

2008-1511, -1512, -1513, -1514, -1595

**United States Court of Appeals
for the Federal Circuit**

THERASENSE, INC. (NOW KNOWN AS ABBOTT
DIABETES CARE, INC.)
AND ABBOTT LABORATORIES
Plaintiffs-Appellants,

v.

BECTON, DICKINSON AND COMPANY,
AND NOVA BIOMEDICAL CORPORATION,
Defendants-Appellees,

AND

BAYER HEALTHCARE LLC,
Defendant-Appellee.

Appeals from the United States District Court for the Northern
District of California in consolidated case nos. 04-CV-2123, 04-CV-
3327, 04-CV-3732, and 05-CV-3117, Judge William H. Alsup.

BRIEF OF AMICUS CURIAE
43 PATENT PRACTITIONERS EMPLOYED BY ELI LILLY AND COMPANY,
IN SUPPORT OF NO PARTY

August 2, 2010

ROBERT A. ARMITAGE
JAMES J. KELLEY
PRINCIPAL ATTORNEY
MARK J. STEWART
ELI LILLY AND COMPANY
LILLY CORPORATE CENTER
940 S. EAST STREET
DROP CODE 1104
INDIANAPOLIS, INDIANA 46225
317.277.8110

TABLE OF CONTENTS

I. STATEMENT OF INTEREST OF AMICUS CURIAE.....	1
II. SUMMARY.....	3
III. INTRODUCTION	6
IV. ARGUMENT.....	7
A. “Inequitable Conduct” Should Reference Only Misconduct by Litigants Themselves Sufficient to Require Dismissal of Their Claims for Want of Equity.....	7
B. “Inequitable Conduct” Should Be Limited to a Fraud or Other Conduct Amounting to a Fraud That Prevented a Patent from Being Kept Within Its Legitimate Scope.	11
C. Neither the Materiality-Intent Balancing Framework nor the Inference of Intent from Materiality Should Remain as Part of “Inequitable Conduct” Law.....	14
D. Deceptive Intent Should Only Be Inferred Where, from All the Facts and Circumstances, Negligence Can Be Excluded as a Reasonable Explanation for the Questioned Conduct.....	19
E. Materiality-Related Measures and Factors Must Be Postured in “Inequitable Conduct” Jurisprudence in Such a Manner to Allow the Office, as the Expert Agency, to Efficiently and Effectively Manage Its Congressional Mandate.....	21
V. CONCLUSION.....	27

TABLE OF AUTHORITIES

Cases

<i>Am. Hoist & Derrick Co. v. Sowa & Sons</i> , 725 F.2d 1350 (Fed Cir. 1984).....	22, 25
<i>AT&T Universal Card Servs. v. Mercer (In re Mercer)</i> , 246 F.3d 391 (5th Cir. 2001)	19
<i>Citibank South Dakota v. Dougherty (In re Dougherty)</i> , 84 B.R. 653 (B.A.P. 9th Cir. 1988)	19
<i>Citibank v. Eashai (In re Eashai)</i> , 87 F.3d 1082 (9th Cir. 1996).....	13, 19
<i>Durland v. United States</i> , 161 U.S. 306 (1896).....	9
<i>Emmett Valley Assocs. v. Woodfield (In re Woodfield)</i> , 978 F.2d 516 (9th Cir. 1992)	20
<i>Field v. Mans</i> , 516 U.S. 59 (1995)	9
<i>Hazel-Atlas Glass Co. v. Hartford-Empire Co.</i> , 322 U.S. 238 (1944), <i>overruled on other grounds sub nom., Standard Oil Co. v. United States</i> , 429 U.S. 17 (1976).....	8, 10
<i>Household Credit Servs. v. Ettell (In re Ettell)</i> , 188 F.3d 1141 (9th Cir. 1999).....	13, 20
<i>James-Dickinson Farm Mortgage Co. v. Harry</i> , 273 U.S. 119 (1927).....	9
<i>Keystone Driller Co. v. Gen. Excavator Co.</i> , 290 U.S. 240 (1933)	8
<i>Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.</i> , 324 U.S. 806 (1945).....	9, 10, 11
<i>Rembert v. AT&T Universal Card Servs., Inc. (In re Rembert)</i> , 141 F.3d 277 (6th Cir. 1998)	20
<i>Soza v. Hill (In re Soza)</i> , 542 F.3d 1060 (5th Cir. 2008).....	20
<i>TSC Indus., Inc. v. Northway, Inc.</i> , 426 U.S. 438 (1976).....	23, 24, 25

<i>United States v. Stevens</i> , 559 U.S. ___, 130 S. Ct. 1577 (2010)	12
<i>Universal Bank, N.A. v. Grause (In re Grause)</i> , 245 B.R. 95 (B.A.P. 8th Cir. 2000).....	20

