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

BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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QUESTION PRESENTED

Whether a court may refuse to enforce an otherwise valid patent on the basis of an inequitable conduct determination premised on a sliding scale between intent and materiality, with no weight whatsoever given either to the magnitude of the patent holder's blameworthiness or to whether patent examiners were ever misled.

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BRIEF OF WASHINGTON LEGAL FOUNDATION AS AMICUS CURIAE IN SUPPORT OF PETITIONERS

INTERESTS OF *AMICUS CURIAE*

The Washington Legal Foundation (WLF) is a non-profit public interest law and policy center with supporters in all 50 States.[1] WLF devotes a substantial portion of its resources to defending free-enterprise, individual rights, and a limited and accountable government.

In particular, WLF has appeared in numerous federal and state courts in cases raising issues related to health care delivery. *See, e.g., Pharmaceutical Research and Manufacturers of America v. Walsh,* 538 U.S. 644 (2003). WLF successfully challenged the constitutionality of Food and Drug Administration (FDA) restrictions on speech regarding off-label uses of FDA-approved products. *Washington Legal Found. v. Friedman,* 13 F. Supp. 2d 51 (D.D.C. 1998), *appeal dism'd,* 202 F.3d 331 (D.C. Cir. 2000). WLF also has participated in numerous court proceedings raising important issues regarding the scope and validity of pharmaceutical patents. *See, e.g., Purdue Pharma, L.P. v. Endo Pharmaceuticals, Inc.,* 438 F.3d 1123 (Fed. Cir. 2006) (opposing efforts to invalidate patent on grounds of inequitable conduct); *Ferring B.V. v. Barr Labs., Inc.,*

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[1] Pursuant to Supreme Court Rule 37.6, WLF states that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than WLF and its counsel, made a monetary contribution intended to fund the preparation and submission of this brief. More than ten days prior to the due date, counsel for WLF provided counsel for Respondents with notice of its intent to file this brief.

437 F.3d 1181 (Fed. Cir.), *cert. denied*, 549 U.S. 1015 (2006) (same).

WLF strongly supports providing patent protection to pharmaceutical manufacturers that develop new and useful drugs. WLF believes that if advances in health care are to continue, it is vital that companies that develop new drugs and medical devices be afforded a substantial period of exclusivity, during which potential competitors are not permitted to market the same product. That exclusivity period provides an economic incentive for new product development by ensuring that pharmaceutical companies that gamble the substantial sums necessary for the development of new therapies will be able to reap substantial rewards in those few instances in which their research and development expenditures bear fruit.

WLF also recognizes that Congress has imposed limits on patent rights and that those limits must be strictly enforced by the courts if competition is to be maintained. Nonetheless, WLF believes that the Federal Circuit's decisions in this and similar cases – which have invalidated numerous important patents on judge-made inequitable conduct grounds – have the potential to undermine our nation's patent system if allowed to stand. WLF is concerned that the Federal Circuit's "inequitable conduct" case law has drifted far afield from its "unclean hands" roots. By lowering the bar for those charging patent invalidity due to inequitable conduct, the Federal Circuit has considerably increased the risks to those asserting patent rights and considerably reduced the market value of all patents. WLF is concerned that if the property rights of patent holders can be so easily

eliminated, the public will quickly lose faith in the viability of our patent system.

WLF is filing this brief because of its interest in promoting the stability of the nation's patent system; it has no interest, financial or other, in the outcome of this lawsuit. Because of its lack of direct economic interests, WLF believes that it can assist the Court by providing a perspective that is distinct from that of any party. WLF is filing its brief with the consent of all parties; letters of consent have been lodged with the Court.

STATEMENT OF THE CASE

This case raises important issues regarding the circumstances under which it is appropriate for federal courts to decline to enforce an otherwise valid patent, on the grounds that the patent holder engaged in inequitable conduct before the U.S. Patent and Trademark Office (PTO).

