

Supreme Court, U.S.
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No.

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**

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Under the judge-made doctrine of “inequitable conduct,” a federal court may decline to enforce an otherwise valid patent that was procured through fraud or deceit. *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806 (1945). As befits the punitive nature of the doctrine, this Court has invoked it only in extreme circumstances involving “deliberate,” “corrupt,” “sordid” and “highly reprehensible” misconduct. Some panels of the Federal Circuit have similarly limited the inequitable conduct doctrine to deliberately planned and carefully executed schemes to defraud, but other Federal Circuit panels—including the majority in this case—have adopted a “sliding scale” under which “less intent” is required as the materiality of an omission or misrepresentation increases. The question presented is:

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, effectively permitting a finding of fraudulent intent to be predicated on gross negligence.

**PARTIES TO THE PROCEEDING
AND RULE 29.6 STATEMENT**

Pursuant to this Court's Rule 29.6, counsel for petitioners certifies that:

Petitioner Aventis Pharma S.A. has no direct parent companies. All corporations that own 10 percent or more of petitioner Aventis Pharma S.A. are: Aventis Inc., Sanofi-Aventis Europe, Sanofi-Aventis, and sanofi-aventis Amerique du Nord.

Petitioner Aventis Pharmaceuticals Inc. is a subsidiary of Aventis Holdings Inc., which is a subsidiary of Aventis Inc., which is a subsidiary of sanofi-aventis Amerique du Nord. A minority interest in Aventis Pharmaceuticals Inc. is held by Aventis Beteiligungsverwaltung GmbH, which is a wholly-owned subsidiary of Hoechst GmbH, which is a wholly-owned subsidiary of Sanofi-Aventis Europe, which is a wholly-owned subsidiary of Sanofi-Aventis.

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PETITION FOR A WRIT OF CERTIORARI

Aventis Pharma S.A. and Aventis Pharmaceuticals Inc. respectfully petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit.

OPINIONS BELOW

The opinion of the court of appeals (App., *infra*, 1a-38a) is reported at 525 F.3d 1334. The opinion of the district court (App., *infra*, 39a-91a) is reported at 475 F. Supp. 2d 970. A previous opinion of the court of appeals (App., *infra*, 95a-109a) is electronically reported at 176 Fed. Appx. 117, and that of the district court (App., *infra*, 110a-143a) at 390 F. Supp. 2d 936.

JURISDICTION

The judgment of the court of appeals was entered on May 14, 2008. Aventis's timely petition for rehearing was denied on September 25, 2008. App., *infra*, 92a-94a. On November 10, 2008, the Chief Justice extended the time to file this petition until January 23, 2009. 08A417. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISION INVOLVED

Section 282 of the Patent Act, 35 U.S.C. § 282, provides, in relevant part:

The following shall be defenses in any action involving the validity or infringement of a patent and shall be pleaded:

(1) Noninfringement, absence of liability for infringement or unenforceability

STATEMENT

After undertaking a comprehensive review of the American patent system, the National Academies of Science and Engineering concluded that the costs and uncertainties associated with the “inequitable conduct” doctrine counsel its elimination or reform. National Research Council, *A Patent System for the 21st Century* (2004) at 123, <http://www.nap.edu/html/patentsystem/0309089107.pdf>. In reaching this conclusion, the Academies singled out for criticism the very standard at issue in this case: the inference of “intent from the materiality of the information that was withheld.” *Ibid.* This is the standard on which the district court found Aventis guilty of “inequitable conduct,” and, as a result, held Aventis’s patent (for a drug with over \$2 billion in annual U.S. sales) entirely unenforceable. Applying the same standard, the Federal Circuit, in a 2-1 decision, affirmed.

This case presents the Court with an ideal opportunity to clarify the circumstances in which a patent holder may be stripped by a district court of extremely valuable patent rights—a frequently recurring question with profound ramifications for the patent system’s ability to foster and encourage innovation, as required under the constitutional mandate “to promote the Progress of . . . useful Arts.” U.S. Const., art. I, § 8, cl. 8.

1. Aventis invented novel compositions of low molecular weight heparins used in the prevention and treatment of thromboses (*i.e.*, blood clotting), and the process for making these compositions. Aventis applied for a patent, which issued in 1995 after a lengthy review process in which the Patent and Trademark Office carefully scrutinized the nov-

elty and other features of Aventis's claims. *See* U.S. Patent No. 5,389,618 ("the '618 patent"). Aventis began marketing and selling the compositions in the United States after the United States Food and Drug Administration approved them for sale in 1993 under the name Lovenox®. Lovenox® currently brings in some \$3.1 billion in annual revenue, with U.S. sales exceeding \$2 billion annually.

2. In 2003, Aventis sued respondents Amphastar Pharmaceuticals, Inc. and Teva Pharmaceuticals USA, Inc. under 35 U.S.C. § 271(e)(2) for infringing the '618 patent by submitting an application to the FDA for approval to manufacture and sell generic versions of Lovenox® before the expiration of the patent. Respondents counterclaimed, accusing Aventis of having procured the patent through "inequitable conduct."

Respondents premised their inequitable conduct theory on a simple omission made by Dr. André Uzan, a non-inventor expert whose help on limited matters involving biology was sought because the inventor, Roger Debrie, was a chemist. Dr. Uzan is a distinguished scientist who has been inducted into the French Legion of Honor for his scientific contributions and lifetime dedication to the public health, a recipient of France's highest award for drug discovery (the Galien Research Prize), and an expert with the French Ministry of Public Health and the French Court of Appeals. C.A. App. 1917-28.

