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No. 08-937

IN THE
Supreme Court of the United States

AVENTIS PHARMA S.A.
AND AVENTIS PHARMACEUTICALS INC.,
Petitioners,

v.

AMPHASTAR PHARMACEUTICALS, INC.
AND TEVA PHARMACEUTICALS USA, INC.,
Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

REPLY BRIEF FOR PETITIONERS

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RULE 29.6 STATEMENT

The corporate disclosure statement included in the petition for a writ of certiorari remains accurate.

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REPLY BRIEF FOR PETITIONERS

While this petition has been pending, the Chief Judge of the Federal Circuit has publicly acknowledged that court's conflicting standards for inequitable conduct.[1] Another Federal Circuit judge has also noted not only this conflict, but also the conflict with this Court's precedent, the impropriety of the standard challenged in this petition, and the need for a more stringent and uniform standard.[2] And one of the Senate's leading proponents of patent reform has also emphasized the exceptional importance of the issue, and (joining numerous judges, scholars, practitioners, and national organizations) noted the acute need for its resolution.[3]

In light of developments such as these, respondents cannot deny that virtually every knowledgeable observer of our patent system has concluded

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1 *See* Nate Raymond, *A Full-Court Press for Patent Credibility: Criticized for Decisions and Threatened by Congress, the Federal Circuit Starts Playing Some Public Defense*, LEGAL TIMES, Mar. 16, 2009, at 13.

2 *Larson Mfg. Co. of S.D.* v. *Aluminart Prods. Ltd.*, No. 2008-1096 (Fed. Cir. Mar. 18, 2009) (Linn, J., concurring); *see also* Nate Raymond, *What's the Right Standard for Inequitable Conduct? A Federal Circuit Judge Calls for the Court to Make Up Its Mind*, The AmLaw Litigation Daily, Mar. 20, 2009, http://www.law.com/jsp/tal/digestTAL.jsp?id=1202429247251.

3 Senator Orrin G. Hatch, Address to the United States Court of Appeals for the Federal Circuit Symposium at 3-4 (Mar. 18, 2009), http://legaltimes.typepad.com/files/03182009-press-club-speech.pdf (explaining, *inter alia*, that the current application of the doctrine encourages applicants to "deluge" the PTO with information, and that reform of the doctrine will thus "have the most favorable impact on patent quality and the ability for the USPTO to reduce its pendency").

that the inequitable conduct doctrine is in disarray. Nor can respondents credibly contest the other factors that demonstrate the need for this Court's review: This Court has not revisited the doctrine in more than 60 years, the lower court decisions are in conflict with one another and this Court's precedents, and the internally divided Federal Circuit has passed up repeated opportunities to take this issue en banc, including in this case. And despite all this, the pending reform legislation does not deal with the issue at all. Thus, the task of sorting out this important aspect of patent law falls on this Court, as it has in other contexts in recent Terms. *See KSR International Co.* v. *Teleflex Inc.*, 550 U.S. 398, 426 (2007); *eBay Inc.* v. *MercExchange LLC*, 547 U.S. 388 (2006). The inequitable conduct doctrine in patent cases is judge-made in every sense, and can (and should) be shaped by the Judiciary to conform to the broader policies of the Progress Clause and the Patent Act.

This case is a particularly appropriate vehicle for this Court to revisit the inequitable conduct doctrine. The decision below, which strips Aventis of patent rights in a drug with billions of dollars in annual sales, is an affront to the traditional principles of equity on which it purports to be based. Review is warranted now.

1. The question presented is whether an inequitable conduct determination may be premised on a sliding scale between intent and materiality. *See* Pet. i. In apparent recognition that this question warrants review, respondents devote much of their energies to denying that it is even presented. Amphastar Opp. i; Teva Opp. i. They are, of course, quite wrong. Respondents' contention that the courts below did not employ a sliding scale of intent and materiality is completely, conclusively, and unequivocally refuted by the opinions that both the dis-

trict court and the court of appeals issued to explain their respective decisions in this case.

The district court could hardly have been clearer: "The more material the omission or the misrepresentation, the lower the level of intent required to establish inequitable conduct." Pet. App. 49a (internal citation omitted); *see also id.* at 87a (finding intentional misconduct because "[t]he elements of nondisclosure and high materiality have been admitted, and no credible excuse demonstrated").

The Federal Circuit majority was just as clear: "'[T]he more material the omission or misrepresentation, the less intent that must be shown to elicit a finding of inequitable conduct.'" Pet. App. 18a (internal citation omitted).

