

No. 06-

IN THE
SUPREME COURT OF THE UNITED STATES

FERRING B.V., PETITIONER,
—AND—
AVENTIS PHARMACEUTICALS, INC., PETITIONER,
v.
BARR LABORATORIES, INC., RESPONDENT.

**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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QUESTIONS PRESENTED

Pursuant to this Court's holding in *Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806, 816 (1945), a federal court may invoke its inherent equitable powers to render unenforceable an otherwise valid patent where the patentee has engaged in "inequitable conduct" during prosecution of the patent application before the United States Patent & Trademark Office ("PTO"). This Court characterized such "inequitable conduct" as a form of unclean hands. Lower courts have formulated a test for evaluating whether a patentee engaged in "inequitable conduct" during patent prosecution, allowing this doctrine to be invoked generally whenever (1) the patentee misrepresented or did not provide the PTO with "material" information and (2) the patentee did so with an "intent" to deceive. The questions presented in this case are:

1. Whether the United States Court of Appeals for the Federal Circuit has improperly expanded the scope of the inequitable conduct doctrine by lowering the threshold of what constitutes "material" information that a patentee must disclose to the PTO so as to include information that has no bearing on patentability.
2. Whether the United States Court of Appeals for the Federal Circuit has improperly expanded the scope of the inequitable conduct doctrine by lowering the threshold for establishing intent to deceive the PTO so as to include a judicial determination that the applicant "knew or should have known" the information not provided to the PTO was "highly material."

LIST OF PARTIES

The names of all parties in the court whose judgment is sought to be reviewed appear in the caption of this Petition for a Writ of Certiorari.

CORPORATE DISCLOSURE STATEMENT

Counsel for petitioners certifies as follows:

All parent corporations and publicly held companies that own 10 percent or more of petitioner Ferring B.V. are as follows: Ferring B.V. is a wholly-owned subsidiary of Ferring Holding S.A., Switzerland.

All parent corporations and publicly held companies that own 10 percent or more of petitioner Aventis Pharmaceuticals, Inc. are as follows: Aventis Pharmaceuticals, Inc. is a subsidiary of Aventis Holdings, Inc., which is a subsidiary of Aventis Inc., which is a subsidiary of sanofi-aventis, a public corporation organized under the laws of France. A minority interest in Aventis Pharmaceuticals, Inc. is held by Aventis Beteiligungsverwaltung GmbH, which is a subsidiary of a Aventis Pharma Holdings GmbH, which is a subsidiary of Hoechst A.G., which is a subsidiary of sanofi-aventis S.A.

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OPINIONS BELOW

The opinion of the United States Court of Appeals for the Federal Circuit is reported at 437 F.3d 1181 (Fed. Cir. 2006) and is set forth in the Appendix ("App.") at App. 1a-49a. The circuit's original and revised orders denying the Petition for Panel Rehearing and Rehearing *En Banc* (App. 86a-87a, 88a-89a) are unreported. The decision of the district court (App. 50a-85a) is unreported.

STATEMENT OF JURISDICTION

The United States Court of Appeals for the Federal Circuit entered its judgment in this case on February 15, 2006, denied the Petition for Panel Rehearing and Rehearing *En Banc* on April 10, 2006, and issued a revised order denying the Petition for Panel Rehearing and Rehearing *En Banc* on April 12, 2006. Chief Justice Roberts issued an order on June 15, 2006, extending the time to file the petition for a writ of certiorari to September 11, 2006. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTES AND REGULATIONS INVOLVED

In shaping the "inequitable conduct" doctrine at issue in this case, courts have looked at times to the regulations governing the patent procurement process to assess what information the United States Patent and Trademark Office ("PTO") considers important to that process. The duty to disclose material information to the PTO is governed by 37 C.F.R. § 1.56 ("Rule 56"). The 1990 version of Rule 56 in effect at the time of the prosecution of the patent-in-suit is reproduced in full at App. 90a-94a. In 1992, the PTO substantially revised this regulation, and these changes are reflected in the current regulation, reproduced in full at App. 95a-97a.

STATEMENT OF THE CASE

This case presents important questions regarding the contours of the “inequitable conduct” doctrine, pursuant to which courts may refuse all enforcement of otherwise valid patents. This Court promulgated the inequitable conduct doctrine more than sixty years ago in accordance with the unclean hands maxim in order to enforce “minimum ethical standards” in cases of extreme misconduct by persons prosecuting patent applications at the PTO.¹ *Precision Instrument Mfg. Co. v. Automotive Maint. Mach. Co.*, 324 U.S. 806, 816 (1945). Since then, the Federal Circuit has vastly expanded the doctrine’s reach in a manner inconsistent with *Precision*, such that parties now invoke it routinely as a defense to patent infringement claims, and the resulting doctrine operates in considerable tension with the PTO’s statutory authority to govern the conduct of proceedings before it, *see* 35 U.S.C. § 2(b)(2)(A).

According to the Federal Circuit, whether a patent applicant has engaged in inequitable conduct during patent prosecution turns on: (1) whether the applicant misrepresented or did not provide the PTO with “material” information and (2) whether the applicant did so with an “intent” to deceive the PTO. However, in applying these requirements, the Federal Circuit has strayed far from the inequitable conduct doctrine’s equitable roots. The notion of “materiality” that the Federal Circuit now employs is sufficiently broad that courts may find materiality—as the Federal Circuit did here—without any proof that the PTO would have considered the information to be material to its administrative process. Moreover, in assessing whether the

¹ The abbreviation PTO will be used in this brief to also refer to the “Patent Office,” which was the agency’s name prior to 1976.

applicant had the requisite intent, the Federal Circuit has applied a “sliding scale” that permits a factual finding of an intent to deceive the PTO based on no more than a negligence finding, *i.e.*, that the applicant “should have known” that information not provided to the PTO was material, if coupled with a judicial determination that the undisclosed information was “highly material.”