Dr. Uzan's involvement with the prosecution of the patent was confined to three isolated instances: providing the information in Example 6 of the '618 patent, a declaration submitted to the PTO nearly three years thereafter, and a second declaration submitted one year after the first. Example 6 was

meant to “illustrate[] the increase in stability” of the invention compared to prior art, App., *infra*, 43a-44a n.3, measured by the increase in plasma half-life (longer half-life means greater stability). In making this comparison in Example 6 (and in his later declarations), Dr. Uzan disclosed the 40 mg and 60 mg dosages of the invention, but failed to disclose that the prior art composition was at 60 mg, and thus that he was making a comparison at different doses.¹

Although it is undisputed that Dr. Uzan knew the dose of the prior composition, there was no evidence indicating that Dr. Uzan intentionally failed to disclose that information. The full prior art study that Dr. Uzan utilized for his comparison does disclose the dose, but the photocopied, unaltered half-

¹ The omission was made in Subsection 3 of Example 6, which provides as follows:

This example illustrates the increase in stability, in vivo, of the mixtures of the invention, expressed by their plasma half-life.

A first pharmacokinetic study was carried out on volunteers between 21 and 30 years of age. . . . The results obtained were as follows:

(1) From the mixtures [of the present invention]:

40 mg dose: in 75% of the cases, the half-life was longer than 4 hours, and was even longer than 4½ hours in approximately 45% of the cases;

60 mg dose: in 75% of the cases, the half-life was longer than 3.7 hours.

(2) . . .

(3) When the product was prepared according to the process described in [the prior art], the half-life was longer than 4½ hours in 17% of the cases.

(4) . . .

App., *infra*, 43a-44a n.3.

life data table (Table III) that he consulted when providing information to the Aventis patent department does not. C.A. App. 1148; 1226.

3. In early 2003, Aventis filed a reissue application for the '618 patent. The PTO reissued the patent on June 14, 2005, with all of the original independent claims, but without Example 6. U.S. Patent No. RE 38,743.

The reissue was granted a day before the district court granted Amphastar's summary judgment motion that the '618 patent was unenforceable. App., *infra*, 38a. In an appeal of this decision, the Federal Circuit affirmed the district court's finding of high materiality, but rejected the finding of deceptive intent as inappropriate on summary judgment. *Id.* at 106a. Under Federal Circuit precedent, Aventis—the party charged with inequitable conduct—was required to demonstrate its innocence in order to prevent a finding of deceptive intent on summary judgment, *i.e.*, it “was required to state specific facts supporting a plausible justification or excuse for its failure to disclose material information.” *Ibid.* (citing *Paragon Podiatry Lab., Inc. v. KLM Labs., Inc.*, 984 F.2d 1182, 1191 (Fed. Cir. 1993)).

Finding that “Aventis has met its burden of setting forth a plausible justification for its failure to disclose material information,” the Federal Circuit reversed and remanded for a trial on inequitable conduct. App., *infra*, 106a. Aventis had explained, among other things, that Dr. Uzan could not have intended to deceive the PTO, because a comparison at different doses was common industry practice and reasonable for clinical reasons. Because the 60 mg dosage for the invented composition caused bleeding in some patients, the 40 mg dosage was therapeuti-

cally preferable for some indications, and thus was the relevant dosage to compare against the 60 mg dosage of the prior art. The district court had rejected this explanation as irrelevant, but the Federal Circuit disagreed, noting that “[t]he reasonableness of the comparison between different dosages is relevant to determining whether the failure to disclose . . . was made with an intent to deceive.” *Ibid.*

4. On remand, after a bench trial, the district court found inequitable conduct, holding that respondents had presented evidence that “there has been a failure to supply highly material information and . . . the record establishes that (1) the applicant knew of the information; (2) the applicant knew or should have known of the materiality of the information; and (3) the applicant has not provided a credible explanation for the withholding.” App., *infra*, 87a (quoting *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1191 (Fed. Cir. 2006)).

“Regarding knowledge,” the district court held that “there is no debate that Dr. Uzan knew the dose[] used in the [prior study] and at trial, Dr. Uzan admitted to knowing that he was comparing the half-lives . . . at different doses.” App., *infra*, 87a-88a. This was undisputed. It also was, however, of limited significance, as it only showed that Dr. Uzan knew that the dosage of the prior composition was 60 mg, not that he realized that he omitted that dosage information.

“Regarding knowledge of materiality,” the district court held, “it was obvious that a reasonable [patent examiner] would have considered dosage important.” App., *infra*, 87a-88a. This test, however, is the test for materiality, not for intent.

The district court acknowledged that it was effectively eliminating the requirement that a patent applicant have actual knowledge that the omitted information is material and may mislead the PTO, but viewed this as supported by Federal Circuit precedent. “Contrary to Aventis’ arguments,” the district court explained, “it is well-established that proof of actual knowledge is not always necessarily required” to prove intent to deceive. App., *infra*, 82a n.18. Knowledge that the omitted information is material and may deceive the PTO can simply be presumed instead from materiality: individuals who fail to supply highly material information “should have known” about the information’s materiality. *Ibid.* (quoting *Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.*, 267 F.3d 1370, 1376 (Fed. Cir. 2001)); *see also ibid.* (“a patentee’s failure to appreciate the legal significance of the facts that it failed to disclose d[oes] not absolve it” of a finding of deliberate deception) (citing *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1256-57 (Fed. Cir. 1997)).

The district court also rejected as “incredible” evidence of Dr. Uzan’s subjective belief that the comparison at different but therapeutic doses was reasonable. App., *infra*, 87a.

Based on its two findings of non-disclosure and high materiality, and *Aventis’s* failure to prove that it was innocent, the district found “intent to deceive.” App., *infra*, 87a (finding inequitable conduct because “[t]he elements of nondisclosure and high materiality have been admitted, and no credible excuse demonstrated”).

5. On appeal, a divided panel of the Federal Circuit affirmed, with the majority applying the same sliding-scale standard as the district court. App., *in-*

fra, 18a (“The more material the omission or misrepresentation, the less intent that must be shown to elicit a finding of inequitable conduct”) (citation omitted). Under this standard, the Federal Circuit majority, like the district court, presumed fraudulent intent from materiality, and shifted the burden to Aventis to clearly and convincingly prove the absence of such intent.