Statutes

11 U.S.C. § 523(a)(2).....	9, 13
11 U.S.C. § 727(a)(2)(A)	20
18 U.S.C. § 1001(a)	26
35 U.S.C. § 282.....	7, 20
Cal. Stat. § 3439.04 (2010)	20
Fla. Stat. § 726.105 (2010)	20
N.C. Gen. Stat. § 39-23.4 (2010).....	20
Neb. Rev. Stat. § 36-705 (2010).....	20
Tex. Bus. & Com. Code § 24.005(b) (2010)	20

Other Authorities

<i>Beaned by a Pitch, Ray Chapman Dies</i> , N.Y. Times, Aug. 17, 1920, available at http://www.nytimes.com/packages/html/sports/year_in_sports/08.17.html	17
Major League Baseball Official Rules § 8.02(d) (2008), available at http://mlb.mlb.com/mlb/downloads/y2008/official_rules/08_the_pitcher.pdf	16
Pasquale J. Federico, <i>Commentary on the New Patent Act</i> , 35 U.S.C.A. (West 1954), reprinted in 75 J. Pat. & Trademark Off. Soc’y 161 (1993)	7
Patent Examining and Appeal Procedures, 42 Fed. Reg. 5588 (Jan. 28, 1977).....	23
Senate Report No. 82-1979, at 1, 6 (1952).....	7

Rules

37 C.F.R § 1.56(a) (1983).....	22
37 C.F.R. § 1.56 (1979)	23

Forty-Three Patent Practitioners employed by Eli Lilly and Company (“Lilly”), whose names are listed in the Appendix, submit this brief as amicus curiae in compliance with Rule 29 of the Federal Rules of Appellate Procedure and with this Court’s Rule 29. Neither the Forty-Three Patent Practitioners individually nor their employer, Lilly, has a stake in the result of this appeal. The parties to this case have not contributed in any way to the preparation of this brief. Each party consented to the filing of this brief.

I. STATEMENT OF INTEREST OF AMICUS CURIAE

This brief is filed by the forty-three of us, individuals registered to practice before the United States Patent and Trademark Office (“Office”) and employed by Eli Lilly and Company. Lilly is a research-based biopharmaceutical company headquartered in Indianapolis, Indiana. Lilly’s ability to invest in research to discover and bring new medicines to patients greatly depends upon the exclusivity accorded under U.S. patents.

Sometimes only a single U.S. patent forms the basis for investing hundreds of millions of dollars to take a medicine through clinical testing to obtain FDA approval for use in patients.

Lilly charges the forty-three of us with the task of securing valid and enforceable U.S. patent rights in its inventions. Collectively, we are responsible for the filing and the subsequent prosecution of patent

applications before the Office on virtually all the inventions and discoveries made by Lilly Research Laboratories. Within Lilly, we operate under procedures and practices designed to foster the utmost in candor and good faith in our dealings with the Office. We take pride, we believe justifiably, in the manner in which we deal with U.S. patent examiners.

During the past decade, those of us handling patents that Lilly has litigated have routinely been accused of misconduct. We have invariably been deposed. When deposed, the primary purpose of our interrogators has been to identify potential flaws in our work. Our every step has been microscopically analyzed for hints of omission or misstatement. Almost without fail, the allegations leveled against us are that we have withheld or misstated highly material information sufficient to support an inference of intent to deceive the Office.

As this Court's jurisprudence is now applied, it remains entirely possible that one or more of us someday may have our professional reputations sullied because a court wrongly infers that we have engaged in deceit. Should that happen, there would be no redress, no forum in which to clear our reputations. Our future as patent practitioners would be compromised and potentially ruined.

Our interest in this appeal is that the Court take full account of the respect due honest patent procurement professionals and of the negative consequences its jurisprudence has on the everyday practice of patent law. In sum, we should not face cavalier charges of misconduct that currently can be sustained even in the absence of any direct evidence of intended deceit, and that could unfairly and prematurely end our professional lives.

II. SUMMARY

The Court has set out six questions for consideration *en banc*:

1. *Should the materiality-intent-balancing framework for inequitable conduct be modified or replaced?* Yes. Materiality, as such, should be effectively abandoned as a factor relevant to intent. The Court should hold that there is no necessary connection or nexus between the seriousness of an omission or misstatement with respect to its impact on patentability and the assessment of whether actual misconduct, rather than merely negligent or blameless conduct, was involved. The “balancing” framework has too great a potential for punishing negligent or even appropriate conduct to be maintained.
2. *If so, how? In particular, should the standard be tied directly to fraud or unclean hands? If so, what is the appropriate standard for fraud or unclean hands?* Pleadings of unenforceability based upon culpable misconduct

before the Office should be permitted only where they can particularize a nefarious scheme or plan that is or amounts to a fraud, perpetrated by the “unclean litigant” that led to an illegitimate claim scope. The explicit addition of the ground of “unenforceability” as a defense in the 1952 Patent Act should be construed to limit “inequitable conduct” charges to the Supreme Court’s “unclean litigant” jurisprudence extant at enactment.