Petitioners Aventis Pharma S.A., *et al.* (collectively, "Aventis"), developed (and for a number of years have been marketing) Lovenox®, a drug approved by the Food and Drug Administration (FDA) for prevention and treatment of thromboses (*i.e.*, blood clotting).

Because of Lovenox's commercial success, numerous generic drug companies are interested in marketing a generic form of Lovenox. But federal law prohibits a generic drug company from doing so, for so long as Aventis's patent on Lovenox (and on the process of making it) remains in place. Accordingly, several generic drug companies, including Respondents

Amphastar Pharmaceuticals, Inc. and Teva Pharmaceuticals USA, Inc., challenged Aventis's patent (the "'618 patent") by including – in applications to FDA for permission to market generic versions of Lovenox – an allegation that the '618 patent was invalid.

Aventis thereafter filed a suit for patent infringement against Amphastar and Teva. It was essentially forced into litigation by the invalidity allegation; had it not responded to the allegation by filing suit, Amphastar and Teva could have obtained permission from FDA to begin generic marketing immediately. Amphastar and Teva counterclaimed, alleging that the '618 patent was invalid on several grounds, including that it had been obtained through inequitable conduct.

The inequitable conduct allegation centered around Aventis's omission of allegedly material information from its patent application. In her initial response to Aventis's patent application, the patent examiner (PE) had indicated that the application was deficient both because the invention was anticipated by prior art (and thus did not meet the patentability requirements of 35 U.S.C. § 102) and because its subject matter would have been obvious to a person having ordinary skill in the art (and thus did not meet the patentability requirements of 35 U.S.C. § 103). In response to the PE's concerns, Aventis submitted a wide range of materials, including materials designed to demonstrate that its invention had increased stability in comparison to the prior art. To demonstrate that increased stability, Dr. Andre Uzon (acting on behalf of Aventis) submitted material comparing the half-life for its invention with the half-life of the prior art. The

submitted materials disclosed that the half-life for the invention was measured using 40 mg and 60 mg dosages, but they did not disclose the dosage at which the half-life of the prior art was measured (it was 60 mg). Amphastar and Teva argue that the omitted dosage was material because a reasonable PE would have wanted to know that Dr. Uzon, in comparing the half-life of a 40 mg dosage of the invention to the half-life of the prior art, was comparing two substances at different dosages.

By the time the PE issued the Third Office Action on March 2, 1993 (*id.* at 43a), she had withdrawn her anticipation objection under § 102, but she continued to raise obviousness objections under § 103. Pet. App. 9a, 25a. The PE stated that the "[a]pplicant has failed to provide evidence that the alleged difference between the half-life of the [prior art] and that of the [claimed] mixture is statistically significant." *Id* at 10a. In other words, the PE could not have relied on evidence regarding differences in half-lives in deciding to withdraw her anticipation objection, but rather must have relied on other types of evidence submitted by Aventis to establish the absence of anticipation. *See, e.g., id.* at 5a, 8a, 22a.[2]

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[2] The purposes for which Dr. Uzan submitted half-life comparisons bears on the issues of materiality and intent. The courts below and the parties agreed that a comparison between half-lives of two substances is not relevant to § 102 anticipation issues if they are being compared at different dosages (*see, e.g., id.* at 63a-65a), and thus a reasonable patent examiner when evaluating anticipation would want to know if the dosages were different. Aventis contends that Dr. Uzan was making those comparisons for the purpose of demonstrating nonobviousness, not for the purpose of refuting anticipation. Because Dr. Uzan

The PE ultimately withdrew the obviousness objections as well, and the '618 patent was issued. In an apparent effort to demonstrate that the half-life comparisons contained in Example 6 were irrelevant to patentability, Aventis resubmitted its patent application without including Example 6. In response to that resubmission, the PTO issued Aventis a new patent with identical claims (the '743 patent) prior to any substantive district court decision in this case.

On April 10, 2006, the Federal Circuit affirmed the district court's summary judgment determination that Aventis's omission of prior art dosage information in connection with the half-life comparison was a "material" omission. *Id.* 95a-109a. The appeals court held that there was no genuine issue that "a reasonable examiner would have considered [the dosage information] important in deciding" whether to grant the patent, and thus that Aventis's omission was "material" as a matter of law. *Id.* 100a.