For example, critical to respondents’ charge of inequitable conduct was their claim that the comparison discussed in Example 6 and in Dr. Uzan’s declarations was meant to show not only the superior stability of the invention, but also a compositional difference between the invention and prior art—in which case a comparison at different doses would have been improper. Example 6 nowhere mentions or discusses compositional difference, and by its very own terms states that it is meant to address the superior “stability” of the invention, *i.e.*, a property of the invention. App., *infra*, 5a (“This example illustrates the increase in stability, *in vivo*, of the mixtures of the invention”). Instead of requiring respondents to clearly and convincingly prove that Example 6 *was meant* to address a compositional difference, the panel majority turned the burden of proof on its head, requiring instead that Aventis clearly and convincingly show that Example 6 *was not meant* to address compositional difference: “Nothing in example 6 suggests that the half-life comparison was designed to show only [superior stability] and not [a compositional difference].” *Id.* at 23a.

In dissent, Judge Rader criticized the improper “[m]erging [of] intent and materiality” under the majority’s sliding-scale standard, and highlighted several previous cases in which the Federal Circuit had “emphasized materiality almost to the exclusion of

[the] intent requirement.” App., *infra*, 33a. According to Judge Rader, Dr. Uzan’s omission, even if material and negligent, could not reasonably support an inference of “culpable intent to deceive,” a finding which is reserved only to “the most extreme cases of fraud and deception.” *Id.* at 31a.

Key to Judge Rader’s analysis was the absence of any evidence that Dr. Uzan knowingly omitted the information. See App., *infra*, 35a (“To make it clear, Dr. Uzan did not attempt to conceal data that were otherwise present. Rather he just submitted the study without adding to the disclosure.”). Furthermore, the absence of a dosage in subsection 3 of Example 6, given its presence in subsections 2 and 4, was “blatantly obvious.” *Id.* at 36a. “[I]f Dr. Uzan had intended to deceive the USPTO, he would not have made this omission so conspicuous.” *Ibid.* In addition, Judge Rader found it simply hard to believe, absent clear evidence to the contrary, that a “world-class scientist would . . . risk his reputation and tarnish his brilliant career for . . . a patent for an invention in which he was not even involved.” *Ibid.*

Judge Rader also pointed out that, aware of the allegations of inequitable conduct brought by respondents, the PTO nonetheless reissued the patent, including all original independent claims, without Example 6 and without reliance on the challenged comparisons of the half-life/stability data. According to Judge Rader, this rendered both materiality and intent “suspect.” App., *infra*, 38a.

Aventis petitioned for en banc review, arguing (among other things) that the sliding-scale standard “effectively dispens[es] with the separate element of ‘intent’ in inequitable conduct cases involving a ma-

terial omission.” Pet. C.A. Reh’g Br. 1. The Federal Circuit declined the invitation to clean its own house.

REASONS FOR GRANTING THE PETITION

The courts below invoked the “inequitable conduct” doctrine to render unenforceable an extremely valuable patent twice granted by the responsible agency of the executive branch (under authority conferred by Congress pursuant to a constitutional mandate), thereby depriving Aventis of the exclusive rights to its invention. And the lower courts did so without requiring the type of outright perjury and other extreme misconduct to which this Court has reserved the doctrine. That was wrong.

As Judge Rader recognized in his dissent, decisions like this one impair the effective functioning of the patent system. A lax standard for inequitable conduct not only encourages unwarranted litigation and threatens investments in research and development, but also interferes with the ability of the PTO to effectively examine patent applications by encouraging applicants to deluge the PTO with hundreds of minimally relevant references.

Numerous judges, scholars, practitioners and national organizations have recommended abolition or reform of the inequitable conduct doctrine. This Court has not revisited the doctrine in more than 60 years, the lower court decisions are in conflict, and the internally divided Federal Circuit has been unable to rein in the unwarranted expansion of the doctrine. It is time.

I. THE DECISION BELOW DISREGARDS THIS COURT’S PRECEDENT AND CONFLICTS WITH TRADITIONAL PRINCIPLES OF EQUITY

A. In three—and only three—cases, this Court has refused to enforce a patent for inequitable conduct in its prosecution or enforcement. Each in-

volved extreme circumstances of “deliberate,” “corrupt,” “sordid,” and “highly reprehensible” fraudulent conduct intentionally committed by the patent holder during prosecution or enforcement of the patent.

Keystone Driller Co. v. General Excavator Co., 290 U.S. 240 (1933), for example, involved a “corrupt transaction” that was “highly reprehensible,” in which the patent owner obtained, in exchange for “valuable considerations,” both a false affidavit and false deposition testimony “to keep secret the details of [a] prior use” which would have been “sufficient to cast doubt upon the validity of the patent.” *Id.* at 243-44.

Hazel-Atlas Glass Co. v. Hartford-Empire Co., 322 U.S. 238 (1944), involved the grant of “[e]quitable relief against [a] fraudulent judgment[.]” *Id.* at 248. There, the patentee paid generously for the fabrication of an “ostensibly disinterested” publication describing the claimed invention as a “remarkable advance in the art,” which was submitted to the PTO and relied on by the patentee in the Court of Appeals. *Id.* at 240, 248. The purported author was also paid to submit a false affidavit. This “sordid story,” *id.* at 243, “a deliberately planned and carefully executed scheme to defraud not only the Patent Office but the Circuit Court of Appeals,” *id.* at 245, came out only after judgment had been entered. Based upon “settled equitable principles,” the Court ordered the judgment set aside. *Id.* at 247.