3. *What is the proper standard for materiality? What role should the United States Patent and Trademark Office’s rules play in defining materiality? Should a finding of materiality require that but for the alleged misconduct, one or more claims would not have issued?* The courts should not countermand, through “inequitable conduct” jurisprudence, the Office’s standards for disclosure, including determinations by the Office of what is *unimportant* and need not and should not be disclosed. The only proper standard for materiality for the purpose of assessing a litigant’s unclean hands is one that does not frustrate the congressional mandate to the Office that it conduct accurate and complete examination of patent applications in an effective and efficient manner, free from defensive patent procurement practices that frustrate that mandate. The standard for materiality must require at least that a patent with an *illegitimate* scope of protection was issued.

4. *Under what circumstances is it proper to infer intent from materiality?*

No inference of intent from materiality should be permitted under any circumstances because materiality by itself is simply not probative of deceptive intent. Indeed, in some situations, high materiality is more probative of *negligence* than of intent; in other situations, it is not probative of anything.

5. *Should the balancing inquiry (balancing materiality and intent) be abandoned?* Yes. The “balancing” inquiry is flawed because high materiality of omitted or misstated information can be (and often is) the result of inadvertence, mistake or other negligence, rather than intentional deception. Materiality, by itself, is typically no more probative of a deception than it is of mere negligence and in many situations “high” materiality may be *more probative* of negligence than an intentional act. The “balancing inquiry,” thus, should be wholly abandoned.

6. *Whether the standards for materiality and intent in other federal agency contexts or at common law shed light on the appropriate standards to be applied in the patent context.* The bankruptcy jurisdiction of the federal courts, analogously applying statutory rules that implicate a court’s equitable jurisdiction, shed significant light on the task of identifying the “unclean litigant.” In particular, bankruptcy jurisprudence underscores the

importance of looking at the totality of the circumstances in discerning whether a fraudulent scheme or plan exists. In addition, this parallel body of equity-grounded jurisprudence might assist in exposing the flaw of reliance on materiality to infer deceptive intent.

III. INTRODUCTION

This Court’s “inequitable conduct” jurisprudence is rife with unintended consequences. These unintended effects have largely overwhelmed the intended policy objective of securing integrity in the patenting process. The specter of “inequitable conduct” pleadings has no impact whatsoever in deterring those who would commit fraud to secure entirely illegitimate patents. Holding that such wholly invalid patents are additionally “unenforceable” is manifestly no punishment and, thus, no deterrent whatsoever to any fraud. On the other hand, “inequitable conduct” jurisprudence can label *inconsequential* conduct undertaken in the course of obtaining a fully *legitimate* patent as culpable misconduct and wholly destroy the entirely valid patent—even if the questioned conduct was not the work of the patentee and the patentee itself is in no way culpable.

Given that this Court’s inequitable conduct “doctrine,” as it now stands, can be far more perverse than purposeful, this Court should use this appeal as an opportunity to assure the doctrine returns to its purposeful roots,

namely serving to sanction the “unclean litigant” who can make no claim to any intervening equities. Moreover, the “doctrine” should not thwart the congressional mandate to the Office that it effectively and efficiently examine patent applications, which it cannot do if the courts gainsay its efforts to define what information patent applicants should disclose and what information they need not and should not disclose.

IV. ARGUMENT

A. “Inequitable Conduct” Should Reference Only Misconduct by Litigants Themselves Sufficient to Require Dismissal of Their Claims for Want of Equity.

In the 1952 Patent Act, Congress added the term “unenforceability” to subdivision (1) of 35 U.S.C. § 282, thereby denominating it as a defense to a patent infringement lawsuit. S. Rep. No. 82-1979, at 1 (1952). The 1952 Patent Act itself does not explain the contours of unenforceability. Federico stated that subdivision (1) would include the “equitable defenses such as laches, estoppel and unclean hands.” Pasquale J. Federico, *Commentary on the New Patent Act*, 35 U.S.C.A. (West 1954), reprinted in 75 J. Pat. & Trademark Off. Soc’y 161, 215 (1993). Senate Report No. 82-1979 declared that section 282 provides that “defenses to a suit for infringement are stated in general terms, changing the language in the present statute, but not materially changing the substance.” *Id.* at 6. Most importantly, by 1952, the

Supreme Court had recognized misconduct-based unenforceability in one and only one context, that of an *unclean litigant*.

In *Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240 (1933), the litigant’s “unclean hands” arose from its conduct in a prior litigation in which the litigant had schemed to suppress evidence of invalidity of one of the same patents that was the subject of the later complaint. The Supreme Court noted that “courts of equity” will “apply the maxim requiring clean hands only where some unconscionable act *of one coming for relief* has immediate and necessary relation to the *equity that he seeks* in respect of the matter in litigation.” *Id.* at 245 (emphasis added).

In another case, the Supreme Court addressed the issue of whether an infringement judgment could be set aside on the ground that it was infected with the claimant’s unclean hands, namely the litigant’s use of contrived evidence to obtain a prior judgment of patent validity. *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238 (1944) , *overruled on other grounds sub nom.*, *Standard Oil Co. v. United States*, 429 U.S. 17 (1976). The Supreme Court concluded that there exists “a rule of equity to the effect that under certain circumstances, one of which is after-discovered fraud, relief will be granted against judgments” *Id.* at 244.

