No. 05-236

In the Supreme Court of the United States

MERCK & CO., INC.,

Petitioner,

v.

TEVA PHARMACEUTICALS USA, INC.

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

REPLY BRIEF FOR PETITIONER

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REPLY BRIEF FOR PETITIONER

Teva's brief in opposition defends very little of what a divided panel actually said in reversing the district court and invalidating one of the most important patents in the pharmaceutical field. Rather, Teva's brief advances numerous factual contentions that the finder of fact did *not* accept, and legal contentions that are *not* the ones the Federal Circuit gave as its bases for reversing. Such a document – akin to first-instance proposed findings of fact and conclusions of law in a trial court – only underscores that the gravamen of Teva's case is issues it lost in the *trial* court, and that no sustainable basis for reversal on appeal existed. To reverse nevertheless, the Federal Circuit acted as if it were the original factfinder and adopted a new rule of law on commercial success, producing several dissents.

Teva does not dispute the continuing disagreement within the Federal Circuit, refute the disarray caused by that court's *de novo* approach to reviewing district court claim construction decisions, or even defend that approach. The Federal Circuit's insupportable methodology has become entrenched by three successive en banc cases[1] declaring and reaffirming that claim construction involves no underlying factual issues to which the "clearly erroneous" standard of Rule 52(a) attaches – a fundamentally mistaken position that warrants review by this Court.

Similarly, Teva does not defend the Federal Circuit's trampling of Rule 52(a) en route to declaring Merck's '329 patent invalid for obviousness under 35 U.S.C. § 103(a). Instead, Teva falsely presumes that the "same invention" was in the prior art – when in fact the prior art contained *no invention at all*. Thus, Teva avoids confronting the Federal Circuit's disregard of the district court's factual determinations concerning this Court's "*Graham* factors" and the secondary considerations required in

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[1] See *Phillips* v. *AWH Corp*., 415 F.3d 1303 (Fed. Cir. 2005) (en banc); *Cybor Corp*. v. *FAS Techs., Inc*., 138 F.3d 1448 (Fed. Cir. 1998) (en banc); *Markman* v. *Westview Instruments, Inc*., 52 F.3d 897 (Fed. Cir. 1995) (en banc), aff'd in part, 517 U.S. 370 (1996).

evaluating obviousness. Indeed, Teva recasts the Federal Circuit's invalidity rationale as rejecting a "legal" theory (Opp. 15) rather than defending its impermissible reweighing of the district court's detailed findings, even though the Federal Circuit summarily declared blanket "clear error" in every finding contrary to its desired invalidity outcome. Pet. App. 22a; see also Pet. App. 16a ("As explained below, we find clear error in the trial court's findings on these underlying facts.").

Finally, in defending the Federal Circuit's declaration that Merck's strong evidence of "commercial success" and "nexus" to the claimed invention was entitled to "no force," Teva ignores that the Federal Circuit again impermissibly reweighed this evidence *and* announced a new rule of law making a long-standing category of evidence irrelevant.

I. No Issue in this Case Is "Moot"

Teva tries to sidestep Merck's first question by alleging that the parties' vigorous dispute about claim construction is "moot." Opp. 8. Teva points to nothing outside of this litigation that has created any arguable source for the alleged mootness. Instead, Teva's "mootness" theory arises solely from the footnote in which the Federal Circuit's majority declared that "[i]t makes no difference to this conclusion [of invalidity] whether the court begins with the claim construction set forth by the panel or by the dissent." App. 16a n.10. Based on nothing more, Teva argues that correcting the Federal Circuit's flawed *de novo* methodology and erroneous construction in this case would not affect the outcome. Opp. 9. That is simply wrong.

As explained at Pet. 23 n.14, the Federal Circuit's footnoted attempt to insulate its claim construction approach and result from further scrutiny is belied by its own detailed claim construction analysis and its concession that its invalidity holding was reached "[i]n light of the corrected claim construction." Pet. App. 15a. At no prior point did Teva accept Merck's vastly different claim construction or contend that the parties' lengthy and hotly contested claim construction dispute was irrelevant. Even now, Teva tries to bolster the Federal Circuit's acceptance

of the claim construction rejected by District Judge Farnan. Opp. 9-13.

In this case, as in any other patent case, a complete and proper claim construction is a necessary prerequisite to and thus inextricably intertwined with any subsequent invalidity analysis. An exception to that rule cannot be created by a Federal Circuit footnote that really does nothing more than expose that court's result-oriented invalidity approach. In *Cardinal Chem. Co.* v. *Morton Int'l*, 508 U.S. 83 (1993), this Court halted the Federal Circuit's practice of vacating district courts' invalidity holdings (in cases with declaratory judgment counterclaims) on the ground that all invalidity issues were rendered "moot" once the Federal Circuit affirmed a finding of no infringement. Similarly, a declaration of the type in the Federal Circuit's footnote cannot moot this Court's ability to review the Federal Circuit's *de novo* claim construction.