Judge Rader dissented on this very point, criticizing the improper "[m]erging [of] intent and materiality" under the majority's standard, and highlighting several previous cases in which the Federal Circuit had "emphasized materiality almost to the exclusion of [the] intent requirement." Pet. App. 33a (dissenting opinion).

Judge Rader is right. As we described in the petition (at 13), the non-disclosure of material information is a necessary but not sufficient element of fraud or inequitable conduct. The complainant also must prove that the material information was *intentionally* withheld. Under the sliding scale, however, intent is conflated with materiality, effectively permitting a finding of inequitable conduct to be predicated on as little as a negligent omission. *See Larson Mfg. Co. of S.D.* v. *Aluminart Prods. Ltd.*, No. 2008-1096, slip op. at 5 (Fed. Cir. Mar. 18, 2009) (Linn, J., concurring) (explaining that the two prongs at which the Federal Circuit looks before inferring intent are not "evidence of deceptive intent. The first is evidence of materiality; the second is evidence of negligence.").

This standard makes a complete mockery of this Court's inequitable conduct and fraud precedents. *See* Pet. 10-19.

2. After denying that the decisions below mean what they say, respondents maintain that Aventis "waived" any challenge to the sliding scale. Nonsense.

The fact that the Federal Circuit, as well as the district court, applied the sliding scale to find intent to deceive wholly disposes of respondents' waiver contention. This Court "may address a question properly presented in a petition for certiorari if it was 'pressed [in] *or passed on*' by the Court of Appeals." *United States* v. *Wells*, 519 U.S. 482, 488 (1997) (citation omitted; emphasis added); *see also United States* v. *Williams*, 504 U.S. 36, 41 (1992) (following "traditional rule" that "permit[s] review of an issue not pressed so long as it has been passed upon"). Accordingly, there can be no dispute that the question presented has been effectively preserved for review.

Moreover, Aventis objected to the finding of intent to deceive (Aventis C.A. Br. 44-58), and in this Court it "can make any argument in support of that claim; parties are not limited to the precise arguments they made below." *Yee* v. *City of Escondido*, 503 U.S. 519, 534-535 (1992).

In short, Aventis consistently argued that respondents failed to prove the legal requirements for finding intent to deceive; the district court rejected these arguments as "contrary" to the sliding scale standard (Pet. App. 82a); when Aventis urged the Federal Circuit to reverse the district court's legally and factually erroneous determination of intent (Aventis C.A. Br. 44, 58), *respondents* urged the panel to apply the sliding scale, arguing that "'[f]ailure to disclose highly material information

known to the patent applicant" is sufficient to show intent to deceive "in the absence" of proof by Aventis of its innocence (Teva C.A. Br. 31); the panel expressly passed on the issue, applying the sliding scale; the dissent criticized the majority for applying the sliding scale; and Aventis then explicitly challenged the sliding scale at the rehearing stage—the first point at which the Federal Circuit could have overturned settled precedent. Respondents' suggestion that this is still not enough to preserve the issue lacks merit.

3. Perhaps recognizing that the courts below applied a legally impermissible *standard*, respondents devote most of their attention to the *facts* of this case. Even if respondents were right on the facts, the confusing, contradictory, and incorrect standard applied in this and other inequitable conduct cases would still warrant review by this Court.

And of course, respondents are just wrong on the merits. As we discussed in the petition (at 13-16), even assuming that the omission was material—a question on which Judge Rader expressed grave doubt in light of the PTO's subsequent reissue of the patent without reliance on Example 6—respondents failed to prove that the omission was intentional. All that the lower courts found was materiality and that *Aventis* could not *disprove* intent. Thus even accepting every one of the district court's factual findings, they do not satisfy this Court's standard for fraud or inequitable conduct: clear and convincing proof by *respondents* of intent. *See Larson Mfg.*, slip op. at 5 (Linn, J., concurring) (the evidence of materiality and negligence based on which the Federal Circuit shifts the burden to the patentee to disprove intent is "insufficient as a matter of law to establish a clear and convincing 'threshold level' of deceptive intent before the [burden-shifting] prong can ever properly

come into play"). That is purely a legal error, and it was caused by the Federal Circuit's sliding scale, which eliminated the separate requirement of proving intent to deceive and shifted the burden of proof to Aventis to demonstrate a credible explanation for the nondisclosure once high materiality was shown. *See* Pet. App. 87a (inferring intent because "[t]he elements of nondisclosure and high materiality have been admitted, and no credible excuse demonstrated"); *see also, e.g., Am. Hoist & Derrick Co.* v. *Sowa & Sons, Inc.*, 725 F.2d 1350, 1363 (Fed. Cir. 1984) (a high showing of materiality "would necessarily create an inference that its nondisclosure was 'wrongful'").