Finally, in *Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806, 815 (1945), the Supreme Court noted the “wide range to the equity court’s use of discretion in refusing to aid *the unclean litigant*,” and cited the use of “unclean hands” as a maxim that “prevents a *wrongdoer* from enjoying the fruits of *his* transgression.” (emphasis added). These decisions, denying remedies to the “unclean litigants” or the “wrongdoers” themselves, represented the full reach of misconduct-based “unenforceability” at the time of enactment of the 1952 Patent Act.

The Supreme Court has an established practice of finding that common-law terms, *when newly introduced into a statute* and when they have *accumulated settled meaning*, will incorporate the settled meaning unless the statute otherwise dictates. *See Field v. Mans*, 516 U.S. 59, 69 (1995); *James-Dickinson Farm Mortgage Co. v. Harry*, 273 U.S. 119, 121 (1927); *Durland v. United States*, 161 U.S. 306, 312 (1896). In *Field*, for example, the Court construed the nature of reliance needed to constitute an “actual fraud” as meaning the common-law understanding of the nature of the reliance required to establish a fraud as of 1978, the year in which the term “actual fraud” was added to the federal bankruptcy provisions of 11 U.S.C. § 523(a)(2)(A). *Field*, 516 U.S. at 70.

Construing the term “unenforceability,” which was added to the patent statute in 1952, requires ascertaining the “accumulated settled meaning” for “unenforceability” defenses as of 1952. Under such a construction, this Court should look to the above array of Supreme Court decisions dealing with “fraud or other inequitable conduct” to provide the meaning for misconduct-based unenforceability defenses at the time when Congress added the word “unenforceability” to the patent statute. The accumulated settled meaning was that “inequitable conduct” referred to the conduct of “the unclean litigant,” i.e., the actual *wrongdoer*, who would be barred from enjoying the fruits of *his* transgression. *Precision Instrument*, 324 U.S. at 815.

The mere fact that fraud or other inequitable conduct may have been perpetrated *by someone* in procuring a patent would not under Supreme Court precedent (pre-1952 or since) permit a court to simply conclude that *the litigant’s hands themselves* are unclean. For example, a court addressing unenforceability must consider whether “equities have intervened” between the alleged misconduct and the litigant’s lawsuit. One example of such intervening equities, referenced in Supreme Court precedent, is the “transfer of the fraudulently procured patent . . . to an innocent purchaser.” *Hazel-Atlas*, 322 U.S. at 246. Other examples of intervening circumstances that

could similarly evidence a litigant's clean hands would be the active concealment of the fraud from a litigant who otherwise neither participated in nor encouraged the misconduct; a litigant who took active steps to assure candor in submissions made to the Office; and the litigant who otherwise not only had no role in the alleged misconduct, but also had no ready means to either detect or prevent the misconduct.

Under the 1952 codification of the "unenforceability" defense, assessing "inequitable conduct" should, therefore, be no more complicated than applying the equity court's use of discretion in refusing to aid the unclean litigant for whom there are no intervening equities. Thus, it should require proof, as was the case in the existing Supreme Court precedents in 1952, of the litigant's active and knowing involvement in a fraudulent scheme or plan to deceive.

B. "Inequitable Conduct" Should Be Limited to a Fraud or Other Conduct Amounting to a Fraud That Prevented a Patent from Being Kept Within Its Legitimate Scope.

The Supreme Court has noted that the overarching public interest involved in the exercise of the court's discretion to deny an "unclean litigant" relief is "that patent monopolies spring from backgrounds free from fraud or other inequitable conduct and that such monopolies are kept within their legitimate scope." *Precision Instrument*, 324 U.S. at 816. The

Supreme Court’s reference to “other inequitable conduct,” in addition to its reference to “fraud,” can only mean that the term “unclean hands” is not strictly tied to the perpetration of an actual fraud, but could include other conduct constituting “unclean hands.”

Had Congress, rather than the Supreme Court, similarly juxtaposed the terms “fraud” and “inequitable conduct,” the doctrine of *noscitur a sociis* (“ambiguous term may be ‘given more precise content by the neighboring words with which it is associated’.” *United States v. Stevens*, 559 U.S. ___, 130 S. Ct. 1577, 1588 (2010) (citations omitted)) could have been invoked as an aid to the understanding of the relationship between the two concepts. It would allow the Supreme Court decision to be read to suggest that the “inequitable conduct” would be other fraud-like conduct, i.e., misconduct that in sum and substance would amount to a fraud.

Further, the succeeding clause in the quotation from *Precision Instrument* provides a policy-based explanation of the nature of the conduct that is problematic, namely, misconduct that prevented the patent from being confined to its *legitimate scope*. This reference to conduct resulting in issuance of a patent with an illegitimate scope is consistent with the common understanding of what constitutes an actual fraud. It commonly entails both reliance on a misrepresentation and a consequent and proximate injury

caused by that reliance. This is consistent with the definition of fraud or other inequitable conduct under federal bankruptcy law where debt is nondischargeable under 11 U.S.C. § 523(a)(2)(A) for false representations.