And *Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806 (1945), involved a situation in which “the history of the patents” was “steeped in perjury and undisclosed knowledge of perjury,” *id.* at 816, including false testimony by Larson (the patentee) in an interference proceeding, and the discovery of Larson’s per-

jury by Automotive, which used that information to blackmail Larson into assigning his patent rights to Automotive and agreeing never to contest the resulting patent. The result of these actions was that Automotive, which never revealed the patent's fraudulent ancestry to the Patent Office, was issued a patent with claims broader than those to which Automotive was actually entitled. Explaining that "he who comes into equity must come with clean hands" (*i.e.*, to have acted "without fraud or deceit"), the Court declined to enforce the patent. *Id.* at 814-15.²

Notwithstanding this Court's careful confining of inequitable conduct to "deliberately planned and carefully executed scheme[s] to defraud," *Hazel-Atlas*, 322 U.S. at 245, the Federal Circuit has permitted, in this case and others, a lesser showing of intent in cases in which the materiality of the alleged improper conduct is high. App., *infra*, 18a ("The more material [a patent applicant's] omission or misrepresentation, the less intent that must be shown"). Under this sliding scale of intent and materiality, high materiality "necessarily" disposes of the need to prove a deliberate deception as required under this Court's precedent: a high showing of materiality "would necessarily create an inference that its non-disclosure was 'wrongful.'" *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1363 (Fed. Cir.

² Unlike *Keystone* and *Hazel-Atlas*, *Precision Instrument* (like this case), involved conduct that occurred solely before the PTO, and not in the action before the court. The standard applied in *Keystone* and *Hazel-Atlas*, on which *Precision Instrument* itself relied, was nevertheless applicable: To the extent that courts may punish allegedly fraudulent conduct that occurred solely before a co-equal branch of the government, the standard should be no less than that applicable to an alleged fraud on the court.

1984). A knowing deception is thus presumed from the mere fact that highly material information was omitted, under the justification that “he who failed to supply highly material information *should have known* about the information’s materiality.” App., *infra*, 81a (quoting *Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.*, 267 F.3d 1370, 1376 (Fed. Cir. 2001)) (emphasis added). But, as early as 1897, this Court recognized that one challenging a patent as fraudulently or wrongfully obtained must prove fraud by “clear and convincing” evidence, and the courts may not “assume[] the existence of a knowledge which no one had; of an intention which is not shown.” *United States v. Am. Bell Tel. Co.*, 167 U.S. 224, 259 (1897). The Federal Circuit engages in precisely such an assumption under its “should have known” standard.

The non-disclosure of material information is a necessary but not sufficient element of fraud or inequitable conduct. The complainant must also prove that the material information was *intentionally* withheld. The Federal Circuit, by presuming intent from materiality, effectively does away with the separate requirement for intent, permitting a finding of intent to be predicated on strict liability for a material omission. That the patent holder is then allowed to prove his innocence (a “credible” explanation for the non-disclosure) does not cure the infirmity of this standard. Indeed, where, as here, a defending party is given the ability to show a “reasonable” explanation for a non-disclosure which would otherwise trigger strict liability, this Court has deemed the standard to be one of “negligence.” *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 208 (1976). And the Federal Circuit itself has couched the “should have known” standard in terms of gross negligence. See *FMC Corp. v. Manitowoc Co., Inc.*, 835 F.2d 1411, 1415 (Fed. Cir. 1987) (“an applicant who knew of the art or information cannot intentionally avoid

learning of its materiality through gross negligence, *i.e.*, it may be found that the applicant ‘should have known’ of that materiality”); *see also id.* at n.9 (“‘gross negligence’ was seen as occurring when a reasonable person ‘should have known of the materiality of a withheld reference’”) (citation omitted).

But neither negligence nor strict liability can sensibly be reconciled with the deliberately fraudulent conduct required by this Court’s patent decisions. Those decisions limit the inequitable conduct doctrine to deliberate schemes to defraud involving extreme circumstances of outright perjury (*Precision Instrument*), or intentionally false and fabricated evidence and testimony (*Hazel-Atlas* and *Keystone*)—not mere negligent failures to disclose.

B. Nor can the Federal Circuit’s sliding scale be reconciled with the Court’s decisions involving fraud or inequitable conduct allegations in other areas of the law. For more than two centuries, the Court has repeatedly reiterated that “[f]raud means an intention to deceive.” *Lord v. Goddard*, 54 U.S. 198, 211 (1851); *see also Wiscart v. D’Auchy*, 3 U.S. 321, 330 (1796) (“fraud must always principally depend upon the *quo animo*,” *i.e.*, on the animus or bad faith); *Moss v. Riddle & Co.*, 9 U.S. 351, 357 (1809) (stating that “[f]raud consists in the intention”); *Magee v. Manhattan Life Ins. Co.*, 92 U.S. 93, 98-99 (1875) (“To constitute fraud, the intent to deceive must clearly appear. The concealment must be wilful and intentional.”) (citation omitted); *Reilly v. Pinkus*, 338 U.S. 269, 275 (1949) (findings of fraud are justified by representations “made with intent to deceive”); *Madigan v. Telemarketing Assocs.*, 538 U.S. 600, 621 (2003) (“the gravamen of the fraud action . . . is particular representations made with intent to mislead”).

In no fraud case has this Court ever indicated that intent to deceive could be judged on a sliding scale, with gross negligence sufficient in cases of high materiality. To the contrary, *Ernst & Ernst* explicitly precludes a gross negligence approach. 425 U.S. at 191 n.7, 197, 201, 215 (holding that securities fraud requires proof of “intent to deceive,” and that this excludes a gross negligence theory of liability).

The relevance of these non-patent cases is beyond serious dispute. The common theme of this Court’s recent patent decisions is that patent cases are subject to the same general principles as other claims brought under federal common law or statutory regimes. See *Microsoft Corp. v. AT&T Corp.*, 550 U.S. 437 (2007); *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007), *eBay Inc. v. MercExchange LLC*, 547 U.S. 388 (2006). If this case had been brought as a fraud case under other federal law regimes, it would not have survived even a motion to dismiss. Even accepting the factual predicates relied on by the courts below (namely, that Dr. Uzan knew the dosage information, that the dosage information was highly material, that Dr. Uzan “should have known” of its materiality, and that Dr. Uzan could not “credibly” prove his innocence (App., *infra*, 87a)), there is still no legally sufficient basis under this Court’s precedent to find intent to deceive.