The dramatic transformation of the inequitable conduct doctrine has produced circuit splits and conflicts with this Court’s precedents, and has interfered with the PTO’s ability to regulate practice before the agency. The practical ramifications of the expansion of the doctrine and the uncertainty surrounding its application (and misapplication) are far-reaching. The enforceability of otherwise valid patents is regularly challenged in litigation, frustrating the incentive goals of the patent system, adversely affecting decisions to invest in innovative technologies,² and escalating patent litigation costs. In fact, the National Academy of Sciences and the National Academy of Engineering (“National Academies of Science and Engineering”), through the National Research Council, have recommended abolishing the inequitable conduct doctrine “to reduce the cost and increase the predictability of patent infringement litigation outcomes, and to avoid other unintended consequences.” *See* National Research Council, A Patent System for the 21st Century (2004), <http://www.nap.edu/html/patentsystem/0309089107.pdf> (last

² Patents have become the backbone for capital investment decisions for small and large companies alike. Patents drive or greatly affect external investment decisions, venture capital investments, allocation of investment capital, and company stock appreciation. A rule of law that creates uncertainty in a property rights system thus constitutes risk for the investment community, and that greater risk leads to less investment.

accessed Sept. 8, 2006) [hereinafter “A Patent System”].

I. The Patent-in-Suit

This is a patent infringement action in which Ferring B.V. (“Ferring”) and Aventis Pharmaceuticals, Inc. (“Aventis”) seek to enforce U.S. Patent No. 5,047,398 (the “’398 patent”), entitled “DDAVP Antidiuretic and Method Therefor.” C.A. App. 59-61. The ’398 patent is directed to antidiuretic compositions containing 1-deamino-8-D-arginine vasopressin (also known as DDAVP) and methods of administering such compositions for treating diabetes insipidus. Ferring is the owner of the ’398 patent, and Aventis is the exclusive licensee and sells DDAVP® in the United States.

The invention described in the ’398 patent relates to a new, safe, and simple method of administering DDAVP, *i.e.*, via tablets which are swallowed and absorbed in the gastrointestinal tract. C.A. App. 60. This was an important advance over the prior art, because, prior to the invention, it was generally believed that proteins and peptides, such as DDAVP, decomposed in the stomach and intestines without substantial, or any, absorption. *Id.* Consequently, before the invention, DDAVP was administered inefficiently and inconveniently via sprays or plastic tubes for absorption through the nasal passages.

II. The Proceedings Before the PTO and the Basis of the Inequitable Conduct Findings

The Federal Circuit’s inequitable conduct holding is based on the trial court’s determination that certain declarations filed with the PTO did not contain information regarding the declarants’ prior relationships with Ferring.

The claims in the patent application that issued as the

'398 patent were initially rejected by the PTO as anticipated by and obvious in light of the "Zaoral patent" (U.S. Patent No. 3,497,491). The PTO interpreted Zaoral's use of "peroral" to cover administration of DDAVP in a pill form suitable for absorption in the gastrointestinal tract ("GI"). The applicants subsequently filed a continuation application in December 1985, and, in an interview with the PTO in May 1986, inventor Dr. Vilhardt explained that Zaoral used the term "peroral" to refer to buccal (inside the cheek) or sublingual (under the tongue) administration, not administration (absorption) via the GI tract. C.A. App. 4385. In response, the PTO "suggested that applicants obtain evidence from a non-inventor to the same effect." C.A. App. 2177. The PTO's official record of the interview, however, did not mention that "non-inventor" declarations were required. *See* C.A. App. 4385.³

In June 1986, the applicants filed a Preliminary Amendment accompanied by two declarations from Dr. Vilhardt (C.A. App. 3523-28, 3588-99) and declarations from two non-inventors, Drs. Myron Miller (C.A. App. 3634-58) and Paul Czernichow (C.A. App. 3601-32). The declarations explained that the term "peroral" was used in the Zaoral patent to refer to sublingual or buccal absorption, not absorption through the GI tract. Despite this declaration evidence, the PTO maintained its rejection. In response, the applicants appealed to the PTO Board of Patent Appeals and Interferences ("the Board"), which disagreed with the PTO Examiner and reversed the rejection. The Board entered a different obviousness rejection based on the Zaoral patent in

³ In accordance with PTO practice, "[a] complete written statement as to the substance of *any* face-to-face or telephone interview with regard to an application *must be made of record in the application*, whether or not an agreement with the examiner was reached at the interview." MPEP § 713.04 (emphasis in original) at C.A. App. 4386.

combination with an article published by Vavra, and returned prosecution to the PTO Examiner.

In November 1990, applicants responded to the Board's rejection by filing an Amendment and a new declaration from Dr. Vilhardt and four additional non-inventor declarations from Drs. Miller and Czernichow (both of whom had submitted declarations in 1986 (C.A. App. 3634-58, 3601-32)), and two new declarants, Drs. Tomislav Barth (C.A. App. 3701-02) and I.C.A.F. Robinson (C.A. App. 3703-05). All were very accomplished scientists. The declarants explained that the Vavra article did not teach or suggest the absorption of DDAVP in the GI tract in humans. The PTO issued the '398 patent on September 10, 1991.

The declarations did not reflect the limited, prior relationships between three of the four non-inventor declarants⁴ and Ferring. Dr. Czernichow, a Professor at the Hospital des Enfants-Malades in Paris, had participated in a small Ferring-funded DDAVP clinical trial for which he was not compensated by Ferring. Dr. Barth, a Professor at the Academy of Science of the Czech Republic at the time of his declaration, had worked on several projects for Ferring while at the Czech Academy. Dr. Robinson, the Head of the Division of Molecular Neuroendocrinology at the National Institute for Medical Research in London at the time of his declaration in 1990, had been a Ferring research director in 1985-86 and was a paid Ferring consultant for some months before that and again from 1986-89.

There was no factual finding or evidence of record that

⁴ Dr. Miller, Chief of Geriatric Medicine at the Veterans Administration Medical Center in Syracuse, the remaining non-inventor declarant who submitted declarations in 1986 and 1990, had no relationship with Ferring at any time.

Drs. Czernichow, Barth, Miller, or Robinson had relationships with Ferring at the time of their declarations, had financial interests in the patent application that led to the '398 patent, or were compensated in any way for their declarations. The record is also devoid of any evidence that the substance of their declarations, *i.e.*, the scientific statements they made to the PTO, was inaccurate or untruthful. Nor is there any evidence that the PTO would have considered such past relationships with Ferring relevant to the patentability issues before the PTO and the declaration discussions regarding the art cited by the PTO. Indeed, although the PTO suggested during an interview that the applicants could submit "non-inventor" declarations with respect to the Zaoral patent, the PTO did not so require in the official Interview Summary Form (C.A. App. 4385), let alone ask for declarations from parties having no prior connections with Ferring.