In that context, to find fraud requires:

(1) that the debtor made the representations; (2) that at the time he knew they were false; (3) that he made them with the intention and purpose of deceiving the creditor; (4) that the creditor relied on such representations; and (5) that the creditor sustained alleged loss and damage as the proximate result of such representations.

Household Credit Servs. v. Ettell (In re Ettell), 188 F.3d 1141, 1144 (9th Cir. 1999) (quoting *Citibank v. Eashai (In re Eashai)*, 87 F.3d 1082, 1086 (9th Cir. 1996)). In a patent procurement context, therefore, a fraud (or misconduct amounting to a fraud) is best characterized as misconduct that resulted in a patent that afforded rights beyond the legitimate scope of protection that could have been realized absent the misconduct.

Hence, as this Court addresses the “inequitable conduct” unenforceability defense en banc, it should first hold that the defense is confined to the *litigant’s* unclean hands, where there are no *intervening equities*, and is otherwise premised on a fraud *or other conduct amounting to a fraud* that prevented the patent from being confined to its legitimate scope. By taking this matrix of concepts as a whole, relevant Supreme Court

precedents would be fully incorporated into this Court's application of the doctrine.

C. Neither the Materiality-Intent Balancing Framework nor the Inference of Intent from Materiality Should Remain as Part of “Inequitable Conduct” Law.

The inference of intent from a high degree of materiality and the use of the Materiality-Intent Balancing Framework to assess “inequitable conduct” depend on the proposition that a high degree of materiality is more probative of intentional deception, rather than inadvertence, negligence, or mistake. Admittedly, in the case of an actual fraud, materiality and intent are not entirely unconnected. The intentional deception is typically associated with a degree of high materiality of the deception. In the case of seeking a patent, it is likely that, if an intentional deception was practiced to obtain the patent, it was for the purpose of gaining issuance of an illegitimate patent—a patent that would not have issued in the form in which it issued had it not been for the omission or misstatement of information. Indeed, the notion that a “fraud” was perpetrated for the purpose of obtaining a fully legitimate, fully valid U.S. patent seems ludicrous.

Thus, it is self-evident that an intentional deception is probative of its high materiality. But this does not conversely imply that establishing high materiality is probative of an intentional deception, for there are alternate

explanations that are at least as plausible and often are more plausible. The core problem with this Court’s “inequitable conduct” jurisprudence arises from the fact that the *materiality* of an omission or misstatement of information that has been made is simply not a reliable indicator of whether such an act was the product of an intentional deception. This statement bears repetition: the high materiality of an act is, by itself, not necessarily probative of whether the act was one of deception, or one of mere inadvertence, negligence, or mistake.

Consider the following analogies that illustrate the logical flaws in attempting to rationally apply either a Materiality-Intent Balancing Framework or a materiality-based inference of intent:

(1) High levels of materiality can be more probative of negligence than of intentional misconduct.

Does the “materiality” of an oil discharge (i.e., materiality in the sense of the quantity of oil released, the nature of the resulting environmental damage, or the aggregate economic injury inflicted) have a bearing on whether such a discharge was an *intentional* act as opposed to a *negligent* one? In the case of either Exxon with the *Valdez* or British Petroleum with the *Deepwater Horizon*, it is virtually certain that no index used to assess the degree of materiality of the oil discharge renders it *more likely* that the oil

release was an *intentional* act of misconduct as opposed to an act of negligence.

For British Petroleum or Exxon executives to intentionally subject their respective shareholders to the consequences arising from a scheme or plan to intentionally trigger a massive oil discharge into the environment would be supremely illogical and irrational. If anything, thus, the *high degree of materiality* present in the *Valdez* and *Deepwater Horizon* incidents renders it far more likely that the release in each case was an act of negligence or gross negligence, not an intentional act.

(2) Balancing materiality and intent to conclude intentional misconduct will result in accident, inadvertence or mistake being erroneously labeled culpable misconduct.

Rule 8.02(d) of Major League Baseball provides that a “pitcher shall not ... intentionally pitch at the batter” and permits an umpire to eject a pitcher who does so. Major League Baseball Official Rules § 8.02(d) (2008), available at http://mlb.mlb.com/mlb/downloads/y2008/official_rules/08_the_pitcher.pdf. A hit batter, however, may be *immaterially affected* by a baseball intentionally pitched at the batter or, in contrast, may be *materially impacted*—be grievously injured—by a pitched baseball thrown at the batter accidentally. Sanctioning a pitcher pursuant to

Rule 8.02(d) by using a “Materiality-Intent Balancing Framework” to determine whether the pitcher should be expelled from the game would make no logical sense.

To illustrate this, one need only consider the great tragedy that took place on August 16, 1920, when Cleveland Indians shortstop Ray Chapman was hit by a baseball pitched by New York Yankee pitcher Carl Mays and died from the resulting head injury. In this context, the absolute ultimate in materiality implied nothing more than a tragic accident, Mays having been exonerated of all blame by the New York Assistant District Attorney.