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submitted his two declarations after the Third Office Action was issued in March 1993 (and thus after the PE had withdrawn the anticipation objection), there is no basis for concluding that the statements regarding half-life comparisons contained in those two declarations were made for the purpose of refuting anticipation. Dr. Uzon's first declaration was submitted on March 29, 1993 (*id.* at 45a n.4), four weeks after the Third Office Action was issued – albeit the Federal Circuit included language in its decision suggesting that it believed that the anticipation issue might still have been open at the time the first declaration was submitted. *See id.* at 24a-25a. Although Example 6 in the '618 patent application (submitted several years prior to the Third Office Action) included half-life comparisons while omitting dosage information for the prior art, the language from the Third Office Action (quoted in the text) makes plain that the PE did not rely on those half-life comparisons in deciding to withdraw the anticipation rejection.

On remand, the district court chose not to focus on validity and infringement issues, but rather conducted a trial that addressed only the "inequitable conduct" defense. After trial, the district court concluded that Aventis had, indeed, engaged in inequitable conduct in pursuing its patent application and thus it declared the '618 and '743 patents unenforceable. *Id.* at 39a-91a. Based on its finding that Aventis did not provide an adequate explanation for its failure to include dosage information that it should have known was material, the district court determined that Aventis intended to deceive the PTO. *Id.* at 90a.[3] *See also id.* at 87a (intent to deceive can be inferred because Aventis knew or should have known that highly material information was omitted, and provided "no credible excuse" for the omission).

The district court recognized that findings of materiality and intent to deceive did not end the matter; rather, it still had to decide whether in light of all the facts, "the severe sanction of holding the patent unenforceable was warranted." *Id.* The court held that unenforceability was warranted based on a single determination: "But for Dr. Uzan's intentional omissions, the probability is high that the '618 patent

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[3] The court interpreted the Federal Circuit's prior decision as establishing that Aventis's omission was "highly material," *id.* at 46a, and thus that intent to deceive could be established based on a lower level of proof. Citing Federal Circuit precedent, the district court held, "The quantum of proof required to show intent is tied to materiality; the more material the omission or the misrepresentation, the lower the level of intent required to establish inequitable conduct." *Id.* at 49a (citation omitted).

would not have issued." *Id.*[4]

A divided Federal Circuit panel affirmed. *Id.* at 1a-38a. It did so despite finding that the district court had made several significant errors. For example, it held that the district court erred in concluding "that obviousness is subsumed by inherency" (*i.e.*, that § 102 anticipation issues ("inherency") predominated throughout PTO proceedings and thus that the half-life comparisons could only have been included for the purpose of refuting anticipation, not for the purpose of demonstrating nonobviousness). *Id.* at 21a.[5] It held that the district court also clearly erred in determining that the anticipation rejection was still pending at the time that the PE issued the Third Office Action (*i.e.*, at a time prior to Dr. Uzan's submission of his declarations). *Id.* at 25a. The appeals court determined that those errors were insufficient to warrant reversal because there was other evidence that Aventis had acted with deceptive intent at earlier stages of the PTO proceedings (*i.e.*, prior to the Third Office Action). *Id.*

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[4] That determination was left unexplained. It is also inexplicable, given that Aventis was granted the '743 re-issue patent several years prior to the district court's determination. Because the PTO granted the '743 patent despite the elimination of all reference to half-life comparisons, there is no reason to conclude that the '618 would not have issued had it included more complete dosage information.

[5] As noted above, there was no finding below that it would have been inappropriate for Aventis to seek to demonstrate nonobviousness by comparing the half-lives of Lovenox and the prior art at different dosage levels. Thus, omission of the fact that the half-lives were compared at different dosage level was material only if the comparison was undertaken for the purpose of refuting anticipation.