There was also no evidence that information regarding the prior connections Drs. Czernichow, Robinson, and Barth had with Ferring was intentionally withheld from the PTO. In fact, there was no evidence that Dr. Vilhardt, himself a distinguished scientist and professor at the University of Copenhagen, even knew of the prior connections between Dr. Czernichow and Ferring.⁵

III. The Infringement Suit and the Decision of the Trial Court

In December 2002, Ferring and Aventis filed suit in the

⁵ From 1977 to 1980, Dr. Vilhardt worked at Ferring as Research and Medical Director. In 1980, he returned to the University of Copenhagen but remained a scientific consultant for Ferring from 1980 until about 1987. Ferring continued to provide funding for Dr. Vilhardt's research until 1990.

United States District Court for the Southern District of New York, asserting that Barr Laboratories, Inc. ("Barr") infringed the '398 patent by filing its abbreviated new drug application seeking FDA approval to market a generic version of the patented DDAVP tablets prior to the expiration of the '398 patent. In February 2005, the district court (Brieant, J.) granted Barr's motions for summary judgment on its inequitable conduct defense and on its non-infringement counterclaim. App. 85a. Specifically, the court held the '398 patent unenforceable for inequitable conduct on the grounds that inventor Dr. Vilhardt had not informed the PTO of prior connections between Ferring and declarants Drs. Robinson, Barth, and Czernichow.

As to materiality, the district court nominally applied the PTO's pre-1992 materiality standard, *i.e.*, "information is material where there is a substantial likelihood that a reasonable examiner would consider it important," holding that declarations submitted in support of a pending patent application are generally considered material and by extension that the prior connections with Ferring were "highly material," without any finding that the substance of any of the declarations was incorrect. App. 61a, 68a. The district court concluded that, even if the declarants were "perfectly capable of objectivity," the PTO should have been informed of "the connections and prior relationships between these experts and Ferring." App. 66a. The district court then found an "intent to deceive" the PTO because "it must have been clear to Dr. Vilhardt at the preliminary meeting with the examiner that a non-inventor affidavit was sought for purposes of obtaining objective evidence that the invention was not anticipated by the prior art or obvious." App. 67a. Based on the foregoing, the court held on summary judgment that inequitable conduct had occurred as a matter of law.

IV. The Decision of the Federal Circuit

The Federal Circuit panel majority affirmed the district court's grant of summary judgment on the defense of inequitable conduct and did not reach the trial court's rulings on patent infringement. App. 2a. The Federal Circuit also cited the pre-1992 PTO regulation, but then stated that "[a]ffidavits are inherently material, even if only cumulative," and that "it is especially important that the examiner has all the information needed to determine whether and to what extent he should rely on declarations presented by the applicant." App. 14a n.9, 11a. The Federal Circuit then invoked "[t]he general law of evidence," which "has long recognized that the testimony of any witness may be rendered suspect by a past relationship with a party," App. 11a, explaining that "[a] witness's interest is always pertinent to his credibility and to the weight to be given to his testimony, and relevant interests are not limited to direct financial interests," App. 13a. The Federal Circuit thus was willing to invoke the inequitable conduct doctrine—which this Court has sparingly used as punishment for unclean hands—due to nothing but a potential for bias.

As to intent, the majority held that an intent to deceive can be inferred from evidence of negligence. Specifically, the Federal Circuit stated

that summary judgment is appropriate on the issue of intent if there has been a failure to supply highly material information and if the summary judgment 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. 19a (emphasis added). In finding under this standard that Dr. Vilhardt intended to mislead the PTO, the Federal Circuit stated that: (1) Barr had “established that Vilhardt knew of significant past relationships of at least two declarants,” (*i.e.*, 1990 declarants Robinson and Barth); (2) Dr. Vilhardt was “on notice that disinterested affidavits were necessary, and knew or should have known that the Ferring affiliations were material”; and (3) Dr. Vilhardt had not submitted an affidavit as to his own good faith in Ferring’s Opposition to Barr’s summary judgment motion on the issue. App. 19a-22a.

Judge Newman vigorously dissented. In a 21-page dissent, Judge Newman criticized the majority opinion for departing from the standard established in the Federal Circuit’s *en banc* decision in *Kingsdown Medical Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867 (Fed. Cir. 1988), which held that “a finding that particular conduct amounts to ‘gross negligence’ does not of itself justify an inference of intent to deceive.” App. 29a-32a. In Judge Newman’s words, the majority opinion served to

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, all on summary judgment, on the theory that the inventor “should have known” that something might be deemed material.

App. 32a. The dissent described the inference that the scientific opinions of the “distinguished” declarants were

“submitted with deceptive intent as a travesty.” App. 35a.

Judge Newman further stated that the “past affiliations” of the declarants were “not clearly and convincingly material as a matter of law.” App. 33a. Judge Newman also noted that the majority’s finding of materiality “is not substantive scientific materiality, but materiality *per se* of the relationship of the affiant to the applicant.” App. 36a. “Whether a past relationship between a declarant and the patent applicant is material to patentability depends on the facts of the relationship and the nature of the declaration. It is not *per se* material; and failure to explain the relationship is not *per se* deception.” App. 39a. Finally, Judge Newman stated that the majority had defied the rules of summary judgment by drawing “adverse inferences against the party opposing summary judgment” in lieu of the requisite “clear and convincing evidence of materiality and deceptive intent.” App. 47a.

REASONS FOR GRANTING THE PETITION

This case involves the Federal Circuit’s exercise of its inherent judicial powers to refuse enforcement of otherwise valid patents where there is real misconduct before the PTO, the administrative agency tasked with examining and issuing patents. In the entire history of the United States patent system, this Court has sustained such a use of inherent judicial power in the patent context precisely once, in *Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806 (1945), where the inventor had engaged in perjury and the inventor’s assignee had entered into contracts to continue to hide perjury from the PTO and the courts. This Court held that the inherent equitable powers of federal courts could be invoked under the unclean hands doctrine to refuse all enforcement of the “perjury tainted patents and contracts” because the patentee’s inequitable conduct did not “conform to minimum ethical

standards.” *Id.* at 816.