Beaned by a Pitch, Ray Chapman Dies, N.Y. Times, Aug. 17, 1920, available at http://www.nytimes.com/packages/html/sports/year_in_sports/08.17.html. Drawing an inference of intent from the materiality of the consequence would only have wrongly compounded this tragedy. Imagine the miscarriage of justice had an after-the-fact tribunal been permitted to conclude that the baseball pitched was a murder weapon, either because high materiality was used to infer intent or a Materiality-Intent Balancing Framework was invoked.

The direct applicability of these analogies to patent procurement is readily apparent from sequentially viewing conduct of a fraud-feasor and an honest patent applicant. Someone who fraudulently schemes to secure an

illegitimate patent is *far more likely* to omit or misstate information that is *highly material* and indeed *highly consequential*. Thus, when an *intentional deception* is being practiced on a patent examiner, the deception may well be probative, therefore, of *high materiality* (i.e., intent → high materiality).

The fraud-feasor seeking a patent is most likely to tell the “big lie” to secure a patent that otherwise would not have issued.

For an honest but fallible patent applicant, however, there is simply no relationship between the degree of materiality and deceptive intent because there is no deceptive intent. Even if the omission or misstatement in question is of the highest quantum of materiality, it only measures the gravity of the honest mistake and it cannot implicate fraud or deceptive intent. Indeed, the error involved may be a *Deepwater Horizon* mistake in the sense having a profound impact, but accident is simply not intent.

Hence, the Court, whatever other disposition is made of the instant appeal en banc, should repudiate the use of the degree of materiality to infer intent. Similarly, it should repudiate any doctrine that would allow the degree of materiality and the evidence of actual intent to be “balanced” against one another in order to reach a conclusion that a patent is infected with a fraud or other inequitable conduct.

D. Deceptive Intent Should Only Be Inferred Where, from All the Facts and Circumstances, Negligence Can Be Excluded as a Reasonable Explanation for the Questioned Conduct.

The federal courts, in other areas of jurisprudence involving equity, address inferences of deceptive intent. Federal bankruptcy jurisprudence is appropriately analogous to patent enforcement given the equitable nature of bankruptcy jurisdiction and the need for a court to determine whether relief provided under statutory provisions should be nonetheless denied in situations of culpable misconduct, i.e., fraud or other inequitable conduct.

To assess whether a debtor's conduct reflects a fraud or other inequitable conduct, federal courts recognize that deceptive intent can be inferred. However, such inferences arise not from a single factor (such as a simple assessment of "materiality"), but rather the totality of the facts and circumstances. The Ninth Circuit, for example, has adopted a non-exclusive, twelve-factor test for use in making inferences of deceptive intent in credit card fraud. *Citibank South Dakota v. Dougherty (In re Dougherty)*, 84 B.R. 653, 657 (B.A.P. 9th Cir. 1988); *Eashai*, 87 F.3d at 1087-88). None of the factors is dispositive and only one might be seen as equivalent to materiality ("the amount of charges made"). Other circuits have adopted the same test. *See AT&T Universal Card Servs. v. Mercer (In re Mercer)*, 246 F.3d 391, 409 (5th Cir. 2001); *Rembert v. AT&T Universal Card Servs., Inc.*

(In re Rembert), 141 F.3d 277, 280-81 (6th Cir. 1998); *Universal Bank, N.A. v. Grause (In re Grause)*, 245 B.R. 95, 99 (B.A.P. 8th Cir. 2000).

Courts likewise use certain “badges of fraud,” i.e., factors, when determining whether to deny discharge to a debtor under 11 U.S.C. § 727(a)(2)(A) for transferring assets in anticipation of bankruptcy. *Soza v. Hill (In re Soza)*, 542 F.3d 1060, 1066-67 (5th Cir. 2008); *Emmett Valley Assocs. v. Woodfield (In re Woodfield)*, 978 F.2d 516, 518 (9th Cir. 1992). Such “badges of fraud” have become so well-ingrained as non-exclusive factors in determining actual intent to fraudulently transfer assets that they have been widely codified. Cal. Stat. § 3439.04 (2010); Fla. Stat. § 726.105 (2010); Neb. Rev. Stat. § 36-705 (2010); N.C. Gen. Stat. § 39-23.4 (2010); Tex. Bus. & Com. Code § 24.005(b) (2010). In order to ferret out “inequitable conduct” from non-culpable transactions, bankruptcy judges look “[t]o identify intent from pattern” and, thus, “have adopted an analysis that allows inference of the debtor’s fraudulent intent from ‘the totality of the circumstances.’” *Ettell*, 188 F.3d at 1144 (citations omitted). This Court should adopt parallel precepts on inferences of deceptive intent and apply them to unenforceability under subdivision (1) of section 282. In other words, to determine a patent litigant’s “unclean hands,” intent should be inferred only where a multi-factor, non-exclusive look at all the relevant

facts and circumstances allows negligence or other reasonable explanations to be excluded. The “level” of materiality should not be a factor.