Under that precedent, the test for deception is not whether the defendant “should have known” that an omission was material and misleading, as the courts below inquired. App., *infra*, 82a. Nor is it whether the allegedly defrauded party would have considered the omitted information important (*id.* at 87a-88a), which is the test for materiality. Nor is it whether the accused declarant has proved his innocence. *Ibid.* It is whether *the complainant* has shown that the material and misleading nature of an

omission was known to the declarant himself and that the omission was made with a misleading purpose. As the Court explained in *Madigan*, “[f]alse statement alone does not [result in] fraud liability.” 538 U.S. at 621. Rather, “the complainant must show that the defendant made a false representation . . . *knowing that the representation was false*” and, further, “with the intent to mislead the listener.” *Ibid.* (emphasis added).

This Court’s requirement that the misleading nature of an omission be known to the defendant is flatly at odds with the holding below that “proof of actual knowledge is not always necessarily required” to prove inequitable conduct. App., *infra*, 81a-82a. Two of the cases criticized in *Ernst & Ernst* on the ground that they set too low a standard for fraud, 425 U.S. at 193 n.12, had explicitly held, as in this case, that “knowledge of the falseness of the impression produced by the statements or omissions made[] is not required” to show fraud. See *Myzel v. Fields*, 386 F.2d 718, 734-35 (8th Cir. 1967); *Kohler v. Kohler & Co.*, 319 F.2d 634, 637-38 (7th Cir. 1963). The PTO has similarly recognized that a standard requiring actual knowledge is the appropriate one for patent law. See 37 C.F.R. § 1.56 (2006) (imposing on a declarant the “duty to disclose to the [PTO] all information *known to that individual to be material to patentability as defined in this section*”) (emphasis added).³

³ To be sure, as respondents have claimed, the intentionality of certain conduct can be inferred from circumstantial evidence. For example, if the version of Table III in the study consulted by Dr. Uzan had included the dosage information, but Dr. Uzan had removed it from the version provided to the PTO, this deletion would tend to suggest a knowing omission (albeit not necessarily a purposive one). But no such facts tending to prove an intentional removal of information are present here: the photo-

C. The Federal Circuit's rigid imposition of the drastic remedy of unenforceability—regardless of the absence of extraordinary circumstances, the presence of alternative remedies, and the impact on the public interest—also contravenes well-settled equitable principles, and this Court's decisions interpreting them.

Equitable principles require inquiry into the inadequacy of legal remedies before equitable relief is awarded. *eBay*, 547 U.S. at 391. In defiance of this well-known threshold for equitable relief, the patent was held unenforceable in this case before the court decided whether respondents would have been entitled to relief on their legal defenses of non-infringement and invalidity. App., *infra*, 32a.

Moreover, the Federal Circuit's one-size-fits-all remedy of "unenforceability" as a punishment for inequitable conduct involving broad ranges of culpability does not comport with the equitable nature of the doctrine. "The essence of equity jurisdiction has been the power of the Chancellor to do equity and to mould each decree to the necessities of the particular case. Flexibility rather than rigidity has distinguished it." *Hecht Co. v. Bowles*, 321 U.S. 321, 329 (1944). In equity remedies are tailored to fit the circumstances of the particular case, with the harshest remedies chosen in the extraordinary circumstances in which they are the "only means" to safeguard the

[Footnote continued from previous page]

copied, unaltered half-life data table (Table III) that Dr. Uzan consulted and provided to the PTO did not contain the dosage information. As Judge Rader explained in his dissent, "Dr. Uzan did not attempt to conceal data that were otherwise present. Rather he just submitted the study without adding to the disclosure." App., *infra*, 35a.

public interest sought to be protected, and less invasive means selected otherwise. *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 312-15 (1982); *see also eBay*, 547 U.S. at 392 (the harshest remedies do not “automatically” follow a determination that a violation has been committed). For example, in *Romero-Barcelo*, the Court held that the goal of ensuring compliance with the permitting requirement imposed by the statute could be achieved by remedies other than an injunction, such as penalties or fines. 456 U.S. at 312-15.

Similarly here, absent the extraordinary circumstance of deliberate fraud resulting in the issuance of an otherwise invalid patent, unenforceability is not the “the only means of” remedying a non-disclosure and “ensuring compliance” with disclosure obligations, as courts could impose “fines” and other “penalties,” *Romero-Barcelo*, 456 U.S. at 314, including a weakened presumption of validity, *see KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1745 (2007). The Federal Circuit, however, automatically imposes the extraordinary remedy of unenforceability even absent the extraordinary circumstances to which this Court has reserved it in *Precision Instrument, Keystone*, and *Hazel-Atlas*.

Nor does the Federal Circuit follow the traditional principle that “[i]n exercising their sound discretion, courts of equity should pay particular regard for the public consequences” of the remedy they impose. *Romero-Barcelo*, 456 U.S. at 312. In fact, as in this case, the Federal Circuit and the lower courts impose the extraordinary remedy of unenforceability without *any* analysis of the impact on the public interest, including the constitutional purpose of promoting innovation. *See Graham v. John Deere Co.*, 383 U.S. 1, 6 (1966) (“promot[ing] the Progress of . . .

useful Arts' ... is the standard expressed in the Constitution and it may not be ignored").

When life-saving innovations and billions of dollars in annual revenue and research and development are at stake (as here), the need to calibrate the interest in ensuring non-misleading disclosures to the PTO with the constitutional interest in promoting innovation is heightened—both in setting the standard for inequitable conduct and in remedying it. In other balancing situations involving similar burden-shifting, this Court has tipped the scales in favor of the constitutional interest. See, e.g., *Philadelphia Newspapers, Inc. v. Hepps*, 475 U.S. 767, 778 (1986) (although placing the burden on the complainant to prove the falsity of defamatory speech “will insulate from liability some speech that is false,” “the Constitution requires us to tip [the scales] in favor of protecting true speech” because otherwise there “would be some cases in which defendants could not bear [the burden to prove their innocence] despite the fact that the speech is in fact true”). And in *Precision Instrument, Keystone*, and *Hazel-Atlas*, this Court has similarly tipped the balance in favor of the constitutional interest by reserving inequitable conduct to exceptional circumstances. In contrast, the Federal Circuit has not only failed to tip the scales in favor of the constitutional interest—it has failed even to consider that interest.