Since *Precision*, the Federal Circuit has adopted a test for inequitable conduct that focuses on: (1) whether the applicant misrepresented or did not provide the PTO with “material” information and (2) whether the applicant did so with an “intent” to deceive the PTO. Although these requirements are consistent with this Court’s reasoning in *Precision*, the lower courts, in applying the requirements, have strayed far beyond the narrow power recognized in *Precision* and developed a body of inequitable conduct law through capacious interpretation of the standards for establishing “materiality” and “intent.”

This case is a telling example. Here, on summary judgment, the Federal Circuit held the ’398 patent unenforceable and destroyed a significant property right because the patentee did not inform the PTO of prior contacts and limited relationships that some of the declarants had with Ferring. This omission pales in comparison to the intentional misconduct that occurred in *Precision*. Indeed, the Federal Circuit found inequitable conduct without pointing to any evidence or PTO regulation indicating that the PTO considers such prior relationships material to its patentability determination. Moreover, in finding an intent to deceive the PTO, the Federal Circuit used a negligence standard, concluding that the applicant “should have known” of the materiality of the undisclosed information.⁶

⁶ In testimony before the United States Senate Committee on the Judiciary, Philip S. Johnson, Esq., Chief Patent Counsel of Johnson & Johnson, testified that in the *Ferring* case the Federal Circuit “affirmed summary judgment of inequitable conduct under what appears to be a new duty of candor, applying a might-have-been-asked-should-have-been-answered standard, for deciding what must have been told to a patent examiner.” Hearing on Perspectives on Patents: Post-Grant
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Because the inequitable conduct doctrine has been enlarged far beyond the narrow bounds of its unclean hands origins in *Precision*, it has become, as the Federal Circuit once observed, “an absolute plague” upon the patent system with “charg[es of] inequitable conduct in almost every major patent case.” *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988). The vast modern expansion of the doctrine—based neither on congressional action nor PTO regulation, nor on any decisions of this Court—has given rise to (i) circuit splits between the Federal Circuit and the regional circuits (as well as intracircuit splits); (ii) conflicts between the Federal Circuit and the PTO; (iii) an inconsistency with the fundamental teachings of this Court concerning the scope and use of the inherent equitable powers of federal courts; (iv) inconsistency between the approach taken for policing misconduct before the PTO and the approach taken for addressing misconduct before other federal administrative agencies; and (v) a call for abolition or dramatic reform of the doctrine from the nation’s leading scientific institutes, the National Academies of Science and Engineering.

I. Traditionally Courts Have Refused to Enforce Patents Because Of Administrative Wrongdoing Only in Exceptionally Rare Circumstances

For more than one hundred years, a private party could not assert, even as a defense to an infringement action, “that the patentee had secured his grant by fraud or corruption.”

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Review Procedures and Other Litigation Reforms Before the S. Comm. on the Judiciary, Statement of Philip S. Johnson, Chief Patent Counsel, Johnson & Johnson, May 23, 2006, http://judiciary.senate.gov/testimony.cfm?id=1911&wit_id=5367 (last visited Sept. 8, 2006).

2 WILLIAM C. ROBINSON, THE LAW OF PATENTS FOR USEFUL INVENTIONS § 717, at 458 (1890). In the mid-1940s, however, this Court recognized a narrow exception to this traditional rule in cases where a party asserting patent rights has been involved in blatant fraud and obstruction of justice. The first suggestion of an exception came in dicta in *Hazel-Atlas Glass Co. v. Hartford Empire Co.*, 322 U.S. 238 (1944). In *Hazel*, the patentee paid handsomely for the fabrication of spurious evidence that it relied upon both during PTO prosecution and in subsequent patent infringement litigation. Years later, the infringement defendant learned the truth about the fraudulent activities and petitioned the courts for relief from the old judgment of infringement. The Supreme Court held that such relief was permissible because the fraud “demands the exercise of the historic power of equity to set aside fraudulently begotten judgments.” *Id.* at 245. The Court stressed that the case presented “a deliberately planned and carefully executed scheme to defraud not only the [PTO] but the Court of Appeals,” *id.* at 246, and that the facts were appropriate for the “judicially devised remedy” permitting “[e]quitable relief against fraudulent judgments,” *id.* at 248. The Court ruled that the “total effect of all this fraud, practiced both on the [PTO] and the courts, calls for nothing less than a complete denial of relief to [the patentee],” and stated in dicta that, “[h]ad the District Court learned of the fraud on the [PTO] at the original infringement trial, it would have been warranted in dismissing [the patentee’s] case.” *Id.* at 250.

The year after *Hazel*, this Court decided *Precision*. The inventor, Larson, was working for Precision when he applied for a patent on an improved “tail piece” for a particular kind of wrench. *Automotive Maint. Mach. Co. v. Precision Instrument Mfg. Co.*, 143 F.2d 332, 334 (7th Cir. 1944). During the course of patent prosecution, Larson fraudulently expanded his claims to encompass the entire wrench. To

support the broader claims, Larson filed a false affidavit concerning his purported invention of the wrench. The PTO declared an interference between Lawson's application and an application being prosecuted by Automotive, which also claimed to have invented the wrench. During the interference, Automotive obtained proof that Larson's affidavit was fraudulent. *Precision*, 324 U.S. at 809-10.

If Automotive had disclosed the fraud to the PTO, it could have prevailed in the interference and obtained patent rights to the wrench. However, Automotive would then have had no rights to patent claims covering Larson's innovative tail piece. Rather than disclose the fraud to the PTO, Automotive used its knowledge of Larson's perjury to achieve a settlement of the interference whereby Automotive received (1) Larson's concession of the whole interference; (2) an assignment of the remaining claims in Larson's perjury-tainted patent application; and (3) a commitment from Larson and his firm, Precision, never to question the validity of the subsequently issued patents. Thereafter, patents issued to Automotive from both its own application and the perjury-tainted application originally filed by Larson.