Notwithstanding footnote 10, the Federal Circuit majority proved that it thought the parties' dispute about claim construction *did* matter to the outcome by resolving that dispute in a lengthy discussion, which the court presumably did not intend to constitute a mere advisory opinion. The court even described its reversal on obviousness as being reached "[i]n light of the corrected claim construction." Pet. App. 15a. Judge Rader's panel dissent focused *entirely* on claim construction, reflecting his view that claim construction had "consequences" (Pet. App. 26a) in this "very close case" (*id*. at 33a) in which the district court's "diligent and intelligent process *and resolution* earned more respect than it received" (*id.* (emphasis added)).[2]

Teva asserts that "the difference between exactly 70 mg * * * and 80 mg, specified by the *Lunar News*, is not a distinc-

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[2] It is fanciful to suggest (Opp. 7) that Judge Rader did not urge a different outcome for this case. Judge Rader's repeated references to the closeness of this case, his express citation of the district court's *resolution* of the case, and the very labeling of his opinion as a dissent rather than a concurrence in the judgment all confirm that he would have affirmed rather than reversed the district court.

tion that could make Merck's invention unobvious." Opp. 9. It is, however, no mere coincidence that the district court rejected both Teva's claim construction and its obviousness defense, whereas the Federal Circuit accepted both. The district court correctly understood that such a dosing difference can be significant within the art, and found that Teva's evidence at trial failed to prove the equivalence of the two doses. "[A]lthough Dr. Russell testified that 80 mg and 70 mg are the same for all practical purposes, * * * in rendering his opinion Dr. Russell did not take into account this Court's construction * * *. Dr. Russell provided no evidence to support his conclusion that 70 and 80 mg were equivalent." Pet. App. 72a. Not only were the validity findings tied to the claim construction, but the *finder of fact* was not persuaded that the difference between 80- and 70-mg doses is insignificant based on the evidence at trial. Teva and the Federal Circuit have no legal basis for insisting on such a finding.

II. This Court Should Review and Reject the Federal Circuit's Refusal to Give Deferential Review to Factual Findings Underlying Claim Construction

Other than its incorrect "mootness" contention, Teva offers nothing to rebut Merck's showing why resolution by this Court of the correct manner of appellate review applicable to district court claim constructions rulings is critically important. Indeed, Teva's conspicuous refusal to cite, much less defend, the Federal Circuit's en banc decisions in *Markman*, *Cybor*, and *Phillips* confirms the need for this Court to review and correct that clearly flawed appellate methodology. See Pet. 18-19 & n.8.

Teva's efforts to defend the merits of the Federal Circuit's *de novo* claim construction are misplaced and mistaken. First, as Judge Rader pointed out, "[t]his is the classic 'close case,' so close in fact that ultimately two federal judges (one of whom conducted an entire bench trial on this issue) and the United States Patent and Trademark Office agreed with [Merck] and two federal judges agreed with [Teva]." Pet. App. 32a. This is exactly the kind of case where there could be no clear error in

the underlying findings. *Anderson* v. *City of Bessemer City*, 470 U.S. 564, 574 (1985). Hence, if this Court decides that claim construction does involve resolving underlying issues of fact, it would be immaterial whether this Court or the Federal Circuit agrees with Merck or with Teva. *Id.* at 573-574. Resolution of the question posed would be determinative of the disputed claim phrase here – the district court's admittedly reasonable construction would have to be accepted, even if an appellate court conceived a construction it thought "more reasonable." Pet. App. 13a.

As the district court understood, the '329 patent contains an explicit definition for the entire claim phrase that was truly at issue. Claim 23, the only claim addressed in Teva's opposition, recites "[a] method for treating osteoporosis * * * comprising administering *about 70 mg of alendronate monosodium trihydrate, on an alendronic acid basis*." Pet. 3. The definition explicitly states that "the phrase 'about 70 mg of a bone resorption inhibiting bisphosphonate selected from the group consisting of alendronate, pharmaceutically acceptable salts thereof, and mixtures thereof, on an alendronate acid active weight basis' *means* that the amount of the bisphosphonate compound selected is calculated based on 70 mg of alendronic acid." Pet. 7 (quoting C.A. App. 3594-95) (emphasis altered). Thus, the specification defines the entire phrase within quotes, not just for the word "about" and not just for the phrase "about 70 mg" that appear within the overall defined phrase.