The panel majority upheld the district court's materiality and intent to deceive findings under a "clear error" standard of review and its unenforceability determination under an "abuse of discretion" standard. *Id.* at 17a. It recognized that, under Federal Circuit precedent, a finding of "inequitable conduct" sufficient to warrant an "unenforceability" determination should be based on a sliding scale involving materiality and intent. *Id.* at 18a ("The more material the omission or misrepresentation, the less intent that must be shown to elicit a finding of inequitable conduct."). But the majority upheld the unenforceability determination without commenting on the district court's complete failure to engage in such a sliding scale analysis.[6]

Judge Rader dissented. *Id.* at 31a-38a. He concluded that Amphastar and Teva failed to present clear and convincing evidence of intent to deceive. *Id* at 31a. He complained that the Federal Circuit was increasingly willing to hold patents unenforceable based on meager materiality and intent showings, *id.* at 33a, with the result that the once-ubiquitous "inequitable conduct tactic" was being "rejuvinated" and was returning to the "plague" levels that the court had complained of in the 1980s. *Burlington Indus. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988). He argued that unenforceability determinations based on inequitable conduct should be restricted "to only the most extreme cases of fraud and deception." *Id.* at 31a.

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[6] Rather, as noted above, the district court engaged in a sliding scale analysis only in connection with its initial finding of deceptive intent – finding that "[t]he quantum of proof required to show intent" is lessened when, as here, the trial court has made a finding that the omission is highly material. *Id.* at 47a.

REASONS FOR GRANTING THE PETITION

The petition raises issues of exceptional importance. This case is yet another example of the willingness of the Federal Circuit to invalidate multi-billion dollar patents based on findings of relatively minor errors by patentees. WLF fully agrees with Aventis that a major part of the problem is the "sliding scale" adopted by the Federal Circuit, whereby patent holders often are deemed to have intended to deceive the PTO based on conduct that amounts to little more than gross negligence.

WLF writes separately to urge the Court to grant review on the grounds that the entire "inequitable conduct" doctrine is in need of a major overhaul. The Court created that doctrine 60 years ago for the purpose of policing the conduct of parties that engage in wholesale fraud before the PTO. But the doctrine has morphed into a trap for the unwary, whereby hugely valuable patents are overturned without regard to the blameworthiness of the patent holder. Whenever a patent challenger can identify information that was not supplied to the PTO but that a PE might have found useful in determining patentability, and whenever a plausible case can be made that the patentee should have known that a reasonable PE would have found the information useful (and thus can be found to have intended to deceive the PTO), the patentee now faces a serious danger that its patent will be invalidated. That danger exists irrespective of whether the patentee can be deemed blameworthy to any significant degree; only materiality and intent, not blameworthiness, enter into the equation. The danger exists even if the PE was not deceived and/or did not rely in any way on the

patentee's omission; indeed, the Federal Circuit explicitly held in this case that absence of reliance is irrelevant in determining whether a patent should be held unenforceable on inequitable conduct grounds. The danger also exists without regard to whether the patentee would have been granted its patent had it supplied the PTO with the omitted evidence.

Review is warranted to once and for all rein in a doctrine that has accurately been termed a "plague" that now infects virtually all patent litigation. As Judge Rader noted in his dissent below, the inequitable conduct doctrine was intended to apply "to only the most extreme cases of fraud and deception." Pet. App. at 31a. Yet, it has expanded to the point that it is now a potent weapon in virtually every patent lawsuit. This case provides a particularly good vehicle for re-visiting the doctrine. It is a case in which we know with virtually 100% certainty (based on the grant of the '743 re-issue patent) that the '618 patent would have been granted even if Aventis had included the omitted dosage information. It is a case in which the omitted information, although deemed "material" to patentability by the district court, was not an omission whose natural tendency was to deceive – it would have been readily apparent to a reasonably inquisitive patent examiner that (s)he had not been given dosage information for the prior art. Indeed, the record is clear that the PE in this case was *not* deceived; she indicated in the Third Office Action in March 1993 that she was unpersuaded by the half-life comparison because the claimed difference in half-lives was not "statistically significant." *Id.* at 10a. Nor is this a case in which the alleged deception was widespread or otherwise particularly blameworthy. While the PTO and the

federal courts quite obviously have an interest in sanctioning any patent applicant, including Aventis, that has been determined by a district court to have engaged in deceptive behavior, the nature of the deception in this case was sufficiently technical that authorizing an unenforceability sanction here is tantamount to a determination that unenforceability is an appropriate sanction in virtually every case in which materiality and intent to deceive are found.