Later, Precision began manufacturing wrenches and Automotive sued Precision for infringement and breach of contract. This Court held that Automotive's lawsuit should be dismissed because a federal court should not assist in the enforcement of "perjury-tainted patents and contracts." *Id.* at 816. The Court stressed that Automotive's misconduct lay in exploiting rather than reporting Larson's perjury and that the conduct did not "conform to minimum ethical standards." *Id.* Requiring disclosure of such known fraud to the PTO when it is uncovered reinforces the agency's responsibility to "pass upon the sufficiency of the evidence" and "to safeguard the public in the first instance against fraudulent patent monopolies." *Id.* at 818. Automotive's exploitation of fraud also extended to the courts, and "inequitable

conduct impregnated Automotive's *entire cause of action*," not merely the administrative proceeding, and such inequitable conduct "justified dismissal by resort to the unclean hands doctrine." *Id.* at 819 (emphasis added).

For at least the next twenty years, *Precision* was interpreted narrowly by lower courts and applied, if at all, only in extreme cases where patent applicants made clear, intentional misrepresentations which bore directly on the issue of patentability.⁷

II. The Lower Courts Expanded the Inequitable Conduct Doctrine by Rejecting Then-Current Administrative Practice

More than two decades after this Court's decision in *Precision*, the doctrine of inequitable conduct underwent a dramatic expansion in some appellate courts. Pivotal in triggering the surge in inequitable conduct litigation was *Norton v. Curtiss*, 433 F.2d 779 (C.C.P.A. 1970), a decision by the Court of Customs and Patent Appeals ("CCPA"), a predecessor of the Federal Circuit that had jurisdiction to review decisions of the PTO. In an interference proceeding, the PTO had rejected one applicant's argument that the PTO should strike a competing application for fraud on the PTO. Although the CCPA ultimately sustained the agency's action, it elaborated on the law concerning fraud on the PTO and held that the agency was applying the materiality and intent elements too narrowly.

⁷ See, e.g., *Armour & Co. v. Wilson & Co.*, 274 F.2d 143, 148 (7th Cir. 1960); *Haloro, Inc. v. Owens-Corning Fibreglas Corp.*, 266 F.2d 918, 919 (D.C. Cir. 1959); *Mas v. Coca-Cola Co.*, 163 F.2d 505, 507 (4th Cir. 1947). We have not identified any case during this twenty year period where a court of appeals affirmed the use of the inequitable conduct doctrine to refuse enforcement of issued patents.

Norton recognized that, in the past, “‘materiality’ ha[d] generally been interpreted to mean that if the [PTO] had been aware of the complete or true facts, the challenged claims would not have been allowed.” *Id.* at 794. The CCPA, however, urged a broader test that included the subjective considerations of the examiner and the applicant. Regarding intent, the CCPA held that the PTO had applied the wrong standard, “narrow[ing] the requirement almost to that of proving actual intent.” *Id.* at 796. In the CCPA’s view, “it may suffice to show nothing more than that the misrepresentations were made in an atmosphere of gross negligence as to their truth.” *Id.*

III. The Expansion of the Inequitable Conduct Doctrine Has Generated Acknowledged Circuit Splits and Conflicts with Administrative Practice

A. Conflicting Standards of Materiality

In the dozen years between the decision in *Norton* and the creation of the Federal Circuit, a deep and widely recognized circuit split had developed. The Federal Circuit noted that “courts have utilized at least three distinct orders of materiality: (1) an objective ‘but for’ standard; (2) a subjective ‘but for’ standard; and (3) a ‘but it may have been’ standard.” *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1362 (Fed. Cir. 1984). The objective “but for” standard is the narrowest in its reach, as it requires a party asserting fraud to prove that but for the misrepresentation, the PTO would not have granted the patent. Although the first “but for” test had a substantial following prior to the CCPA’s influential decision in *Norton*,⁸ the circuit split that has developed since 1970 has

⁸ See, e.g., *Feed Serv. Corp. v. Kent Feeds, Inc.*, 528 F.2d 756, 762 (7th Cir. 1976); *Cataphote Corp. v. DeSoto Chem. Coatings, Inc.*,
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been dominated by the second and third tests, plus a new test created and applied by the Federal Circuit.

At least three circuits have applied the second test—the subjective “but for” test—which requires that a court determine whether the misrepresentation was a crucial factor or substantial cause of the granting of the patent. *See Skil Corp. v. Lucerne Prods., Inc.*, 684 F.2d 346, 350 (6th Cir. 1982); *Pfizer, Inc. v. Int’l Rectifier Corp.*, 685 F.2d 357, 359 (9th Cir. 1982); *Plastic Container Corp. v. Cont’l Plastics*, 607 F.2d 885, 900 (10th Cir. 1979). Other circuits have embraced the third test under which omissions or misrepresentations may be viewed as material if they *may* or *might* have resulted in a rejection of the patent application. *See CMI Corp. v. Barber-Greene Co.*, 683 F.2d 1061, 1066 (7th Cir. 1982); *Timely Prods. Corp. v. Arron*, 523 F.2d 288, 297-98 (2d Cir. 1975); *Monsanto Co. v. Rohm & Haas Co.*, 456 F.2d 592, 600 (3d Cir. 1972); *Trio Process Corp. v. L. Goldstein’s Sons, Inc.*, 461 F.2d 66, 73 (3d Cir. 1972).

In *American Hoist*, the Federal Circuit explicitly acknowledged the use of the three materiality tests but adopted a fourth broader test under which information is deemed material where there is “a substantial likelihood” that a reasonable examiner would consider it “important” in deciding whether to allow the application to issue as a patent. *American Hoist*, 725 F.2d at 1362.