Neither Teva nor the Federal Circuit has made any attempt to be faithful to what the patent says the disputed phrase "means." The Federal Circuit resorted to declaring its "belie[f]" that the patent's definitional clarity was "likely an inadvertent error," Pet. App. 13a n.8, an exercise of appellate factfinding so bizarre that Teva says not one word in defense of it. Yet Teva resorts to what may be an even more bizarre tactic, simply omitting the word "means" from its quotation of the patent's definition – despite emphasizing that the key question is whether the specification says in so many words what the key phrase "*means*." See Opp. 10. Such gymnastics to avoid the patent's

clear definition both show the error of the decision below and confirm that the standard of review mattered greatly in this case.

In any event, resolution of any ambiguity in the claim language requires a trial court to evaluate the conflicting evidence cited by both parties bearing on the ambiguous word or phrase. Merck's citation to certain portions of the specification and Teva's citation to others does not change the fundamental nature of the pertinent inquiry – a resolution of conflicting evidence, which is factfinding, even when done by a trial court on a matter reserved for its (rather than a jury's) decision. Thus, as amicus BPLA observes, "this case * * * provides an excellent opportunity to reconsider the Federal Circuit's *de novo* review standard." BPLA Amicus Br. 4.

Second, Teva's defense of the Federal Circuit's claim construction misdirects this Court by addressing a claim phrase that was never at issue. Contrary to Teva's position, no one at trial disputed the ordinary meaning of the term "about" and no court should have decided whether Merck's specification clearly redefined the claim phrase "about 70 mg" to mean "exactly 70 mg." Opp. 9. Even if the meaning of the term "about" or "about 70 mg" were both at issue and ambiguous, resolving their meaning would similarly be a question of fact to be determined by weighing the conflicting evidence related to those terms.[3]

Finally, Teva complains that Merck would require the Federal Circuit always to defer to a district court's construction even if it was contrary to the entire patent. Opp. 12. That is untrue. First, if all the evidence supports only one reasonable interpretation, there is no ambiguity, and no factfinder should find otherwise. In that case, a district court's contrary construction

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[3] Where expert or inventor testimony is offered, credibility determinations may also factor into a trial court's fact finding. See Pet. 8. No Merck witness testified on the meaning of "about 70 mg" because that phrase was not at issue. Opp. 12. While Teva concedes that the district court did not credit Teva's expert on that phrase, Teva ignores that the district court recognized that Dr. Russell understood the specification's express definition for the entire claim phrase at issue. Pet. 8.

can and should be reversed, as would any other factfinding on which the evidence permits no reasonable dispute. See *Warner Jenkinson Co.* v. *Hilton Davis Chem. Co.*, 517 U.S. 17, 39 n.8 (1997). Here, however, Teva merely recites its version of the disputed evidence in disregard of Merck's directly contrary evidence credited by the finder of fact (Pet. App. 58a-64a). This highlights rather than disproves the existence of underlying factual disputes that were plausibly resolved at trial.

Teva's opposition also confirms that the Federal Circuit's form of *de novo* review wrongly encourages patent litigants to proceed on appeal as if they have free license to reargue the factual issues underlying their claim construction positions from scratch. This Court should not allow the Federal Circuit to ignore Rule 52(a) any longer. Moreover, there can be no question that the Federal Circuit's *de novo* methodology that refuses to accord Rule 52(a) deference to district court fact findings has spawned widespread and unacceptable confusion, unpredictability, and uncertainty in patent cases for more than a decade. See Pet. 18-19; BPLA Amicus Br. 9-11. The time has come for this Court to review that entrenched but controversial Federal Circuit practice, and this "classic 'close case'" (Pet. App. 32a) is the perfect vehicle in which to do so.

III. This Court Should Correct the Federal Circuit's Insistence that Any Factual Finding that Got in the Way of the Majority's Obviousness Conclusion Was Automatically "Clearly Erroneous"

With obviousness, as with claim construction, Teva refuses to address or refute the substance of Merck's challenge to the Federal Circuit's increasingly bold disregard of the limits on its appellate review authority under Fed. R. Civ. P. 52(a). Contrary to Teva's assertion (Opp. 13), Merck is not seeking to alter an appellate court's role as specified by this Court in *Bessemer City*, but is urging this Court to rein the Federal Circuit back into operating within those important limits. Hence, Teva has left wholly unrebutted Merck's showing that the Federal Circuit's approach to *de novo* review of claim construction has equally infected its approach when reviewing other legal issues

such as obviousness that indisputably have underlying factfindings. See Pet. 23-24.

Teva's opposition argues invalidity on the ground – *not* accepted by the Federal Circuit – that the "same invention" was allegedly in the prior art, rather than confronting the district court's explicit and detailed findings (Pet. App. 83a-94a) showing why the differences between Merck's invention and the prior art as a whole were nonobvious. Even the Federal Circuit agreed that the *Lunar News* articles did not disclose the "same invention" as the '329 patent and thus could not anticipate under 35 U.S.C. § 102. Pet. App. 16a. Indeed, the *Lunar News* articles on which Teva and the Federal Circuit exclusively rely do not disclose an invention, but merely contain an untested suggestion and a hope for future improvements.