Review is also warranted because of the tremendous uncertainty among patent holders being created by the Federal Circuit's inequitable conduct decisions. At the same time that the Federal Circuit is inexorably expanding the definition of a "material" omission, it is reducing the level of proof necessary to establish intent to deceive. Review is warranted to permit this Court to establish a readily comprehensible inequitable conduct standard on which applicants can rely. In the absence of such certainty, there is a very real danger that investors will become far less willing to risk the huge amounts of capital necessary to develop new, life-saving therapies. Any such decrease in research and development expenditures cannot bode well for the future of health care in this country.

I. REVIEW IS WARRANTED BECAUSE THE DECISION BELOW CONFLICTS WITH THIS COURT'S UNDERSTANDING OF WHAT CONSTITUTES "INEQUITABLE CONDUCT"

Review is warranted because the Federal Circuit has departed so fundamentally from this Court's rationale for creating an "inequitable conduct" defense to a patent infringement claim. As the Court explained more than 60 years ago, "[t]he guiding doctrine" in patent cases in which inequitable conduct is alleged "is the equitable maxim that 'he who comes into equity must come with clean hands.'" *Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806, 814 (1945). The "unclean hands" doctrine "closes the doors of a court of equity to one tainted with inequitableness or bad faith relative to the matter in which he seeks relief." *Id.* An important limitation on application of the unclean hands doctrine is that it has never been applied to a plaintiff based simply on the fact that the plaintiff has engaged in misconduct; rather, the doctrine is strictly limited to situations in which some unconscionable act committed by the plaintiff has *immediate and necessary* relation to the equity he seeks.

One searches the Federal Circuit's "inequitable conduct" decisions in vain for any indication that that court is basing its decisions on anything remotely resembling the "unclean hands" approach mandated by *Precision Instrument.* Instead, the Federal Circuit has developed an elaborate set of rules for determining when omitted information should be deemed material and when the patentee should be deemed to have acted

with the requisite intent. Once those findings are made, trial courts are granted virtually free rein to declare the patent unenforceable, without regard to the magnitude of the patent holder's blameworthiness or to whether patent examiners were actually misled. All too frequently, the result of those rules has been travesties such as the decision at issue here: a patent is struck down based on alleged "inequitable conduct" based on a relatively minor omission of information, despite *the absence of any evidence that the PE drew any inaccurate inferences from the omission or that she relied on such inferences to her detriment.* By interpreting materiality, intent, and inequitable conduct so broadly, the Federal Circuit in essence is attempting to write the rules of evidence for the PTO; such rules have little relationship to the "unclean hands" doctrine and – because they are being written after the fact – have thrown into doubt the validity of numerous existing patents. Review is warranted to resolve the sharp conflict between this Court's understanding of "inequitable conduct" and the Federal Circuit's recent "inequitable conduct" decisions.

A. Unenforceability Determinations Should Be Limited to Cases in Which Patent Holders Have Committed "Unconscionable" Acts That Bear Some "Immediate and Necessary Relation" to the Equity Sought

It has now been more than 60 years since the Court last addressed the circumstances under which an otherwise valid patent should be held unenforceable based on the applicant's inequitable conduct before the Patent Office. That case, *Precision Instrument,* held a patent unenforceable based on findings that: (1)

Automotive, the applicant, learned that a competing applicant had committed perjury during interference proceedings; (2) Automotive used that information to blackmail the competing applicant into assigning his patent rights to Automotive and agreeing never to contest the resulting patent; (3) Automotive never revealed the patent's fraudulent ancestry to the Patent Office; and (4) the result of its actions was that Automotive was issued a patent with claims broader than those to which Automotive was actually entitled. *Precision Instrument*, 324 U.S. at 818-19. The Court held that those facts "all add up to the inescapable conclusion that Automotive has not displayed that standard of conduct requisite to the maintenance of this suit in equity," and it applied the "unclean hands" doctrine to deny enforcement of any part of the patent. *Id.* at 819.