E. Materiality-Related Measures and Factors Must Be Postured in “Inequitable Conduct” Jurisprudence in Such a Manner to Allow the Office, as the Expert Agency, to Efficiently and Effectively Manage Its Congressional Mandate.

Potential for a “collision effect” between materiality used in different forums, for different purposes, to vindicate different public policy imperatives, is highly relevant to this appeal. One standard for materiality may operate to wholly frustrate important public policy objectives that dictate the content of another.

The congressional mandate to the Office is to translate roughly two-dozen hours (on average) of a professional patent examiner’s time into a fully examined, reliably valid U.S. patent. In part to assure effectiveness and efficiency of patent examination, starting in 1979, the Office sought both *to encourage* and *to limit* what patent applicants would be required to disclose to patent examiners through rulemaking efforts. It promulgated original Rule 56, limiting materiality to information situations where there was “[1] a *substantial likelihood* that [2] a *reasonable examiner* [3] would consider it *important* [4] in deciding *whether to allow the application to issue as a patent.*” See *Am. Hoist & Derrick Co. v. Sowa & Sons*, 725 F.2d

1350, 1362 (Fed Cir. 1984) (quoting 37 C.F.R § 1.56(a), third sentence (1983), with emphasis and annotation in quotation).

In carrying out its congressional mandate, the Office's efforts at *limiting* have been no less critical than their efforts at *encouraging* applicant-supplied information disclosures. For the Office, it was and remains counterproductive to require disclosure of, much less provide an incentive to make disclosures of, *unimportant* and *inconsequential* information. The objective of an efficient patent examination process can only work if both the encouraging of disclosure of truly important information and the limiting of disclosure of unimportant information are kept in balance.

The Office's efforts at rulemaking to *limit*, as well as encourage, applicant disclosures, have taken several approaches. In 1988, for example, the Office proposed a clearer *limitation* on information to be disclosed than under the 1979 rulemaking. Under a proposed, but never adopted, 37 C.F.R § 1.57, the Office would have limited applicants to providing only such information that would have rendered a claimed invention unpatentable. Ultimately, in 1992, the Office concluded a third effort at more clearly defining (and, thus, *limiting*) patent-applicant disclosures so that, in effect, only information creating *prima facie* unpatentability would need to be submitted to the Office.

One factor that likely prompted these three major rulemaking initiatives is this Court's tendency to treat the Office's efforts to set *limiting* tests for disclosure as nonetheless *expansive* ones, thereby working at cross-purposes to the Office's efforts at managing the efficiency and effectiveness of the patent procurement process. These cross-purposes are best exemplified by Rule 56, in its original (1979) incarnation. Historically, the 1979 Rule 56 standard was envisioned by the Office *not* as a requirement to provide *all* information of actual or potential relevance to the patent examiner's decision on a patent. Rather, it implored the patent community only for information that could pass muster as being *important* to that decision.

The original Rule 56 standard was intended to adopt the disclosure-limiting features of the securities-law standard from *TSC Industries, Inc. v. Northway, Inc.*, 426 U.S. 438 (1976). Patent Examining and Appeal Procedures, 42 Fed. Reg. 5588, 5589 (Jan. 28, 1977). That Supreme Court decision dealt with disclosures a company must make to its shareholders in making their investment decisions. The Supreme Court expressly rejected as an appropriate standard in *TSC Industries* "all facts which a reasonable shareholder *might* consider important" in favor of the standard that "[a]n omitted fact is material if there is a substantial likelihood that a reasonable

shareholder would consider it important in deciding how to vote.” *Id.* at 445, 449. In other words, “the omitted fact would have assumed actual significance in the deliberations of the reasonable shareholder.” *Id.* at 449.

The Supreme Court’s view has meant that reasonable investors have not become victims of over-disclosures of information of marginal relevance in deciding whether to make an investment decision, for

if the standard for materiality is unnecessarily low, not only may the corporation and its management be subjected to liability for insignificant omissions and misstatements, but also management’s fear of exposing itself to substantial liability may cause it to simply bury the shareholders in an avalanche of trivial information—a result that is hardly conducive to informed decision-making.

Id. at 448-49.

While a “reasonable investor” is a term potentially inclusive of investors of widely varying degrees of education, sophistication and experience, a “reasonable patent examiner” is an individual trained by the Office, given explicit instructions in examination through the Manual of Patent Examining Procedure and either experienced enough to work proficiently and independently or under the supervision of a more senior patent examiner of such capabilities. Thus, the “reasonable examiner” test coupled with the “importance” filter should have meant that the Office would obtain information from patent applicants when it was *consequential*

to the experienced professional in the Office in making “yes-no” decisions on patentability.