II. THE LOWER COURT DECISIONS ARE IN CONFLICT

Although this Court has emphasized that fraud and inequitable conduct require a deliberate deception, the lower appellate courts have split regarding the requisite level of culpability, and that division of authority is reflected in the Federal Circuit's own caselaw.

A. Before the creation of the Federal Circuit in 1982, at least five regional circuits rejected a gross negligence predicate for fraud or inequitable conduct. See *Scott Paper Co. v. Fort Howard Paper Co.*, 432 F.2d 1198, 1204 (7th Cir. 1970) (finding that the equitable defense of “[u]nclean hands can be asserted only if there has been a deliberate misrepresentation in the [PTO]”); *Carter-Wallace, Inc. v. Davis Edwards Pharmacal Corp.*, 443 F.2d 867, 882 (2d Cir. 1971) (“in order for nondisclosure to constitute inequitable misconduct there must be something more than negligence”); *Parker v. Motorola*, 524 F.2d 518, 535 (5th Cir. 1975) (“mere negligent omissions or misstatements to the Patent Office do not provide sufficient basis for a finding of fraud”); *Pfizer, Inc. v. Int’l Rectifier Corp.*, 538 F.2d 180, 186 (8th Cir. 1976) (same); see also *Haloro, Inc. v. Owens-Corning Fibreglas Corp.*, 266 F.2d 918, 919 (D.C. Cir. 1959) (reversing finding of inequitable conduct because the challenged misrepresentations did not involve the type of deliberate fraud and exceptional circumstances at issue in *Precision Instruments* and *Hazel-Atlas*).

Three other circuits premised inequitable conduct on gross negligence, at least in cases of high materiality. *DeLong Corp. v. Raymond Int’l, Inc.*, 622 F.2d 1135, 1146 (3d Cir. 1980) (inequitable conduct requires “at least a gross negligence or recklessness in misrepresenting the truth”); *True Temper Corp. v. CF&I Steel Corp.*, 601 F.2d 495, 502 (10th Cir. 1979) (rejecting “intentional fraud” as the “only ground for withholding enforcement of patents,” and allowing unenforceability “where misrepresentations are made in an atmosphere of gross negligence as to their truth”) (internal quotation and citation omitted); *Digital Equip. Corp. v. Diamond*, 653 F.2d 701, 716 (1st Cir. 1981). Of the three, the First Circuit is the inventor of the sliding scale. It held, just like

American Hoist (the Federal Circuit case adopting the sliding scale in 1984), that “a lesser showing of [materiality] may suffice when an intentional scheme to defraud is established, whereas a greater showing of the [materiality] would necessarily create an inference that its nondisclosure was ‘wrongful.’” *Digital Equip.*, 653 F.2d at 716.

Given the Federal Circuit’s inability to resolve this conflict, the split between the regional circuits addressing the inequitable conduct issue presents a compelling case for this Court’s review. Not only do regional circuit decisions identify *patent* cases that “merit this Court’s attention,” see *Holmes Group, Inc. v. Vornado Air Circulation Sys., Inc.*, 535 U.S. 826, 839 (2002) (Stevens, J., concurring), but as inequitable conduct is an issue of federal common law, the conflict between the circuits has repercussions beyond the confines of patent law. Cf. *Dollar Sys., Inc. v. Avcar Leasing Sys., Inc.*, 890 F.2d 165, 173 (9th Cir. 1989) (holding, outside the patent context, that “grossly negligent” conduct “did not rise to the level of misconduct necessary for the application of the unclean hands doctrine” because “[b]ad intent is the essence of the defense of unclean hands”); *Eresch v. Braecklein*, 133 F.2d 12, 14 (10th Cir. 1943) (it is “well-settled” “that it is only fraud or willful misconduct which bars one from recovering in a court of equity under the [inequitable conduct] maxim, ‘He who comes into equity must come with clean hands’”).

B. The split among the regional circuits is mirrored in the Federal Circuit’s own decisions, which are deeply divided between those requiring actual proof of intent to deceive, and those merely presuming it under the sliding-scale standard.

Soon after its creation in 1982, the Federal Circuit adopted the First Circuit’s sliding scale of intent and materiality, under which a high showing of ma-

teriality “would necessarily create an inference that its nondisclosure was ‘wrongful.’” *Am. Hoist*, 725 F.2d at 1363. Around the same time, the Federal Circuit also adopted a “gross negligence” standard for finding intent to deceive. *J.P. Stevens Co. v. Lex Tex, Ltd.*, 747 F.2d 1553 (Fed. Cir. 1984).

Within a few years, inequitable conduct had become a “plague” on patent holders and the court system. *Burlington Indus. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988). In response, the en banc Federal Circuit tried to clarify that inequitable conduct was not a remedy for every mistake, blunder, or fault in the patent procurement process. *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988) (en banc).