As Petitioners note, in the ensuing decades the federal appeals courts struggled to determine just how relevant the omitted information must be to issues raised in PTO proceedings before the omission can be deemed material and intentionally deceptive, and just how egregious the patent holder's misconduct must be to warrant application of the "unclean hands" doctrine. Pet. 20-21. The appeals courts developed at least three conflicting standards of materiality, intent, and unclean hands. *Id.*

Following creation of the Federal Circuit, that court adopted far broader standards. For example, omitted data are deemed sufficiently material where there is "a substantial likelihood" that a reasonable examiner would consider them "important" in deciding to allow the application to issue as a patent. *American*

Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1362 (Fed. Cir. 1984). Intent and materiality are considered on a sliding scale, so that the "quantum of evidence required to show intent" is reduced when the materiality of the omitted data is deemed high. Pet. App. 49a. A patentee can be deemed to have intended to deceive the PTO if the trial court deems insufficiently credible the patentee's explanation for failing to supply the data. *Ferring*, 437 F.3d at 1191. The trial court is to determine whether the patentee engaged in inequitable conduct (and thus whether the patent should be declared unenforceable) based solely on the strength of the evidence regarding materiality and intent. *Hoffman-LaRoche, Inc. Promega Corp.*, 323 F.3d 1354, 1372 (Fed. Cir. 2003). Thus, whether a patent is declared unenforceable bears no relation to the magnitude of its blameworthiness; if the evidence is sufficiently clear that the patentee intended to deceive the PTO by withholding material evidence, a gargantuan penalty is imposed, regardless whether the scope of the deceit was relatively minor. It is sufficient that a reasonable patent examiner would have considered the omitted material "important." Moreover, for purposes of determining inequitable conduct, it does not matter whether a reasonable examiner would have been misled by the omission or whether the actual examiner was, in fact, misled: the omitted material "'need not be relied on by the examiner in deciding to allow the patent. The matter misrepresented need only be within a reasonable examiner's realm of consideration.'" Pet. App. 134a-135a (quoting *Merck & Co. v. Danbury Pharmacal, Inc.*, 873 F.2d 1418, 1421 (Fed. Cir. 1989)).

Those standards of materiality, intent, and

inequitable conduct bear little resemblance to "unclean hands" doctrine and conflict sharply with this Court's understanding of what constitutes "inequitable conduct." In particular, the Federal Circuit's sliding-scale approach fails to heed this Court's admonition regarding strict limits on application of "unclean hands" doctrine:

> But courts of equity do not make the quality of suitors the test. They apply the maxim requiring clean hands only where some *unconscionable* act of one coming for relief has *immediate and necessary relation* to the equity that he seeks in respect of the matter in litigation.

Keystone Driller Co. v. General Excavator Co., 290 U.S. 240, 245 (1933) (emphasis added).

In *Keystone Driller*, the Court applied "unclean hands" doctrine to dismiss a patent infringement action, where the evidence showed that: (1) an individual may have engaged in prior use of the claimed invention (a circumstance which, if true, would have invalidated a patent); (2) following issuance of the patent, the patentee paid the individual not to disclose his prior use and to sign an affidavit stating that his use of the device was merely an abandoned experiment; and (3) the individual failed to disclose these arrangements in his subsequent deposition. *Id.* at 243. But in other cases, the court has declined to apply "unclean hands" doctrine where the plaintiffs' misconduct did not have a sufficiently "immediate and necessary relation" to the equitable relief sought, to warrant non-enforcement of the patent. *See, e.g., Corona Cord Tire Co. v. Donovan Chemical Corp.*, 276 U.S. 358, 373-74 (1928) (applicant's

submission of false affidavits to Patent Office did not warrant non-enforcement of patent, because the falsehoods were not crucial to issuance of the patent).