The pre-1992 Rule 56 articulated the same standard for materiality, *i.e.*, what “a reasonable examiner would consider . . . important.” 37 C.F.R. § 1.56(a) (1991). In 1992, the

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450 F.2d 769, 773 (9th Cir. 1971); *Wen Prods. Inc. v. Portable Elec. Tools, Inc.*, 367 F.2d 764, 767 (7th Cir. 1966).

rule was “amended to present a clearer and more objective definition of what information the [PTO] considers material to patentability,” PTO, Notice of Final Rulemaking, Duty of Disclosure, 57 Fed. Reg. 2021, 2024 (Jan. 17, 1992). The new rule articulates a fifth materiality standard, wherein information is material to patentability when it is not “cumulative” to information of record and it helps to establish “a *prima facie* case of unpatentability of a claim,” or is “inconsistent” with the applicant’s position on patentability. 37 C.F.R. § 1.56(b) (2006). Taken together, the pre-1992 and post-1992 versions of Rule 56 demonstrate that the PTO considers information material if it is new information that directly bears on the substantive question of patentability.

Nonetheless, the Federal Circuit has held that the new rule does not “supplant” the common law tests developed to enforce the “judicially created” inequitable conduct doctrine. *Digital Control, Inc. v. Charles Machine Works*, 437 F.3d 1309, 1315-16 (Fed. Cir. 2006). In effect, the Federal Circuit has ignored the PTO’s view of materiality. *See* R. CARL MOY, *MOY’S WALKER ON PATENTS* § 2.9 at 2-23 n.2 (2005) (stating that the 1992 rule “has proven ineffective” in “overturn[ing] common-law precedents of the Federal Circuit”).

That there is no specific PTO regulation or guideline requiring disclosure of all prior connections between declarants and applicants is yet another indication that these connections are not considered important by the PTO. As the Federal Circuit noted, “examiners have broad authority to request information that they deem relevant to the issue of patentability.” App. 11a. Yet, the PTO here did not require disinterested declarations; did not inquire about any connections between the declarants and Ferring; did not request the CVs of Drs. Barth and Robinson whose declarations were submitted without them; and did not ask

whether the declarants were paid for their declarations (they were not).

B. Conflicting Standards of Intent

Prior to the creation of the Federal Circuit, there existed a three-way regional circuit split on the showing of “intent” necessary to trigger an inequitable conduct holding. Some circuits required scienter (*i.e.*, the patentee had knowingly and intentionally lied), while other circuits held that only a showing of gross negligence is sufficient. *Compare, e.g., Scott Paper Co. v. Fort Howard Paper Co.*, 432 F.2d 1198, 1204 (7th Cir. 1970) (“Unclean hands can be asserted only if there has been a deliberate misrepresentation in the [PTO].”), with *Delong Corp. v. Raymond Int’l, Inc.*, 622 F.2d 1135, 1146 (3d Cir. 1980) (stating inequitable conduct requires at least a finding of “gross negligence”). One circuit (the First) adopted an intermediate position that embraced a sliding scale permitting a lower showing of intent if coupled with a greater showing of materiality, and vice-versa. *See Digital Equip. Corp. v. Diamond*, 653 F.2d 701, 716 (1st Cir. 1981).

Following its formation in 1982, the Federal Circuit initially required evidence of intentional misconduct. *See Orthopedic Equip. Co. v. All Orthopedic Appliances, Inc.*, 707 F.2d 1376, 1383 (Fed. Cir. 1983). The Federal Circuit relaxed the intent standard shortly thereafter, however, holding that evidence of gross negligence could support an inequitable conduct finding. *See Driscoll v. Cebalo*, 731 F.2d 878, 885 (Fed. Cir. 1984).

The Federal Circuit again reversed course in its *en banc* decision in *Kingsdown*, expressly overruling *Driscoll* and holding that inequitable conduct required proof of an “intent to deceive” the PTO, and that “a finding that particular conduct amounts to ‘gross negligence’ does not of itself justify an inference of intent to deceive.” *Kingsdown*, 863

F.2d at 876. *Kingsdown* did not, however, explicitly disavow or discuss the First Circuit’s “sliding scale” theory and its application to the intent standard. That theory had been embraced by the Federal Circuit prior to *Kingsdown*. See *American Hoist*, 725 F.2d at 1363.

Recent cases, including this one, show that the Federal Circuit has now engrafted the sliding scale approach onto *Kingsdown*.⁹ As the Federal Circuit panel majority held in this case, an “intent to deceive” sufficient to satisfy *Kingsdown* may be predicated upon a combination of a “high degree” of materiality coupled with a finding that the patentee “should have known” about the materiality of the omissions. Moreover, the procedural posture of this case—a finding of inequitable conduct on summary judgment—confirms that the Federal Circuit doctrine is not merely articulating that certain *permissible* inferences may be drawn from certain facts. Rather, intent to deceive is now being demonstrated *as a matter of law* in cases where the court determines that a “high degree of materiality” is coupled with negligence. But negligence is not intent.

The Federal Circuit’s “should have known” standard is also inconsistent with current PTO regulations. During prosecution, a patent applicant has a legal and ethical “duty to disclose to the [PTO] all information *known* to that individual to be material to patentability as defined in this

⁹ See, e.g., *Abbott Labs. v. Torpharm, Inc.*, 300 F.3d 1367, 1380 (Fed. Cir. 2002) (“[T]he intent necessary to establish inequitable conduct is based on a sliding scale related to materiality of the omission.”); see also *Novo Nordisk Pharms., Inc. v. Bio-Tech. Gen. Corp.*, 424 F.3d 1347, 1359 (Fed. Cir. 2005); *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1239 (Fed. Cir. 2003); *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1257 (Fed. Cir. 1997).

section.” 37 C.F.R. § 1.56 (2006) (emphasis added). According to the PTO, the Rule was clarified in 1992 “to indicate that the duty of an individual to disclose information is based on the knowledge of that individual that the information is material to patentability.” Duty of Disclosure, 57 Fed. Reg. 2021, 2022 (Jan. 17, 1992). This difference between the Federal Circuit standard and the PTO standard can only create needless confusion. The expanded judicial tests for intent and materiality force patent applicants to expend resources seeking and disclosing information that the PTO regulations and guidelines do not require and, in turn, the PTO must expend more resources reviewing this additional information.

Though the circuit splits on materiality and intent arose before the establishment of the Federal Circuit, this Court has made clear that such splits on patent issues remain significant in making certiorari decisions. *See Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 60 (1998); *see also Holmes Group, Inc. v. Vornado Air Circulation Sys., Inc.*, 535 U.S. 826, 839 (2002).