Although *Kingsdown* purported to overrule the “gross negligence” standard, it did not discard the sliding scale adopted in 1984 by its *American Hoist* decision. As a result, while paying lip-service to prior decisions that reject gross negligence and reciting the principle that “materiality does not presume intent,” courts (as in this case) nonetheless proceed to apply a radically different standard—the sliding scale, with its “necessary[]” inference of intent from high materiality. And, unable to recognize that this “should have known” standard is logically incompatible with its rejection of gross negligence, the Federal Circuit has created a morass of conflicting, confusing, and contradictory decisions. Compare *FMC Corp. v. Manitowoc Co., Inc.*, 835 F.2d 1411, 1415 (Fed. Cir. 1987) (equating the “should have known” standard with gross negligence), with *GFI, Inc. v. Franklin, Corp.*, 265 F.3d 1268, 1274 (Fed. Cir. 2001) (“[M]ateriality does not presume intent, which is a separate and essential component of inequitable conduct”) (internal quotation and citation omitted). Thus, some panels understand that intent

and materiality are separate elements, which must *both* be proven *before* any balancing or burden-shifting is undertaken; others (like the majority in this case) deem high materiality sufficient to establish a *prima facie* case of intent.

In light of this decisional rift, the sliding scale's conflation of materiality and intent is (unsurprisingly) deemed improper by some on the Federal Circuit bench. For example, Judge Newman has noted that the "should have known" standard "replac[es] the need for evidence of intent" with "a positive inference of wrongdoing," and results in decisions in which the court "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 1196 (Newman, J., dissenting). Judge Rader similarly criticized the improper "[m]erging [of] intent and materiality" caused by the sliding scale, considering that the Federal Circuit has often "emphasized materiality almost to the exclusion of [the] intent requirement." App., *infra*, 33a. Judge Lourie has expressed similar views. *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1329 (Fed. Cir. 2008) (Lourie, J., dissenting).

Despite its internal critics and numerous calls for reform, the Federal Circuit has consistently refused to overrule the sliding scale (and its "should have known" test for highly material omissions) en banc. Cases such as *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357 (Fed. Cir. 2008), in which the Federal Circuit scrupulously followed *Kingsdown* and reiterated that materiality and intent are separate elements that must *both* be proven as part of a complainant's *prima facie* case, before

any burden-shifting is undertaken, cannot overrule the sliding scale unless they are taken en banc. They were not. See 2008 U.S. App. LEXIS 25385 (Fed. Cir. Oct. 22, 2008) (denying en banc review in *Star Scientific*). Indeed, no more than a month after the *Star Scientific* decision, the Federal Circuit in *Praxair* again deemed high materiality sufficient to establish intent. 543 F.3d at 1329 (Lourie, J., dissenting) (arguing that the standard applied by the majority and the district court improperly “conflat[ed] intent with materiality”).

This case, therefore, does not represent a mere isolated deviation from *Kingsdown*’s disapproval of a gross negligence standard for inequitable conduct. It follows an equally applicable and long-standing precedent, and highlights the entrenched and deepening rift in the Federal Circuit that leaves rights to inventions worth billions of dollars entirely at the mercy of the Federal Circuit’s panel selection process. If left uncorrected, this rift will continue to sow substantial confusion in an area of law where settled and clear standards are paramount and (ironically) the *raison d’être* for the Federal Circuit.

III. THE ISSUE WARRANTS THIS COURT’S ATTENTION

A. Inequitable conduct is asserted in virtually every patent infringement case. At the appellate level alone, the Federal Circuit has decided no fewer than 42 inequitable conduct cases over the past three years. Inequitable conduct (or unclean hands) charges are also common outside the patent context, further underscoring the need for this Court’s guidance regarding the circumstances and level of culpability that justify application of the doctrine.

This recurring question is of far-reaching national importance. The reflexive resort to charges of inequitable conduct without regard to actual culpability is a “plague” on litigants and the courts. *Hoffmann-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1381 (Fed. Cir. 2003) (Newman, J., dissenting) (commenting on the “New Plague”); see also National Association of Manufacturers, Response to the Advisory Commission on Patent Law Reform 10 (1991) (viewing “inequitable conduct” allegations—which “are made with a distressing frequency, litigated at enormous cost, and contribute enormously to the uncertainty of inventors seeking to enforce their rights”—as a “plague”).

Although many inequitable conduct charges may not ultimately succeed, see Katherine Nolan-Stevaux, *Inequitable Conduct Claims in the 21st Century: Combating the Plague*, 20 Berkeley Tech. L. J. 147, 148-49 (2005), the Federal Circuit’s diluted standard for “intent” is far from harmless. A large part of the harm is inflicted by costly discovery, or trials, on unwarranted charges of inequitable conduct that could have been abated on a dispositive motion had this Court’s *scienter* requirement been followed. The harm is even greater when inequitable conduct claims prevail even though premised on mere proof of materiality and inferences of intent from materiality, in contravention of this Court’s teachings. The “enormous” harm in this case—involving patent rights in a drug with *billions* of dollars in annual sales—is itself “a strong factor in deciding whether to grant certiorari.” *Fid. Fed. Bank & Trust v. Kehoe*, 126 S. Ct. 1612 (2006) (Scalia, J., concurring in the denial of certiorari).

The uncertainty and expense imposed by the expansive application of the “inequitable conduct” doc-

trine are further magnified by the Federal Circuit's elimination of another meaningful check on unwarranted claims of fraud: the reliance (*i.e.*, causation) requirement normally applicable to claims of fraud and to equitable claims akin to fraud, such as promissory estoppel. *Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc.*, 128 S. Ct. 761, 769 (2008); *Anza v. Ideal Steel Supply Corp.*, 126 S. Ct. 1991 (2006). Without the need for reliance, a non-intentional misrepresentation whose culpability is presumed from its materiality can give rise to inequitable conduct even if it is not the "but-for" cause for the examiner's approval of the patent. But even if it were appropriate to punish patentees for *intentional* misrepresentations despite the absence of some showing of causation (and Aventis submits it is not), any rationale for such punishment disappears when the misrepresentation is not shown to be deliberate.

The question presented is extraordinarily important not only to every person and company affected by weak or baseless assertions of inequitable conduct, but also to the effective functioning of our patent system. The proliferation of inequitable conduct charges gives patent applicants strong incentives to inundate the PTO with information in the hopes of forestalling a later inequitable conduct charge. Ironically, this decreases patent quality: Applicants "disclose too much prior art for the PTO to meaningfully consider, and do not explain its significance, all out of fear that to do otherwise risks a claim of inequitable conduct." American Bar Association Section of Intellectual Property Law, A Section White Paper: Agenda for 21st Century Patent Reform 18 (2007).