The two *Lunar News* articles merely state that alendronate "*potentially could be* given in a 40 or 80 mg dose once/week" or that "[a]n intermittent treatment program (for example, once per week * * *) * * * *needs to be tested*." C.A. App. 3677, 3641 (emphasis added). Teva's Wright Brothers analogy (Opp. 16 n.4) usefully illustrates the point: Teva's premise that the *Lunar News* suggestions constitute an earlier invention of the '329 patent would mean that the Wright Brothers' patents would have been invalidated by countless articles in the pre-1900s predicting that man one day potentially could build bird-like flying machines and suggesting that such ideas need to be tested.

The critical question for this Court's review is whether to condone the Federal Circuit's cavalier practice of reaching its own legal conclusion before announcing its disregard or reversal of any contrary district court finding. The issue is not whether this Court would agree in the first instance with Merck and the district court or with Teva and the Federal Circuit on whether Merck's invention was obvious. Rather than trying to defend the Federal Circuit's inverted approach, Teva advances the preposterous propositions that the Federal Circuit merely rejected "Merck's legal theory" (Opp. 15) and "did not base its decision on a rejection of district court fact findings." Opp. 16. It is telling that Teva mischaracterizes the Federal Circuit's stated

basis for its obviousness conclusion rather than attempting to justify the court's *de novo* review methodology.

Contrary to Teva's premise, Merck's nonobviousness proof did not require "nullifying" the Lunar News articles as prior art, nor did Merck's position require the district court to find that Dr. Mazess was not an expert. Opp. 6, 15-16. Instead, Merck rebutted Teva's evidence with extensive evidence showing that Dr. Mazess's untested conjecture would not have persuaded those skilled in the art of treating osteoporosis patients at the pertinent time that alendronate could be safely administered at doses higher than 20 mg. See Pet. 9-10. Regardless of his credentials, the district court properly weighed all the conflicting evidence, including the other prior art and expert testimony, and found that Dr. Mazess's naked suggestions provided no advance to the art and could not overcome the prior art teachings as a whole. See Pet. 25-27. Thus, it is the Federal Circuit's *sua sponte* findings on appeal that are unsupported. Its invalidity conclusion is the product of improper reweighing of disputed evidence and result-oriented hindsight, a continuing problem in that court worthy of this Court's review.

IV. As the Amicus Briefs Attest, the Federal Circuit's Refusal to Give Weight to the Commercial Success of an Improvement Patent Merits Review

Merck offers two main points regarding Teva's lengthy but mostly irrelevant defense of the Federal Circuit's misguided new rule disabling the probative value of commercial success evidence in cases where a patentee improves its own patented invention. Pet. App. 23a-24a. First, the most Teva can assert now is that the commercial success of Merck's once-weekly Fosamax® product "is not necessarily attributable to its non-obviousness." Opp. 18. On its face, a proposition that is "not necessarily" true is the epitome of a disputed factual question, which the district court resolved in favor of Merck. Pet. App. 91a-93a. The Federal Circuit's and Teva's preference that the district court have given Merck's evidence less weight is not a proper basis for inventing on appeal a new rule of law that throws that evidence out altogether.

Second, the Federal Circuit's new rule creating a broad and virtually irrebuttable presumption discriminating against patent owners that have prior market exclusivity is ill conceived, unfounded, and contrary to the fundamental premise of the patent system to encourage innovations over current technology. Pet. 28-29; PhRMA Amicus Br.; Procter & Gamble Amicus Br. Notably, Teva does not acknowledge or explain its own efforts to develop alendronate-based osteoporosis treatment inventions, despite Merck's existing exclusivities. See Pet. 29. Teva also offers no justification for creating this obstacle to obtaining improvement patents. See Pet. 28-29. If improvement patents are encouraged only at spaced intervals of 20 years, the constitutional goal of promoting progress of science and useful arts will certainly be thwarted.

As further detailed in the PhRMA amicus brief, the Federal Circuit's assumption that no one else has incentive to innovate in the face of existing patent or other market exclusivity is simply wrong. See PhRMA Br. 11-13 (listing incentives from obtaining separate patent rights, licensing or cross-licensing opportunities, foreign sales and licensing, and further research incentives). On that basis alone, the rule should be reviewed and reversed by this Court. Taken as a whole, the defective factual assumptions underlying the Federal Circuit's new rule confirm why such rulemaking is better done by Congress, not the courts.

CONCLUSION

For the reasons stated above and in the petition, Merck's petition for a writ of certiorari should be granted.

Respectfully submitted,

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