IV. The Federal Circuit’s Standards of Materiality and Intent Have No Foundation in This Court’s Patent Decisions or in Other Areas of Law

A. The Federal Circuit’s Materiality Standard

Neither in patent inequitable conduct cases nor in other substantive legal areas has this Court ever applied a materiality standard that could be triggered by the nondisclosure of information related to tangential matters. In *Precision*, for example, the patent applicant had filed a statement with the PTO providing false dates as to the conception, disclosure, drawing, description, and reduction to practice of his claimed invention, 324 U.S. at 809, and also falsely claimed that he was the sole inventor of the

entire wrench, *id.* at 810. These statements directly related to the patentability issue.

On the other hand, this Court has held that even an outright misrepresentation is not material where the misrepresentation raises a peripheral issue which does not impact the patentability of the claimed invention. In *Corona Cord Tire Co. v. Dovan Chemical Corp.*, 276 U.S. 358, 373-74 (1928), the inventor submitted blatantly false affidavits to the PTO claiming to have used his new vulcanization process to produce retail products when, in fact, the inventor had produced only some test sheets. This Court held that the misrepresentations, “though perhaps reckless, were not the basis for [the patent] or essentially material to its issue,” and thus did not destroy the “reasonable presumption of validity furnished by the grant of the patent.” *Id.* at 374.¹⁰

The standard of materiality applied by the Federal Circuit here also conflicts with the standard for materiality applied by this Court in statutory cases concerning fraud or misrepresentation. In *Kungys v. United States*, 485 U.S. 759, 770 (1988), the Court endorsed a standard under which “a concealment or misrepresentation is material if it ‘has a natural tendency to influence, or was capable of influencing, the decision of the decisionmaking body to which it was addressed.’” Three Justices (Justice Stevens joined by Justices Marshall and Blackmun) applied an even narrower standard of materiality; in their view, a misrepresentation

¹⁰ The *Corona* standard has been used by the lower courts in developing a “but for” standard of materiality for establishing fraud on the PTO, *i.e.*, a misrepresentation or omission is material only if “but for” the misrepresentation or omission, the patent would not have issued. *See, e.g., Corning Glass Works v. Anchor Hocking Glass Corp.*, 253 F. Supp. 461, 469 (D. Del. 1966); *Baldwin-Lima-Hamilton Corp. v. Tatnall Measuring Sys. Co.*, 169 F. Supp. 1, 24-25 (E.D. Pa. 1958).

could be material only if it “concealed a disqualifying fact or hindered the discovery of a disqualifying fact.” *Id.* at 789.

If either of these materiality standards were applied here, the information regarding past relationships between the declarants and the applicant would not be deemed material to the patentability of the invention claimed in the '398 patent. There is no evidence, let alone “clear, unequivocal, and convincing” evidence, *id.* at 772, that knowledge of those past relationships would have had the natural tendency of influencing the PTO to issue a rejection. Indeed, the Federal Circuit acknowledges the reality that it is normal practice “for the inventor to recommend, and even contact, his own colleagues or people who are, or who have been, affiliated with his employer and to submit declarations from such people,” App. at 26a, suggesting that the PTO, when reviewing a declaration, routinely assumes that the declaration is from an individual known to the patent applicant.

B. The Federal Circuit’s Intent Standard

The Federal Circuit’s sliding scale standard for intent, which permits a finding of intent to deceive based only on evidence of a negligent non-disclosure of information the court deems highly material, has no basis in this Court’s decisions or in its guidance in other substantive areas with an intent inquiry. Indeed, this Court has applied the inequitable conduct doctrine only once—in *Precision*—when the patentee knew about the relevant fraudulent conduct and “chose to act in disregard of the public interest,” *Precision*, 324 U.S. at 816, by exploiting rather than reporting the fraud. Moreover, the Federal Circuit’s intent standard is inconsistent with the malevolent intent standard that various

courts have used in applying the unclean hands doctrine¹¹ or in establishing fraud.¹² In none of these cases—covering many different areas of law—has this Court ever endorsed the view that intent would be judged on a sliding scale, with mere negligence sufficient in cases of high materiality.

V. The Federal Circuit’s Inequitable Conduct Law Is Inconsistent With Settled Principles Governing Inherent Judicial Power and Administrative Law

In recognizing the power of federal courts to refuse enforcement of patents based on misconduct before the PTO, this Court invoked “the equitable maxim that ‘he who comes into equity must come with clean hands,’” which is a “self-imposed ordinance” of the federal courts. *Precision*, 324 U.S. at 814. Federal courts possess such inherent equitable powers “to prevent abuses, oppression, and injustice,” *Gumbel v. Pitkin*, 124 U.S. 131, 144 (1888), but this Court has employed a “traditionally cautious approach” to permitting federal courts’ exercise of their “inherent equitable power.” *Grupo Mexicano de Desarrollo, S.A. v. Alliance Bond Fund, Inc.*, 527 U.S. 308, 329 (1999). This approach is reflected in the field of copyright law, where federal courts recognize an inherent equitable power to refuse enforcement of intellectual property rights based on

¹¹ See *Dollar Sys., Inc. v. Avcar Leasing Sys., Inc.*, 890 F.2d 165, 173 (9th Cir. 1989) (affirming district court’s finding 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”); *A.H. Emery Co. v. Marcan Prods. Corp.*, 389 F.2d 11, 18 n.4 (2d Cir. 1968); *Eresch v. Braecklein*, 133 F.2d 12, 14 (10th Cir. 1943).

¹² See *United States v. U.S. Gypsum Co.*, 438 U.S. 422, 435 (1978); *Reilly v. Pinkus*, 338 U.S. 269, 276 (1949); *Dunbar v. United States*, 156 U.S. 185, 194 (1895).

fraud upon the agency but apply the doctrine “only rarely, when the [rightholder’s] transgression is of serious proportions.” 4 MELVILLE B. NIMMER & DAVID NIMMER, NIMMER ON COPYRIGHT § 13.09[B], at 13-310 (2006); *see also, e.g., Original Appalachian Artworks, Inc. v. Toy Loft, Inc.*, 684 F.2d 821, 828 (11th Cir. 1982); *Santrayll v. Burrell*, 993 F. Supp. 173, 176-77 (S.D.N.Y. 1998).