The information overload resulting from the hundreds of (barely relevant) cited references interferes with efforts to produce higher quality examinations

and contributes to the PTO's record workload crisis. As a recent Director of the PTO has emphasized, the inequitable conduct doctrine "has a perverse effect" on the actions of applicants before the PTO, "discourag[ing] many applicants from conducting a search and lead[ing] others to be indiscriminate in the information they submit." Jon W. Dudas, Testimony before the Committee on the Judiciary, U.S. Senate (June 6, 2007). That "[a]pplicants . . . have an incentive to submit a deluge of information that the [agency] neither wants nor needs, resulting in additional burdens on the [agency's] evaluation of an application," counsels not only against allowing a private right of action for fraud on an agency, as this Court held in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 351 (2001), but also against allowing inequitable conduct claims to proceed in any but the most extreme cases of fraud and deception.

The ease with which billion-dollar patent rights can be obliterated under the Federal Circuit's weak standard for intent also erodes confidence in the patent system. Property owners value certainty and Congress intended the Federal Circuit to promote that kind of certainty. If the business community loses faith in the enforceability of patents, it is unlikely to continue to invest in research and development, producing a chilling effect on the "progress of the useful arts" that the patent system was meant to promote. The consequences from decreased innovation are especially severe in the pharmaceutical industry, on which the American public depends for disease-curing, life-saving innovations.

In light of these and other considerations, the Federal Circuit's "return[] to the 'plague' of encouraging unwarranted charges of inequitable conduct" (*McKesson Info. Solutions, Inc. v. Bridge Med., Inc.*,

487 F.3d 897, 926-27 (Fed. Cir. 2007) (Newman, J., dissenting)), has attracted calls for reform. For example, one national organization advocates limiting the doctrine “to cases where a fraud resulted in the PTO issuing one or more invalidated claims,” which is tantamount to the adoption of a “reliance” requirement. American Bar Association Section of Intellectual Property Law, A Section White Paper: Agenda for 21st Century Reform 18 (2007). *See also*, e.g., Paul M. Janicke, *Do We Really Need So Many Mental and Emotional States in United States Patent Law?*, 8 Tex. Intell. Prop. L.J. 279, 292 (2000) (arguing that the “remedy is worse than the illness” and that, because true inequitable conduct is rare, this does “not seem to justify putting every patentee through the cost and jeopardy of a trial on inequitable conduct”).

And, after undertaking a comprehensive review of the patent system, the National Academies of Science and Engineering similarly concluded in 2004 that the costs and uncertainties associated with application of the inequitable conduct doctrine counsel its “elimination” or reform. National Research Council, *A Patent System for the 21st Century* (2004) at 123, <http://www.nap.edu/html/patentsystem/0309089107.pdf>. In reaching this conclusion, the Academies singled out for criticism the very standard at issue here: the Federal Circuit’s practice of inferring “intent from the materiality of the information that was withheld.” *Ibid.*

B. This case, which comes to the Court on final judgment after a bench trial, presents a sound vehicle for shaping the inequitable conduct doctrine. The district court held unenforceable a patent twice granted by the PTO, which provides more than \$2 billion in annual revenue. Essential to that holding

was the Federal Circuit's sliding-scale test, and its "should have known" standard for inferring intent from high materiality. Aventis argued that respondents failed to prove the requisite "intent to deceive," including "actual knowledge." App., *infra*, 82a. "Contrary to Aventis' arguments," the district court explained, "it is well-established that proof of actual knowledge is not always necessarily required" to prove intent to deceive; rather, individuals who fail to supply highly material information "should have known" about the information's materiality." *Ibid.* (citation omitted).

The district court also found that *Aventis* failed to prove a credible explanation for the non-disclosure, but the sliding scale was nonetheless essential to its holding. In fact, it is precisely because of the sliding scale that the district court shifted the burden to *Aventis* to prove a credible explanation once high materiality was shown, instead of requiring *respondents* to make a prima facie case of intent. App., *infra*, 87a (finding inequitable conduct because "[t]he elements of nondisclosure and high materiality have been admitted, and no credible excuse demonstrated"); see also, e.g., *Am. Hoist*, 725 F.2d at 1363 (a high showing of materiality "would necessarily create an inference that its nondisclosure was 'wrongful'").

In affirming, the panel majority applied a deferential standard of review and the same sliding scale applied by the district court. No such deference is due, however, should this Court reject the sliding scale. *Koon v. United States*, 518 U.S. 81, 100, 116 (1996) ("A district court by definition abuses its discretion when it makes an error of law"). Therefore, this case cleanly presents the legal issue of whether a court may refuse to enforce an otherwise valid pat-

ent based on a finding of inequitable conduct that lowers the intent requirement as the materiality of an omission or misrepresentation increases, effectively permitting a finding of intent to deceive based on nothing more than gross negligence. If the question presented is resolved in Aventis's favor, Aventis will be entitled to judgment on respondents' counterclaim, or, at minimum, to a redetermination of its culpability under the correct standard on remand.

The decision below disregards the careful confines that the Court has imposed on the inequitable conduct doctrine and exacerbates a troubling division of authority that has attracted widespread calls for reform. This Court has repeatedly granted certiorari to adjust the lower courts' expansion of judicially created doctrines. See *Exxon Shipping Co. v. Baker*, 128 S. Ct. 2605 (2008); *Stoneridge*, 128 S. Ct. at 761. 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, as well as the general run of federal law. This issue will not benefit from further percolation in the circuits. The split in the lower courts and within the Federal Circuit itself is deep and mature, and the Federal Circuit has exhibited a steadfast unwillingness to revisit the issue en banc. Four decades of confusion are enough. The question presented is ripe—indeed overdue—for this Court's review.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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