 (2005) (citation omitted).

Correspondingly, litigation costs have skyrocketed because the prospect of *de novo* review and reversal prolongs litigation and compounds expenses. The Federal Circuit's high reversal rate is a strong incentive to litigate patent claims to judgment and appeal after receiving an early adverse claim construction ruling. Moore, *District Court Judges*, *supra*, at 27–28. Studies estimate that the median cost of patent litigation is about \$2 to 4 million, depending on the amount of damages at risk. Bessen & Meurer, *supra*, at 2 (*citing* Am. Intellectual Prop. Law Assoc., *Report of the Economic Survey 2003* (2003)).

In sum, de novo review of claim construction rulings discourages settlement, prolongs litigation, and compounds expenses. The ability of the patent system to promote certainty among property owners and diminish disputes has been weakened by the lack of deference to the trial courts.

III. A PROPOSED STANDARD OF REVIEW AND ITS APPLICATION TO THIS CASE

The BPLA proposes a standard of review that defers to the "evidentiary underpinnings" of claim construction. In particular, this Court has analogized claim construction to judicial exegesis of other written instruments, such as contracts. *Markman*, 517 U.S. at 381–2. The Federal Circuit holds that when trial courts receive evidence to resolve interpretation of contract terms, the Federal Circuit reviews the resulting findings of fact for clear error and reviews *de novo* the ultimate contract interpretation based on those facts. *C. Sanchez & Son, Inc. v. United States*, 6 F.3d 1539, 1544 (Fed. Cir. 1993).

Likewise, by analogy to contract cases, the Federal Circuit should review any factual findings underlying a trial judge's claim construction for clear error — particularly as to how one of ordinary skill would read the patent.

In this case, the trial judge found that, on cross-examination, Teva's own expert, Dr. Russell, admitted that one of ordinary skill would have read the patent as Merck proposes. The trial judge found that Dr. Russell "testified that Merck's proffered construction is the definition as it is described in the patent." See Merck's Appendix at 64a. This fact played an important role in the trial judge's construction of the disputed claims.

The Federal Circuit's opinion, however, nowhere mentions this testimony. Had the Federal Circuit deferred to this finding, it would have at least considered the point of view of one skilled in the art. The Federal Circuit thus would have avoided the battle of semantics over the word "about" and would have gotten closer to the machine, so to speak—closer to the methods and compositions claimed in Merck's patent.

CONCLUSION

The Boston Patent Law Association urges this Court to grant a writ of *certiorari* and to modify the Federal Circuit's *de novo* standard of review of claim construction rulings.

Respectfully submitted,

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