In more recent times, the Court upheld the NLRB's decision not to apply the "unclean hands" doctrine to bar reinstatement of a fired employee, despite the employee's perjured testimony regarding the reason he was late for work. *Air Freight System, Inc. v. NLRB,* 510 U.S. 317 (1993). The NLRB had reasoned that the perjury was not sufficiently material to the issue of reinstatement, because (the NLRB determined) the employee had actually been fired in retaliation for union activity, not (as the company alleged) because of his tardiness. *Id.* at 321. Similarly, the Fourth Circuit declined to apply the "unclean hands" doctrine to bar an award of equitable relief to a foreign government accused of persecuting a political opponent, where there was no "close nexus between a party's unethical conduct and the transactions on which that party seeks relief." *Republic of Rwanda v. Uwimana*, 274 F.3d 806, 810 (4th Cir. 2001) (citing *Keystone Driller*).

The decisions below – as well as numerous other inequitable conduct decisions arising out of the Federal Circuit – cannot be squared with the "unclean hands" standards set forth in *Keystone Drilling*. Review is warranted to address that conflict.

B. The Federal Circuit's Inequitable Conduct Doctrine Does Not Provide Any Mechanism for Gradation of Penalties, Nor Does It Require Consideration of All the Equities

Review is also warranted because of a fundamental deficiency in the Federal Circuit's inequitable conduct case law: when a patentee is determined to have acted wrongly, the only sanction provided for under that case law is an order declaring the patent unenforceable. Such an all-or-nothing approach inevitably biases the outcome in favor of draconian penalties once the patentee has been determined to have acted wrongfully. Moreover, the Federal Circuit case law is deficient in not requiring district courts to consider all the equities before granting equitable relief.

Absent from the decision below or Federal Circuit inequitable conduct case law is a recognition of the extraordinary nature of equitable relief. Indeed, the Federal Circuit in this case indicated that the district court's unenforceability determination was subject to abuse-of-discretion review, Pet. App. 17a, and then it omitted any discussion of such review from its decision. Had it included such a discussion, it would have been forced to concede that the district court explicitly declined to engage in any sort of weighing of the equities. *Id.* at 91a ("The Court need not be detained by intricate questions of weight.").[7]

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[7] Instead, the district court based its unenforceability determination on a single statement: "But for Dr. Uzon's intentional omissions, the probability is high that the '618 patent

Injunctive or declaratory relief "is a matter of equitable discretion; it does not follow from success on the merits as a matter of course." *Winter v. Natural Resources Defense Council, Inc.*, 129 S. Ct. 365, 381 (2008). "[A] federal judge sitting as chancellor is not mechanically obligated to grant an injunction for every violation of the law." *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 313 (1982). Among the factors that federal judges must take into account in determining whether to grant injunction relief are the balance of equities among the parties and the public interest. *Winter*, 129 S. Ct. at 381.

The district court engaged in no such analysis, nor was it required to do so by Federal Circuit case law

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would not have issued." *Id.* The court included no citation to support that statement, and it cannot be taken seriously in light of the PTO's decision to grant the '743 re-issue patent several years earlier. *See supra* at 8 n.4.

Indeed, the district court's seemingly cavalier attitude toward the unenforceability determination well illustrates a major problem caused by the Federal Circuit's lax inequitable conduct standards. Patent cases can be extraordinarily complex, and it can require considerable resources for a federal district judge to decide whether a patent was validly issued and/or whether it was infringed. As Judge Radar noted in his dissenting opinion, the inequitable conduct doctrine provides district courts with an easy out – they can avoid addressing the more difficult invalidity and infringement issues by making an inequitable conduct finding. Pet. App. 31a-32a ("The allegation of inequitable conduct . . . even offers the trial court a way to dispose of a case without the rigors of claim construction and other complex patent doctrines. This court has even observed a number of cases, such as this one, that arrive on appeal solely on the basis of inequitable conduct where the trial court has apparently elected to try this issue in advance of the issues of infringement and validity.")