Again, this interpretation is borne out in *TSC Industries*, where the Supreme Court was quite explicit that imposing civil consequences on a “but there might have been” consequentiality did not pass muster. “We simply hold that, if liability is to be imposed in this case upon a theory that it was misleading to fail to disclose purchases suggestive of market manipulation, there must be some showing that there was in fact market manipulation.” *Id.* at 463. This quotation can be readily applied to patent law by simply striking “purchases” and “market manipulation” and respectively inserting “references” and “invalidity”: *We simply hold that, if liability is to be imposed in this case upon a theory that it was misleading to fail to disclose references suggestive of invalidity, there must be some showing that there was, in fact, invalidity.*

To understand how fully this Court moved away from the “important” standard, one need only look to decisions citing original Rule 56 as the *broadest* and most all-encompassing disclosure standard: “The PTO ‘standard’ is an appropriate starting point . . . for it appears to be the broadest . . .and because [it] most closely aligns with how one ought to conduct business with the PTO.” *American Hoist*, 725 F.2d at 1363.

Whatever the en banc disposition of this case, that disposition should reflect the realities of the patent procurement process and the broader public interest in facilitating the congressional mandate that the Office, not the courts, manage the patenting process through both encouraging *and limiting* disclosures from patent applicants. If the Court adopts any materiality standard, that standard should be high enough that it does not negate the Office's own efforts to limit disclosures from patent applicants.

Indeed, the Department of Justice would never override the Office's rulemaking through concerted, overzealous enforcement of the criminal laws i.e., by contending, in the context of patent procurement, that the "materiality" element under 18 U.S.C. § 1001(a)'s criminal provisions would be triggered by the most minor or slight omissions or misstatements. Congress's efficiency-effectiveness mandate to the Office is a compelling policy reason for the courts to similarly confine "inequitable conduct" jurisprudence to convincing evidence of a deceptive scheme or plan by the litigant, who cannot avail itself of any intervening equities, to obtain a patent of illegitimate scope, that the totality of facts and circumstances indicate could not have reasonably been the product of negligent omissions or misstatements.

V. CONCLUSION

Allegations of inequitable conduct plague the patent system, impair the ability of the Office to examine patent applications effectively and efficiently, and sully the reputations of honest patent applicants through easily-made allegations that they are culpable wrongdoers. Confining allegations of fraud or other inequitable conduct to its roots in equity, where it turns on the litigant's unclean hands in pursuit of a deceptive scheme or plan to secure a patent of illegitimate scope, would both reflect controlling Supreme Court precedents and vindicate an array of public policy objectives, among which are that honest individuals should not be so easily tarred with allegations and inferences of wrongdoing.

Respectfully submitted,

ROBERT A. ARMITAGE
COUNSEL FOR *AMICUS CURIAE*
Eli Lilly and Company
Lilly Corporate Center
940 S. East Street
Drop Code 1200
Indianapolis, Indiana 46225
(317) 433-5499 TEL.
(317) 433-3000 FAX

Appendix

Forty-Three Patent Practitioners Employed by Eli Lilly and Company

Robert E. Lee, Jr., Reg. No. 27919	James J. Kelley, Reg. No. 41888	Gregory A. Cox, Reg. No. 47504
Lawrence T. Welch, Reg. No. 29487	James B. Myers, Jr., Reg. No. 42021	Paula K. Davis, Reg. No. 47517
John C. Demeter, Reg. No. 30167	Manisha A. Desai, Reg. No. 43585	Dan L. Wood, Reg. No. 48613
Donald L. Corneglio, Jr., Reg. No. 30741	Mark J. Stewart, Reg. No. 43936	Gary M. Birch, Reg. No. 48881
Paul J. Koivuniemi, Reg. No. 31533	Gilbert T. Voy, Reg. No. 43972	Ted J. Ebersole, Reg. No. 51641
Amy E. Hamilton, Reg. No. 33894	Elizabeth A. McGraw, Reg. No. 44646	Danica Hostettler, Reg. No. 51820
James P. Leeds, Reg. No. 35241	Francis O. Ginah, Reg. No. 44712	Mark A. Winter, Reg. No. 53782
Steven P. Caltrider, Reg. No. 36467	R. Craig Tucker, Reg. No. 45165	Nicole S. Woods, Reg. No. 56579
Paul R. Cantrell, Reg. No. 36470	Arvie Anderson, Reg. No. 45263	Averie K. Hason, Reg. No. 57722
MaCharri Vorndran- Jones, Reg. No. 36711	Lynn D. Apelgren, Reg. No. 45341	Tonya Combs, Reg. No. 57909
Paul J. Gaylo, Reg. No. 36808	MaryAnn Wiskerchen, Reg. No. 45511	Alejandro Martinez, Reg. No. 58163
Edward J. Prein, Reg. No. 37212	Robert L. Sharp, Reg. No. 45609	Sanjay Jivraj, Reg. No. 61806
Brian P. Barrett, Reg. No. 39597	Alexander Wilson, Reg. No. 45782	Robert B. Johnson, Reg. No. 63813
Robert D. Titus, Reg. No. 40206	Tina M. Tucker, Reg. No. 47145	Andrea M. Castetter, Reg. No. 63964
		Elizabeth Dingess- Hammond, Reg. No. 63996