Such legal error is "by definition" an abuse of discretion. *Koon* v. *United States*, 518 U.S. 81, 100, 116 (1996); *see also Cooter & Gell* v. *Hartmarx Corp.*, 496 U.S. 384, 400-402 (1990). That is a complete response to respondents' invocation of the abuse-of-discretion standard. It also dispels any notion that this case is unduly fact-bound: All fraud cases come from particular facts, but they merit this Court's attention when those facts are analyzed under the wrong legal standard. *See, e.g.*, *Ernst & Ernst* v. *Hochfelder*, 425 U.S. 185 (1976).

Respondents also observe that intent may be proved by circumstantial evidence. Teva Opp. 10-11. But that uncontroversial proposition is not at issue here. *See* Pet. 16 n.3. By focusing on the type of evidence, respondents hope to obscure the more fundamental point that intent is an *essential element* of their claim, on which *they* bore the *burden of proof*. The invocation of the sliding scale in the courts below relieved respondents of that burden, and thus no court has found, under the proper legal standard, whether respondents proved intentional misconduct *with any kind of evidence*.

Indeed, this Court has recognized that a legal test that impacts the burden of proof is often outcome-determinative. *See In re Winship*, 397 U.S. 358, 367-68 (1970); *Philadelphia Newspapers, Inc.* v. *Hepps*, 475 U.S. 767, 778 (1986). This case is no exception from that rule: Judge Pfaelzer, the district judge who presided over the inequitable conduct proceedings, has in fact indicated that the court might reach a different result under the standard proposed by Aventis in this Court. In an opinion addressing Amphastar's antitrust counterclaims in the same litigation, issued while this petition was pending, the district court expressly acknowledged its prior factual findings but noted—citing the petition filed in this Court—that Aventis has advanced a good-faith argument for a change in the law that could alter the result.[4]

4. Respondents also attempt to downplay the Federal Circuit's departure from this Court's precedent, arguing that there is nothing in this Court's inequitable conduct cases "that suggests that the application of the doctrine of inequitable conduct is limited to the extreme conduct identified in those cases." Teva Opp. 17-18. But in doing so, they concede that the conduct here is not the kind of "extreme conduct identified in those cases," while at the same time failing to recognize that it is not only the actual facts of those cases, but also this Court's requirement of *deceptive intent* that cannot be squared with the sliding scale and its resulting *negligence* standard.

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[4] *See Aventis Pharma S.A.* v. *Amphastar Pharms., Inc.*, No. 03-00887, slip op. at 16 (C.D. Cal. Feb. 17, 2009) ("Even though Aventis' factual position suffered from 'a total absence of indicia of credibility,' . . . , [Aventis's petition for certiorari] has made credible legal arguments to change the law or to adopt a not-unreasonable legal interpretation *that may change the legal implications of the facts*") (emphasis added).

Respondents' attempt to distinguish this Court's non-patent decisions addressing the intent element of fraud actions fares no better. By arguing that *Ernst & Ernst* and other cases have "nothing to do with determining intent to deceive in the context of inequitable conduct" (Teva Opp. 14 n.3), respondents are asking the Court to recognize a special rule (and a more lenient one at that) for patent cases than other federal-law cases. As we show in the petition (at 15), the Court's recent patent decisions, in sharp contrast, uniformly hold that patent litigants are subject to the *same* standards as parties to other complex federal litigation.

In this regard, it bears noting how little either respondent has to say on the "one size fits all" remedy imposed by the Federal Circuit—upon a finding of inequitable conduct, a patent is automatically rendered unenforceable with no weighing of the equities. Such an inflexible bright-line rule is inconsistent with the equitable moorings of the doctrine, and runs smack into this Court's decision in *eBay*, 547 U.S. at 391-92, which reminds lower courts that equitable principles must be applied equitably in patent cases. There is nothing equitable about the result here.

5. Finally, respondents suggest that review is unwarranted because the inequitable conduct doctrine plays an important role in our patent system. But Aventis does not dispute that the doctrine is important; our concern is not with the doctrine itself, but with its haphazard and overly lenient application, with the result that all participants in the patent system have no clear rules by which to guide their conduct, and the owners of extremely valuable patents may have them stripped by one panel and sustained by another. We think the standard should be more rigorously tailored to instances of actual fraud on the PTO; but at minimum it should be uni-

form to ensure a level playing field for all. The National Academies of Science and Engineering, the ABA Section of Intellectual Property Law, a number of Federal Circuit judges, and various *amici* agree. *See, e.g.*, Pet. 26-28. This Court should step in to clarify the burden and standard for proving inequitable conduct, and to address the remedy for such conduct if proved.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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