– which directs district courts merely to look at the extent of materiality and intent to deceive, and to apply a sliding-scale test involving those two factors. Based on the factual findings that Aventis engaged in misconduct, some type of sanction might be appropriate (*e.g.*, a fine or an order re-opening the patent proceedings). But, given the evidence of Aventis's rather limited culpability (*see, e.g.,* the discussion of the underlying facts set forth *supra* at 4-8), the Federal Circuit would have a difficult time explaining why it is equitable to determine that a multi-billion dollar patent should be held unenforceable. Amphastar and Teva, generic manufacturers who played no role in the PTO proceedings and are merely hoping to make a profit from Aventis's misfortune, would seem to have few equities in their favor.

It is unclear precisely where the public interest would lie. On the one hand, there is a public interest in providing an incentive for patent applicants to be honest in their dealings with the PTO. On the other hand, there is a public interest in maintaining public confidence in the patent system; and if the public comes to believe that valuable patents will be invalidated based on minor transgressions, individuals will be less likely to devote the extraordinary time and resources necessary to develop new, potentially life-saving products. But the important point is this: the Federal Circuit does not require *any* balancing of the public interest in inequitable conduct cases. Review is warranted to resolve the conflict between this Court's traditional equitable principles and the Federal Circuit's inequitable conduct case law.

II. REVIEW IS WARRANTED BECAUSE OF THE TREMENDOUS UNCERTAINTY BEING CREATED BY THE FEDERAL CIRCUIT'S INEQUITABLE CONDUCT DECISIONS

As Petitioners have well documented, the Federal Circuit's expansion of the inequitable conduct doctrine far beyond its unclean hands origins has led to inclusion of inequitable conduct defenses in virtually all patent infringement actions. Pet. 24-28. The Federal Circuit itself has described the proliferation of such claims as "an absolute plague" on the patent system. *Burlington Industries, Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988). The Federal Circuit attempted to address that problem a number of years ago by tightening somewhat the standards for establishing that a patent applicant intended to deceive the PTO. *See Kingsdown Medical Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 876-77 (Fed. Cir. 1988) (*en banc*). But as this case illustrates, *Kingsdown* has not been consistently followed, and the Federal Circuit continues to apply broad standards regarding what constitutes materiality, intent to deceive, and inequitable conduct. As Judge Newman argued in dissent in *Ferring*, the Federal Circuit:

> [N]ot only ignore[s] *Kingsdown* and restore[s] a casually subjective standard, they also impose a positive inference of wrongdoing, replacing the need for evidence with a "should have known" standard of materiality, from which deceptive intent is inferred, even in the total absence of evidence. Thus the panel majority infers material misrepresentation, infers malevolent

> intent, presumes inequitable conduct, and wipes out a valuable property right, . . . on the theory that the inventor "should have known" that something might be deemed material.

Ferring, 437 F.3d at 1996 (Newman, J., dissenting).

It is difficult to overestimate the chilling effect that such decisions have on the research and development activities that the patent system is intended to foster. If the business community loses faith in the willingness of courts to uphold patents, they are unlikely to be willing to continue to invest the hundreds of millions of dollars typically required to bring a new drug through research and testing and eventually to obtain marketing approval. Indeed, the costs and uncertainties associated with application of the inequitable conduct doctrine led the National Research Council of the National Academies of Science and Engineering in 2004 to recommend "the elimination of the inequitable conduct doctrine or changes in its implementation." National Research Council, *A Patent System for the 21st Century* (2004) at 123, http://www.nap.edu/html/patentsystem/0309089107.pdf. Review is warranted to prevent the Federal Circuit's inequitable conduct standards from further eroding confidence in our patent system.

CONCLUSION

Amicus curiae Washington Legal Foundation respectfully requests that the Court grant the petition for a writ of certiorari.

Respectfully submitted,

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