The inequitable conduct standards applied in this case reflect that Federal Circuit jurisprudence has dramatically departed from the traditional approach in this area. As previously mentioned, only once has this Court found cause to hold a patent unenforceable because of inequitable conduct before the administrative agency. But as of 1988, a study by the American Intellectual Property Law Association estimated that 80% of all patent infringement cases included charges of inequitable conduct.¹³ This flood of inequitable conduct allegations is driven by the expansion of the inequitable conduct doctrine by the federal courts, as well as the uncertainty surrounding the doctrine. The result has been circuit splits and conflicts with this Court’s precedents and with PTO practice.

An aggressive use of inherent judicial power is particularly inappropriate where a court is attempting to police the integrity of information submitted to an

¹³ Ad Hoc Committee on Rule 56 and Inequitable Conduct, American Intellectual Property Law Association, *The Doctrine of Inequitable Conduct and The Duty of Candor in Patent Prosecution: Its Current Adverse Impact on the Operation of the United States Patent System*, 16 AIPLA Q.J. 74, 75 (1988); *see also* Katherine Nolan-Stevaux, *Inequitable Conduct Claims in the 21st Century: Combating the Plague*, 20 BERKELEY TECH. L.J. 147, 163-64 (2005) (describing an empirical study that showed that 75% of inequitable conduct charges were found by the courts to be of no merit).

administrative agency. It is fundamental that issues concerning administrative process are particularly within the competence and expertise of federal agencies, and that the courts should permit agencies to be masters of their own procedures. See *Vermont Yankee Nuclear Power Corp. v. NRDC*, 435 U.S. 519, 524-25 (1978). In this case, the Federal Circuit's inequitable conduct rules directly regulate both the amount of information that must be disclosed to the agency and the penalties for non-compliance. These are precisely the sort of matters that this Court has held *should* be left to the agency, with limited intervention from courts exercising inherent common law powers.

Moreover, this Court has made clear that it is the administrative agency's "responsibility to police fraud consistently with the Agency's judgment and objectives." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001). Indeed, for other administrative agencies, the Court has been willing to enforce an administrative order even though the beneficiary of the order committed perjury during the administrative proceedings. See *ABF Freight Sys., Inc. v. NLRB*, 510 U.S. 317 (1994).

Far from reinforcing the PTO's authority to police the integrity of its own proceedings, the Federal Circuit doctrine has displaced the agency-created standards and procedures. The Federal Circuit has now repeatedly held that, in judging materiality, federal courts are *not* constrained by the PTO's attempt through administrative rulemaking to define a more narrow standard of materiality than the one established in judicial caselaw. See, e.g., *Digital Control*, 437 F.3d at 1316 (stating that the "reasonable examiner" standard and the Federal Circuit's caselaw interpreting that standard "were

not supplanted by the PTO's adoption of a new Rule 56").¹⁴ So dominant have courts become in this area that the PTO has now ceded to the courts primary responsibility for determining whether frauds or misrepresentations have occurred in its own proceedings.¹⁵

VI. The National Academies of Science and Engineering Have Endorsed Abolition or Reform of the Inequitable Conduct Doctrine

In 2004, the National Research Council of the National Academies of Science and Engineering released a report calling for various reforms of the current patent system. *See A Patent System, supra*. The report was produced by a committee of eminent lawyers, economists, legal academics, and corporate executives, and was funded by a broad cross-section of government agencies, foundations, and private corporations. This distinguished committee endorsed certain concrete proposals "to ensure the vitality and improve the functioning of the patent system," *id.* at 5 (executive summary) and specifically recommended "the elimination of the inequitable conduct doctrine or changes in its implementation," finding it imposes high costs in

¹⁴ To confirm the existing conflict between the PTO and the Federal Circuit, this Court could call for the views of the Solicitor General (CVSG)—an action this Court has increasingly used in evaluating certiorari petitions in patent cases.

¹⁵ *See* PTO, Notice of Proposed Rulemaking, Duty of Disclosure, 56 Fed. Reg. 37321, 37323 (Aug. 6, 1991) (stating that the PTO "generally will not comment on duty of disclosure issues" and will exercise its authority to reject a patent application during the normal *ex parte* examination process "only in the most egregious and clear cases, e.g., where there is a final court decision that inequitable conduct has occurred").

litigation and yet has “limited deterrent value,” *id.* at 123.¹⁶

The National Academies of Science and Engineering singled out for criticism the practice of inferring “intent from the materiality of the information that was withheld.” *Id.* This case involved such an inference, and the court applied the inference as a matter of law on summary judgment. Similarly, the uncertainty and the litigation burden cited by the National Academies of Science and Engineering also exist in this case. The decision below opens a new vein of inequitable conduct litigation—past employment relationships between declarants and assignees (and arguably licensees and other similar entities), other professional connections, and perhaps even friendships among the relevant parties, will now be fertile ground for inequitable conduct allegations. Even where, as in this case, the PTO showed no interest in obtaining such information about the declarants, a court can still find, 15 years after the fact, that the patent applicant intentionally deceived the PTO by failing to disclose tangential information that had no bearing on the patentability of the claimed invention.

The report also stressed that many other remedies exist for unethical conduct before the PTO. *Id.* at 122-23. Thus, narrowing the inequitable conduct doctrine to its traditional limits could “increase predictability of patent dispute outcomes and reduce the cost of litigation without substantially affecting the underlying principles that [this

¹⁶ The inequitable conduct doctrine has been widely criticized. See, e.g., P.M. Janicke, *Do We Really Need So Many Mental and Emotional States in United States Patent Law?* 8 TEX. INTELL. PROP. L.J. 279 (2000); J.F. Lynch, *An Argument for Eliminating the Defense of Patent Unenforceability Based on Inequitable Conduct*, 16 AIPLA Q.J. 7 (1988); C.M. McMahon, *Intent to Commit Fraud on the USPTO: Is Mere Negligence Once Again Inequitable?* 27 AIPLA Q.J. 49 (1999).

aspect] of the enforcement system [was] meant to promote.”
Id. at 117-18.

CONCLUSION

For the reasons stated, this petition for a writ of certiorari should be granted.

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